CABL001J12302, ASC4START - AMNOG initial full Dossier Submission (Cut-off date: 15MAY2025)

ClinStat GmbH

Sponsor: Novartis

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1. Baseline characteristics

Table 1-1.1: Patient disposition (Full Analysis Set)

	Treatment groups	
	Asciminib (N = 284)	**Nilotinib (N = 284)**
Number (%) of patients who were treated	284 (100.0)	282 (99.3)
Number (%) of patients who are still on-treatment	234 (82.4)	204 (71.8)
Number (%) of patients who discontinued the study treatment phase overall	50 (17.6)	78 (27.5)
Primary reason for study treatment phase discontinuation overall		
ADVERSE EVENT	20 (7.0)	44 (15.5)
DEATH	2 (0.7)	1 (0.4)
PHYSICIAN DECISION	2 (0.7)	3 (1.1)
PREGNANCY	0	2 (0.7)
PROGRESSIVE DISEASE	3 (1.1)	1 (0.4)
PROTOCOL DEVIATION	2 (0.7)	1 (0.4)
REQUIRES PROHIBITED MEDICATION	0	1 (0.4)
SUBJECT DECISION	1 (0.4)	3 (1.1)
TECHNICAL PROBLEMS	0	1 (0.4)
UNSATISFACTORY THERAPEUTIC EFFECT	19 (6.7)	21 (7.4)

	Treatment groups	
	Asciminib (N = 284)	**Nilotinib (N = 284)**
WITHDRAWAL OF INFORMED CONSENT	1 (0.4)	0
Number (%) of patients who have entered the survival follow-up	44 (15.5)	68 (23.9)

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Table 1-1.2: Demographics and disease characteristics (Full Analysis Set)

	Treatment groups	
	Asciminib (N = 284)	**Nilotinib (N = 284)**
Age (years)		
n	284	284
mean (SD)	48.3 (14.7)	48.8 (15.0)
median	49.0	50.0
range (Min - Max)	19.0-82.0	18.0-84.0
Height at Baseline (cm)		
n	283	284
mean (SD)	171.2 (10.0)	170.6 (10.2)
median	171.0	170.0
range (Min - Max)	144.0-196.0	140.0-196.0
Weight at Baseline (kg)		
n	283	282
mean (SD)	76.0 (16.1)	74.1 (16.9)
median	75.5	72.0
range (Min - Max)	41.0-134.0	38.7-145.8
BMI at Baseline (kg/m2)		

	Treatment groups	
	Asciminib (N = 284)	**Nilotinib (N = 284)**
n	282	282
mean (SD)	25.9 (5.2)	25.4 (4.7)
median	25.1	24.6
range (Min - Max)	16.4-45.9	15.8-46.6
Time since initial diagnosis of CML to randomization (weeks)		
n	284	284
mean (SD)	4.9 (2.7)	5.1 (2.8)
median	4.1	4.5
range (Min - Max)	0.0-15.4	0.7-16.0
Blasts in bone marrow (%)		
n	270	273
mean (SD)	2.3 (2.4)	2.1 (2.0)
median	2.0	2.0
range (Min - Max)	0.0-23.8	0.0-11.0
Promyelocytes in bone marrow (%)		
n	256	256
mean (SD)	5.5 (5.7)	5.3 (6.2)
median	4.0	3.0

	Treatment groups	
	Asciminib (N = 284)	**Nilotinib (N = 284)**
range (Min - Max)	0.0-28.0	0.0-30.0
Blasts and promyelocytes in bone marrow (%)		
n	270	273
mean (SD)	7.5 (6.3)	7.1 (6.6)
median	6.0	5.0
range (Min - Max)	0.0-30.4	0.0-40.0
Ph+-metaphases in bone marrow (%)		
n	254	254
mean (SD)	92.1 (22.1)	91.4 (22.9)
median	100.0	100.0
range (Min - Max)	0.0-100.0	0.0-100.0
Sex (n, %)		
Female	107 (37.7)	126 (44.4)
Male	177 (62.3)	158 (55.6)
Race (n, %)		
American Indian Or Alaska Native	1 (0.4)	1 (0.4)
Asian	40 (14.1)	46 (16.2)
Black Or African American	12 (4.2)	10 (3.5)

	Treatment groups	
	Asciminib (N = 284)	**Nilotinib (N = 284)**
Multiple	0	2 (0.7)
Native Hawaiian Or Other Pacific Islander	0	1 (0.4)
Not Reported	2 (0.7)	6 (2.1)
White	227 (79.9)	217 (76.4)
Unknown	2 (0.7)	1 (0.4)
Ethnicity (n, %)		
Hispanic Or Latino	16 (5.6)	24 (8.5)
Not Hispanic Or Latino	254 (89.4)	247 (87.0)
Not Reported	10 (3.5)	10 (3.5)
Unknown	4 (1.4)	3 (1.1)
Geographic region (n, %)		
America	20 (7.0)	36 (12.7)
Asia	45 (15.8)	47 (16.5)
Europe excluding Germany	138 (48.6)	141 (49.6)
Germany	72 (25.4)	53 (18.7)
Others	9 (3.2)	7 (2.5)
ELTS risk Score Group (IRT) (n, %)		
High	38 (13.4)	37 (13.0)

	Treatment groups	
	Asciminib (N = 284)	**Nilotinib (N = 284)**
Intermediate	75 (26.4)	75 (26.4)
Low	171 (60.2)	172 (60.6)
Pooled Age Group 1 (n, %)		
18 - < 65 years	237 (83.5)	247 (87.0)
65 - < 75 years	38 (13.4)	24 (8.5)
>= 75 years	9 (3.2)	13 (4.6)
ECOG at Baseline (n, %)		
0	226 (79.6)	235 (82.7)
1	57 (20.1)	49 (17.3)
2	1 (0.4)	0
Any extramedullary involvement (n, %)		
No	252 (88.7)	248 (87.3)
Yes	32 (11.3)	36 (12.7)
Blasts (%) in bone marrow, categorized (n, %)		
Missing	14 (4.9)	11 (3.9)
0%	41 (14.4)	43 (15.1)
> 0% - < 5%	184 (64.8)	193 (68.0)
>= 5% - < 15%	44 (15.5)	37 (13.0)

	Treatment groups	
	Asciminib (N = 284)	**Nilotinib (N = 284)**
>= 15%	1 (0.4)	0
Ph+-metaphases (%) in bone marrow, categorized (n, %)		
Missing	30 (10.6)	30 (10.6)
0%	8 (2.8)	2 (0.7)
> 0% - 35%	5 (1.8)	14 (4.9)
> 35% - 65%	6 (2.1)	7 (2.5)
> 65% - 95%	38 (13.4)	37 (13.0)
> 95%	197 (69.4)	194 (68.3)
Prior TKI (n, %)		
None	284 (100.0)	284 (100.0)
Prior non-TKI therapy (n, %)		
No	87 (30.6)	99 (34.9)
Yes	197 (69.4)	185 (65.1)

SD: Standard deviation
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Table 1-1.3: Follow-up times (Full Analysis Set)

	Treatment groups	
	Asciminib (N=284)	**Nilotinib (N=284)**
Overall survival (months)		
n	284	284
mean (SD)	17.2 (5.0)	16.9 (5.2)
median	16.7	16.6
range (Min - Max)	1.2-27.9	0.0-29.4
Progression free survival (months)		
n	284	284
mean (SD)	17.0 (5.1)	16.8 (5.3)
median	16.7	16.6
range (Min - Max)	1.2-27.9	0.0-29.4
Follow-up time (months) for patient reported outcome (PRO)		
EORTC QLQ-C30 V3.0		
n	276	272
mean (SD)	10.0 (5.5)	9.6 (6.1)
median	11.1	11.1
range (Min - Max)	0.0-22.6	0.0-26.4

	Treatment groups	
	Asciminib (N=284)	**Nilotinib (N=284)**
EORTC QLQ-CML24		
n	274	272
mean (SD)	9.9 (5.5)	9.6 (6.1)
median	11.1	11.1
range (Min - Max)	0.0-22.6	0.0-26.4
FACT-ITEM GP5 V4		
n	277	275
mean (SD)	13.7 (6.4)	12.6 (7.0)
median	13.8	12.1
range (Min - Max)	0.3-27.6	0.0-27.7
PRO-CTCAE V1.0		
n	277	275
mean (SD)	13.7 (6.4)	12.6 (7.0)
median	13.8	12.1
range (Min - Max)	0.3-27.6	0.0-27.7
Follow-up time AE (months)		
n	284	282
mean (SD)	16.8 (5.9)	15.6 (6.7)

	Treatment groups	
	Asciminib (N=284)	**Nilotinib (N=284)**
median	16.9	15.8
range (Min - Max)	1.2-29.0	1.1-29.0

SD: Standard deviation
.....
n for PRO are the patients who have filled at least one PRO at any time.
Data Cut/15MAY2025

Table 1-1.4: PRO compliance (Full Analysis Set)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
EORTC QLQ-C30 V3.0			
Baseline Returns	168 (59.2)	165 (58.1)	333 (58.6)
Extended Baseline Returns	244 (85.9)	247 (87.0)	491 (86.4)
Week 4 Returns	255 (89.8)	232 (81.7)	487 (85.7)
Week 8 Returns	175 (61.6)	150 (52.8)	325 (57.2)
Week 12 Returns	230 (81.0)	210 (73.9)	440 (77.5)
Week 24 Returns	210 (73.9)	191 (67.3)	401 (70.6)
Week 48 Returns	188 (66.2)	164 (57.7)	352 (62.0)
Week 96 Returns	31 (10.9)	34 (12.0)	65 (11.4)
EOT Returns	18 (6.3)	29 (10.2)	47 (8.3)
EOT + 4 Weeks Returns	16 (5.6)	21 (7.4)	37 (6.5)
EOT + 8 Weeks Returns	9 (3.2)	16 (5.6)	25 (4.4)
EOT + 12 Weeks Returns	8 (2.8)	15 (5.3)	23 (4.0)
EORTC QLQ-CML24			
Baseline Returns	161 (56.7)	157 (55.3)	318 (56.0)
Extended Baseline Returns	230 (81.0)	230 (81.0)	460 (81.0)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 4 Returns	251 (88.4)	227 (79.9)	478 (84.2)
Week 8 Returns	171 (60.2)	149 (52.5)	320 (56.3)
Week 12 Returns	224 (78.9)	207 (72.9)	431 (75.9)
Week 24 Returns	209 (73.6)	188 (66.2)	397 (69.9)
Week 48 Returns	186 (65.5)	164 (57.7)	350 (61.6)
Week 96 Returns	30 (10.6)	34 (12.0)	64 (11.3)
EOT Returns	18 (6.3)	28 (9.9)	46 (8.1)
EOT + 4 Weeks Returns	15 (5.3)	21 (7.4)	36 (6.3)
EOT + 8 Weeks Returns	8 (2.8)	16 (5.6)	24 (4.2)
EOT + 12 Weeks Returns	8 (2.8)	15 (5.3)	23 (4.0)
FACT-ITEM GP5 V4			
Baseline Returns	156 (54.9)	152 (53.5)	308 (54.2)
Extended Baseline Returns	221 (77.8)	219 (77.1)	440 (77.5)
Week 1 Returns	193 (68.0)	185 (65.1)	378 (66.5)
Week 2 Returns	203 (71.5)	203 (71.5)	406 (71.5)
Week 3 Returns	179 (63.0)	173 (60.9)	352 (62.0)
Week 4 Returns	215 (75.7)	182 (64.1)	397 (69.9)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 5 Returns	191 (67.3)	167 (58.8)	358 (63.0)
Week 6 Returns	175 (61.6)	167 (58.8)	342 (60.2)
Week 7 Returns	177 (62.3)	155 (54.6)	332 (58.5)
Week 8 Returns	153 (53.9)	133 (46.8)	286 (50.4)
Week 9 Returns	178 (62.7)	156 (54.9)	334 (58.8)
Week 10 Returns	167 (58.8)	162 (57.0)	329 (57.9)
Week 11 Returns	176 (62.0)	155 (54.6)	331 (58.3)
Week 12 Returns	189 (66.5)	179 (63.0)	368 (64.8)
Week 13 Returns	173 (60.9)	151 (53.2)	324 (57.0)
Week 14 Returns	159 (56.0)	139 (48.9)	298 (52.5)
Week 15 Returns	163 (57.4)	149 (52.5)	312 (54.9)
Week 16 Returns	164 (57.7)	149 (52.5)	313 (55.1)
Week 17 Returns	162 (57.0)	145 (51.1)	307 (54.0)
Week 18 Returns	164 (57.7)	144 (50.7)	308 (54.2)
Week 19 Returns	161 (56.7)	141 (49.6)	302 (53.2)
Week 20 Returns	163 (57.4)	140 (49.3)	303 (53.3)
Week 21 Returns	162 (57.0)	146 (51.4)	308 (54.2)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 22 Returns	148 (52.1)	145 (51.1)	293 (51.6)
Week 23 Returns	161 (56.7)	153 (53.9)	314 (55.3)
Week 24 Returns	215 (75.7)	205 (72.2)	420 (73.9)
Week 36 Returns	188 (66.2)	160 (56.3)	348 (61.3)
Week 40 Returns	124 (43.7)	93 (32.7)	217 (38.2)
Week 44 Returns	114 (40.1)	84 (29.6)	198 (34.9)
Week 48 Returns	169 (59.5)	148 (52.1)	317 (55.8)
Week 52 Returns	95 (33.5)	72 (25.4)	167 (29.4)
Week 56 Returns	86 (30.3)	70 (24.6)	156 (27.5)
Week 60 Returns	113 (39.8)	88 (31.0)	201 (35.4)
Week 64 Returns	74 (26.1)	53 (18.7)	127 (22.4)
Week 68 Returns	70 (24.6)	43 (15.1)	113 (19.9)
Week 72 Returns	79 (27.8)	67 (23.6)	146 (25.7)
Week 76 Returns	50 (17.6)	43 (15.1)	93 (16.4)
Week 80 Returns	42 (14.8)	40 (14.1)	82 (14.4)
Week 84 Returns	47 (16.5)	44 (15.5)	91 (16.0)
Week 88 Returns	31 (10.9)	28 (9.9)	59 (10.4)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 92 Returns	23 (8.1)	20 (7.0)	43 (7.6)
Week 96 Returns	25 (8.8)	30 (10.6)	55 (9.7)
Week 100 Returns	18 (6.3)	18 (6.3)	36 (6.3)
Week 104 Returns	17 (6.0)	14 (4.9)	31 (5.5)
Week 108 Returns	8 (2.8)	9 (3.2)	17 (3.0)
Week 112 Returns	8 (2.8)	9 (3.2)	17 (3.0)
Week 116 Returns	7 (2.5)	4 (1.4)	11 (1.9)
Week 120 Returns	2 (0.7)	2 (0.7)	4 (0.7)
EOT Returns	22 (7.7)	40 (14.1)	62 (10.9)
EOT + 4 Weeks Returns	22 (7.7)	29 (10.2)	51 (9.0)
EOT + 8 Weeks Returns	13 (4.6)	20 (7.0)	33 (5.8)
EOT + 12 Weeks Returns	12 (4.2)	17 (6.0)	29 (5.1)
PRO-CTCAE V1.0			
Baseline Returns	157 (55.3)	154 (54.2)	311 (54.8)
Extended Baseline Returns	222 (78.2)	224 (78.9)	446 (78.5)
Week 1 Returns	195 (68.7)	186 (65.5)	381 (67.1)
Week 2 Returns	205 (72.2)	206 (72.5)	411 (72.4)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 3 Returns	180 (63.4)	173 (60.9)	353 (62.1)
Week 4 Returns	215 (75.7)	184 (64.8)	399 (70.2)
Week 5 Returns	191 (67.3)	167 (58.8)	358 (63.0)
Week 6 Returns	176 (62.0)	167 (58.8)	343 (60.4)
Week 7 Returns	180 (63.4)	156 (54.9)	336 (59.2)
Week 8 Returns	153 (53.9)	133 (46.8)	286 (50.4)
Week 9 Returns	180 (63.4)	157 (55.3)	337 (59.3)
Week 10 Returns	168 (59.2)	162 (57.0)	330 (58.1)
Week 11 Returns	178 (62.7)	156 (54.9)	334 (58.8)
Week 12 Returns	191 (67.3)	180 (63.4)	371 (65.3)
Week 13 Returns	174 (61.3)	150 (52.8)	324 (57.0)
Week 14 Returns	162 (57.0)	140 (49.3)	302 (53.2)
Week 15 Returns	166 (58.5)	149 (52.5)	315 (55.5)
Week 16 Returns	165 (58.1)	149 (52.5)	314 (55.3)
Week 17 Returns	163 (57.4)	145 (51.1)	308 (54.2)
Week 18 Returns	165 (58.1)	145 (51.1)	310 (54.6)
Week 19 Returns	162 (57.0)	141 (49.6)	303 (53.3)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 20 Returns	165 (58.1)	140 (49.3)	305 (53.7)
Week 21 Returns	164 (57.7)	147 (51.8)	311 (54.8)
Week 22 Returns	149 (52.5)	145 (51.1)	294 (51.8)
Week 23 Returns	162 (57.0)	154 (54.2)	316 (55.6)
Week 24 Returns	218 (76.8)	205 (72.2)	423 (74.5)
Week 36 Returns	189 (66.5)	160 (56.3)	349 (61.4)
Week 40 Returns	125 (44.0)	93 (32.7)	218 (38.4)
Week 44 Returns	115 (40.5)	84 (29.6)	199 (35.0)
Week 48 Returns	169 (59.5)	149 (52.5)	318 (56.0)
Week 52 Returns	97 (34.2)	74 (26.1)	171 (30.1)
Week 56 Returns	88 (31.0)	70 (24.6)	158 (27.8)
Week 60 Returns	113 (39.8)	89 (31.3)	202 (35.6)
Week 64 Returns	75 (26.4)	53 (18.7)	128 (22.5)
Week 68 Returns	70 (24.6)	43 (15.1)	113 (19.9)
Week 72 Returns	80 (28.2)	68 (23.9)	148 (26.1)
Week 76 Returns	51 (18.0)	43 (15.1)	94 (16.5)
Week 80 Returns	43 (15.1)	40 (14.1)	83 (14.6)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 84 Returns	47 (16.5)	44 (15.5)	91 (16.0)
Week 88 Returns	31 (10.9)	28 (9.9)	59 (10.4)
Week 92 Returns	23 (8.1)	20 (7.0)	43 (7.6)
Week 96 Returns	26 (9.2)	31 (10.9)	57 (10.0)
Week 100 Returns	18 (6.3)	18 (6.3)	36 (6.3)
Week 104 Returns	17 (6.0)	14 (4.9)	31 (5.5)
Week 108 Returns	8 (2.8)	9 (3.2)	17 (3.0)
Week 112 Returns	8 (2.8)	9 (3.2)	17 (3.0)
Week 116 Returns	7 (2.5)	4 (1.4)	11 (1.9)
Week 120 Returns	2 (0.7)	2 (0.7)	4 (0.7)
EOT Returns	22 (7.7)	40 (14.1)	62 (10.9)
EOT + 4 Weeks Returns	22 (7.7)	29 (10.2)	51 (9.0)
EOT + 8 Weeks Returns	13 (4.6)	20 (7.0)	33 (5.8)
EOT + 12 Weeks Returns	12 (4.2)	18 (6.3)	30 (5.3)

N: Number of patients
n (%): Number and percentage of patients with event
.....
Return rates include PROs that were fully and partially completed at the respective visit.
The return rate is the proportion of patients with valid data at the given visit based on the whole study population.
Extended Baseline Returns include PRO returns after randomization but before start of treatment (as used in one of the sensitivity analyses).
Data Cut/15MAY2025

Table 1-1.5: PRO compliance based on baseline returns (Full Analysis Set)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
EORTC QLQ-C30 V3.0			
n	168	165	333
Baseline Returns	168 (100.0)	165 (100.0)	333 (100.0)
Week 4 Returns	151 (89.9)	132 (80.0)	283 (85.0)
Week 8 Returns	114 (67.9)	94 (57.0)	208 (62.5)
Week 12 Returns	143 (85.1)	130 (78.8)	273 (82.0)
Week 24 Returns	134 (79.8)	120 (72.7)	254 (76.3)
Week 48 Returns	114 (67.9)	109 (66.1)	223 (67.0)
Week 96 Returns	16 (9.5)	24 (14.5)	40 (12.0)
EOT Returns	11 (6.5)	16 (9.7)	27 (8.1)
EOT + 4 Weeks Returns	15 (8.9)	11 (6.7)	26 (7.8)
EOT + 8 Weeks Returns	7 (4.2)	8 (4.8)	15 (4.5)
EOT + 12 Weeks Returns	7 (4.2)	9 (5.5)	16 (4.8)
EORTC QLQ-CML24			
n	161	157	318
Baseline Returns	161 (100.0)	157 (100.0)	318 (100.0)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 4 Returns	145 (90.1)	127 (80.9)	272 (85.5)
Week 8 Returns	108 (67.1)	91 (58.0)	199 (62.6)
Week 12 Returns	133 (82.6)	124 (79.0)	257 (80.8)
Week 24 Returns	130 (80.7)	113 (72.0)	243 (76.4)
Week 48 Returns	110 (68.3)	105 (66.9)	215 (67.6)
Week 96 Returns	15 (9.3)	24 (15.3)	39 (12.3)
EOT Returns	10 (6.2)	16 (10.2)	26 (8.2)
EOT + 4 Weeks Returns	13 (8.1)	10 (6.4)	23 (7.2)
EOT + 8 Weeks Returns	6 (3.7)	7 (4.5)	13 (4.1)
EOT + 12 Weeks Returns	7 (4.3)	8 (5.1)	15 (4.7)
FACT-ITEM GP5 V4			
n	156	152	308
Baseline Returns	156 (100.0)	152 (100.0)	308 (100.0)
Week 1 Returns	102 (65.4)	92 (60.5)	194 (63.0)
Week 2 Returns	110 (70.5)	118 (77.6)	228 (74.0)
Week 3 Returns	94 (60.3)	101 (66.4)	195 (63.3)
Week 4 Returns	129 (82.7)	107 (70.4)	236 (76.6)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 5 Returns	101 (64.7)	91 (59.9)	192 (62.3)
Week 6 Returns	98 (62.8)	93 (61.2)	191 (62.0)
Week 7 Returns	94 (60.3)	87 (57.2)	181 (58.8)
Week 8 Returns	87 (55.8)	76 (50.0)	163 (52.9)
Week 9 Returns	104 (66.7)	86 (56.6)	190 (61.7)
Week 10 Returns	94 (60.3)	84 (55.3)	178 (57.8)
Week 11 Returns	98 (62.8)	88 (57.9)	186 (60.4)
Week 12 Returns	109 (69.9)	102 (67.1)	211 (68.5)
Week 13 Returns	103 (66.0)	81 (53.3)	184 (59.7)
Week 14 Returns	88 (56.4)	75 (49.3)	163 (52.9)
Week 15 Returns	91 (58.3)	82 (53.9)	173 (56.2)
Week 16 Returns	93 (59.6)	80 (52.6)	173 (56.2)
Week 17 Returns	90 (57.7)	79 (52.0)	169 (54.9)
Week 18 Returns	98 (62.8)	77 (50.7)	175 (56.8)
Week 19 Returns	90 (57.7)	72 (47.4)	162 (52.6)
Week 20 Returns	92 (59.0)	73 (48.0)	165 (53.6)
Week 21 Returns	89 (57.1)	80 (52.6)	169 (54.9)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 22 Returns	85 (54.5)	76 (50.0)	161 (52.3)
Week 23 Returns	93 (59.6)	82 (53.9)	175 (56.8)
Week 24 Returns	130 (83.3)	117 (77.0)	247 (80.2)
Week 36 Returns	107 (68.6)	94 (61.8)	201 (65.3)
Week 40 Returns	72 (46.2)	57 (37.5)	129 (41.9)
Week 44 Returns	62 (39.7)	50 (32.9)	112 (36.4)
Week 48 Returns	100 (64.1)	97 (63.8)	197 (64.0)
Week 52 Returns	50 (32.1)	39 (25.7)	89 (28.9)
Week 56 Returns	43 (27.6)	36 (23.7)	79 (25.6)
Week 60 Returns	56 (35.9)	54 (35.5)	110 (35.7)
Week 64 Returns	35 (22.4)	32 (21.1)	67 (21.8)
Week 68 Returns	41 (26.3)	23 (15.1)	64 (20.8)
Week 72 Returns	39 (25.0)	40 (26.3)	79 (25.6)
Week 76 Returns	20 (12.8)	21 (13.8)	41 (13.3)
Week 80 Returns	21 (13.5)	22 (14.5)	43 (14.0)
Week 84 Returns	26 (16.7)	25 (16.4)	51 (16.6)
Week 88 Returns	14 (9.0)	14 (9.2)	28 (9.1)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 92 Returns	9 (5.8)	12 (7.9)	21 (6.8)
Week 96 Returns	13 (8.3)	21 (13.8)	34 (11.0)
Week 100 Returns	8 (5.1)	11 (7.2)	19 (6.2)
Week 104 Returns	7 (4.5)	10 (6.6)	17 (5.5)
Week 108 Returns	2 (1.3)	6 (3.9)	8 (2.6)
Week 112 Returns	4 (2.6)	7 (4.6)	11 (3.6)
Week 116 Returns	3 (1.9)	3 (2.0)	6 (1.9)
Week 120 Returns	2 (1.3)	2 (1.3)	4 (1.3)
EOT Returns	12 (7.7)	21 (13.8)	33 (10.7)
EOT + 4 Weeks Returns	15 (9.6)	13 (8.6)	28 (9.1)
EOT + 8 Weeks Returns	8 (5.1)	10 (6.6)	18 (5.8)
EOT + 12 Weeks Returns	8 (5.1)	9 (5.9)	17 (5.5)
PRO-CTCAE V1.0			
n	157	154	311
Baseline Returns	157 (100.0)	154 (100.0)	311 (100.0)
Week 1 Returns	103 (65.6)	93 (60.4)	196 (63.0)
Week 2 Returns	111 (70.7)	120 (77.9)	231 (74.3)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 3 Returns	94 (59.9)	102 (66.2)	196 (63.0)
Week 4 Returns	130 (82.8)	107 (69.5)	237 (76.2)
Week 5 Returns	101 (64.3)	92 (59.7)	193 (62.1)
Week 6 Returns	99 (63.1)	94 (61.0)	193 (62.1)
Week 7 Returns	95 (60.5)	87 (56.5)	182 (58.5)
Week 8 Returns	89 (56.7)	76 (49.4)	165 (53.1)
Week 9 Returns	104 (66.2)	87 (56.5)	191 (61.4)
Week 10 Returns	94 (59.9)	84 (54.5)	178 (57.2)
Week 11 Returns	98 (62.4)	89 (57.8)	187 (60.1)
Week 12 Returns	111 (70.7)	103 (66.9)	214 (68.8)
Week 13 Returns	103 (65.6)	80 (51.9)	183 (58.8)
Week 14 Returns	90 (57.3)	77 (50.0)	167 (53.7)
Week 15 Returns	93 (59.2)	83 (53.9)	176 (56.6)
Week 16 Returns	93 (59.2)	81 (52.6)	174 (55.9)
Week 17 Returns	90 (57.3)	80 (51.9)	170 (54.7)
Week 18 Returns	98 (62.4)	77 (50.0)	175 (56.3)
Week 19 Returns	90 (57.3)	73 (47.4)	163 (52.4)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 20 Returns	92 (58.6)	73 (47.4)	165 (53.1)
Week 21 Returns	90 (57.3)	80 (51.9)	170 (54.7)
Week 22 Returns	85 (54.1)	77 (50.0)	162 (52.1)
Week 23 Returns	93 (59.2)	83 (53.9)	176 (56.6)
Week 24 Returns	132 (84.1)	118 (76.6)	250 (80.4)
Week 36 Returns	107 (68.2)	95 (61.7)	202 (65.0)
Week 40 Returns	72 (45.9)	58 (37.7)	130 (41.8)
Week 44 Returns	62 (39.5)	50 (32.5)	112 (36.0)
Week 48 Returns	100 (63.7)	97 (63.0)	197 (63.3)
Week 52 Returns	51 (32.5)	40 (26.0)	91 (29.3)
Week 56 Returns	44 (28.0)	37 (24.0)	81 (26.0)
Week 60 Returns	55 (35.0)	54 (35.1)	109 (35.0)
Week 64 Returns	35 (22.3)	32 (20.8)	67 (21.5)
Week 68 Returns	41 (26.1)	23 (14.9)	64 (20.6)
Week 72 Returns	39 (24.8)	40 (26.0)	79 (25.4)
Week 76 Returns	20 (12.7)	21 (13.6)	41 (13.2)
Week 80 Returns	21 (13.4)	22 (14.3)	43 (13.8)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 84 Returns	26 (16.6)	25 (16.2)	51 (16.4)
Week 88 Returns	14 (8.9)	14 (9.1)	28 (9.0)
Week 92 Returns	9 (5.7)	12 (7.8)	21 (6.8)
Week 96 Returns	13 (8.3)	22 (14.3)	35 (11.3)
Week 100 Returns	8 (5.1)	11 (7.1)	19 (6.1)
Week 104 Returns	7 (4.5)	10 (6.5)	17 (5.5)
Week 108 Returns	2 (1.3)	6 (3.9)	8 (2.6)
Week 112 Returns	4 (2.5)	7 (4.5)	11 (3.5)
Week 116 Returns	3 (1.9)	3 (1.9)	6 (1.9)
Week 120 Returns	2 (1.3)	2 (1.3)	4 (1.3)
EOT Returns	12 (7.6)	21 (13.6)	33 (10.6)
EOT + 4 Weeks Returns	15 (9.6)	13 (8.4)	28 (9.0)
EOT + 8 Weeks Returns	8 (5.1)	10 (6.5)	18 (5.8)
EOT + 12 Weeks Returns	8 (5.1)	9 (5.8)	17 (5.5)

N: Number of patients
n (%): Number and percentage of patients with event
.....
Return rates include PROs that were fully and partially completed at the respective visit.
The return rate is the proportion of patients with valid data at the given visit based on the patients with a baseline return.
Data Cut/15MAY2025
Data Cut/15MAY2025

Table 1-1.6: PRO compliance based on patients on study (Full Analysis Set)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
EORTC QLQ-C30 V3.0			
Baseline N	284	284	568
Baseline Returns	168 (59.2)	165 (58.1)	333 (58.6)
Week 4 N	273	264	537
Week 4 Returns	255 (93.4)	232 (87.9)	487 (90.7)
Week 8 N	264	252	516
Week 8 Returns	175 (66.3)	150 (59.5)	325 (63.0)
Week 12 N	258	248	506
Week 12 Returns	230 (89.1)	210 (84.7)	440 (87.0)
Week 24 N	233	221	454
Week 24 Returns	210 (90.1)	191 (86.4)	401 (88.3)
Week 48 N	192	174	366
Week 48 Returns	188 (97.9)	164 (94.3)	352 (96.2)
Week 96 N	32	34	66
Week 96 Returns	31 (96.9)	34 (100.0)	65 (98.5)
EOT N	47	75	122

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
EOT Returns	18 (38.3)	29 (38.7)	47 (38.5)
EOT + 4 Weeks N	17	24	41
EOT + 4 Weeks Returns	16 (94.1)	21 (87.5)	37 (90.2)
EOT + 8 Weeks N	12	21	33
EOT + 8 Weeks Returns	9 (75.0)	16 (76.2)	25 (75.8)
EOT + 12 Weeks N	10	18	28
EOT + 12 Weeks Returns	8 (80.0)	15 (83.3)	23 (82.1)
EORTC QLQ-CML24			
Baseline N	284	284	568
Baseline Returns	161 (56.7)	157 (55.3)	318 (56.0)
Week 4 N	273	264	537
Week 4 Returns	251 (91.9)	227 (86.0)	478 (89.0)
Week 8 N	264	252	516
Week 8 Returns	171 (64.8)	149 (59.1)	320 (62.0)
Week 12 N	258	248	506
Week 12 Returns	224 (86.8)	207 (83.5)	431 (85.2)
Week 24 N	233	221	454

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 24 Returns	209 (89.7)	188 (85.1)	397 (87.4)
Week 48 N	192	174	366
Week 48 Returns	186 (96.9)	164 (94.3)	350 (95.6)
Week 96 N	32	34	66
Week 96 Returns	30 (93.8)	34 (100.0)	64 (97.0)
EOT N	47	75	122
EOT Returns	18 (38.3)	28 (37.3)	46 (37.7)
EOT + 4 Weeks N	17	24	41
EOT + 4 Weeks Returns	15 (88.2)	21 (87.5)	36 (87.8)
EOT + 8 Weeks N	12	21	33
EOT + 8 Weeks Returns	8 (66.7)	16 (76.2)	24 (72.7)
EOT + 12 Weeks N	10	18	28
EOT + 12 Weeks Returns	8 (80.0)	15 (83.3)	23 (82.1)
FACT-ITEM GP5 V4			
Baseline N	284	284	568
Baseline Returns	156 (54.9)	152 (53.5)	308 (54.2)
Week 1 N	276	274	550

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 1 Returns	193 (69.9)	185 (67.5)	378 (68.7)
Week 2 N	275	270	545
Week 2 Returns	203 (73.8)	203 (75.2)	406 (74.5)
Week 3 N	275	269	544
Week 3 Returns	179 (65.1)	173 (64.3)	352 (64.7)
Week 4 N	275	266	541
Week 4 Returns	215 (78.2)	182 (68.4)	397 (73.4)
Week 5 N	273	263	536
Week 5 Returns	191 (70.0)	167 (63.5)	358 (66.8)
Week 6 N	273	261	534
Week 6 Returns	175 (64.1)	167 (64.0)	342 (64.0)
Week 7 N	273	260	533
Week 7 Returns	177 (64.8)	155 (59.6)	332 (62.3)
Week 8 N	272	259	531
Week 8 Returns	153 (56.3)	133 (51.4)	286 (53.9)
Week 9 N	271	257	528
Week 9 Returns	178 (65.7)	156 (60.7)	334 (63.3)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 10 N	270	256	526
Week 10 Returns	167 (61.9)	162 (63.3)	329 (62.5)
Week 11 N	268	255	523
Week 11 Returns	176 (65.7)	155 (60.8)	331 (63.3)
Week 12 N	266	253	519
Week 12 Returns	189 (71.1)	179 (70.8)	368 (70.9)
Week 13 N	265	253	518
Week 13 Returns	173 (65.3)	151 (59.7)	324 (62.5)
Week 14 N	263	251	514
Week 14 Returns	159 (60.5)	139 (55.4)	298 (58.0)
Week 15 N	262	249	511
Week 15 Returns	163 (62.2)	149 (59.8)	312 (61.1)
Week 16 N	261	249	510
Week 16 Returns	164 (62.8)	149 (59.8)	313 (61.4)
Week 17 N	260	247	507
Week 17 Returns	162 (62.3)	145 (58.7)	307 (60.6)
Week 18 N	257	246	503

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 18 Returns	164 (63.8)	144 (58.5)	308 (61.2)
Week 19 N	254	244	498
Week 19 Returns	161 (63.4)	141 (57.8)	302 (60.6)
Week 20 N	253	242	495
Week 20 Returns	163 (64.4)	140 (57.9)	303 (61.2)
Week 21 N	251	241	492
Week 21 Returns	162 (64.5)	146 (60.6)	308 (62.6)
Week 22 N	250	241	491
Week 22 Returns	148 (59.2)	145 (60.2)	293 (59.7)
Week 23 N	250	239	489
Week 23 Returns	161 (64.4)	153 (64.0)	314 (64.2)
Week 24 N	246	233	479
Week 24 Returns	215 (87.4)	205 (88.0)	420 (87.7)
Week 36 N	235	218	453
Week 36 Returns	188 (80.0)	160 (73.4)	348 (76.8)
Week 40 N	223	205	428
Week 40 Returns	124 (55.6)	93 (45.4)	217 (50.7)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 44 N	218	198	416
Week 44 Returns	114 (52.3)	84 (42.4)	198 (47.6)
Week 48 N	212	193	405
Week 48 Returns	169 (79.7)	148 (76.7)	317 (78.3)
Week 52 N	165	152	317
Week 52 Returns	95 (57.6)	72 (47.4)	167 (52.7)
Week 56 N	153	141	294
Week 56 Returns	86 (56.2)	70 (49.6)	156 (53.1)
Week 60 N	144	127	271
Week 60 Returns	113 (78.5)	88 (69.3)	201 (74.2)
Week 64 N	127	105	232
Week 64 Returns	74 (58.3)	53 (50.5)	127 (54.7)
Week 68 N	121	98	219
Week 68 Returns	70 (57.9)	43 (43.9)	113 (51.6)
Week 72 N	104	92	196
Week 72 Returns	79 (76.0)	67 (72.8)	146 (74.5)
Week 76 N	85	76	161

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 76 Returns	50 (58.8)	43 (56.6)	93 (57.8)
Week 80 N	75	68	143
Week 80 Returns	42 (56.0)	40 (58.8)	82 (57.3)
Week 84 N	63	61	124
Week 84 Returns	47 (74.6)	44 (72.1)	91 (73.4)
Week 88 N	49	46	95
Week 88 Returns	31 (63.3)	28 (60.9)	59 (62.1)
Week 92 N	40	39	79
Week 92 Returns	23 (57.5)	20 (51.3)	43 (54.4)
Week 96 N	35	35	70
Week 96 Returns	25 (71.4)	30 (85.7)	55 (78.6)
Week 100 N	28	21	49
Week 100 Returns	18 (64.3)	18 (85.7)	36 (73.5)
Week 104 N	21	17	38
Week 104 Returns	17 (81.0)	14 (82.4)	31 (81.6)
Week 108 N	14	14	28
Week 108 Returns	8 (57.1)	9 (64.3)	17 (60.7)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 112 N	11	10	21
Week 112 Returns	8 (72.7)	9 (90.0)	17 (81.0)
Week 116 N	8	5	13
Week 116 Returns	7 (87.5)	4 (80.0)	11 (84.6)
Week 120 N	2	2	4
Week 120 Returns	2 (100.0)	2 (100.0)	4 (100.0)
EOT N	48	76	124
EOT Returns	22 (45.8)	40 (52.6)	62 (50.0)
EOT + 4 Weeks N	25	30	55
EOT + 4 Weeks Returns	22 (88.0)	29 (96.7)	51 (92.7)
EOT + 8 Weeks N	18	22	40
EOT + 8 Weeks Returns	13 (72.2)	20 (90.9)	33 (82.5)
EOT + 12 Weeks N	15	20	35
EOT + 12 Weeks Returns	12 (80.0)	17 (85.0)	29 (82.9)
PRO-CTCAE V1.0			
Baseline N	284	284	568
Baseline Returns	157 (55.3)	154 (54.2)	311 (54.8)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 1 N	276	274	550
Week 1 Returns	195 (70.7)	186 (67.9)	381 (69.3)
Week 2 N	275	270	545
Week 2 Returns	205 (74.5)	206 (76.3)	411 (75.4)
Week 3 N	275	269	544
Week 3 Returns	180 (65.5)	173 (64.3)	353 (64.9)
Week 4 N	275	266	541
Week 4 Returns	215 (78.2)	184 (69.2)	399 (73.8)
Week 5 N	273	263	536
Week 5 Returns	191 (70.0)	167 (63.5)	358 (66.8)
Week 6 N	273	261	534
Week 6 Returns	176 (64.5)	167 (64.0)	343 (64.2)
Week 7 N	273	260	533
Week 7 Returns	180 (65.9)	156 (60.0)	336 (63.0)
Week 8 N	272	259	531
Week 8 Returns	153 (56.3)	133 (51.4)	286 (53.9)
Week 9 N	271	257	528

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 9 Returns	180 (66.4)	157 (61.1)	337 (63.8)
Week 10 N	270	256	526
Week 10 Returns	168 (62.2)	162 (63.3)	330 (62.7)
Week 11 N	268	255	523
Week 11 Returns	178 (66.4)	156 (61.2)	334 (63.9)
Week 12 N	266	253	519
Week 12 Returns	191 (71.8)	180 (71.1)	371 (71.5)
Week 13 N	265	253	518
Week 13 Returns	174 (65.7)	150 (59.3)	324 (62.5)
Week 14 N	263	251	514
Week 14 Returns	162 (61.6)	140 (55.8)	302 (58.8)
Week 15 N	262	249	511
Week 15 Returns	166 (63.4)	149 (59.8)	315 (61.6)
Week 16 N	261	249	510
Week 16 Returns	165 (63.2)	149 (59.8)	314 (61.6)
Week 17 N	260	247	507
Week 17 Returns	163 (62.7)	145 (58.7)	308 (60.7)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 18 N	257	246	503
Week 18 Returns	165 (64.2)	145 (58.9)	310 (61.6)
Week 19 N	254	244	498
Week 19 Returns	162 (63.8)	141 (57.8)	303 (60.8)
Week 20 N	253	242	495
Week 20 Returns	165 (65.2)	140 (57.9)	305 (61.6)
Week 21 N	251	241	492
Week 21 Returns	164 (65.3)	147 (61.0)	311 (63.2)
Week 22 N	250	241	491
Week 22 Returns	149 (59.6)	145 (60.2)	294 (59.9)
Week 23 N	250	239	489
Week 23 Returns	162 (64.8)	154 (64.4)	316 (64.6)
Week 24 N	246	233	479
Week 24 Returns	218 (88.6)	205 (88.0)	423 (88.3)
Week 36 N	235	218	453
Week 36 Returns	189 (80.4)	160 (73.4)	349 (77.0)
Week 40 N	223	205	428

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 40 Returns	125 (56.1)	93 (45.4)	218 (50.9)
Week 44 N	218	198	416
Week 44 Returns	115 (52.8)	84 (42.4)	199 (47.8)
Week 48 N	212	193	405
Week 48 Returns	169 (79.7)	149 (77.2)	318 (78.5)
Week 52 N	165	152	317
Week 52 Returns	97 (58.8)	74 (48.7)	171 (53.9)
Week 56 N	153	141	294
Week 56 Returns	88 (57.5)	70 (49.6)	158 (53.7)
Week 60 N	144	127	271
Week 60 Returns	113 (78.5)	89 (70.1)	202 (74.5)
Week 64 N	127	105	232
Week 64 Returns	75 (59.1)	53 (50.5)	128 (55.2)
Week 68 N	121	98	219
Week 68 Returns	70 (57.9)	43 (43.9)	113 (51.6)
Week 72 N	104	92	196
Week 72 Returns	80 (76.9)	68 (73.9)	148 (75.5)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 76 N	85	76	161
Week 76 Returns	51 (60.0)	43 (56.6)	94 (58.4)
Week 80 N	75	68	143
Week 80 Returns	43 (57.3)	40 (58.8)	83 (58.0)
Week 84 N	63	61	124
Week 84 Returns	47 (74.6)	44 (72.1)	91 (73.4)
Week 88 N	49	46	95
Week 88 Returns	31 (63.3)	28 (60.9)	59 (62.1)
Week 92 N	40	39	79
Week 92 Returns	23 (57.5)	20 (51.3)	43 (54.4)
Week 96 N	35	35	70
Week 96 Returns	26 (74.3)	31 (88.6)	57 (81.4)
Week 100 N	28	21	49
Week 100 Returns	18 (64.3)	18 (85.7)	36 (73.5)
Week 104 N	21	17	38
Week 104 Returns	17 (81.0)	14 (82.4)	31 (81.6)
Week 108 N	14	14	28

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**
Week 108 Returns	8 (57.1)	9 (64.3)	17 (60.7)
Week 112 N	11	10	21
Week 112 Returns	8 (72.7)	9 (90.0)	17 (81.0)
Week 116 N	8	5	13
Week 116 Returns	7 (87.5)	4 (80.0)	11 (84.6)
Week 120 N	2	2	4
Week 120 Returns	2 (100.0)	2 (100.0)	4 (100.0)
EOT N	48	76	124
EOT Returns	22 (45.8)	40 (52.6)	62 (50.0)
EOT + 4 Weeks N	25	30	55
EOT + 4 Weeks Returns	22 (88.0)	29 (96.7)	51 (92.7)
EOT + 8 Weeks N	18	22	40
EOT + 8 Weeks Returns	13 (72.2)	20 (90.9)	33 (82.5)
EOT + 12 Weeks N	15	20	35
EOT + 12 Weeks Returns	12 (80.0)	18 (90.0)	30 (85.7)

	Treatment groups		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**Total (N = 568) n (%)**

N: Number of patients
n (%): Number and percentage of patients with event
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Return rates include PROs that were fully and partially completed at the respective visit.
The return rate is the proportion of patients with valid data at the given visit based on the patients on study at this visit.
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Table 1-1.7: Duration of exposure to study treatment (Safety Analysis Set)

	Treatment groups	
	Asciminib (N = 284)	**Nilotinib (N = 282)**
Duration of exposure (n, %)		
Less than 24 weeks	18 (6.3)	31 (11.0)
At least 24 weeks	13 (4.6)	25 (8.9)
At least 48 weeks	199 (70.1)	179 (63.5)
At least 96 weeks	54 (19.0)	47 (16.7)
Duration of exposure in patient years	394.17	362.87

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Table 1-1.8: Actual cumulative dose, Average daily dose, Dose intensity and Relative dose intensity (Safety Analysis Set)

	Treatment groups	
	Asciminib (N = 284)	**Nilotinib (N = 282)**
Actual cumulative dose (mg)		
n	284	282
mean (SD)	38645 (15197)	266007 (127401)
median	38680	274800
range (Min - Max)	800-70640	1200-522000
Average daily dose (mg/day)		
n	284	282
mean (SD)	77.3 (8.6)	568.6 (77.9)
median	80.0	600.0
range (Min - Max)	42.4-109.3	0.0-827.6
Dose intensity (mg/day)		
n	284	282
mean (SD)	75.2 (11.3)	550.9 (87.2)
median	80.0	599.8
range (Min - Max)	18.1-101.7	91.8-725.3
Relative dose intensity (%)		

	Treatment groups	
	Asciminib (N = 284)	**Nilotinib (N = 282)**
n	284	282
mean (SD)	94.0 (14.2)	91.8 (14.5)
median	100.0	100.0
range (Min - Max)	22.6-127.1	15.3-120.9

SD: Standard deviation

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Table 1-1.9: Dose changes (Safety Analysis Set)

	Treatment groups	
	Asciminib (N = 284)	**Nilotinib (N = 282)**
Dose changes (n, %)		
Decrease	36 (12.7)	73 (25.9)
Increase	2 (0.7)	4 (1.4)
No change	246 (86.6)	204 (72.3)
Planned	11 (3.9)	25 (8.9)
Reasons for dose changes (n, %)		
ADVERSE EVENT	22 (7.7)	35 (12.4)
AS PER PROTOCOL	18 (6.3)	29 (10.3)
DISPENSING ERROR	0	2 (0.7)
DOSING ERROR	4 (1.4)	16 (5.7)
PHYSICIAN DECISION	0	14 (5.0)
SUBJECT DECISION	0	7 (2.5)

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Table 1-1.10: Dose interruptions (Safety Analysis Set)

	Treatment groups	
	Asciminib (N = 284)	**Nilotinib (N = 282)**
Dose interruptions (n, %)		
No	190 (66.9)	193 (68.4)
Yes	94 (33.1)	89 (31.6)
Reasons for dose interruptions (n, %)		
ADVERSE EVENT	77 (27.1)	83 (29.4)
AS PER PROTOCOL	1 (0.4)	0
DISPENSING ERROR	1 (0.4)	1 (0.4)
DOSING ERROR	13 (4.6)	4 (1.4)
PHYSICIAN DECISION	3 (1.1)	3 (1.1)
SUBJECT DECISION	4 (1.4)	6 (2.1)
TECHNICAL PROBLEMS	2 (0.7)	2 (0.7)
Duration of interruptions (days)		
n	94	89
mean (SD)	18.0 (17.3)	18.0 (17.9)
median	13.0	14.0
range (Min - Max)	1.0-114.0	1.0-138.0

	Treatment groups	
	Asciminib (N = 284)	**Nilotinib (N = 282)**

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Table 1-1.11: Dose permanent discontinuations (Safety Analysis Set)

	Treatment groups	
	Asciminib (N = 284)	**Nilotinib (N = 282)**
Permanent discontinuations (n, %)		
No	232 (81.7)	202 (71.6)
Yes	52 (18.3)	80 (28.4)
Reasons for permanent discontinuations (n, %)		
ADVERSE EVENT	20 (7.0)	44 (15.6)
DEATH	2 (0.7)	1 (0.4)
PHYSICIAN DECISION	2 (0.7)	4 (1.4)
PREGNANCY	0	2 (0.7)
PROGRESSIVE DISEASE	3 (1.1)	2 (0.7)
PROTOCOL DEVIATION	2 (0.7)	1 (0.4)
REQUIRES PROHIBITED MEDICATION	0	1 (0.4)
SUBJECT DECISION	1 (0.4)	3 (1.1)
TECHNICAL PROBLEMS	0	1 (0.4)
UNSATISFACTORY THERAPEUTIC EFFECT	21 (7.4)	21 (7.4)
WITHDRAWAL OF INFORMED CONSENT	1 (0.4)	0

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Table 1-1.12: First therapy since discontinuation of study drug by ATC class (Full analysis set)

Therapies by ATC Class	Asciminib N=284 n (%)	Nilotinib N=284 n (%)	All Subjects N=568 n (%)
Number of subjects with at least one medication	43 (15.1)	70 (24.6)	113 (19.9)
Antineoplastic and immunomodulating agents	43 (15.1)	70 (24.6)	113 (19.9)
Dasatinib	16 (5.6)	29 (10.2)	45 (7.9)
Imatinib	10 (3.5)	10 (3.5)	20 (3.5)
Nilotinib	9 (3.2)	7 (2.5)	16 (2.8)
Bosutinib	3 (1.1)	7 (2.5)	10 (1.8)
Nilotinib Hydrochloride Monohydrate	3 (1.1)	2 (0.7)	5 (0.9)
Ponatinib	1 (0.4)	2 (0.7)	3 (0.5)
Hydroxycarbamide	1 (0.4)	1 (0.4)	2 (0.4)
Asciminib	0	6 (2.1)	6 (1.1)
Dasatinib Monohydrate	0	2 (0.7)	2 (0.4)
Peginterferon Alfa-2a	0	2 (0.7)	2 (0.4)
Cytarabine	0	1 (0.4)	1 (0.2)
Imatinib Mesilate	0	1 (0.4)	1 (0.2)

Therapies by ATC Class	Asciminib N=284 n (%)	Nilotinib N=284 n (%)	All Subjects N=568 n (%)
Systemic hormonal preparations, excl. sex hormones and insulins	0	1 (0.4)	1 (0.2)
Prednisone	0	1 (0.4)	1 (0.2)

Medications started on or after the treatment discontinuation date are summarized.

A medication can be included in more than one ATC class.

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Table 1-1.13: All therapies since discontinuation of study drug by ATC class (Full analysis set)

Therapies by ATC Class	Asciminib N=284 n (%)	Nilotinib N=284 n (%)	All Subjects N=568 n (%)
Number of subjects with at least one medication	43 (15.1)	70 (24.6)	113 (19.9)
Antineoplastic and immunomodulating agents	43 (15.1)	70 (24.6)	113 (19.9)
Dasatinib	19 (6.7)	32 (11.3)	51 (9.0)
Imatinib	11 (3.9)	11 (3.9)	22 (3.9)
Nilotinib	10 (3.5)	7 (2.5)	17 (3.0)
Bosutinib	3 (1.1)	7 (2.5)	10 (1.8)
Ponatinib	3 (1.1)	5 (1.8)	8 (1.4)
Nilotinib Hydrochloride Monohydrate	3 (1.1)	2 (0.7)	5 (0.9)
Hydroxycarbamide	2 (0.7)	1 (0.4)	3 (0.5)
Methotrexate	1 (0.4)	1 (0.4)	2 (0.4)
Blinatumomab	1 (0.4)	0	1 (0.2)
Pegaspargase	1 (0.4)	0	1 (0.2)
Ponatinib Hydrochloride	1 (0.4)	0	1 (0.2)

Therapies by ATC Class	Asciminib N=284 n (%)	Nilotinib N=284 n (%)	All Subjects N=568 n (%)
Ruxolitinib	1 (0.4)	0	1 (0.2)
Vincristine Sulfate	1 (0.4)	0	1 (0.2)
Asciminib	0	17 (6.0)	17 (3.0)
Peginterferon Alfa-2a	0	3 (1.1)	3 (0.5)
Dasatinib Monohydrate	0	2 (0.7)	2 (0.4)
Cytarabine	0	1 (0.4)	1 (0.2)
Fludarabine	0	1 (0.4)	1 (0.2)
Imatinib Mesilate	0	1 (0.4)	1 (0.2)
Rituximab	0	1 (0.4)	1 (0.2)
Vincristine	0	1 (0.4)	1 (0.2)
Systemic hormonal preparations, excl. sex hormones and insulins	0	1 (0.4)	1 (0.2)
Methylprednisolone	0	1 (0.4)	1 (0.2)
Prednisone	0	1 (0.4)	1 (0.2)

Medications started on or after the treatment discontinuation date are summarized.

A medication can be included in more than one ATC class.

WHODD version 202503.

CABL001J12302 - Primary Analysis (Cut-off date: 15MAY2025)

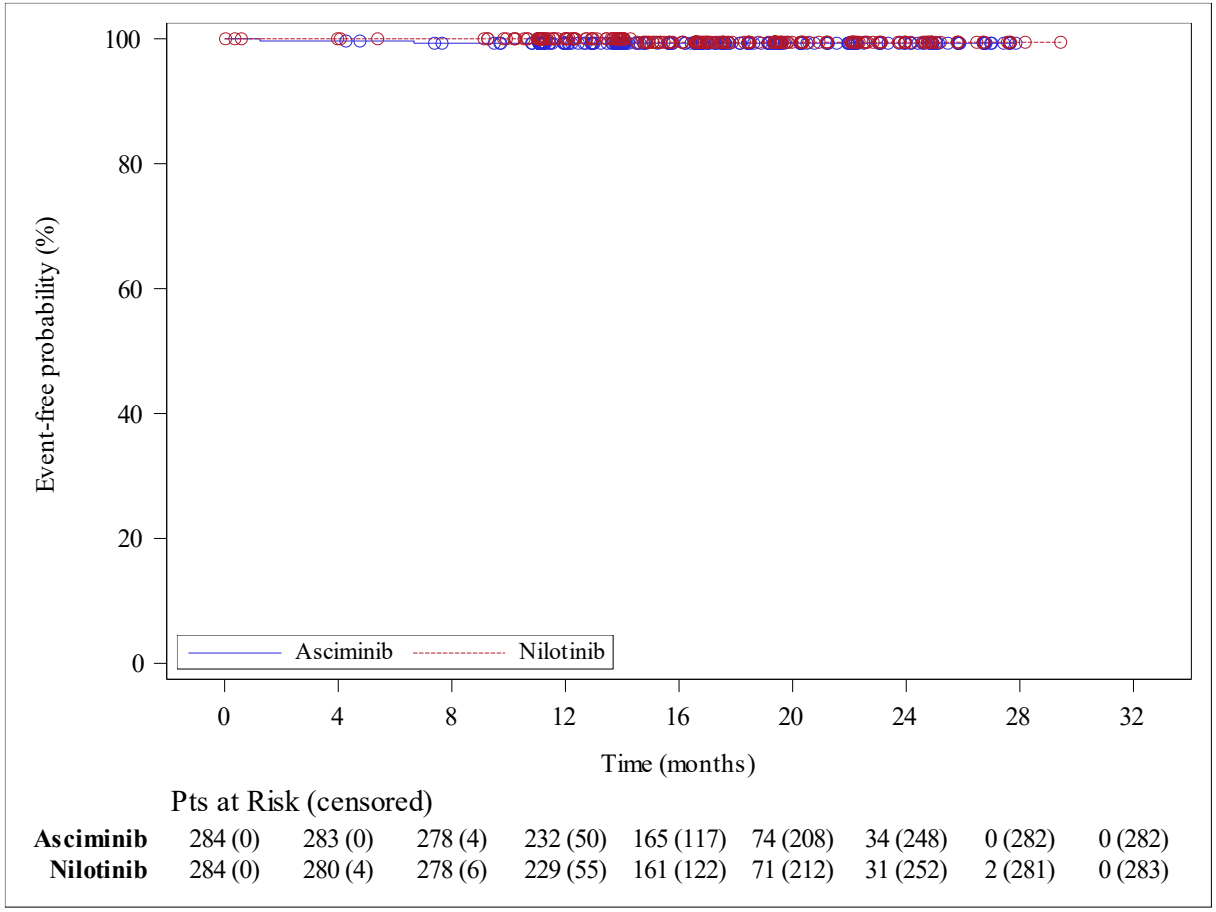
2. Efficacy

Table 2-1.1 Overall Survival (OS): time to event analysis (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
N*	284	284	1.98
Number of patients with events, n (%)	2 (0.7)	1 (0.4)	[0.18; 21.89]
			0.568
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 2-1.1 Overall Survival (OS): Kaplan-Meier plot (Full Analysis Set)



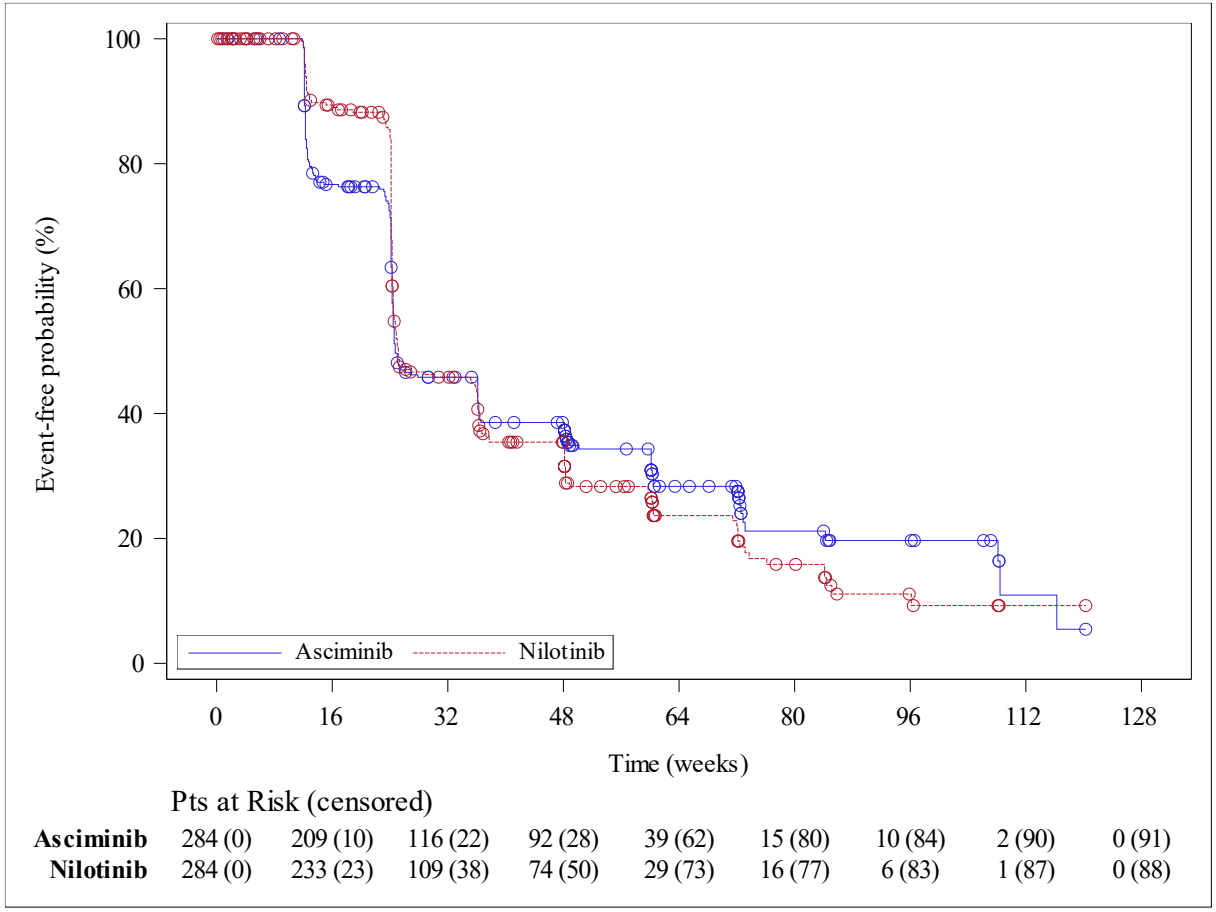
Note: o = Censored observations
Data Cut/15MAY2025

Table 2-1.2 MMR: time to event analysis (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
N*	284	284	0.99
Number of patients with events, n (%)	193 (68.0)	196 (69.0)	[0.81; 1.20]
			0.921
Percentiles (weeks) [95% CI]			
25th	23.3 [12.9; 24.1]	24.1 [N.E.; N.E.]	
Median	24.7 [24.4; 36.1]	25.1 [24.4; 36.0]	
75th	72.6 [60.3; 108]	60.4 [48.3; 72.4]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 2-1.2 MMR: Kaplan-Meier plot (Full Analysis Set)



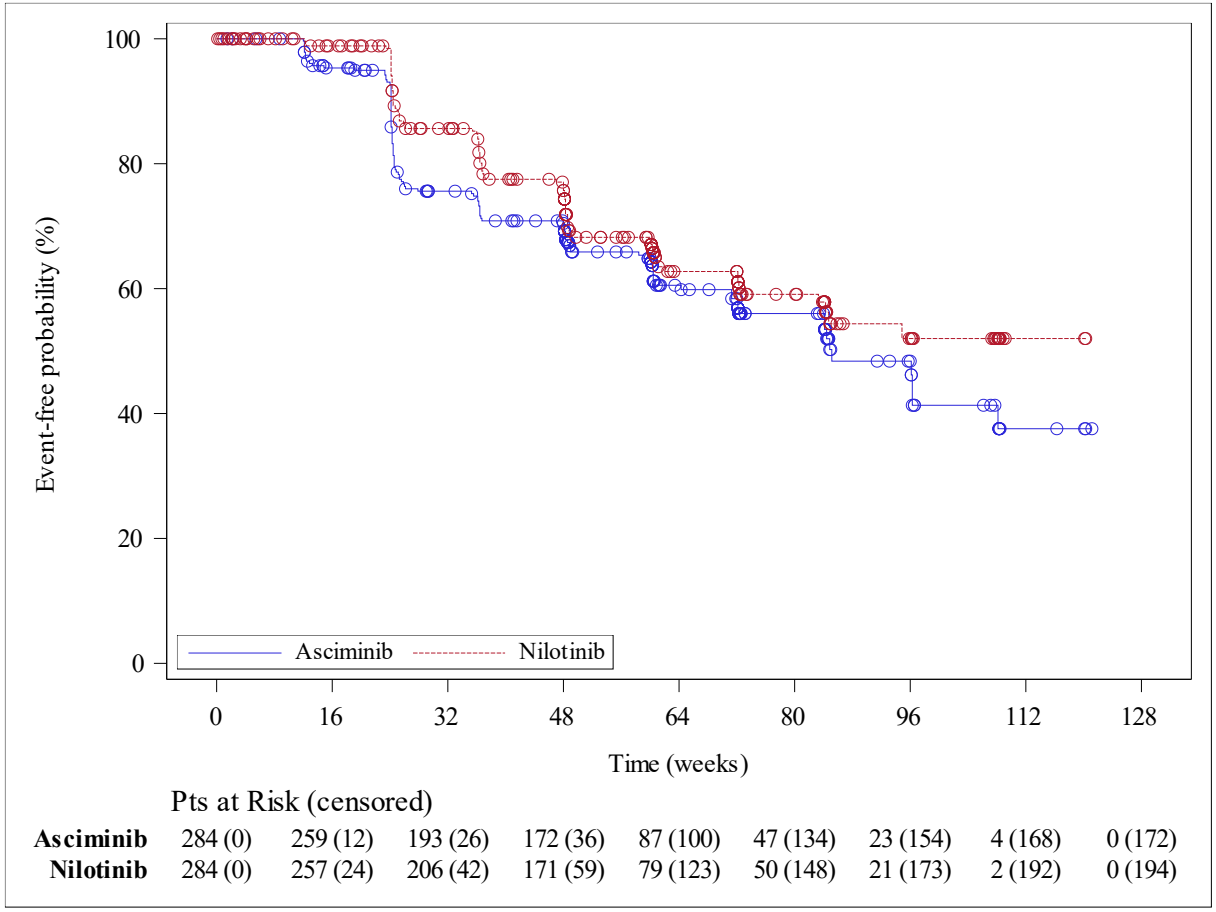
Note: o = Censored observations
Data Cut/15MAY2025

Table 2-1.3 MR4.0: time to event analysis (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
N*	284	284	1.30
Number of patients with events, n (%)	112 (39.4)	90 (31.7)	[0.99; 1.72]
			0.063
Percentiles (weeks) [95% CI]			
25th	35.6 [24.6; 48.1]	48.1 [36.4; 48.7]	
Median	85.1 [72.1; 108]	N.E. [84.3; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 2-1.3 MR4.0: Kaplan-Meier plot (Full Analysis Set)



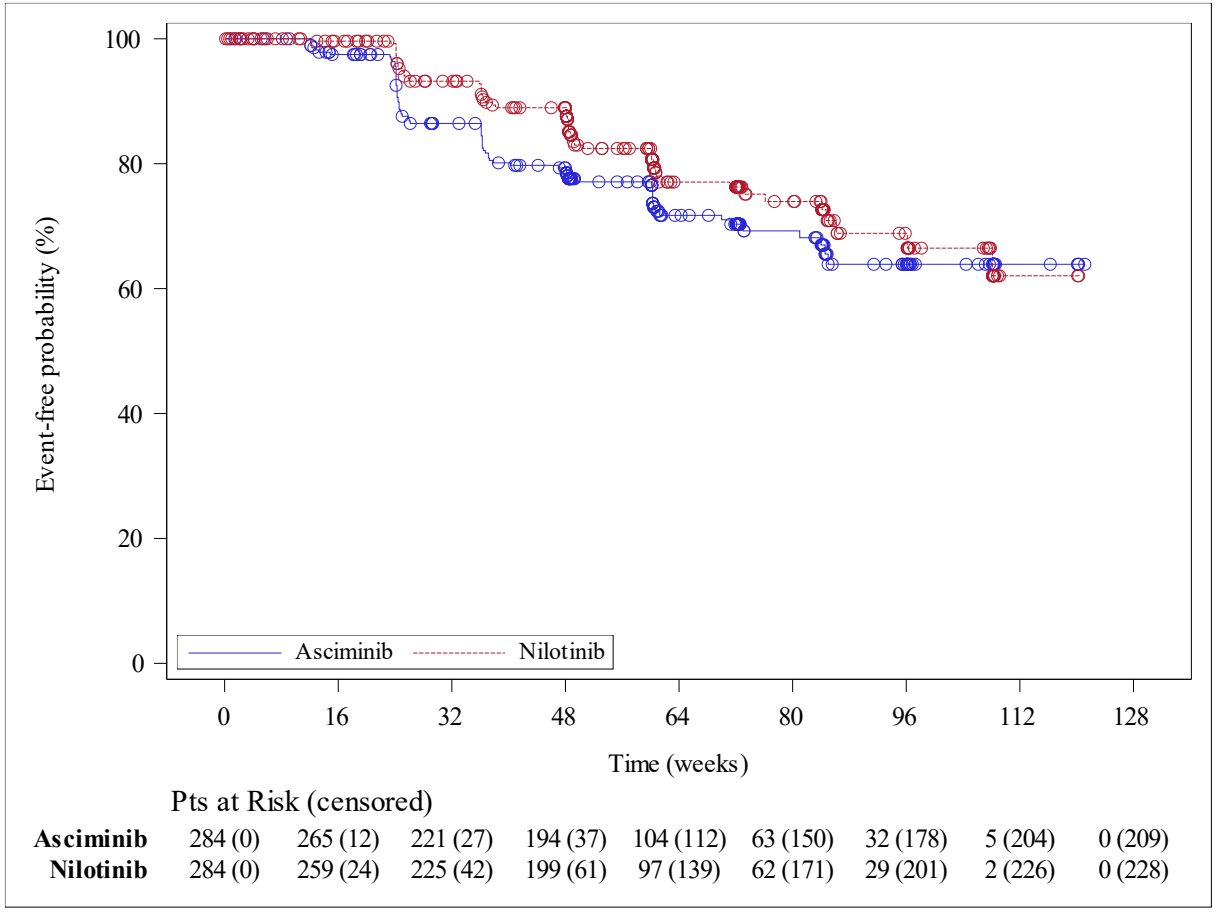
Note: o = Censored observations
Data Cut/15MAY2025

Table 2-1.4 MR4.5: time to event analysis (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
N*	284	284	1.37
Number of patients with events, n (%)	75 (26.4)	56 (19.7)	[0.97; 1.94]
			0.075
Percentiles (weeks) [95% CI]			
25th	60.3 [37.9; 81.0]	76.1 [60.1; 96.1]	
Median	N.E. [N.E.; N.E.]	N.E. [108; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 2-1.4 MR4.5: Kaplan-Meier plot (Full Analysis Set)



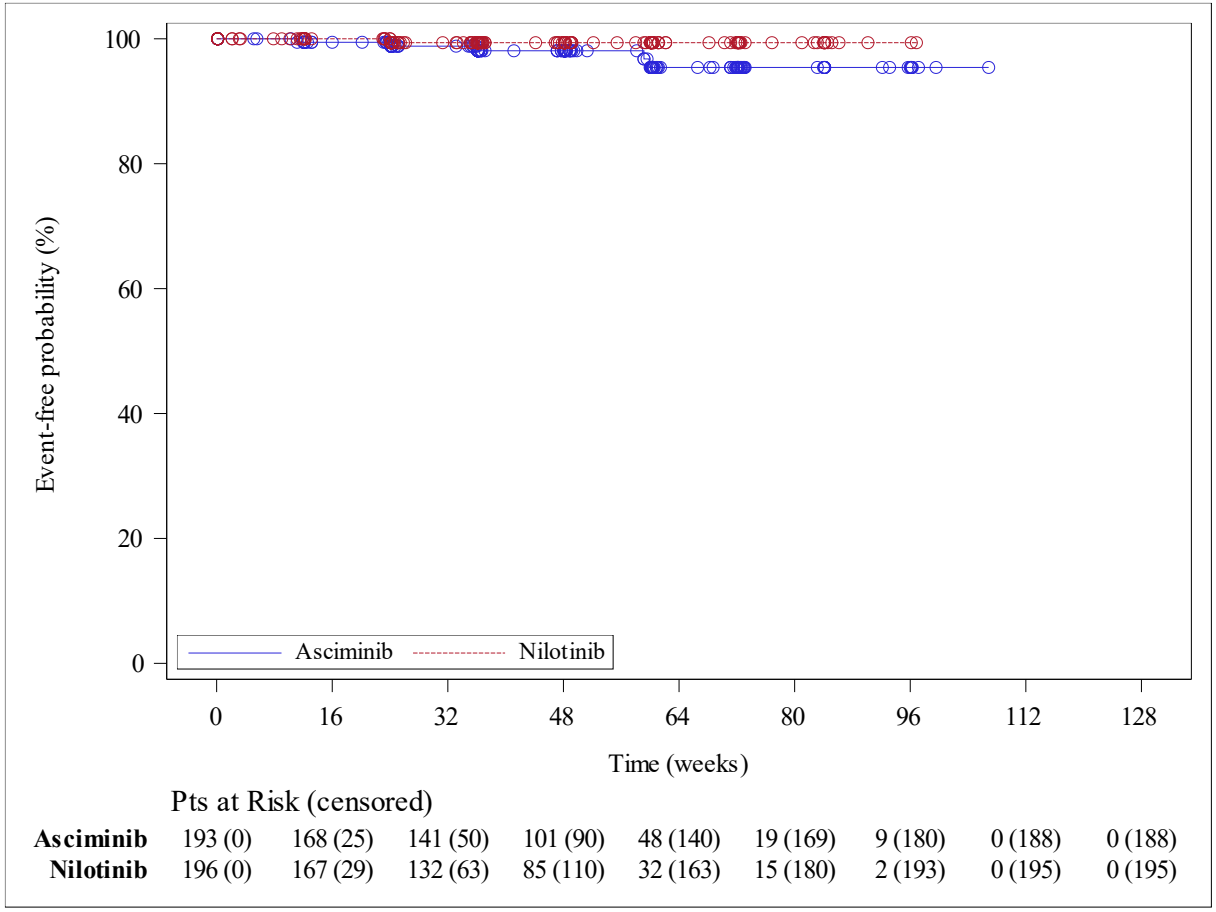
Note: o = Censored observations
Data Cut/15MAY2025

Table 2-1.5 Duration of MMR: duration of event (MMR Responder Set)

	Treatment groups		Comparison
	Asciminib (N = 193)	**Nilotinib (N = 196)**	**HR [95% CI] p-value**
N*	193	196	4.62
Number of patients with events, n (%)	5 (2.6)	1 (0.5)	[0.54; 39.75]
			0.123
Percentiles (weeks) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 2-1.5 Duration of MMR: Kaplan-Meier plot (MMR Responder Set)



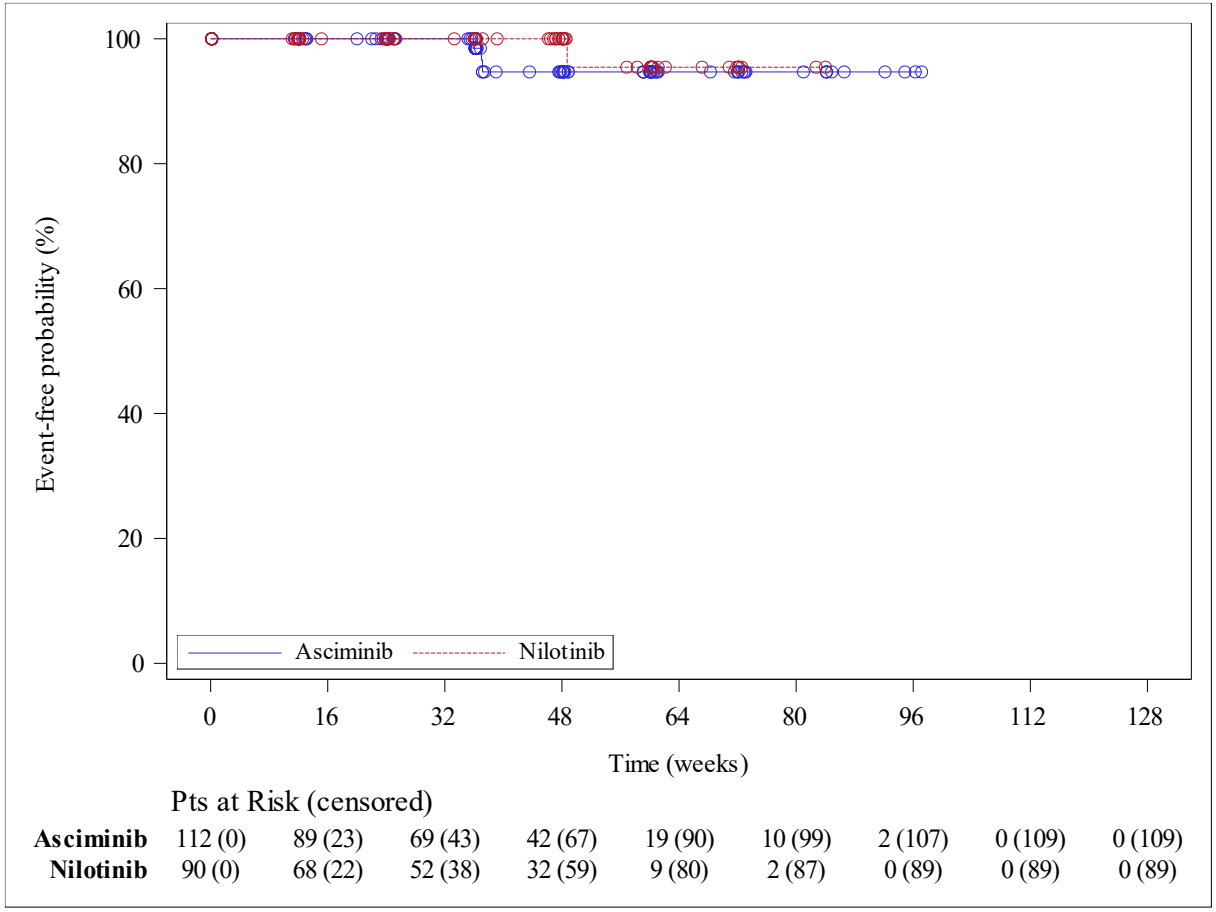
Note: o = Censored observations
Data Cut/15MAY2025

Table 2-1.6 Duration of MR4.0: duration of event (MR4.0 Responder Set)

	Treatment groups		Comparison
	Asciminib (N = 112)	**Nilotinib (N = 90)**	**HR [95% CI] p-value**
N*	112	90	2.44
Number of patients with events, n (%)	3 (2.7)	1 (1.1)	[0.25; 23.59]
			0.425
Percentiles (weeks) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [48.7; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 2-1.6 Duration of MR4.0: Kaplan-Meier plot (MR4.0 Responder Set)



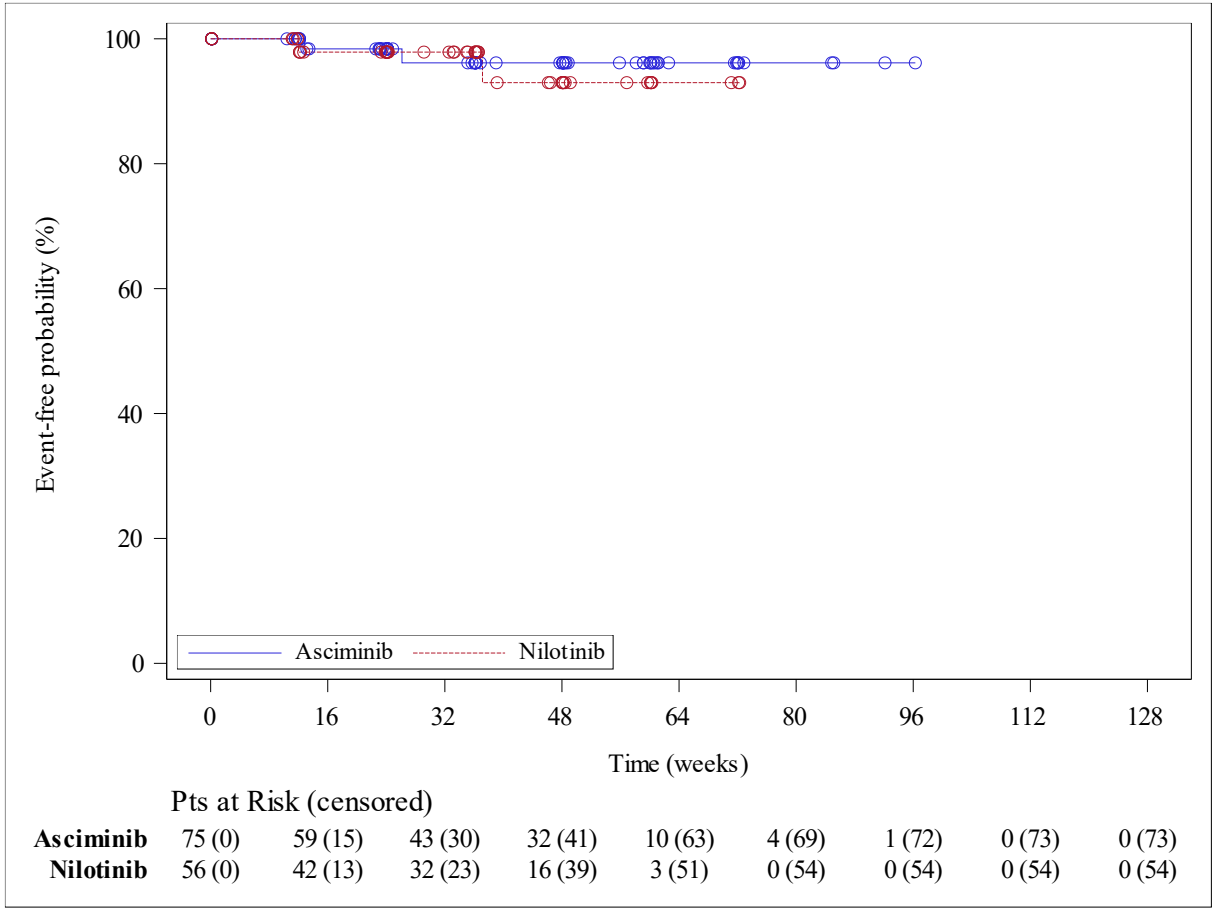
Note: o = Censored observations
Data Cut/15MAY2025

Table 2-1.7 Duration of MR4.5: duration of event (MR4.5 Responder Set)

	Treatment groups		Comparison
	Asciminib (N = 75)	**Nilotinib (N = 56)**	**HR [95% CI] p-value**
N*	75	56	0.58
Number of patients with events, n (%)	2 (2.7)	2 (3.6)	[0.08; 4.11]
			0.579
Percentiles (weeks) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [37.1; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 2-1.7 Duration of MR4.5: Kaplan-Meier plot (MR4.5 Responder Set)



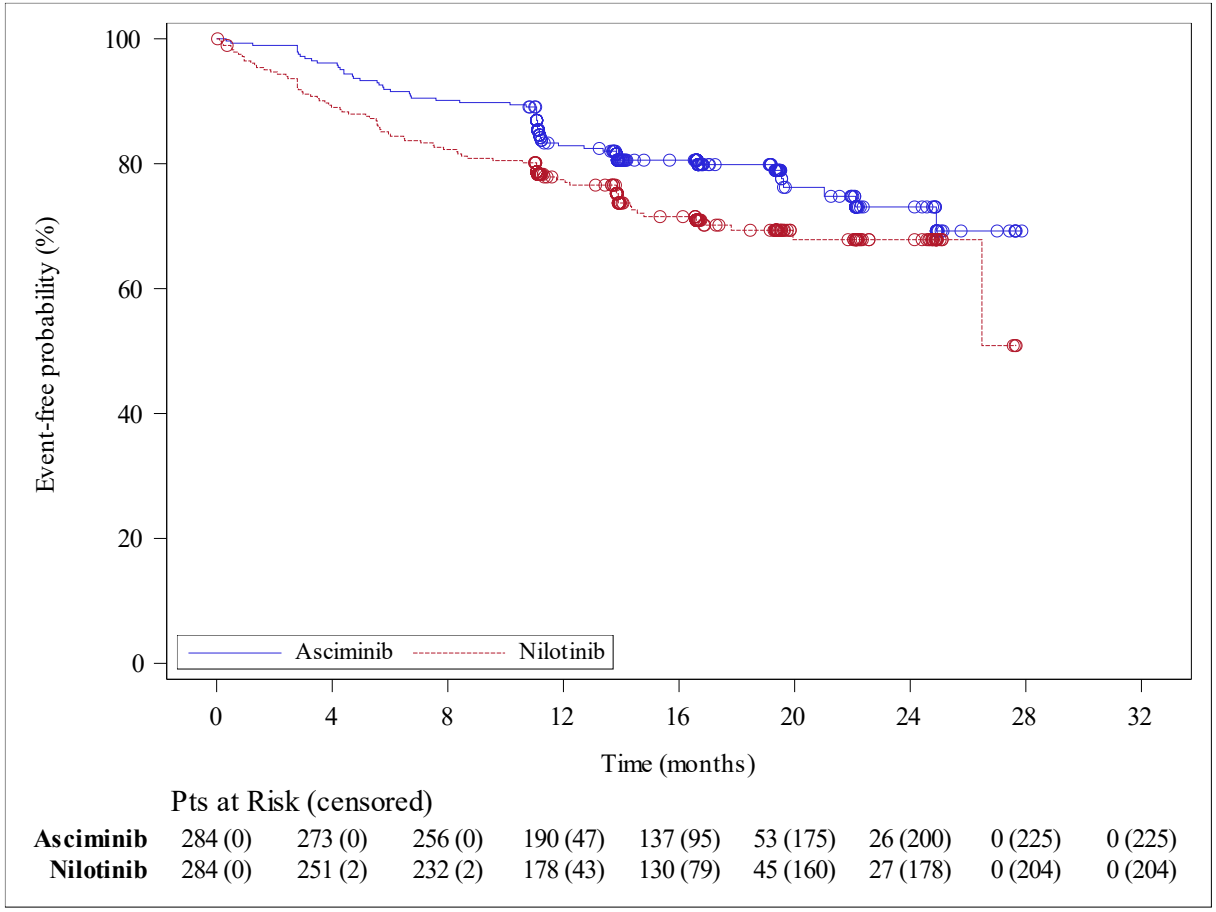
Note: o = Censored observations
Data Cut/15MAY2025

Table 2-1.8 Time to treatment failure: time to event analysis (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
N*	284	284	0.68
Number of patients with events, n (%)	59 (20.8)	80 (28.2)	[0.48; 0.95]
			0.022
Percentiles (months) [95% CI]			
25th	21.0 [16.7; N.E.]	13.9 [10.6; 17.8]	
Median	N.E. [N.E.; N.E.]	N.E. [26.5; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [26.5; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 2-1.8 Time to treatment failure: Kaplan-Meier plot (Full Analysis Set)



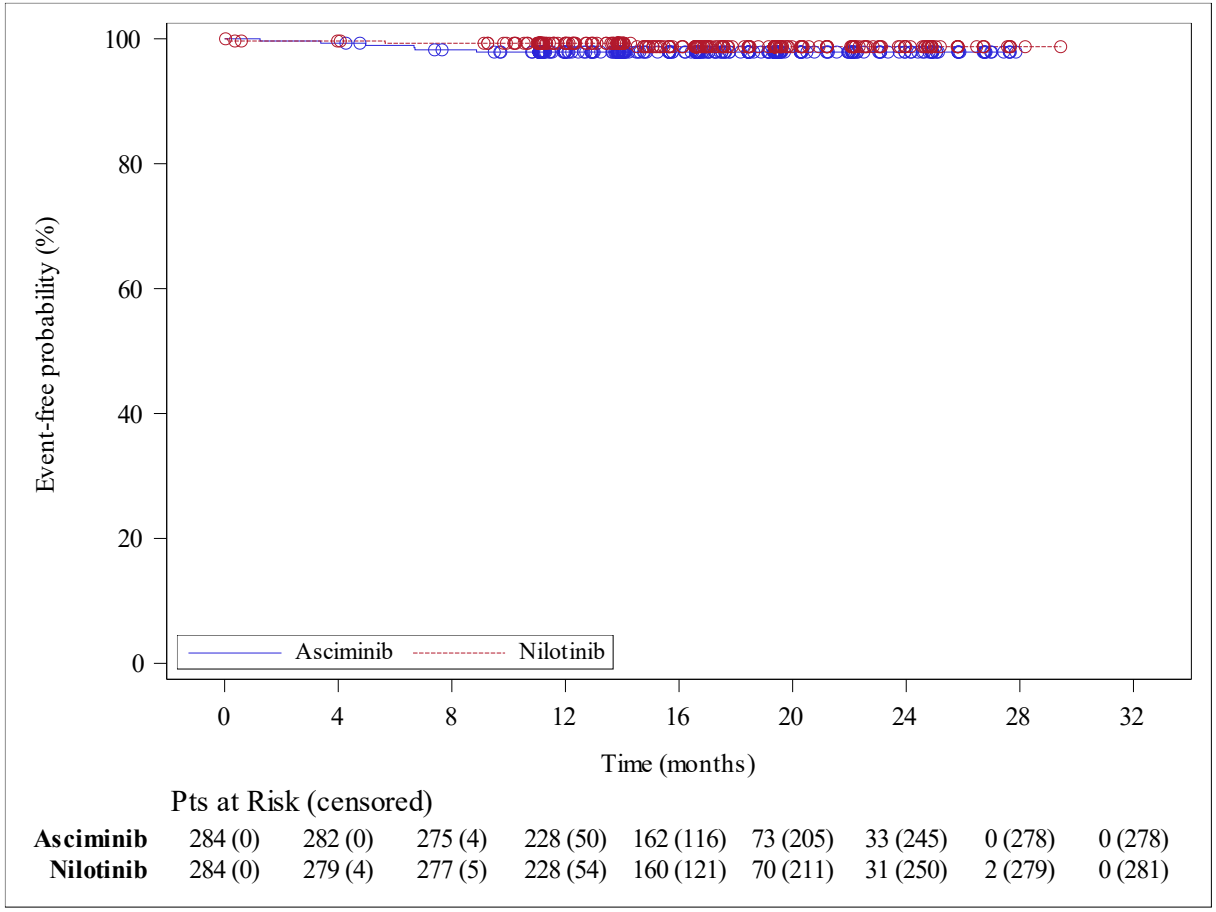
Note: o = Censored observations
Data Cut/15MAY2025

Table 2-1.9 Progression free survival: time to event analysis (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
N*	284	284	1.97
Number of patients with events, n (%)	6 (2.1)	3 (1.1)	[0.49; 7.89]
			0.327
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 2-1.9 Progression free survival: Kaplan-Meier plot (Full Analysis Set)



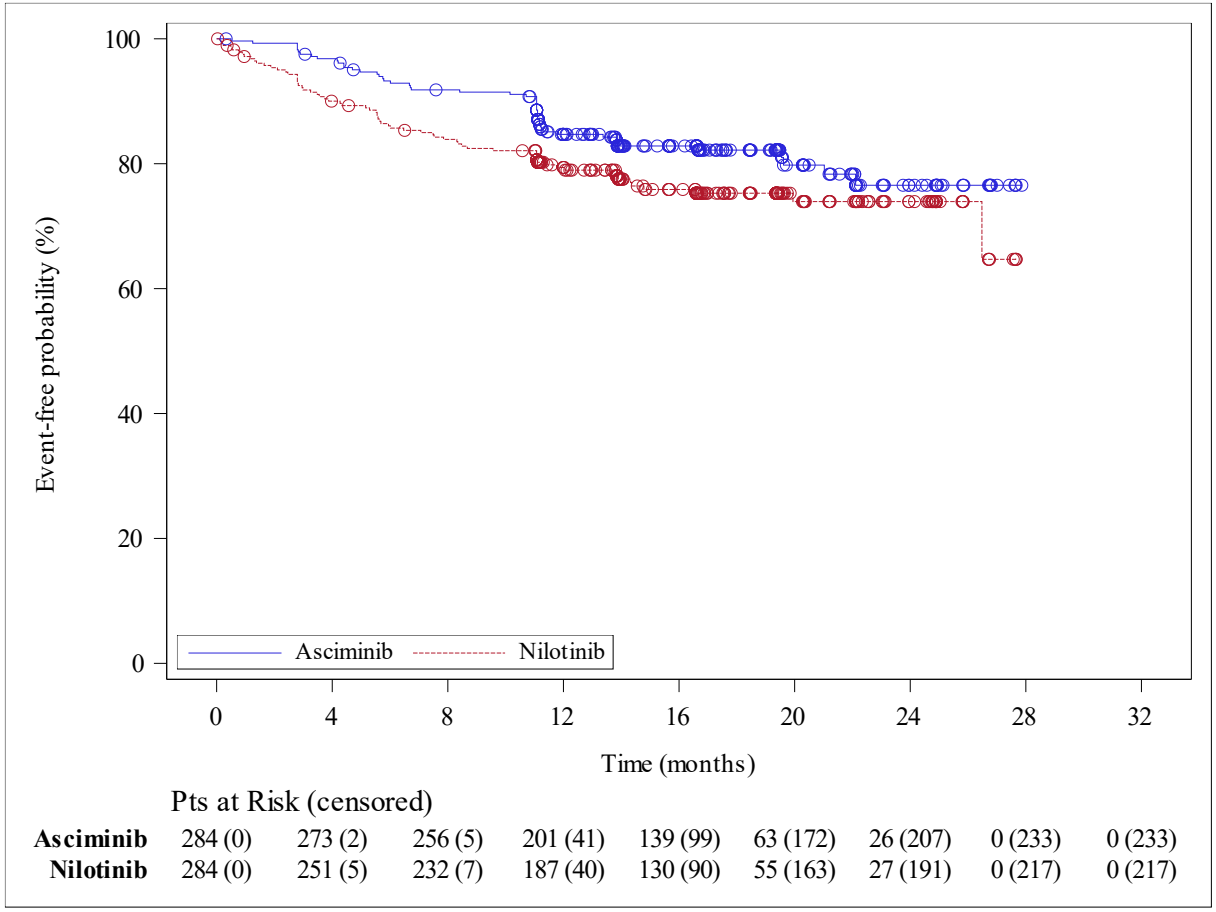
Note: o = Censored observations
Data Cut/15MAY2025

Table 2-1.10 Event free survival: time to event analysis (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
N*	284	284	0.69
Number of patients with events, n (%)	51 (18.0)	67 (23.6)	[0.48; 1.00]
			0.046
Percentiles (months) [95% CI]			
25th	N.E. [19.6; N.E.]	19.9 [11.3; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [26.5; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 2-1.10 Event free survival: Kaplan-Meier plot (Full Analysis Set)



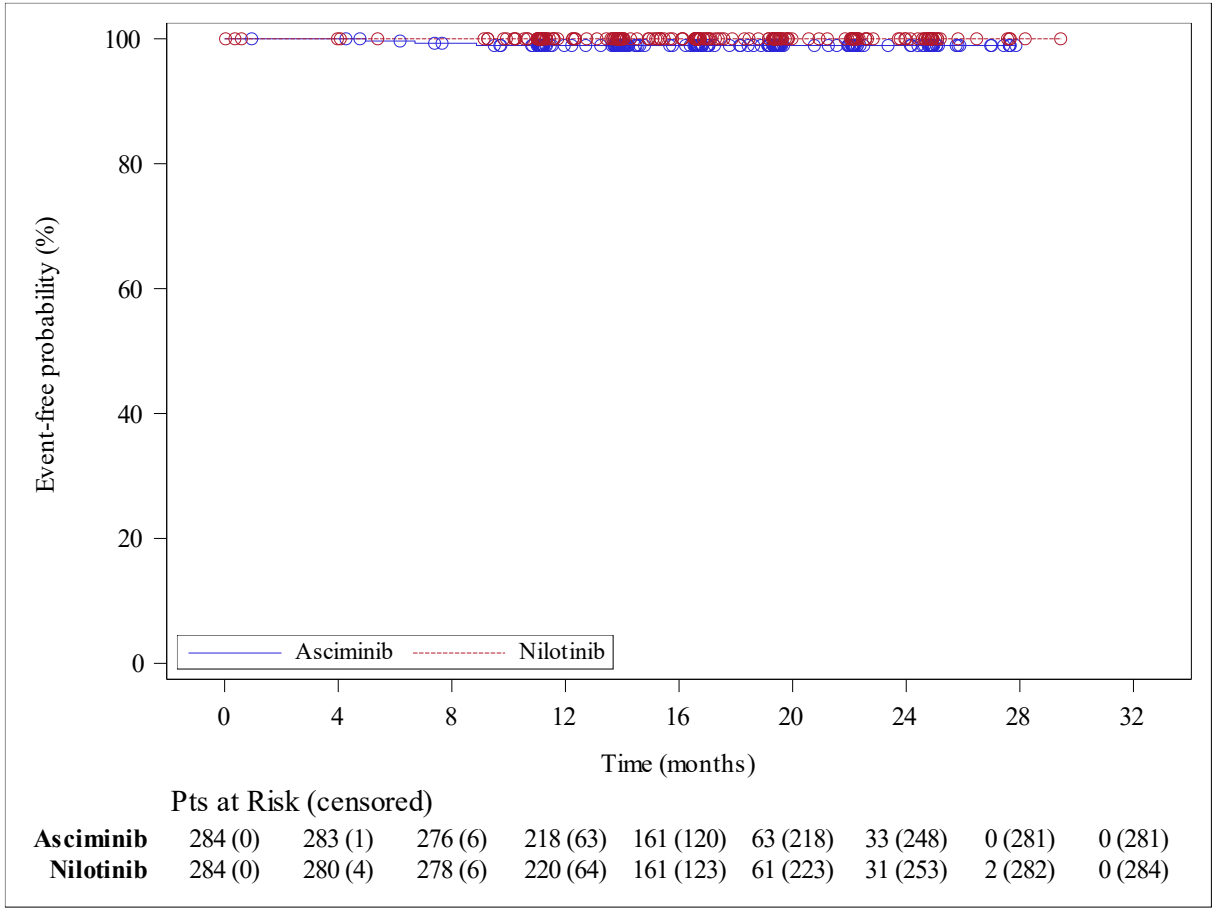
Note: o = Censored observations
Data Cut/15MAY2025

Table 2-1.12 Progression to blast crisis (BC): time to event analysis (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
N*	284	284	6.99
Number of patients with events, n (%)	3 (1.1)	0	[0.23; 214.0]
			0.083
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 2-1.12 Progression to blast crisis (BC): Kaplan-Meier plot (Full Analysis Set)



Note: o = Censored observations
Data Cut/15MAY2025

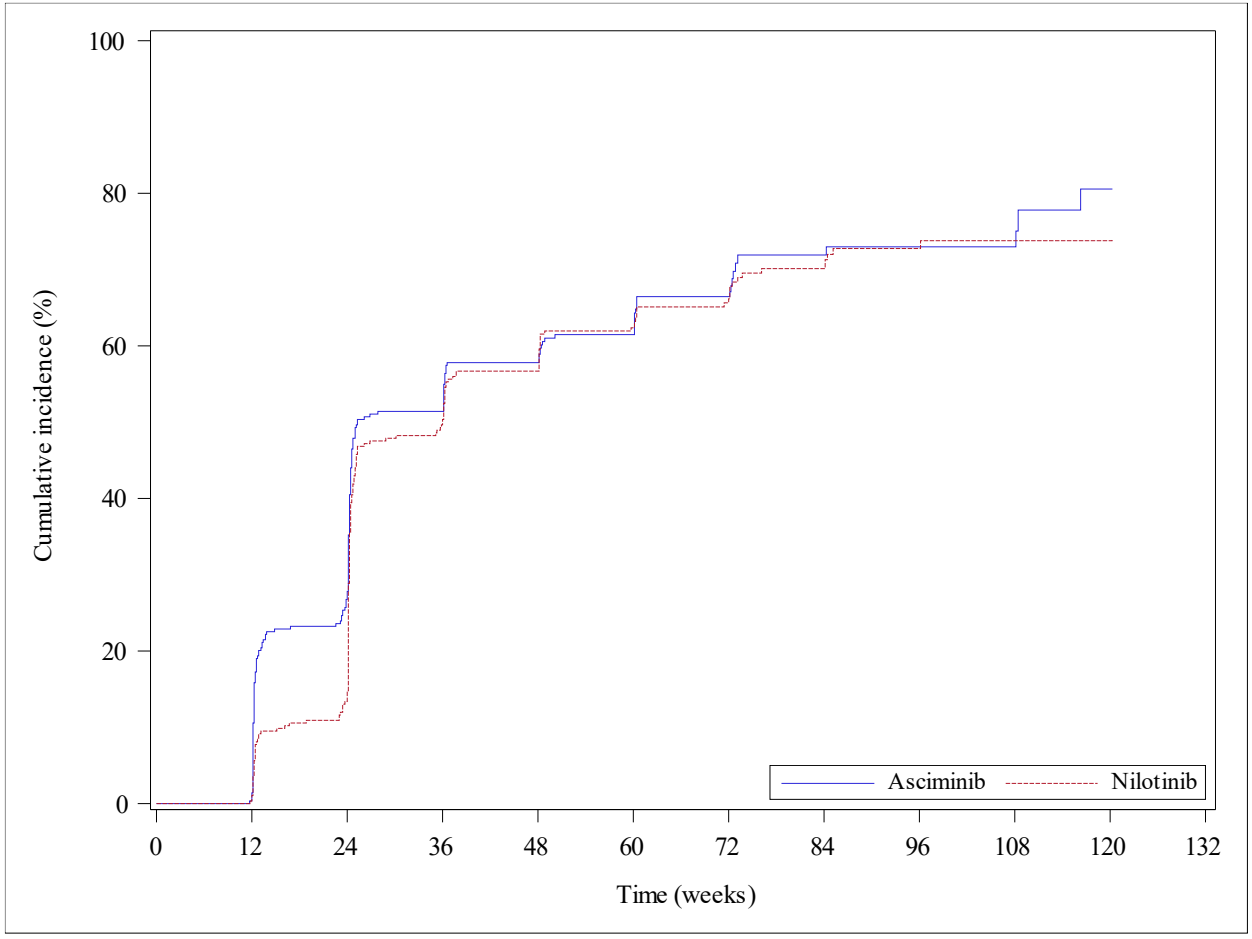
Table 2-1.13 MMR: Competing risks analysis (Full Analysis Set)

	Treatment groups		Comparison		
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**sHR**	**[95%-CI]**	**P-Value**
N*	284	284			
Number of patients with events, n (%)	193 (68.0)	196 (69.0)	1.11	[0.91; 1.34]	0.243
Number of patients with competing risk, n (%)	34 (12.0)	57 (20.1)			
Number of patients censored, n (%)	57 (20.1)	31 (10.9)			
Cumulative incidence (%) [95%-CI]					
Week 12	1.4 [0.5; 3.4]	1.1 [0.3; 2.9]			
Week 24	27.8 [22.7; 33.1]	14.8 [10.9; 19.2]			
Week 36	51.4 [45.4; 57.1]	50.4 [44.4; 56.0]			
Week 48	57.8 [51.8; 63.3]	56.7 [50.7; 62.2]			
Week 60	61.5 [55.5; 66.9]	62.4 [56.4; 67.8]			
Week 72	66.5 [60.3; 71.9]	66.2 [60.1; 71.5]			
Week 84	71.9 [65.0; 77.7]	70.1 [64.0; 75.4]			
Week 96	73.0 [66.0; 78.8]	72.8 [66.6; 78.0]			
Week 108	73.0 [66.0; 78.8]	73.8 [67.5; 79.0]			
Week 120	80.6 [70.3; 87.6]	73.8 [67.5; 79.0]			
Week 132	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]			

	Treatment groups		Comparison		
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**sHR**	**[95%-CI]**	**P-Value**

sHR: Sub-distribution Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients
.....
Competing risk for the event of interest (MMR) is the premature discontinuation of study medication for any reason.
Two-sided 95% CI for the cumulative incidence functions are computed by Kaplan-Meier methods.
The sub-distribution HR and 95% CI values are from a stratified Fine-Gray proportional hazard model for competing risk analysis with stratification factor ELTS Score (IRT).
P-Values are from a stratified Gray test for competing risks with stratification factor ELTS Score (IRT).
Data Cut/15MAY2025

Figure 2-1.13 MMR: Competing risks analysis: Plot of cumulative incidence functions (Full Analysis Set)



Data Cut/15MAY2025

Table 2-2.1 Overall Survival: Time to event analysis by subgroups (Full Analysis Set)

No subgroup analyses were performed, because for every attribute there are not at least 10 patients for every subgroup or not at least 10 events in at least one subgroup.

.....
Data Cut/15MAY2025

Table 2-2.2 MMR: Time to event analysis by subgroups (Full Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (weeks) [95% CI]	n/N* (%)	Median (weeks) [95% CI]			
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.893)							
Low	126/171 (73.7)	24.4 [24.1; 25.0]	133/172 (77.3)	24.4 [24.3; 25.0]	0.99	[0.77; 1.26]	0.962
Intermediate	50/75 (66.7)	36.1 [24.4; 48.6]	45/75 (60.0)	36.3 [24.9; 59.7]	1.03	[0.69; 1.54]	0.880
High	17/38 (44.7)	60.4 [24.7; N.E.]	18/37 (48.6)	48.1 [35.3; N.E.]	0.86	[0.44; 1.67]	0.654
Sex							
(Interaction test: p = 0.737)							
Female	78/107 (72.9)	24.4 [24.1; 36.1]	87/126 (69.0)	24.4 [24.3; 26.1]	1.06	[0.78; 1.45]	0.677
Male	115/177 (65.0)	25.3 [24.4; 36.4]	109/158 (69.0)	35.3 [24.7; 37.3]	0.96	[0.74; 1.25]	0.791
Race							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (weeks) [95% CI]	n/N* (%)	Median (weeks) [95% CI]			
(Interaction test: p = 0.991)							
Asian	27/40 (67.5)	24.3 [24.1; 36.1]	34/46 (73.9)	24.4 [24.1; 36.1]	0.97	[0.58; 1.62]	0.913
White	155/227 (68.3)	25.0 [24.4; 36.3]	150/217 (69.1)	25.3 [24.6; 36.1]	0.99	[0.79; 1.24]	0.961
Other	11/17 (64.7)	26.9 [23.3; 48.4]	12/21 (57.1)	36.1 [24.1; N.E.]	0.93	[0.41; 2.15]	0.863
Age groups							
(Interaction test: p = 0.471)							
18 - < 65 years	153/237 (64.6)	36.1 [24.4; 36.4]	170/247 (68.8)	25.1 [24.4; 36.1]	0.93	[0.74; 1.16]	0.532
65 - < 75 years	32/38 (84.2)	24.3 [24.1; 25.0]	15/24 (62.5)	25.1 [24.1; 48.3]	1.38	[0.74; 2.57]	0.311
>= 75 years	8/9 (88.9)	24.4 [12.1; 36.1]	11/13 (84.6)	24.3 [12.4; 36.3]	1.57	[0.58; 4.27]	0.326
Geographic region							
(Interaction test: p = 0.633)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (weeks) [95% CI]	n/N* (%)	Median (weeks) [95% CI]			
Europe excluding Germany	95/138 (68.8)	26.9 [24.3; 48.1]	98/141 (69.5)	25.1 [24.3; 36.0]	0.94	[0.71; 1.25]	0.710
Germany	52/72 (72.2)	24.6 [24.4; 36.1]	36/53 (67.9)	36.3 [24.4; 48.3]	1.11	[0.71; 1.71]	0.621
Others	46/74 (62.2)	24.7 [24.1; 48.1]	62/90 (68.9)	24.7 [24.3; 36.1]	0.90	[0.61; 1.32]	0.592

N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
If there are not at least 10 patients in every subgroup or not at least 10 events in at least one subgroup, no subgroup analyses were performed for the corresponding attribute.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variable ELTS Score (IRT) and covariate treatment arm.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variable ELTS Score (IRT).
For the subgroups of Stratification factor: ELTS based on IRT randomisation data no stratification variable was used.
The reference group in the stratified Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Table 2-2.3 Progression free survival: Time to event analysis by subgroups (Full Analysis Set)

No subgroup analyses were performed, because for every attribute there are not at least 10 patients for every subgroup or not at least 10 events in at least one subgroup.

.....
Data Cut/15MAY2025

Table 2-2.4 Progression to blast crisis (BC): Time to event analysis by subgroups (Full Analysis Set)

No subgroup analyses were performed, because for every attribute there are not at least 10 patients for every subgroup or not at least 10 events in at least one subgroup.

.....
Data Cut/15MAY2025

Table 2-3.1 MMR: Responder analyses for 'at' all scheduled data collection time points (Full Analysis Set)

	Treatment groups		Comparison		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**OR [95% CI] p-value**	**RR [95% CI] p-value**	**RD [95% CI] p-value**
Week 4	0	0	N.E.	N.E.	N.E.
Week 12	66 (23.2)	30 (10.6)	2.67 [1.66; 4.30] <0.001	2.21 [1.49; 3.27] <0.001	0.13 [0.07; 0.19] <0.001
Week 24	144 (50.7)	134 (47.2)	1.17 [0.83; 1.63] 0.375	1.08 [0.91; 1.27] 0.376	0.04 [-0.04; 0.12] 0.374
Week 36	157 (55.3)	154 (54.2)	1.05 [0.75; 1.47] 0.776	1.02 [0.88; 1.18] 0.776	0.01 [-0.07; 0.09] 0.776
Week 48	164 (57.7)	163 (57.4)	1.02 [0.73; 1.43]	1.01 [0.88; 1.16]	0.00 [-0.08; 0.08]

	Treatment groups		Comparison		
	Asciminib (N = 284) n (%)	**Nilotinib (N = 284) n (%)**	**OR [95% CI] p-value**	**RR [95% CI] p-value**	**RD [95% CI] p-value**
			0.912	0.912	0.912

CI: Confidence Interval
N: Number of patients
OR: Odds ratio
RR: Relative risk
RD: Risk difference
.....
The OR, 95%-CI and corresponding p-Value are from a logistic regression model with ELTS Score (IRT) (stratification factor) and treatment arm as covariates.
The RR and RD, the pertaining 95%-CIs and p-values are obtained by (Cochran-)Mantel-Haenszel methods for stratified categorical data with stratificaton factor ELTS Score (IRT).
In case the contingency table for a stratum contained at least one zero event, 0.5 were added to each cell in the pertaining 2x2 table for this stratum.
Data Cut/15MAY2025

Table 2-3.2 MMR: Completion status (Full Analysis Set)

Treatment Group = All (N = 568, n(%))

	done	imputed missing	expected	true missing	discontinued	died
Week 4	546 (96.1)	0	0	20 (3.5)	2 (0.4)	0
Week 12	543 (95.6)	0	0	6 (1.1)	18 (3.2)	1 (0.2)
Week 24	514 (90.5)	2 (0.4)	0	16 (2.8)	35 (6.2)	1 (0.2)
Week 36	490 (86.3)	2 (0.4)	0	22 (3.9)	52 (9.2)	2 (0.4)
Week 48	476 (83.8)	1 (0.2)	0	29 (5.1)	60 (10.6)	2 (0.4)
Week 60	359 (63.2)	3 (0.5)	94 (16.5)	41 (7.2)	69 (12.1)	2 (0.4)
Week 72	266 (46.8)	1 (0.2)	190 (33.5)	31 (5.5)	77 (13.6)	3 (0.5)
Week 84	174 (30.6)	0	285 (50.2)	26 (4.6)	80 (14.1)	3 (0.5)
Week 96	96 (16.9)	0	366 (64.4)	19 (3.3)	84 (14.8)	3 (0.5)
Week 108	52 (9.2)	0	418 (73.6)	10 (1.8)	85 (15.0)	3 (0.5)
Week 120	10 (1.8)	0	466 (82.0)	3 (0.5)	86 (15.1)	3 (0.5)

Table 2-3.2 MMR: Completion status (Full Analysis Set)

Treatment Group = Asciminib (N = 284, n(%))

	done	imputed missing	expected	true missing	discontinued	died
Week 4	272 (95.8)	0	0	12 (4.2)	0	0
Week 12	279 (98.2)	0	0	1 (0.4)	3 (1.1)	1 (0.4)
Week 24	268 (94.4)	1 (0.4)	0	5 (1.8)	9 (3.2)	1 (0.4)
Week 36	254 (89.4)	2 (0.7)	0	8 (2.8)	18 (6.3)	2 (0.7)
Week 48	252 (88.7)	0	0	11 (3.9)	19 (6.7)	2 (0.7)
Week 60	186 (65.5)	1 (0.4)	50 (17.6)	21 (7.4)	24 (8.5)	2 (0.7)
Week 72	138 (48.6)	0	103 (36.3)	17 (6.0)	24 (8.5)	2 (0.7)
Week 84	90 (31.7)	0	152 (53.5)	16 (5.6)	24 (8.5)	2 (0.7)
Week 96	52 (18.3)	0	194 (68.3)	9 (3.2)	27 (9.5)	2 (0.7)
Week 108	25 (8.8)	0	221 (77.8)	8 (2.8)	28 (9.9)	2 (0.7)
Week 120	6 (2.1)	0	246 (86.6)	1 (0.4)	29 (10.2)	2 (0.7)

Table 2-3.2 MMR: Completion status (Full Analysis Set)

Treatment Group = Nilotinib (N = 284, n(%))

	done	imputed missing	expected	true missing	discontinued	died
Week 4	274 (96.5)	0	0	8 (2.8)	2 (0.7)	0
Week 12	264 (93.0)	0	0	5 (1.8)	15 (5.3)	0
Week 24	246 (86.6)	1 (0.4)	0	11 (3.9)	26 (9.2)	0
Week 36	236 (83.1)	0	0	14 (4.9)	34 (12.0)	0
Week 48	224 (78.9)	1 (0.4)	0	18 (6.3)	41 (14.4)	0
Week 60	173 (60.9)	2 (0.7)	44 (15.5)	20 (7.0)	45 (15.8)	0
Week 72	128 (45.1)	1 (0.4)	87 (30.6)	14 (4.9)	53 (18.7)	1 (0.4)
Week 84	84 (29.6)	0	133 (46.8)	10 (3.5)	56 (19.7)	1 (0.4)
Week 96	44 (15.5)	0	172 (60.6)	10 (3.5)	57 (20.1)	1 (0.4)
Week 108	27 (9.5)	0	197 (69.4)	2 (0.7)	57 (20.1)	1 (0.4)
Week 120	4 (1.4)	0	220 (77.5)	2 (0.7)	57 (20.1)	1 (0.4)

N: Number of patients
n (%): Number and percentage of patients with event
.....
Imputed missing are missing assesments that were imputed as response because the two adjacent assessments are true responses
Expected are missing assessments for which the planned assessment date is after data cut.
True missing are missing assessments for which the planned assessment date is prior to data cut.
Data Cut/15MAY2025

3. PRO

Table 3-1.1 EORTC QLQ-C30: Time to first deterioration (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Global health status/QoL (MID=10)			
N*	284	284	0.89
Number of patients with events, n (%)	59 (20.8)	63 (22.2)	[0.62; 1.27]
			0.529
Percentiles (months) [95% CI]			
25th	5.6 [1.9; 11.1]	2.7 [1.9; 5.5]	
Median	22.1 [11.1; N.E.]	N.E. [11.1; N.E.]	
75th	22.1 [22.1; N.E.]	N.E. [N.E.; N.E.]	
Physical functioning (MID=10)			
N*	284	284	0.91
Number of patients with events, n (%)	49 (17.3)	50 (17.6)	[0.61; 1.35]
			0.616
Percentiles (months) [95% CI]			
25th	5.6 [2.0; 11.1]	2.8 [1.1; 11.1]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	N.E. [11.2; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Role functioning (MID=10)			
N*	284	284	1.08
Number of patients with events, n (%)	64 (22.5)	59 (20.8)	[0.76; 1.55]
			0.587
Percentiles (months) [95% CI]			
25th	1.9 [1.8; 5.6]	2.8 [1.9; 5.6]	
Median	22.1 [11.1; N.E.]	22.1 [11.1; N.E.]	
75th	22.5 [22.1; N.E.]	22.3 [22.1; N.E.]	
Emotional functioning (MID=10)			
N*	284	284	0.65
Number of patients with events, n (%)	47 (16.5)	59 (20.8)	[0.44; 0.96]
			0.120
Percentiles (months) [95% CI]			
25th	8.0 [2.0; 11.1]	2.8 [2.0; 5.6]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	N.E. [11.2; N.E.]	N.E. [11.1; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Cognitive functioning (MID=10)			
N*	284	284	0.92
Number of patients with events, n (%)	75 (26.4)	77 (27.1)	[0.67; 1.26]
			0.626
Percentiles (months) [95% CI]			
25th	1.9 [1.8; 2.8]	2.0 [1.8; 2.8]	
Median	11.1 [11.0; 22.1]	11.1 [5.6; N.E.]	
75th	22.1 [22.1; N.E.]	N.E. [N.E.; N.E.]	
Social functioning (MID=10)			
N*	284	284	0.76
Number of patients with events, n (%)	58 (20.4)	64 (22.5)	[0.53; 1.09]
			0.203
Percentiles (months) [95% CI]			
25th	2.7 [1.9; 5.6]	1.9 [1.0; 2.8]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	22.1 [11.2; N.E.]	N.E. [11.0; N.E.]	
75th	22.5 [22.1; N.E.]	N.E. [N.E.; N.E.]	
Fatigue (MID=10)			
N*	284	284	0.74
Number of patients with events, n (%)	50 (17.6)	58 (20.4)	[0.51; 1.09]
			0.214
Percentiles (months) [95% CI]			
25th	5.6 [1.9; 11.1]	2.7 [1.1; 5.5]	
Median	N.E. [11.2; N.E.]	22.1 [11.8; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Nausea and vomiting (MID=10)			
N*	284	284	0.75
Number of patients with events, n (%)	39 (13.7)	47 (16.5)	[0.49; 1.16]
			0.176
Percentiles (months) [95% CI]			
25th	11.1 [5.6; 22.1]	5.5 [2.0; 22.0]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	22.1 [22.1; N.E.]	N.E. [22.0; N.E.]	
75th	N.E. [22.1; N.E.]	N.E. [N.E.; N.E.]	
Pain (MID=10)			
N*	284	284	0.90
Number of patients with events, n (%)	76 (26.8)	79 (27.8)	[0.66; 1.23]
			0.453
Percentiles (months) [95% CI]			
25th	1.8 [1.0; 1.9]	1.1 [1.0; 1.9]	
Median	11.1 [5.6; N.E.]	11.1 [2.8; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Dyspnoea (MID=10)			
N*	284	284	0.86
Number of patients with events, n (%)	45 (15.8)	50 (17.6)	[0.57; 1.29]
			0.524
Percentiles (months) [95% CI]			
25th	5.8 [2.8; 22.1]	2.8 [1.2; 11.1]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	22.1 [22.1; N.E.]	N.E. [11.8; N.E.]	
75th	N.E. [22.1; N.E.]	N.E. [N.E.; N.E.]	
Insomnia (MID=10)			
N*	284	284	0.74
Number of patients with events, n (%)	55 (19.4)	64 (22.5)	[0.52; 1.07]
			0.122
Percentiles (months) [95% CI]			
25th	5.6 [2.7; 11.1]	1.9 [1.1; 2.8]	
Median	22.1 [11.1; N.E.]	22.0 [11.1; N.E.]	
75th	22.5 [22.1; N.E.]	N.E. [22.2; N.E.]	
Appetite loss (MID=10)			
N*	284	284	0.78
Number of patients with events, n (%)	31 (10.9)	39 (13.7)	[0.48; 1.25]
			0.229
Percentiles (months) [95% CI]			
25th	22.1 [11.1; N.E.]	11.1 [2.8; 22.2]	

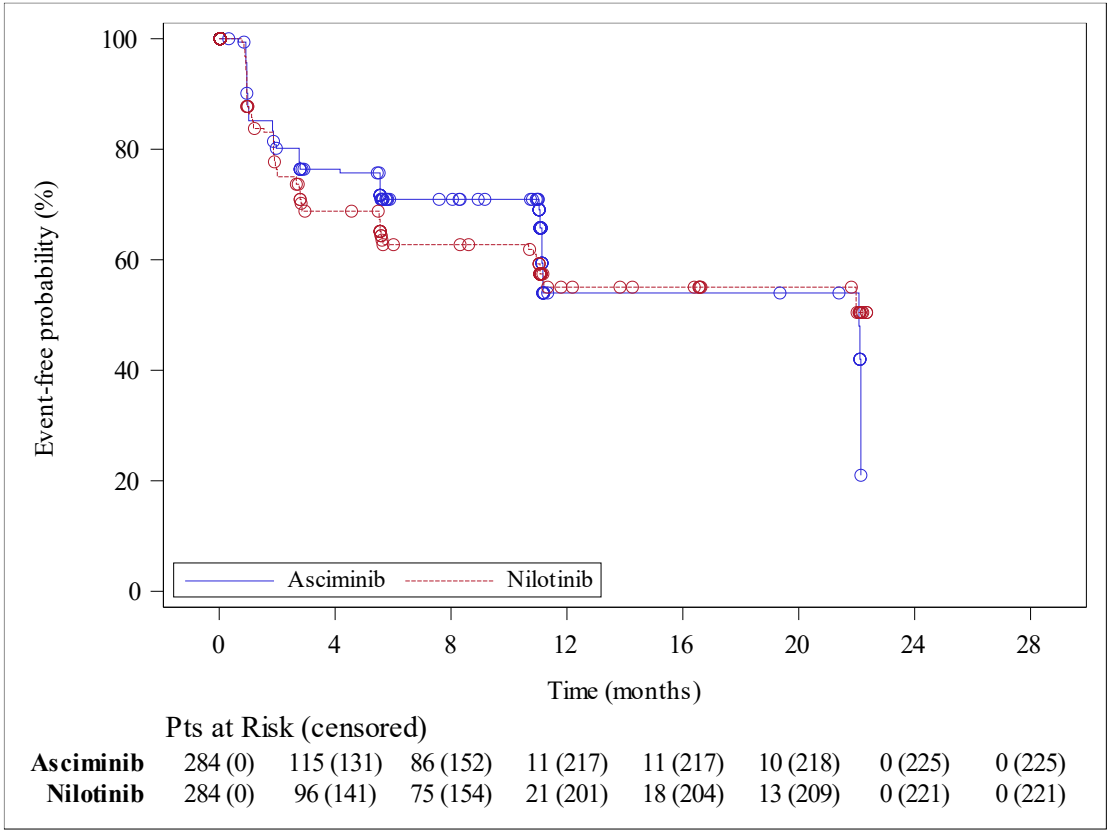
	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	22.1 [22.1; N.E.]	N.E. [22.1; N.E.]	
75th	N.E. [22.1; N.E.]	N.E. [N.E.; N.E.]	
Constipation (MID=10)			
N*	284	284	0.63
Number of patients with events, n (%)	44 (15.5)	60 (21.1)	[0.42; 0.93]
			0.026
Percentiles (months) [95% CI]			
25th	11.1 [5.6; 11.3]	2.8 [1.8; 5.6]	
Median	22.1 [11.3; N.E.]	N.E. [11.1; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Diarrhoea (MID=10)			
N*	284	284	0.72
Number of patients with events, n (%)	39 (13.7)	53 (18.7)	[0.48; 1.09]
			0.055
Percentiles (months) [95% CI]			
25th	11.2 [2.9; N.E.]	2.8 [2.0; 5.6]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	N.E. [22.0; N.E.]	N.E. [22.2; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Financial difficulties (MID=10)			
N*	284	284	1.18
Number of patients with events, n (%)	40 (14.1)	37 (13.0)	[0.75; 1.86]
			0.477
Percentiles (months) [95% CI]			
25th	11.1 [2.8; N.E.]	22.2 [2.8; 22.3]	
Median	N.E. [N.E.; N.E.]	22.3 [22.2; N.E.]	
75th	N.E. [N.E.; N.E.]	26.4 [22.3; N.E.]	

MID: Minimal important difference
HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factor ELTS Score (IRT) and covariates baseline score and treatment arm.
P-Values are from a stratified logrank test with stratification factor ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 3-1.1 EORTC QLQ-C30: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

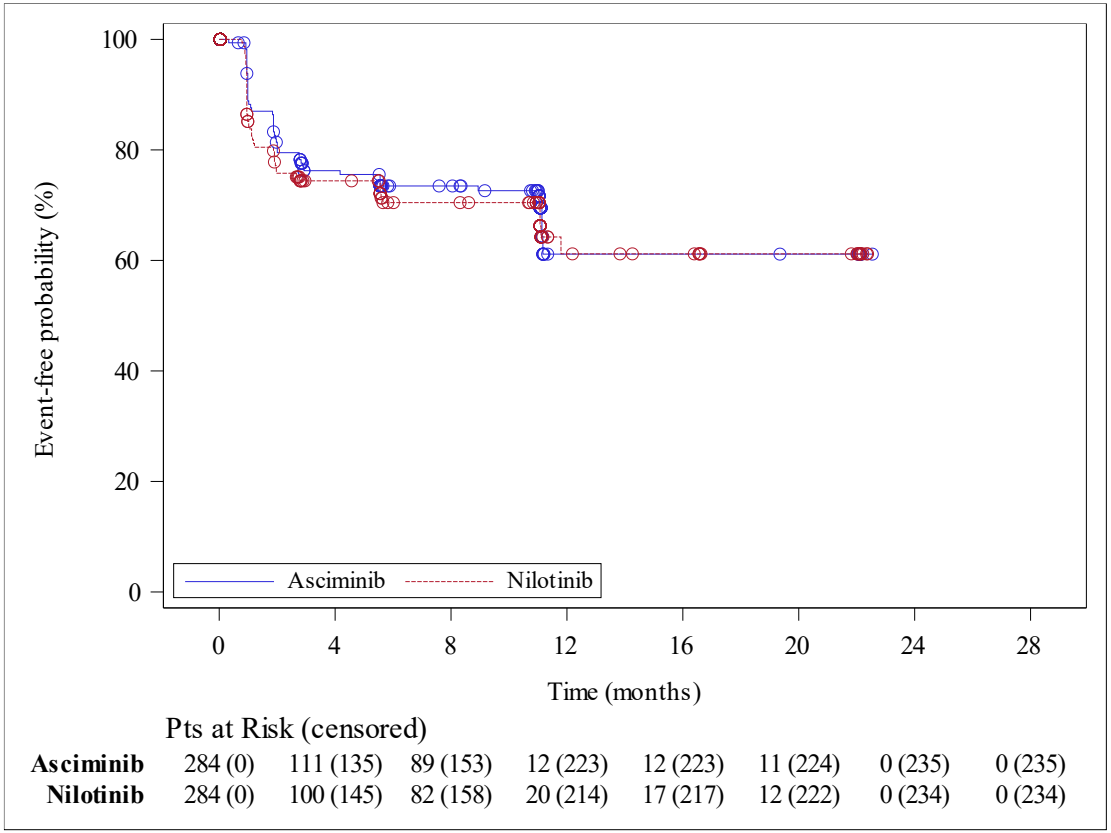
Global health status/QoL (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.1 EORTC QLQ-C30: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

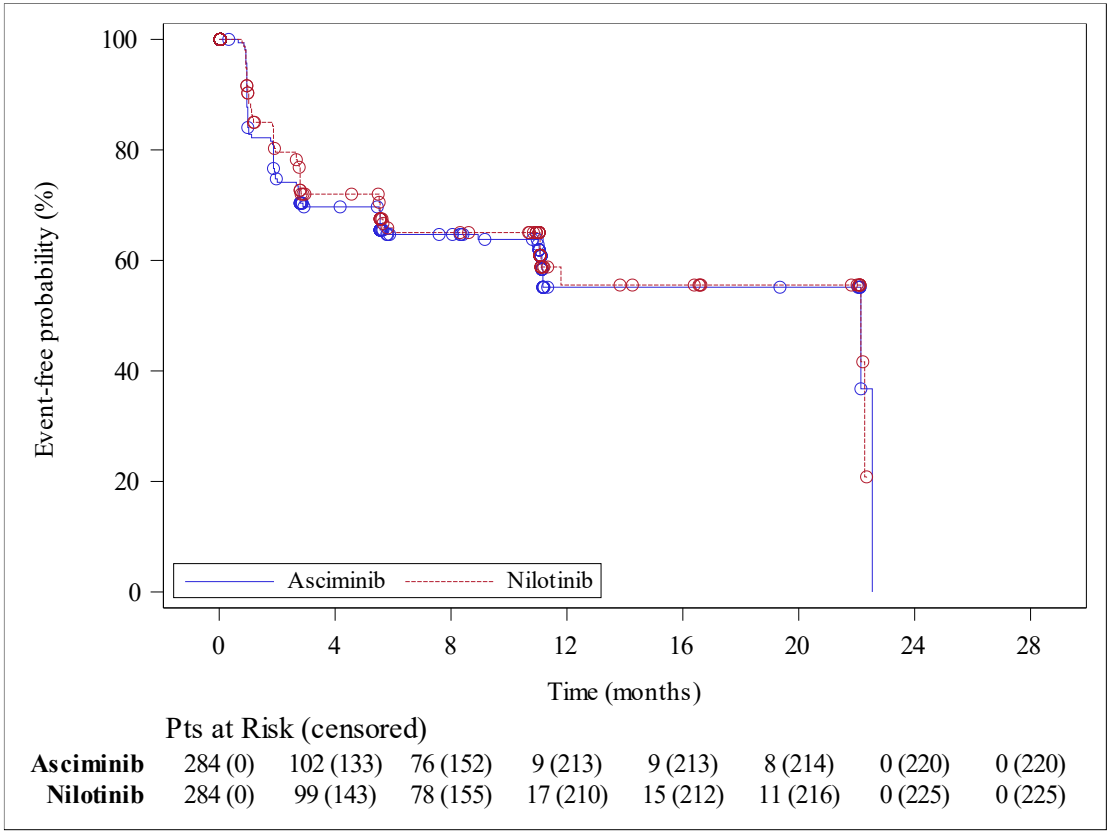
Physical functioning (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.1 EORTC QLQ-C30: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

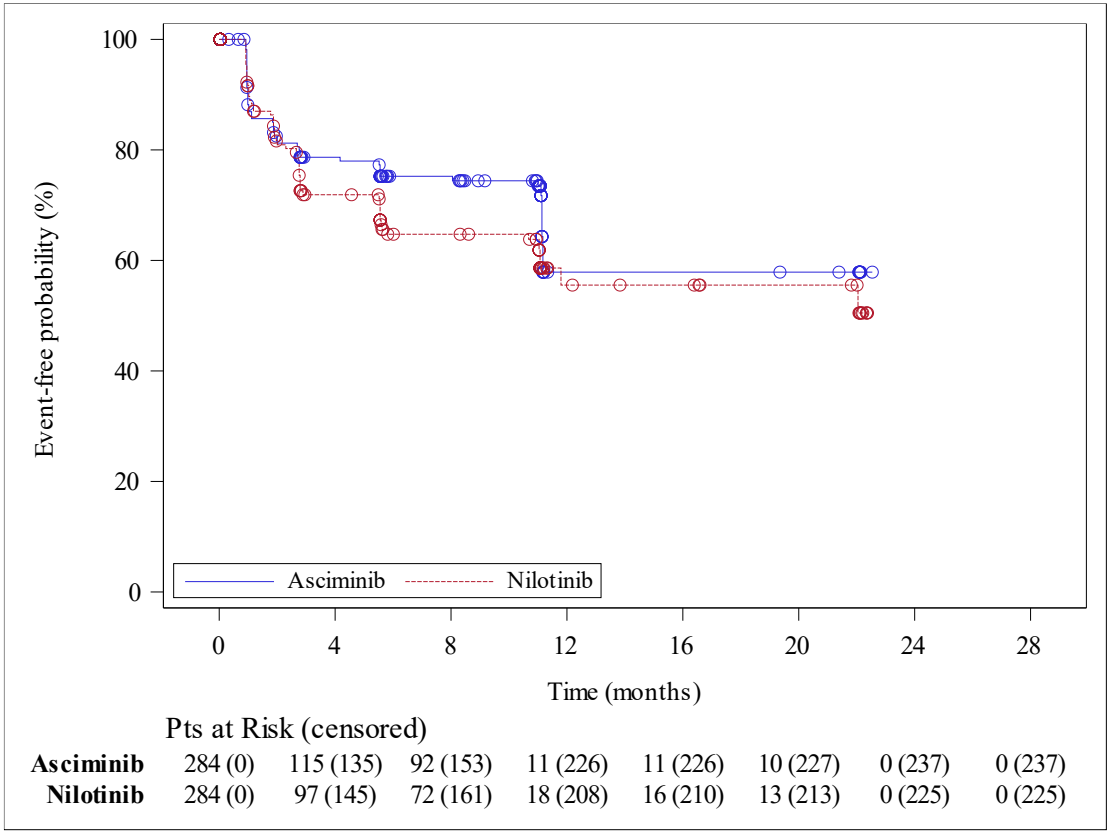
Role functioning (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.1 EORTC QLQ-C30: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

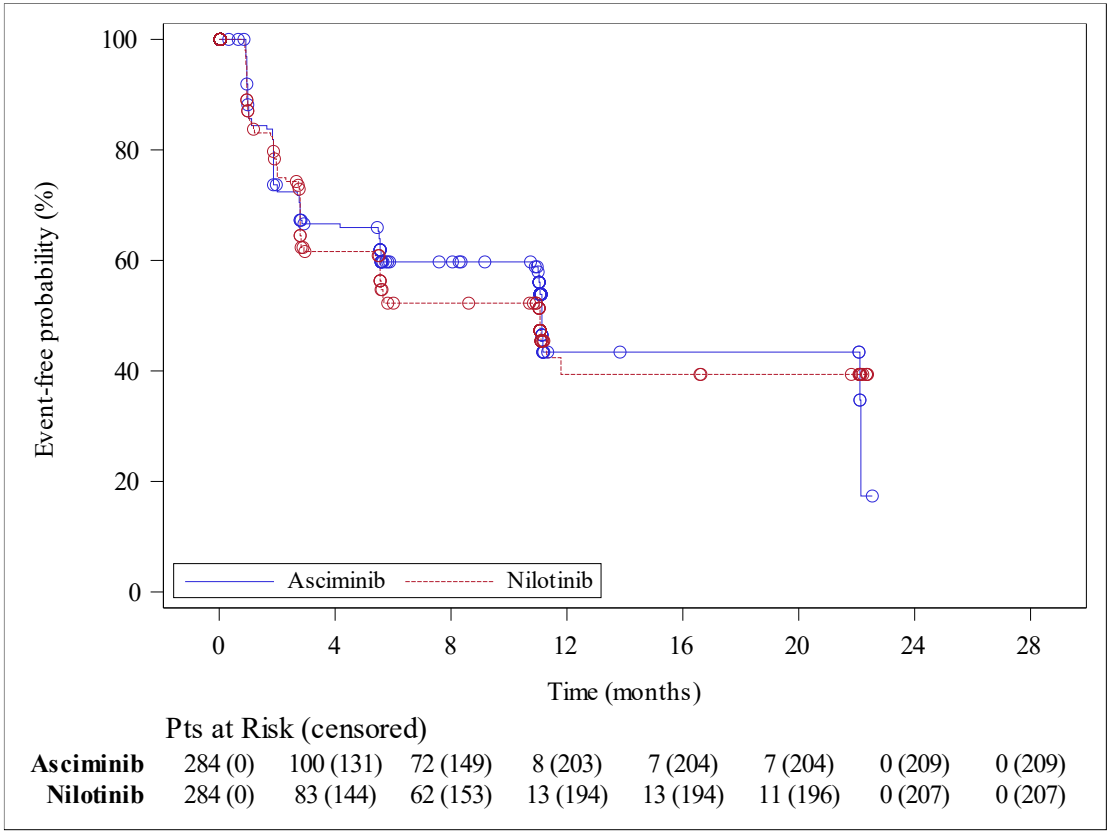
Emotional functioning (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.1 EORTC QLQ-C30: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

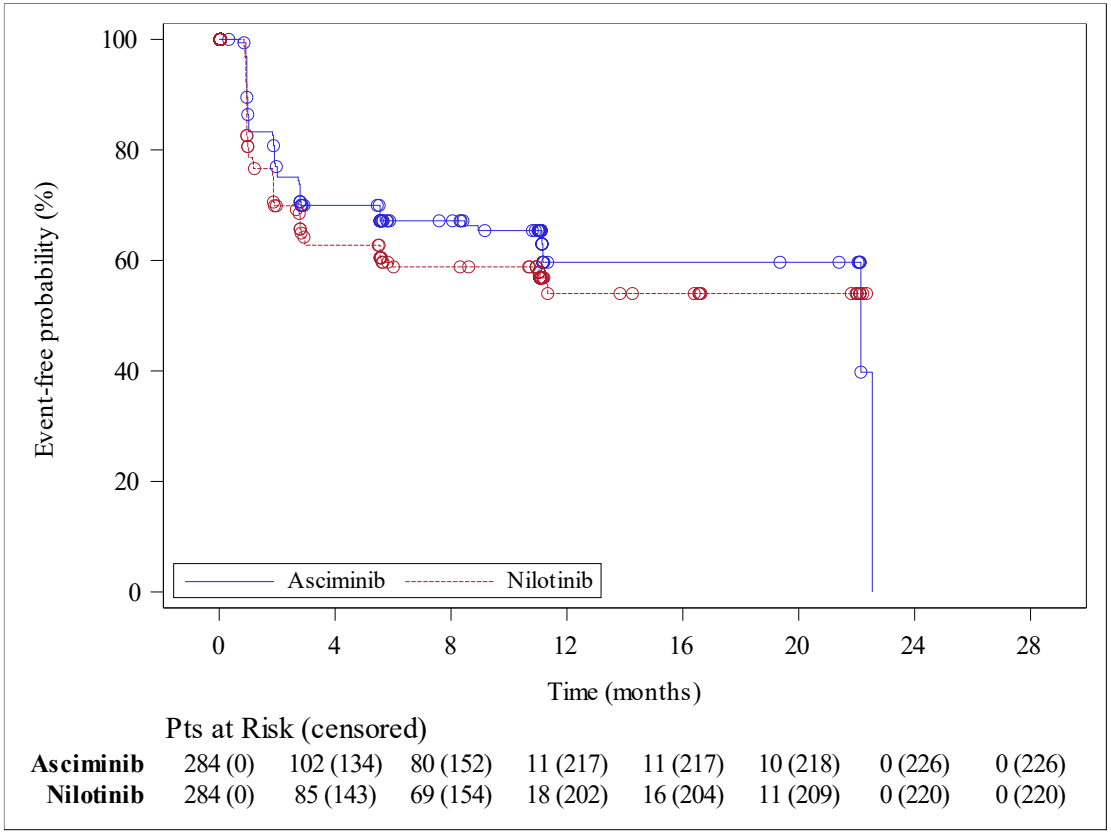
Cognitive functioning (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.1 EORTC QLQ-C30: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

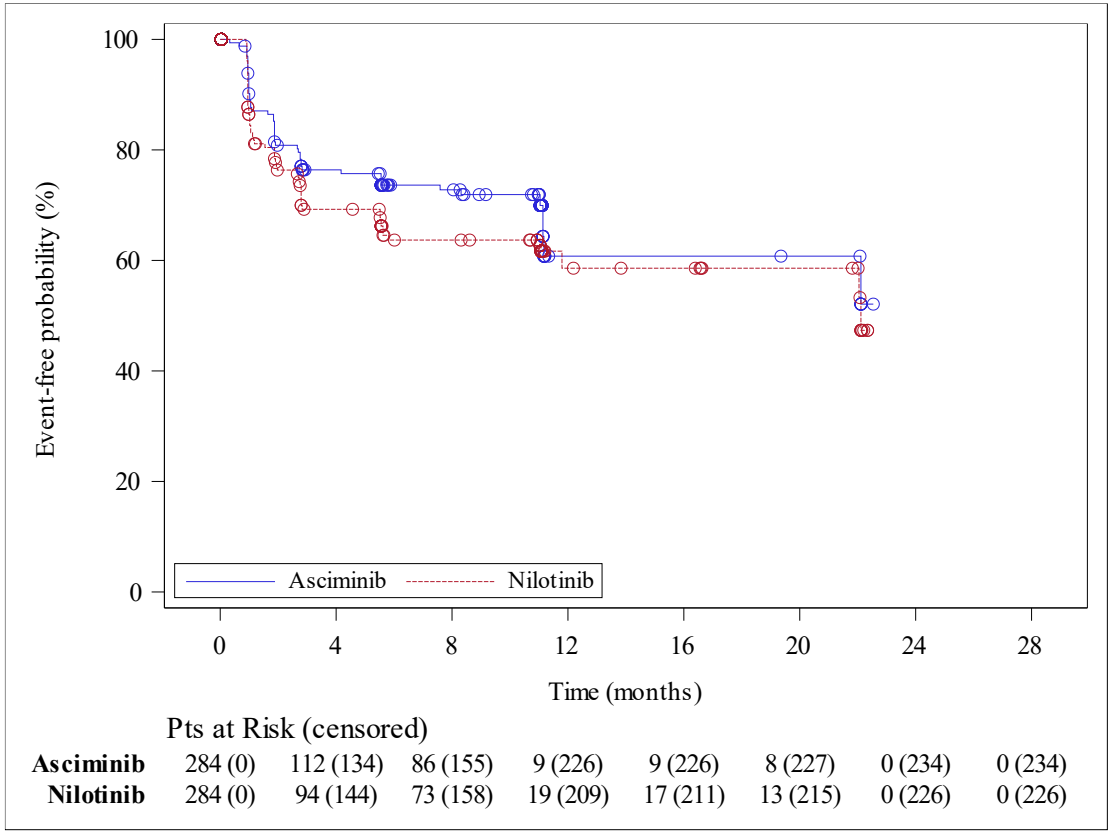
Social functioning (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.1 EORTC QLQ-C30: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

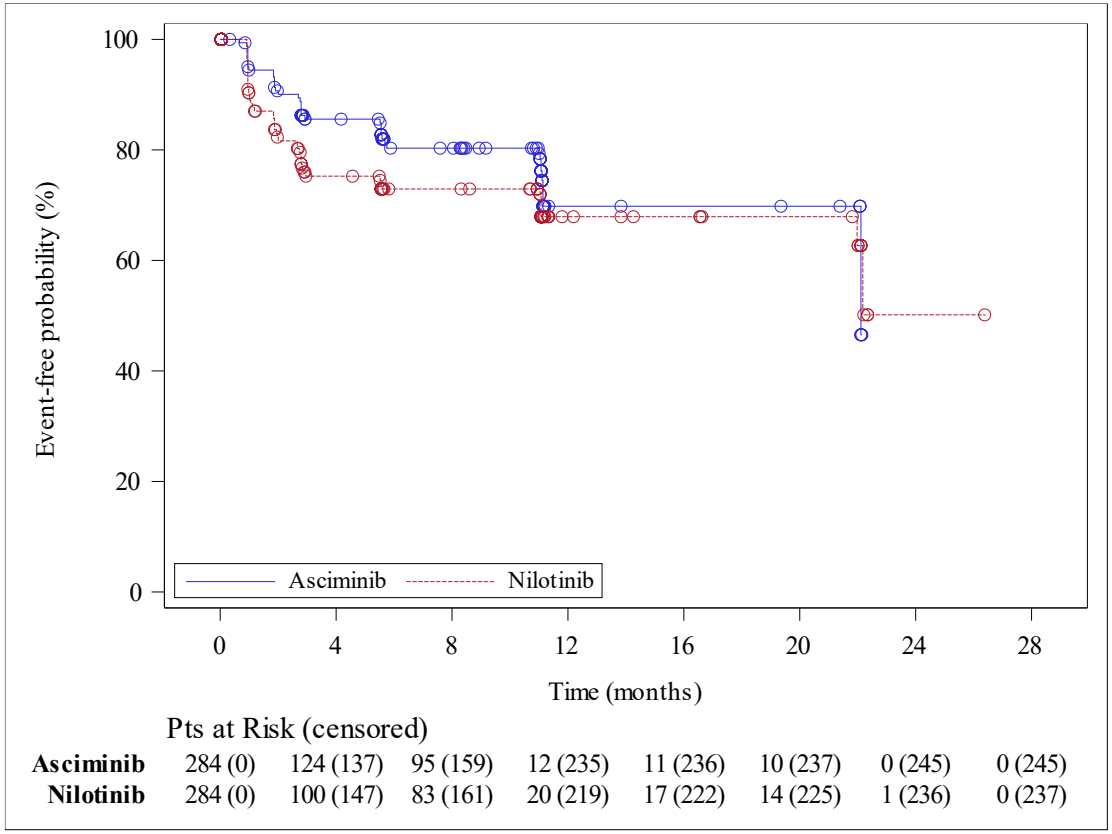
Fatigue (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.1 EORTC QLQ-C30: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

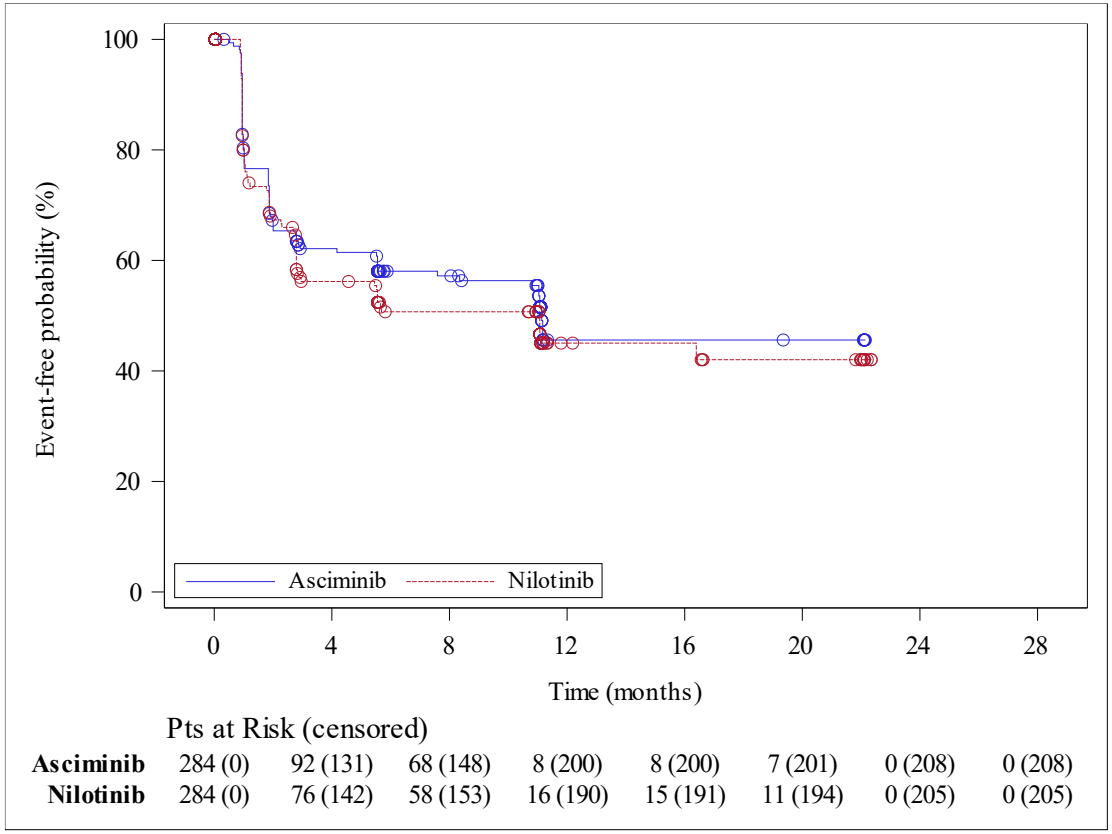
Nausea and vomiting (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.1 EORTC QLQ-C30: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

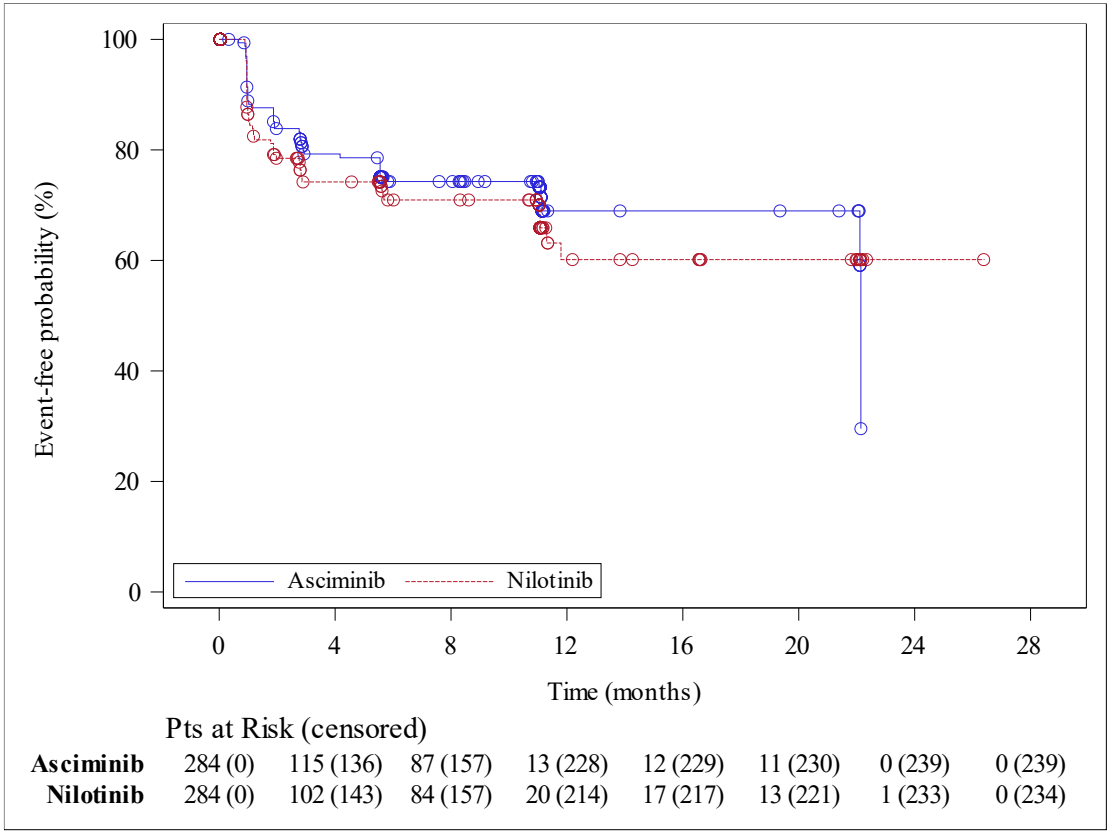
Pain (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.1 EORTC QLQ-C30: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

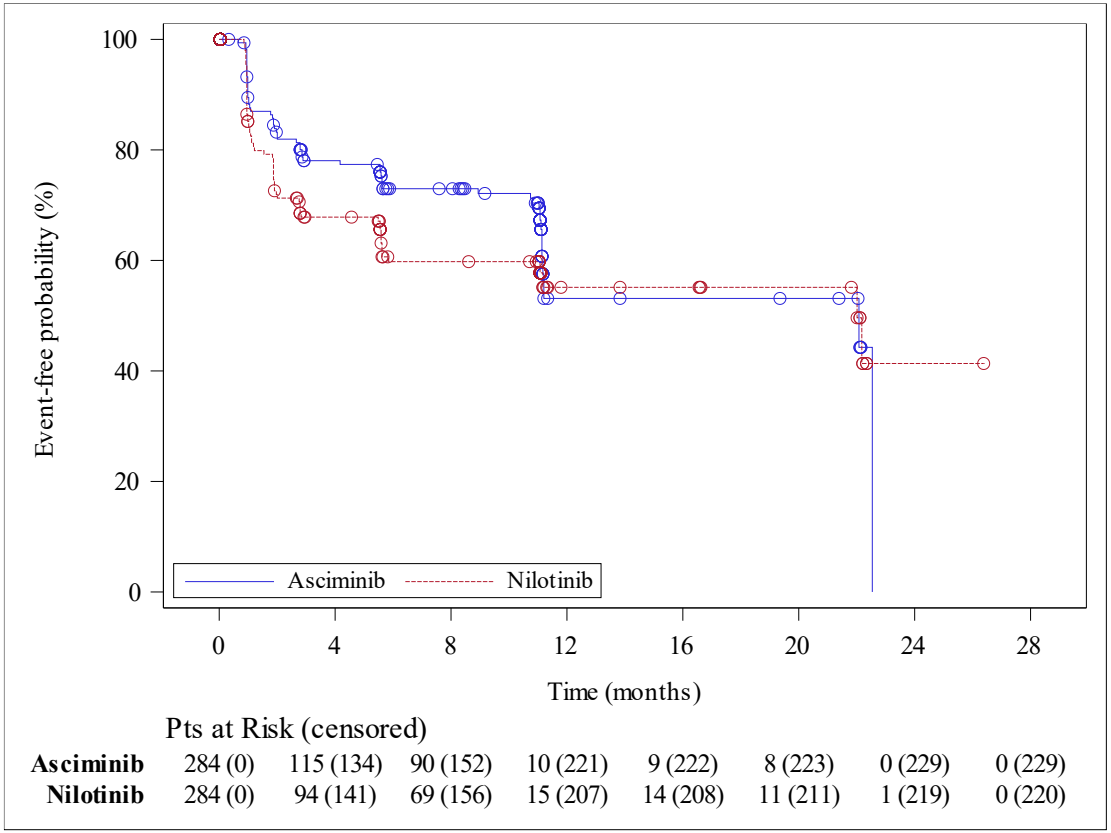
Dyspnoea (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.1 EORTC QLQ-C30: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

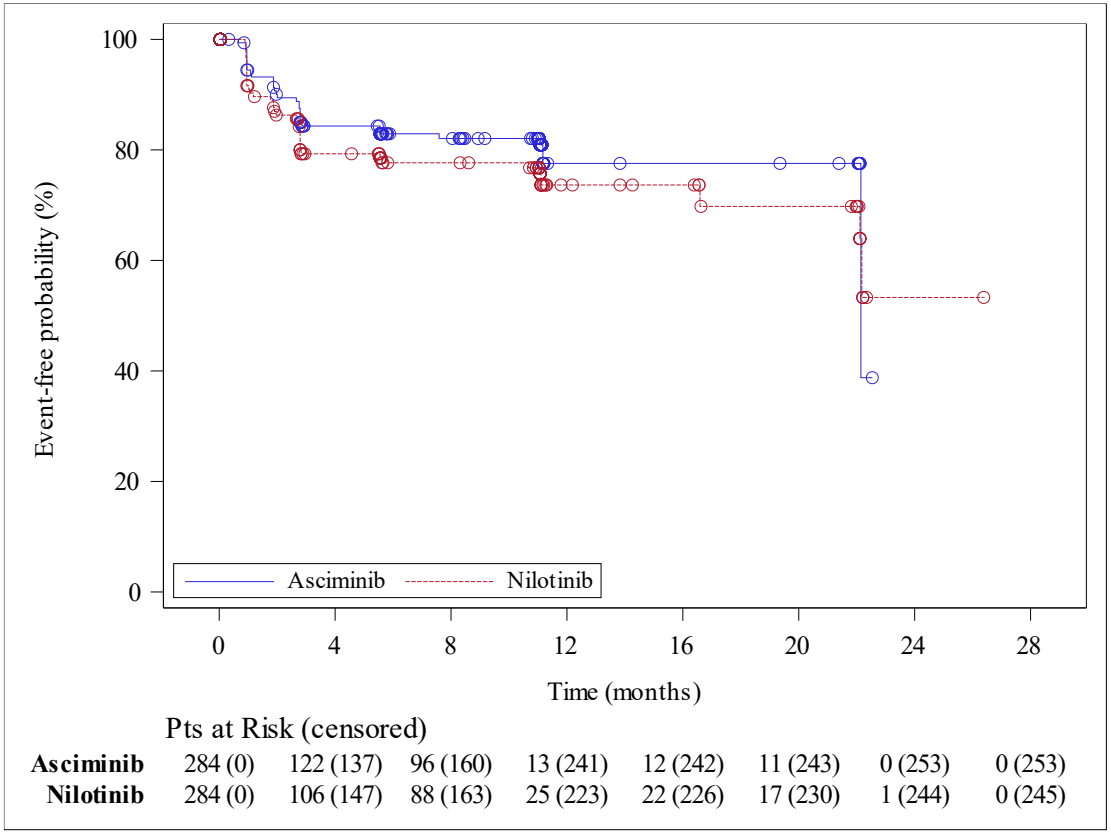
Insomnia (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.1 EORTC QLQ-C30: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

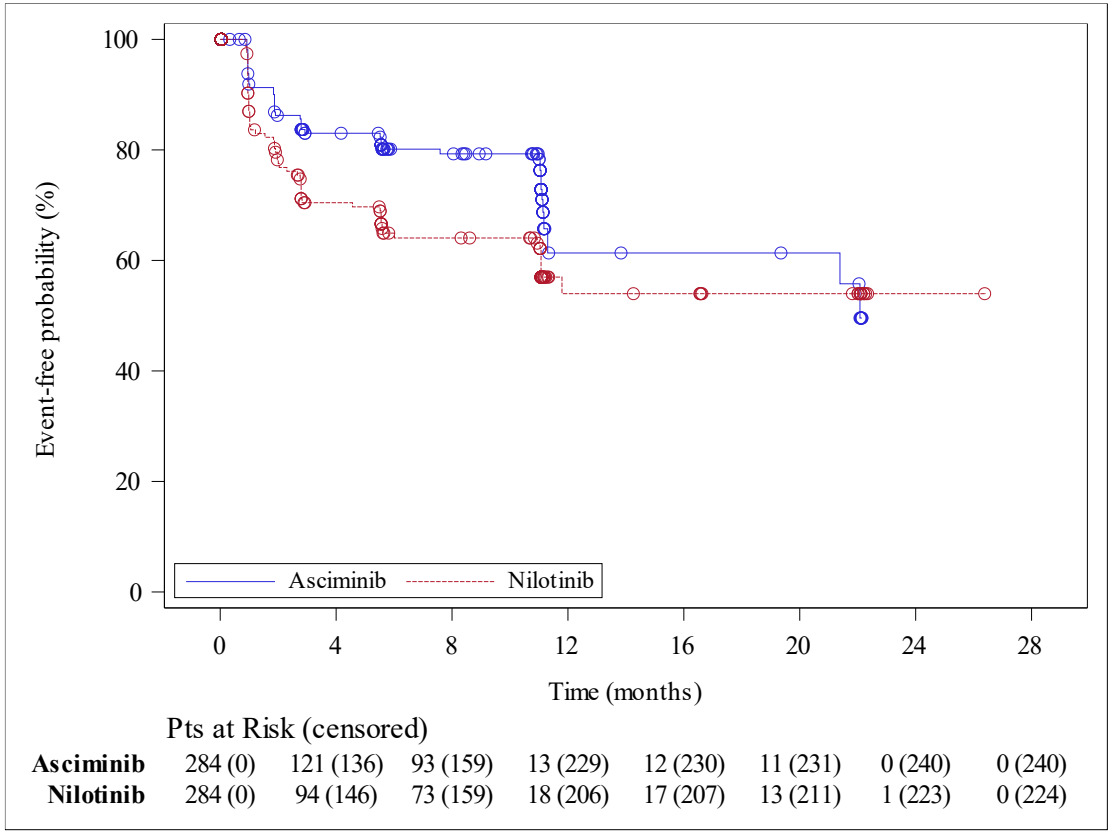
Appetite loss (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.1 EORTC QLQ-C30: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

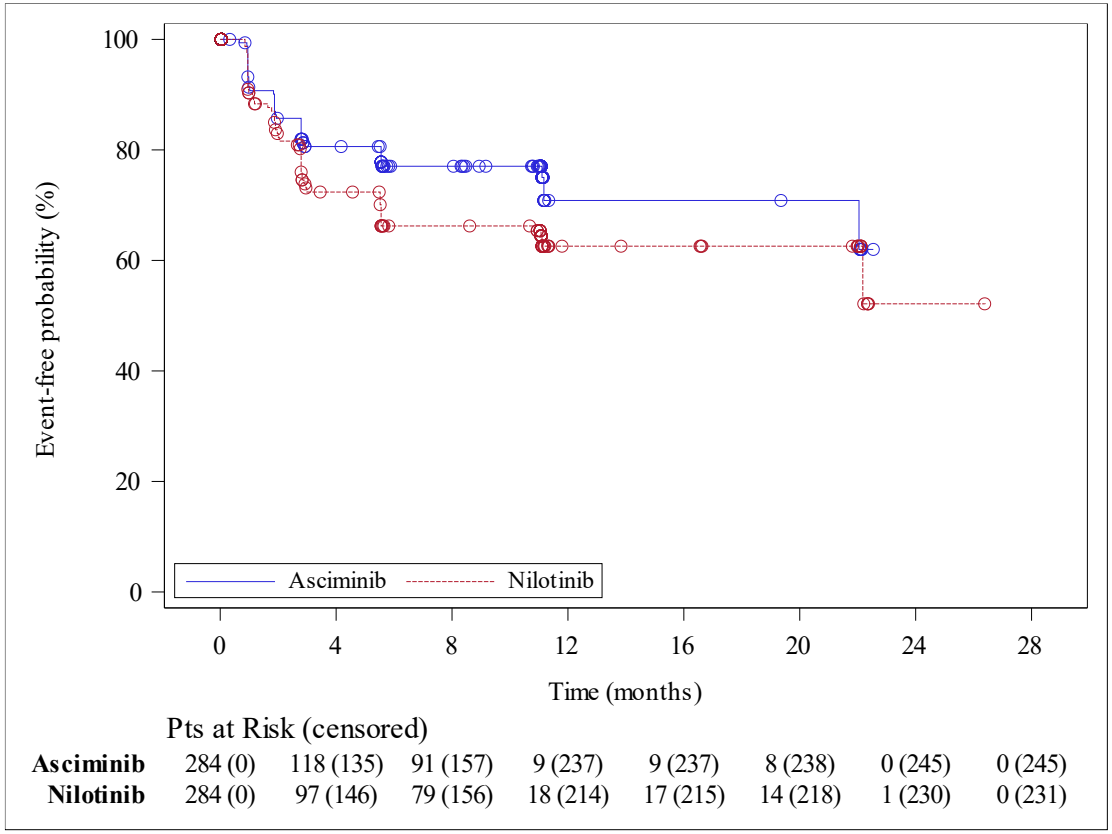
Constipation (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.1 EORTC QLQ-C30: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

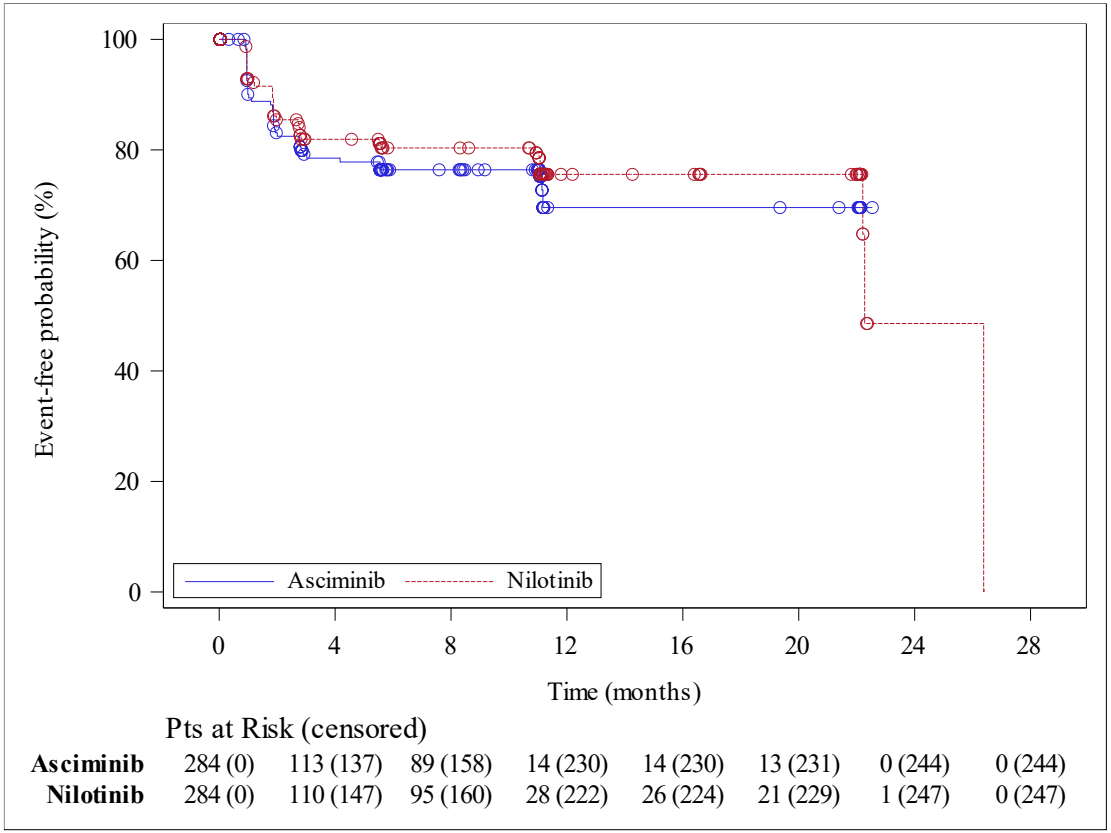
Diarrhoea (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.1 EORTC QLQ-C30: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

Financial difficulties (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Table 3-1.2 EORTC QLQ-CML24: Time to first deterioration (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Body Image Problems (MID=15)			
N*	284	284	1.03
Number of patients with events, n (%)	62 (21.8)	57 (20.1)	[0.72; 1.48]
			0.874
Percentiles (months) [95% CI]			
25th	2.8 [1.9; 5.6]	2.9 [1.9; 5.6]	
Median	N.E. [11.1; N.E.]	22.1 [11.1; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Impact on Daily Life (MID=15)			
N*	284	284	0.67
Number of patients with events, n (%)	42 (14.8)	54 (19.0)	[0.44; 1.00]
			0.106
Percentiles (months) [95% CI]			
25th	11.0 [5.6; 11.2]	2.8 [1.9; 5.8]	
Median	N.E. [N.E.; N.E.]	N.E. [11.3; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Impact on Worry/Mood (MID=15)			
N*	284	284	1.15
Number of patients with events, n (%)	31 (10.9)	24 (8.5)	[0.67; 1.97]
			0.417
Percentiles (months) [95% CI]			
25th	11.2 [8.9; N.E.]	N.E. [11.1; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Symptom Burden (MID=15)			
N*	284	284	0.46
Number of patients with events, n (%)	13 (4.6)	26 (9.2)	[0.24; 0.91]
			0.026
Percentiles (months) [95% CI]			
25th	N.E. [22.1; N.E.]	11.3 [11.2; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Satisfaction with Care and Information (MID=15)			

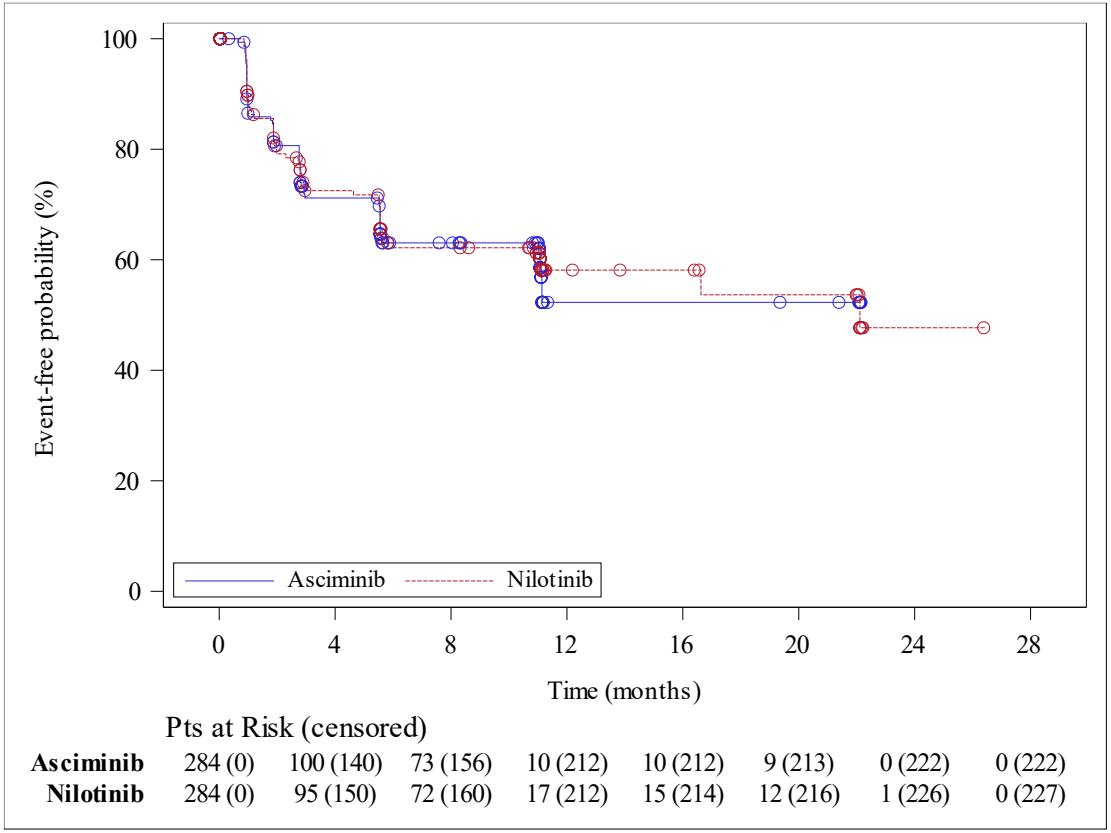
	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
N*	284	284	1.19
Number of patients with events, n (%)	52 (18.3)	39 (13.7)	[0.78; 1.80]
			0.332
Percentiles (months) [95% CI]			
25th	5.6 [2.8; 11.0]	5.6 [2.8; N.E.]	
Median	13.1 [11.2; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Satisfaction with Social Life (MID=15)			
N*	284	284	1.10
Number of patients with events, n (%)	79 (27.8)	70 (24.6)	[0.80; 1.52]
			0.599
Percentiles (months) [95% CI]			
25th	1.1 [1.0; 2.0]	1.9 [1.0; 2.0]	
Median	11.1 [5.6; N.E.]	11.3 [3.0; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**

MID: Minimal important difference
HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factor ELTS Score (IRT) and covariates baseline score and treatment arm.
P-Values are from a stratified logrank test with stratification factor ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 3-1.2 EORTC QLQ-CML24: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

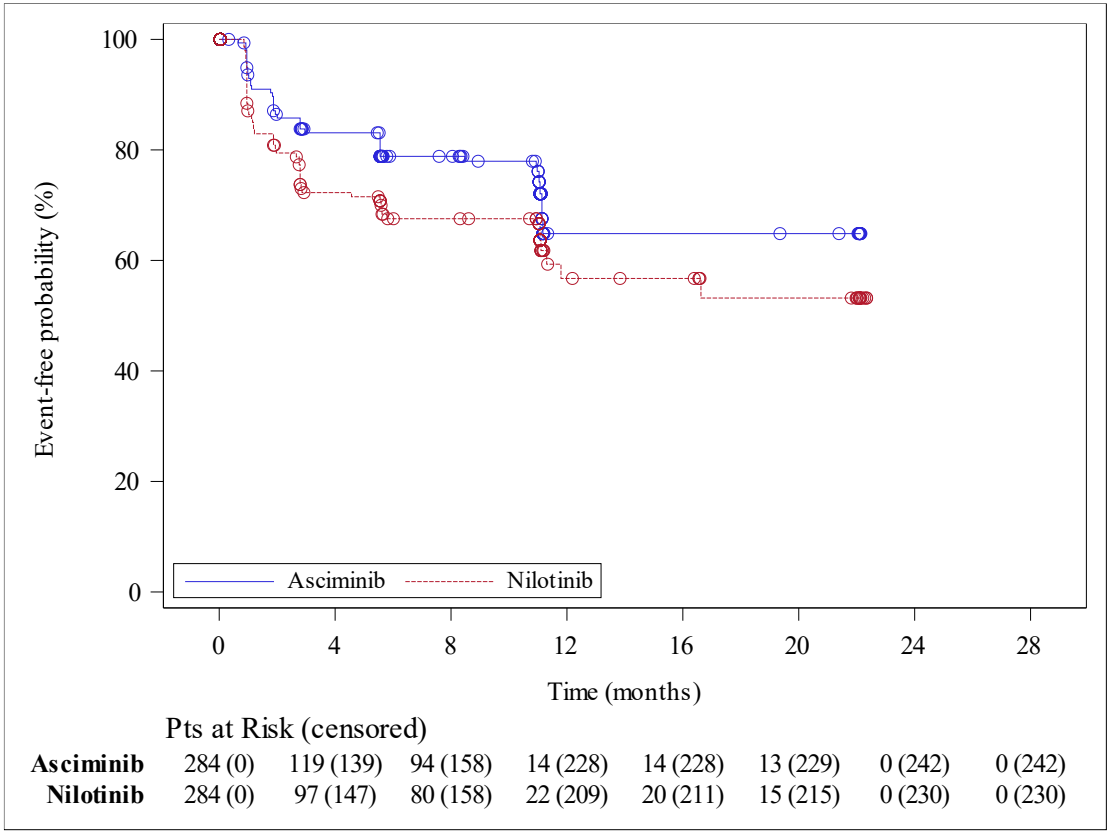
Body Image Problems (MID=15)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.2 EORTC QLQ-CML24: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

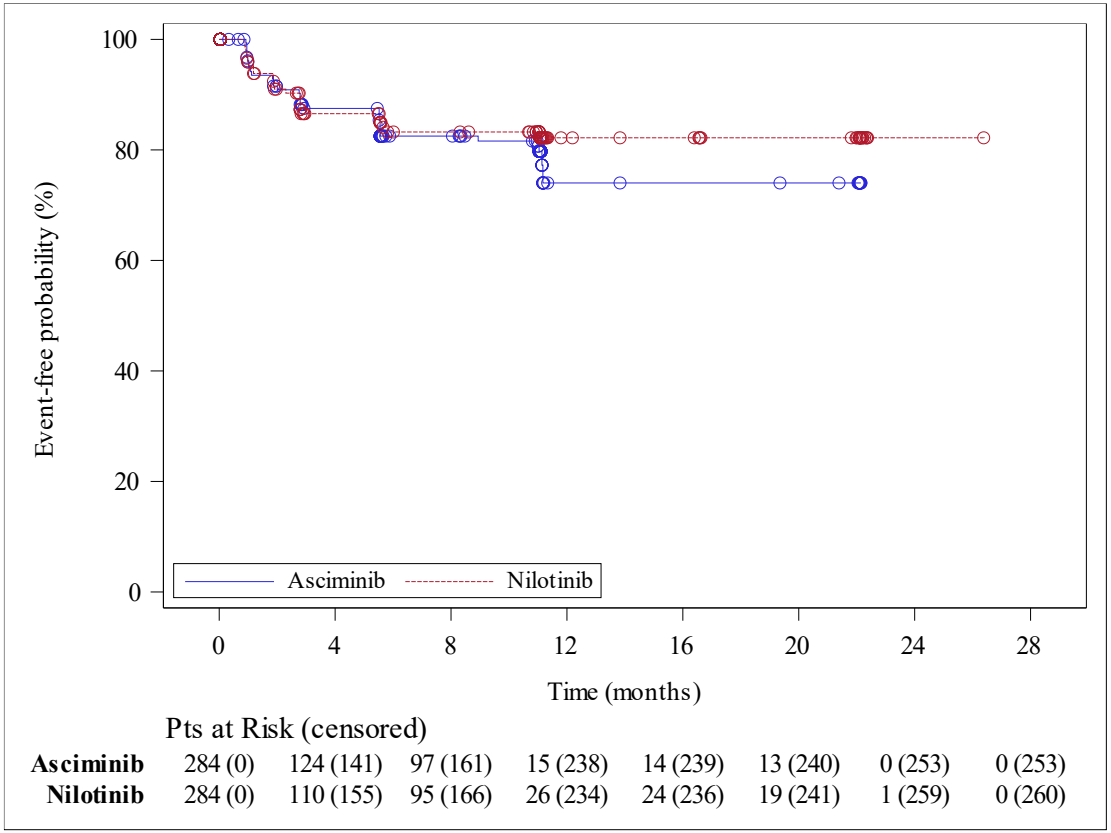
Impact on Daily Life (MID=15)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.2 EORTC QLQ-CML24: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

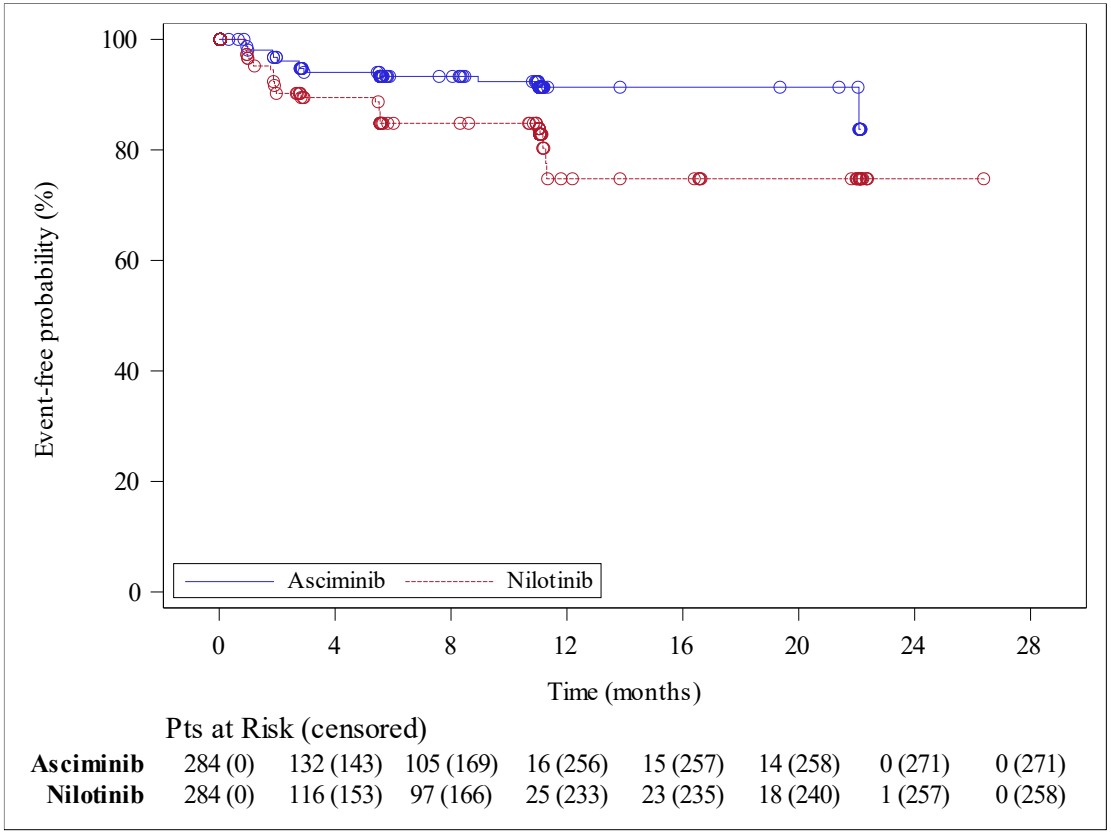
Impact on Worry/Mood (MID=15)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.2 EORTC QLQ-CML24: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

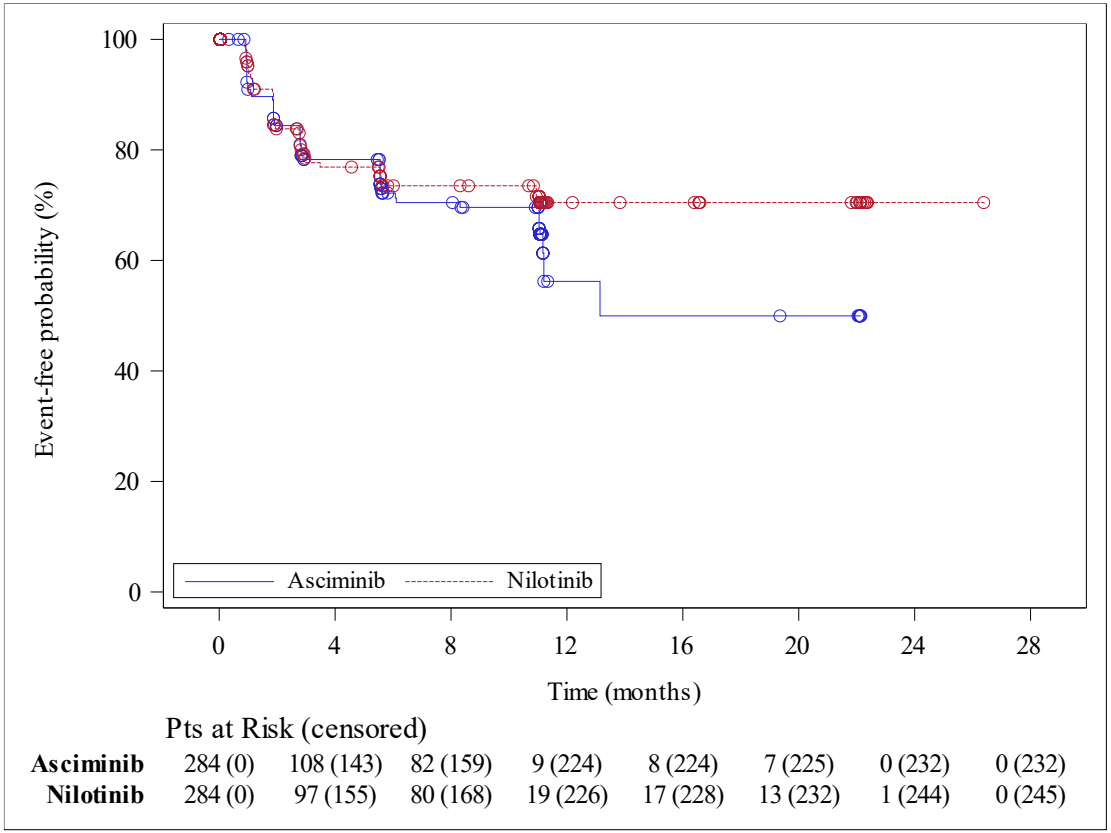
Symptom Burden (MID=15)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.2 EORTC QLQ-CML24: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

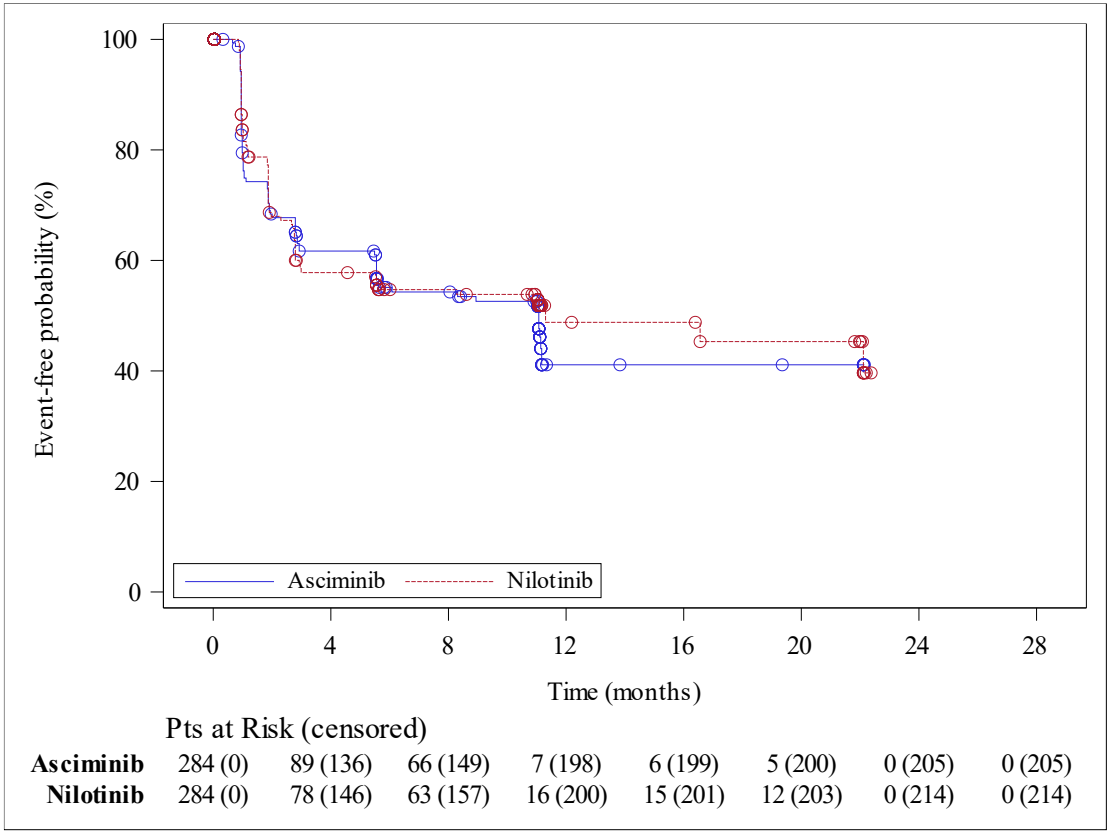
Satisfaction with Care and Information (MID=15)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.2 EORTC QLQ-CML24: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

Satisfaction with Social Life (MID=15)



Note: o = Censored observations
Data Cut/15MAY2025

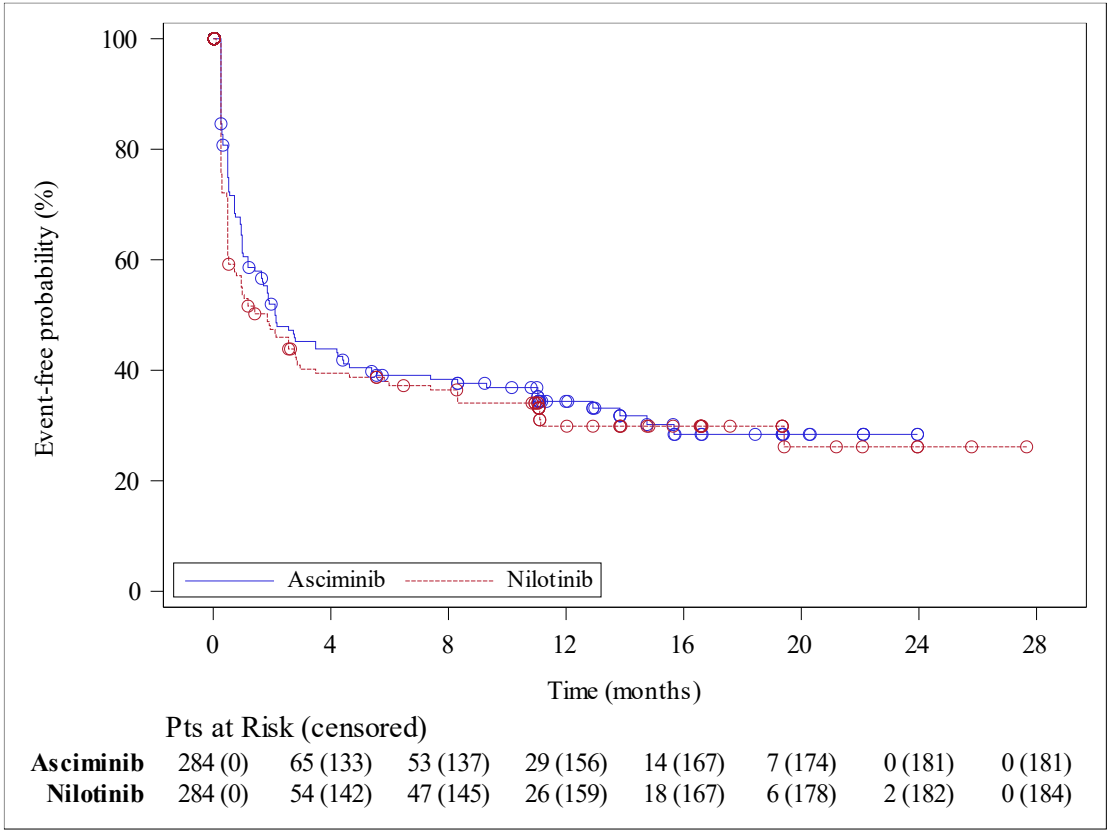
Table 3-1.3 FACT-ITEM GP5: Time to first deterioration (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
V4 (MID=1)			
N*	284	284	0.85
Number of patients with events, n (%)	103 (36.3)	100 (35.2)	[0.65; 1.12]
			0.484
Percentiles (months) [95% CI]			
25th	0.5 [0.3; 0.8]	0.3 [0.3; 0.5]	
Median	2.1 [1.4; 4.4]	1.8 [0.7; 2.8]	
75th	N.E. [13.8; N.E.]	N.E. [11.1; N.E.]	

MID: Minimal important difference
HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factor ELTS Score (IRT) and covariates baseline score and treatment arm.
P-Values are from a stratified logrank test with stratification factor ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 3-1.3 FACT-ITEM GP5: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

V4 (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Table 3-1.4 PRO-CTCAE - Frequency: Time to first deterioration (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Headache - Frequency (MID=1)			
N*	284	284	0.65
Number of patients with events, n (%)	99 (34.9)	112 (39.4)	[0.49; 0.85]
			0.004
Percentiles (months) [95% CI]			
25th	0.8 [0.5; 1.2]	0.3 [0.3; 0.5]	
Median	3.7 [2.1; 5.6]	1.3 [0.7; 2.6]	
75th	N.E. [22.1; N.E.]	10.2 [5.4; N.E.]	
Rash - Presence/Absence (MID=1)			
N*	284	284	0.57
Number of patients with events, n (%)	80 (28.2)	90 (31.7)	[0.42; 0.77]
			0.007
Percentiles (months) [95% CI]			
25th	1.9 [1.4; 2.9]	0.5 [0.5; 1.0]	
Median	10.2 [5.1; N.E.]	2.8 [1.6; 5.6]	
75th	N.E. [N.E.; N.E.]	N.E. [19.4; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Diarrhea - Frequency (MID=1)			
N*	284	284	1.00
Number of patients with events, n (%)	96 (33.8)	92 (32.4)	[0.75; 1.33]
			0.945
Percentiles (months) [95% CI]			
25th	0.7 [0.5; 1.0]	0.5 [0.3; 1.0]	
Median	2.4 [1.8; 5.3]	2.8 [2.0; 7.4]	
75th	N.E. [17.5; N.E.]	N.E. [17.5; N.E.]	
Vomiting - Frequency (MID=1)			
N*	284	284	0.42
Number of patients with events, n (%)	24 (8.5)	47 (16.5)	[0.25; 0.68]
			<0.001
Percentiles (months) [95% CI]			
25th	N.E. [17.5; N.E.]	4.6 [2.7; 10.2]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Nausea - Frequency (MID=1)			

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
N*	284	284	0.60
Number of patients with events, n (%)	61 (21.5)	80 (28.2)	[0.43; 0.84]
			0.003
Percentiles (months) [95% CI]			
25th	2.3 [1.0; 3.7]	0.7 [0.3; 1.4]	
Median	22.1 [15.7; N.E.]	5.5 [2.8; N.E.]	
75th	N.E. [25.8; N.E.]	N.E. [24.9; N.E.]	
Edema - Frequency (MID=1)			
N*	284	284	0.95
Number of patients with events, n (%)	65 (22.9)	63 (22.2)	[0.67; 1.35]
			0.762
Percentiles (months) [95% CI]			
25th	2.1 [1.4; 3.5]	2.8 [1.0; 4.6]	
Median	22.1 [16.6; N.E.]	24.9 [11.1; N.E.]	
75th	N.E. [22.1; N.E.]	N.E. [24.9; N.E.]	
Muscle Pain - Frequency (MID=1)			
N*	284	284	0.92

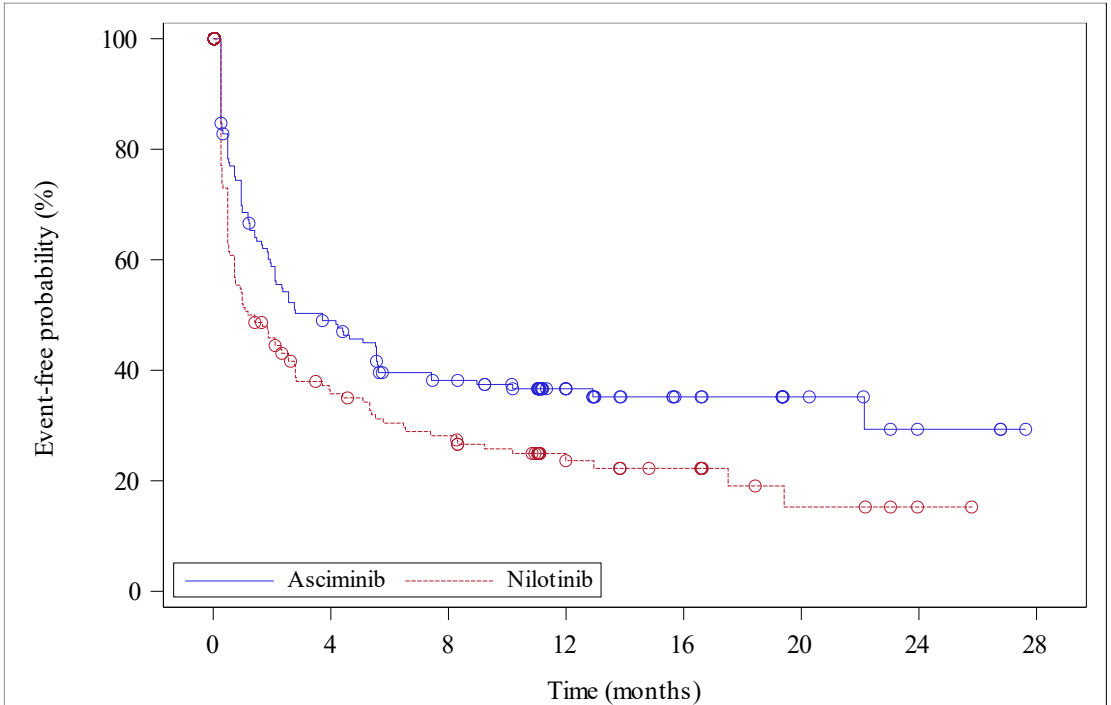
	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Number of patients with events, n (%)	105 (37.0)	104 (36.6)	[0.70; 1.21] 0.568
Percentiles (months) [95% CI]			
25th	0.5 [0.3; 0.5]	0.3 [0.3; 0.5]	
Median	1.4 [1.0; 2.2]	1.2 [0.7; 2.8]	
75th	N.E. [12.0; N.E.]	22.2 [9.3; N.E.]	
Increased Sweating - Frequency (MID=1)			
N*	284	284	1.12
Number of patients with events, n (%)	76 (26.8)	71 (25.0)	[0.81; 1.55] 0.546
Percentiles (months) [95% CI]			
25th	1.0 [0.6; 1.7]	1.2 [0.7; 2.6]	
Median	13.8 [5.1; N.E.]	12.9 [8.3; N.E.]	
75th	22.1 [22.1; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**

MID: Minimal important difference
HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factor ELTS Score (IRT) and covariates baseline score and treatment arm.
P-Values are from a stratified logrank test with stratification factor ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 3-1.4 PRO-CTCAE - Frequency: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

Headache - Frequency (MID=1)



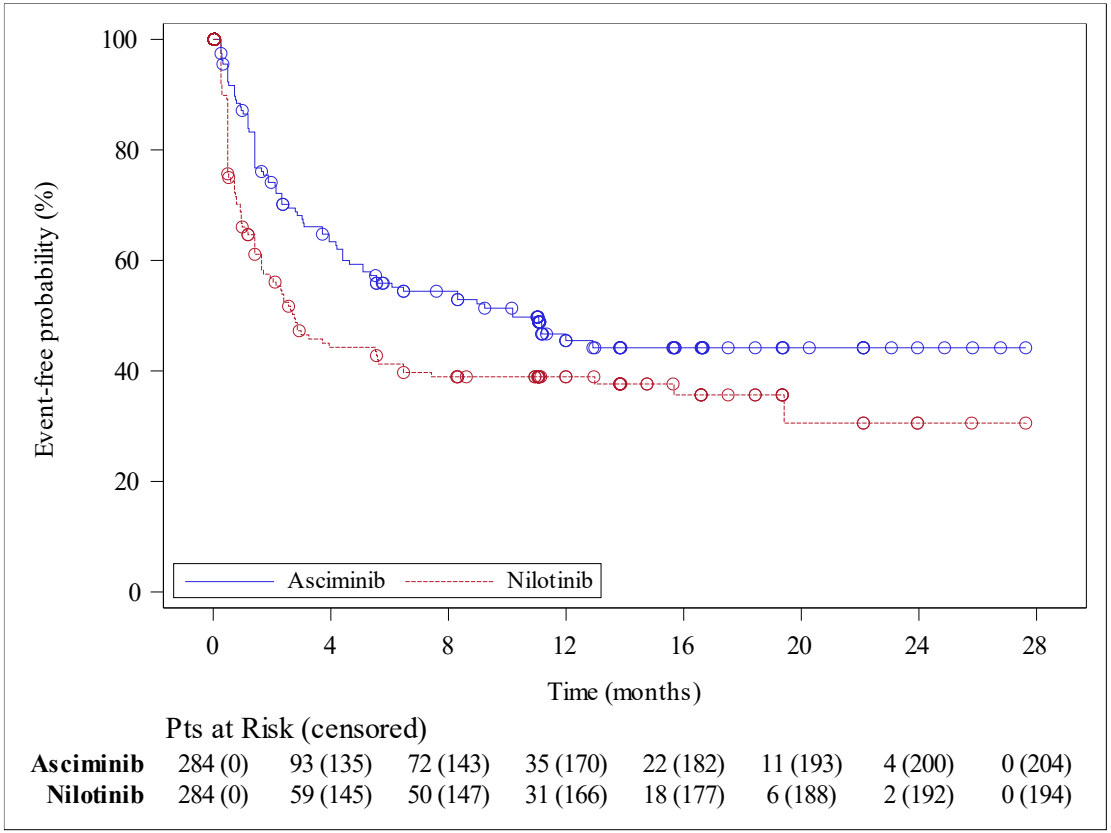
Pts at Risk (censored)

Asciminib	284 (0)	74 (131)	53 (136)	25 (162)	15 (171)	8 (178)	3 (182)	0 (185)
Nilotinib	284 (0)	48 (142)	37 (143)	17 (158)	12 (162)	4 (168)	1 (171)	0 (172)

Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.4 PRO-CTCAE - Frequency: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

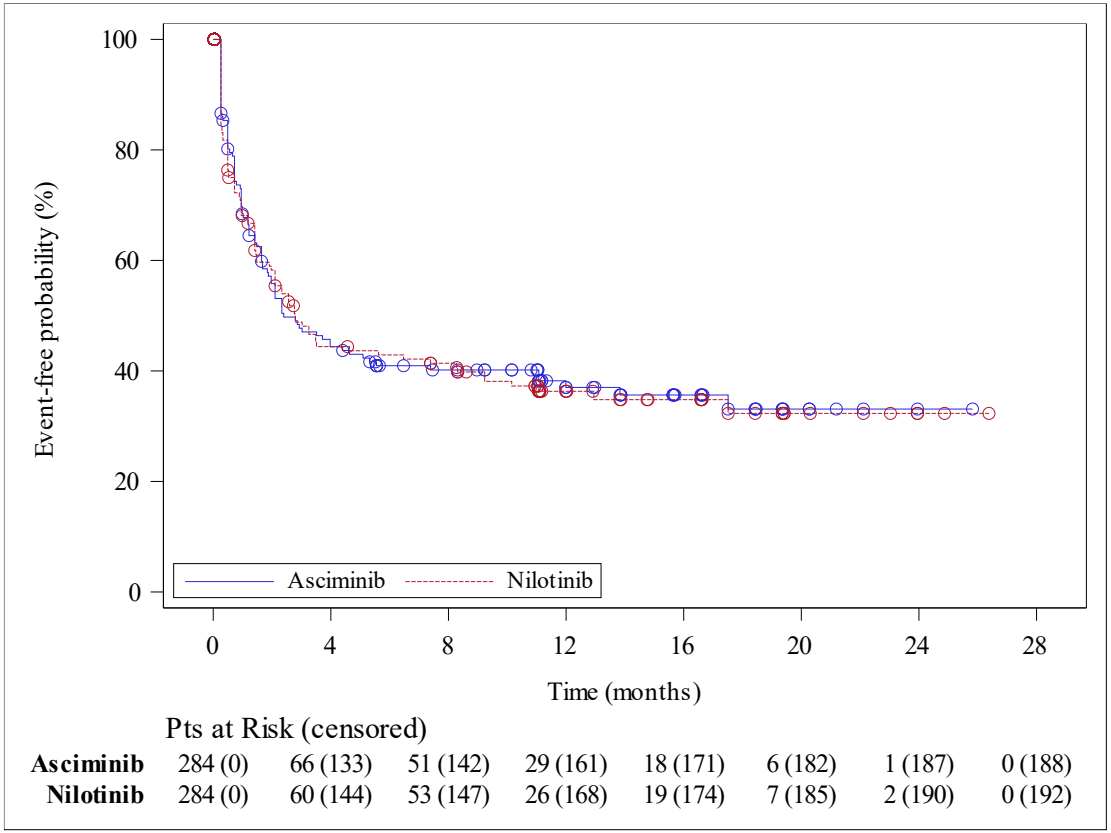
Rash - Presence/Absence (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.4 PRO-CTCAE - Frequency: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

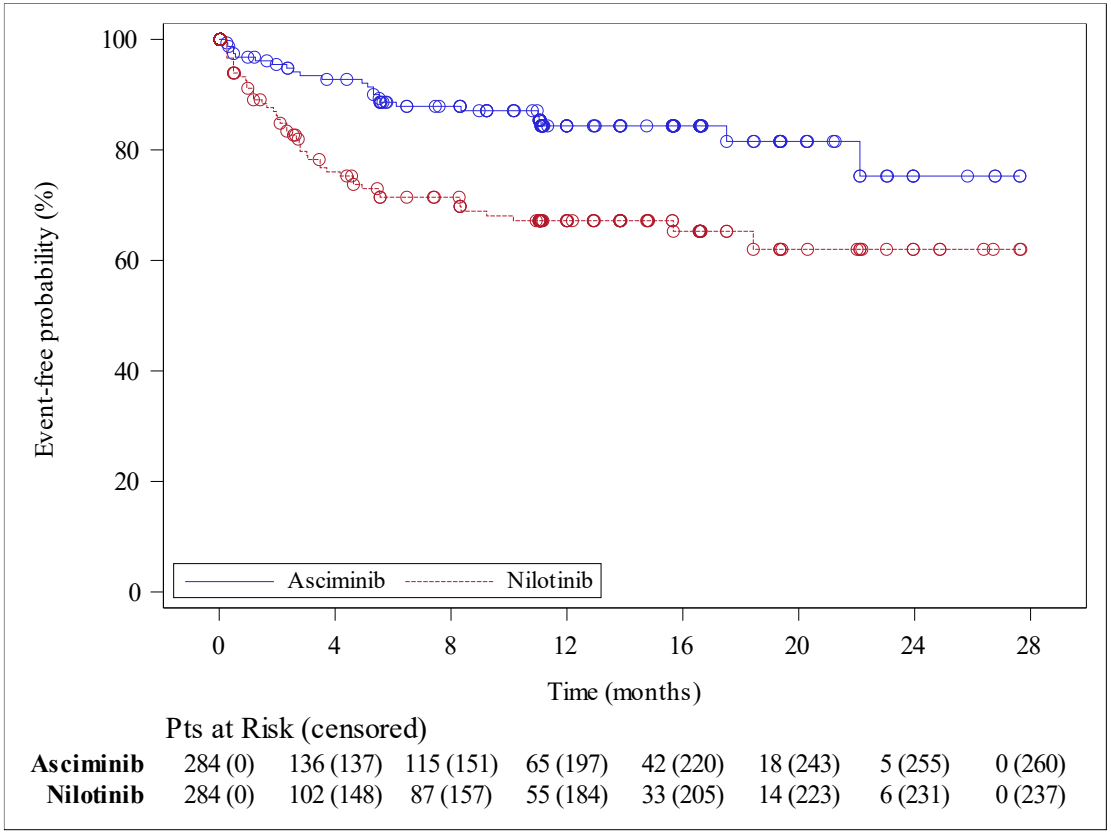
Diarrhea - Frequency (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.4 PRO-CTCAE - Frequency: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

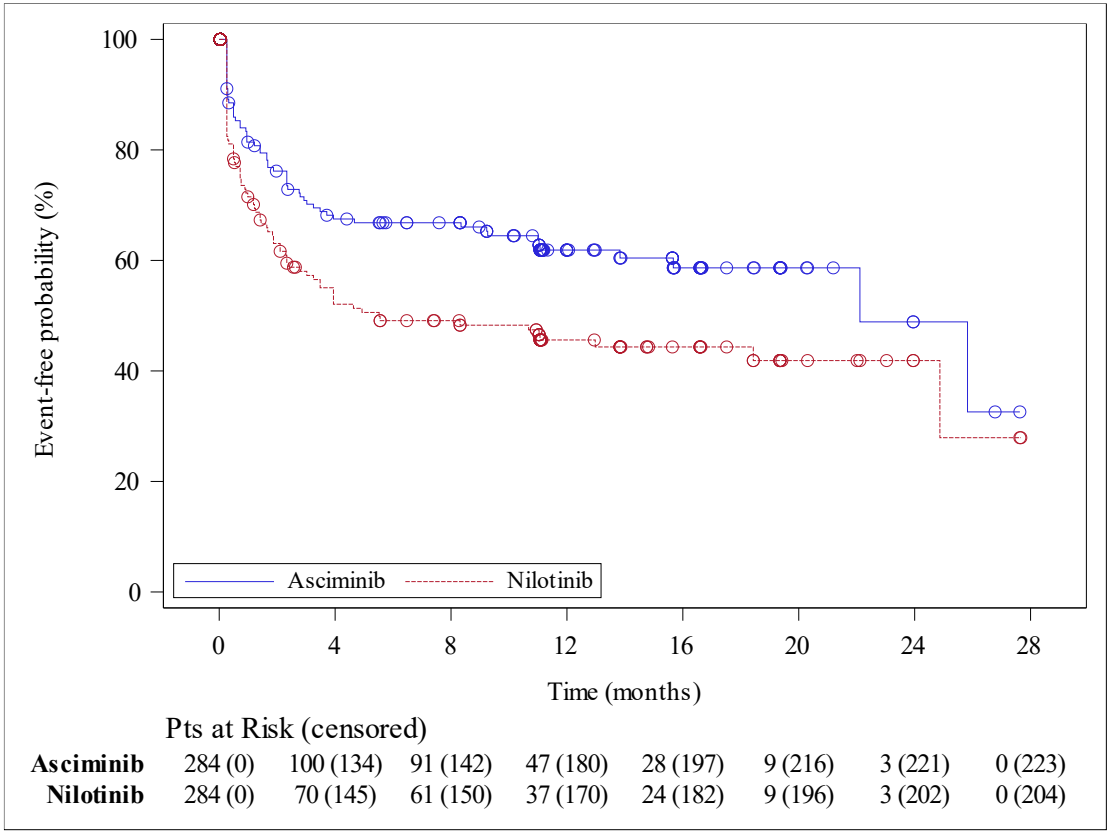
Vomiting - Frequency (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.4 PRO-CTCAE - Frequency: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

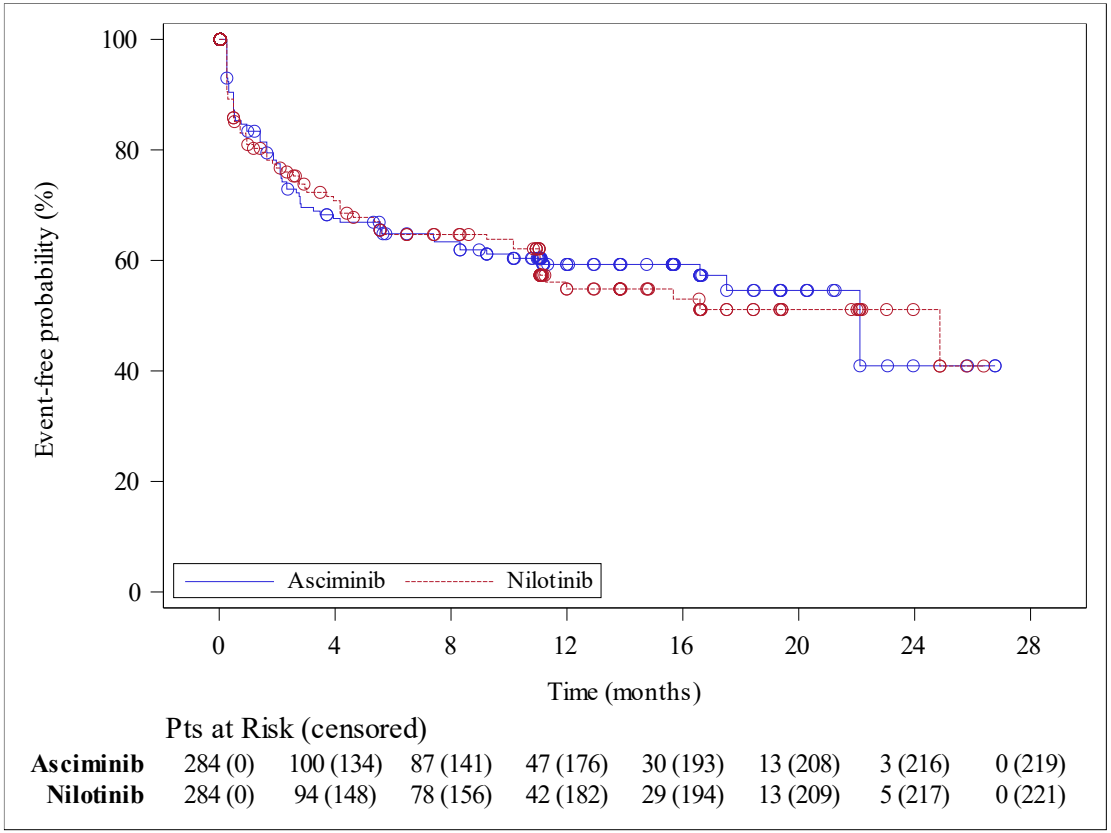
Nausea - Frequency (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.4 PRO-CTCAE - Frequency: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

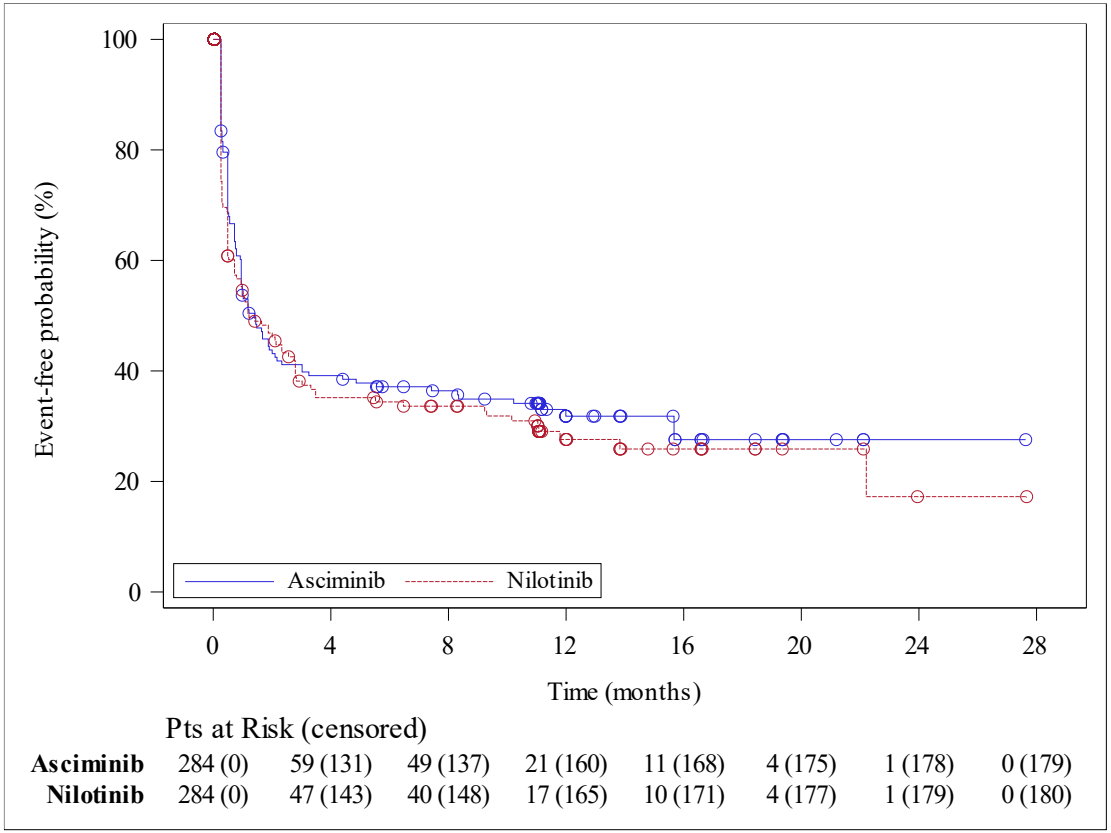
Edema - Frequency (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.4 PRO-CTCAE - Frequency: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

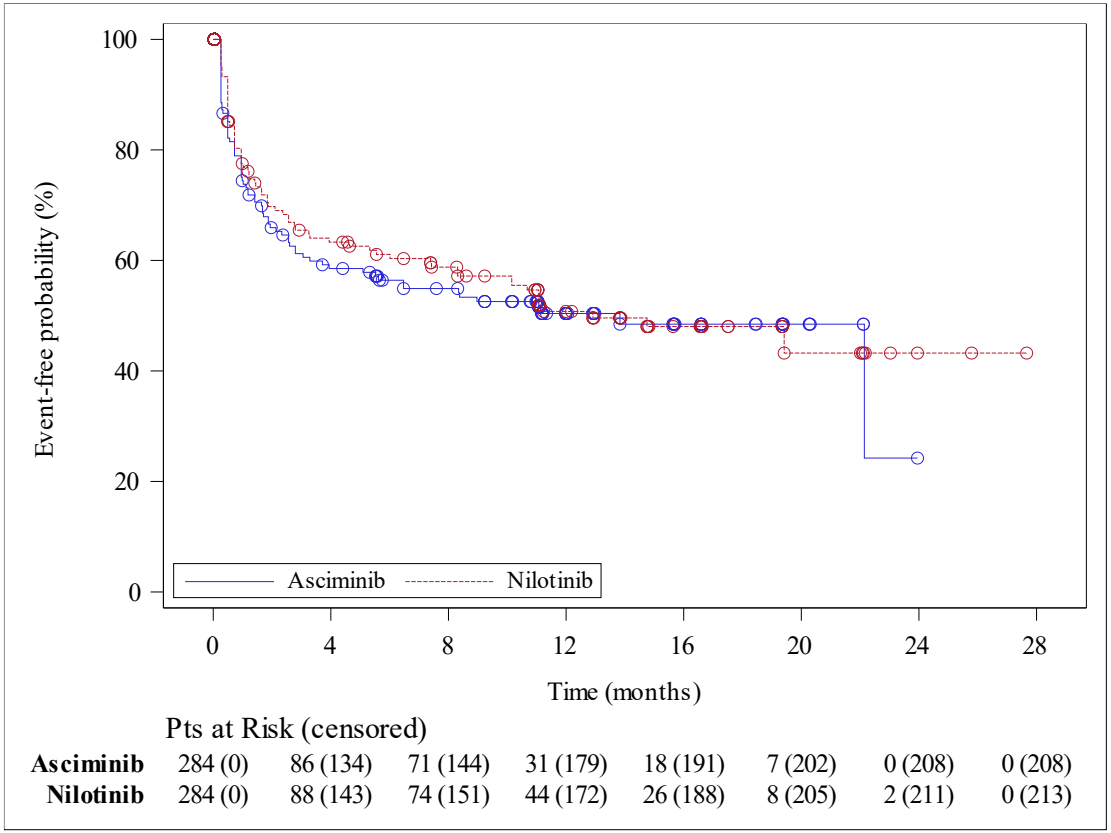
Muscle Pain - Frequency (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.4 PRO-CTCAE - Frequency: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

Increased Sweating - Frequency (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Table 3-1.5 PRO-CTCAE - Severity: Time to first deterioration (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Fatigue - Severity (MID=1)			
N*	284	284	0.86
Number of patients with events, n (%)	99 (34.9)	98 (34.5)	[0.65; 1.14]
			0.554
Percentiles (months) [95% CI]			
25th	0.5 [0.3; 1.0]	0.5 [0.3; 0.7]	
Median	3.0 [1.9; 9.2]	2.8 [1.0; 5.4]	
75th	22.1 [15.7; N.E.]	N.E. [11.8; N.E.]	
Headache - Severity (MID=1)			
N*	284	284	0.72
Number of patients with events, n (%)	97 (34.2)	105 (37.0)	[0.54; 0.95]
			0.051
Percentiles (months) [95% CI]			
25th	1.0 [0.5; 1.2]	0.3 [0.3; 0.5]	
Median	2.8 [2.1; 5.6]	1.7 [1.0; 3.3]	
75th	N.E. [22.1; N.E.]	17.5 [8.3; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Vomiting - Severity (MID=1)			
N*	284	284	0.45
Number of patients with events, n (%)	23 (8.1)	43 (15.1)	[0.27; 0.75]
			0.002
Percentiles (months) [95% CI]			
25th	N.E. [17.5; N.E.]	8.3 [3.1; 18.4]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Nausea - Severity (MID=1)			
N*	284	284	0.59
Number of patients with events, n (%)	59 (20.8)	82 (28.9)	[0.42; 0.82]
			0.002
Percentiles (months) [95% CI]			
25th	2.3 [1.0; 6.1]	0.8 [0.5; 1.6]	
Median	N.E. [15.7; N.E.]	5.5 [3.3; 18.4]	
75th	N.E. [N.E.; N.E.]	24.9 [22.0; N.E.]	
Edema - Severity (MID=1)			

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
N*	284	284	0.88
Number of patients with events, n (%)	55 (19.4)	55 (19.4)	[0.60; 1.28]
			0.512
Percentiles (months) [95% CI]			
25th	2.8 [1.9; 7.4]	3.0 [1.4; 5.6]	
Median	N.E. [17.5; N.E.]	N.E. [16.6; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Muscle Pain - Severity (MID=1)			
N*	284	284	0.79
Number of patients with events, n (%)	96 (33.8)	105 (37.0)	[0.60; 1.05]
			0.071
Percentiles (months) [95% CI]			
25th	0.5 [0.3; 0.7]	0.3 [0.3; 0.5]	
Median	2.2 [1.2; 5.6]	1.9 [0.7; 2.8]	
75th	N.E. [N.E.; N.E.]	15.7 [6.5; N.E.]	
Pruritus - Severity (MID=1)			
N*	284	284	0.56

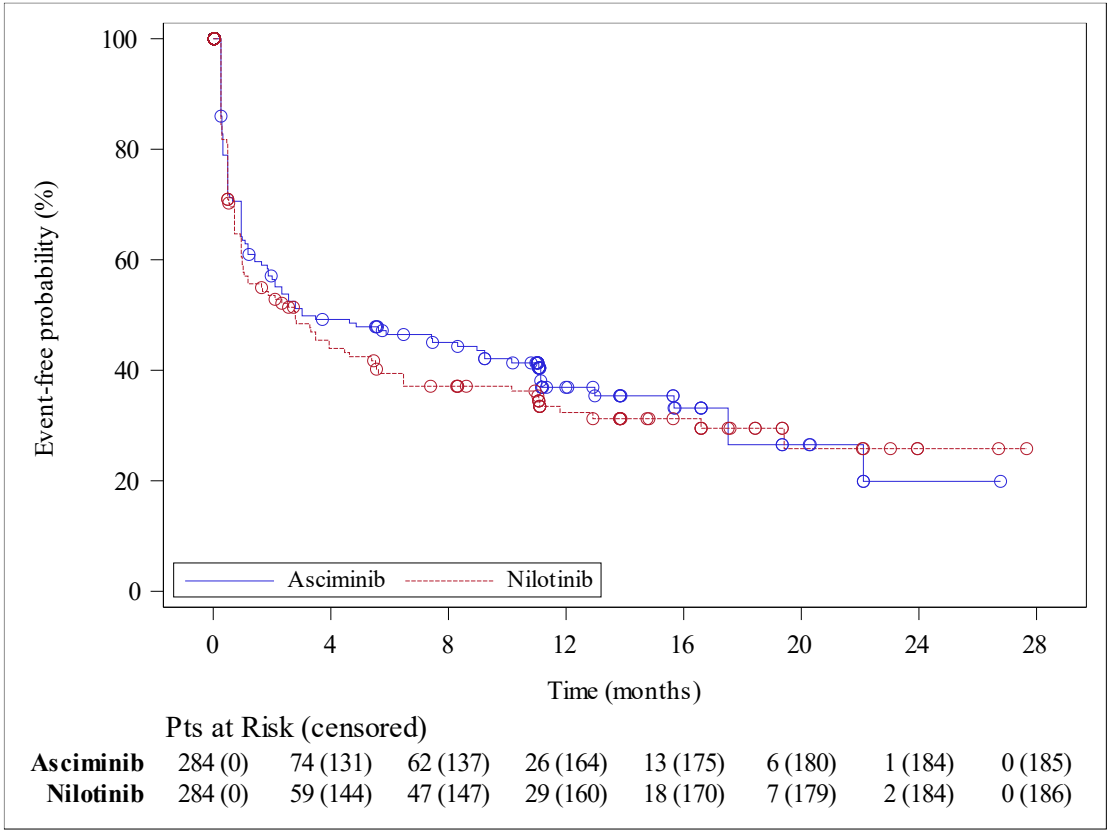
	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Number of patients with events, n (%)	92 (32.4)	114 (40.1)	[0.42; 0.74]
			<0.001
Percentiles (months) [95% CI]			
25th	1.2 [0.9; 1.4]	0.5 [N.E.; N.E.]	
Median	4.4 [2.8; 11.1]	1.7 [1.0; 2.6]	
75th	24.0 [22.1; N.E.]	11.1 [5.6; 19.4]	
Increased Sweating - Severity (MID=1)			
N*	284	284	1.01
Number of patients with events, n (%)	66 (23.2)	65 (22.9)	[0.72; 1.43]
			0.963
Percentiles (months) [95% CI]			
25th	1.4 [1.0; 2.6]	1.2 [0.7; 2.6]	
Median	22.1 [8.4; N.E.]	19.4 [11.0; N.E.]	
75th	N.E. [22.1; N.E.]	N.E. [N.E.; N.E.]	
Cough - Severity (MID=1)			
N*	284	284	0.80
Number of patients with events, n (%)	91 (32.0)	96 (33.8)	[0.60; 1.07]

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
			0.068
Percentiles (months) [95% CI]			
25th	1.4 [1.0; 2.8]	1.0 [0.7; 1.2]	
Median	9.2 [4.5; 13.9]	3.9 [2.3; 7.4]	
75th	22.1 [17.5; N.E.]	19.4 [12.9; N.E.]	

MID: Minimal important difference
HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factor ELTS Score (IRT) and covariates baseline score and treatment arm.
P-Values are from a stratified logrank test with stratification factor ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 3-1.5 PRO-CTCAE - Severity: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

Fatigue - Severity (MID=1)



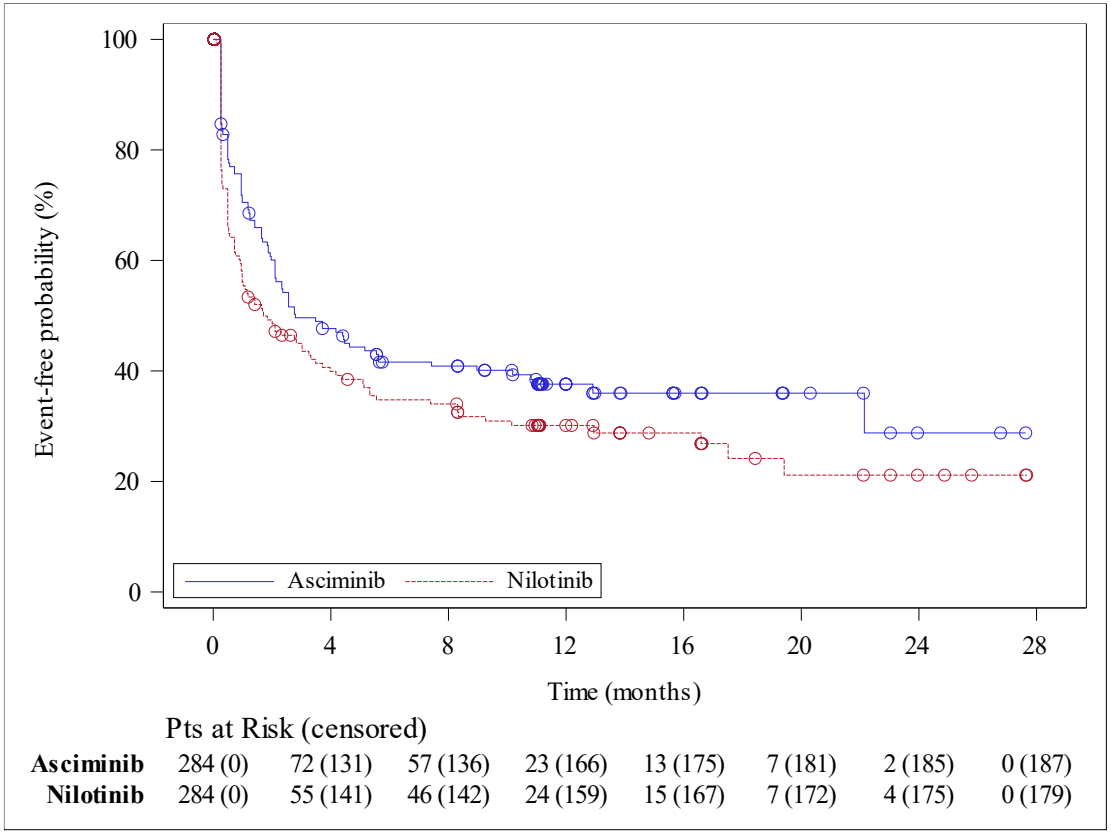
Pts at Risk (censored)

Asciminib	284 (0)	74 (131)	62 (137)	26 (164)	13 (175)	6 (180)	1 (184)	0 (185)
Nilotinib	284 (0)	59 (144)	47 (147)	29 (160)	18 (170)	7 (179)	2 (184)	0 (186)

Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.5 PRO-CTCAE - Severity: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

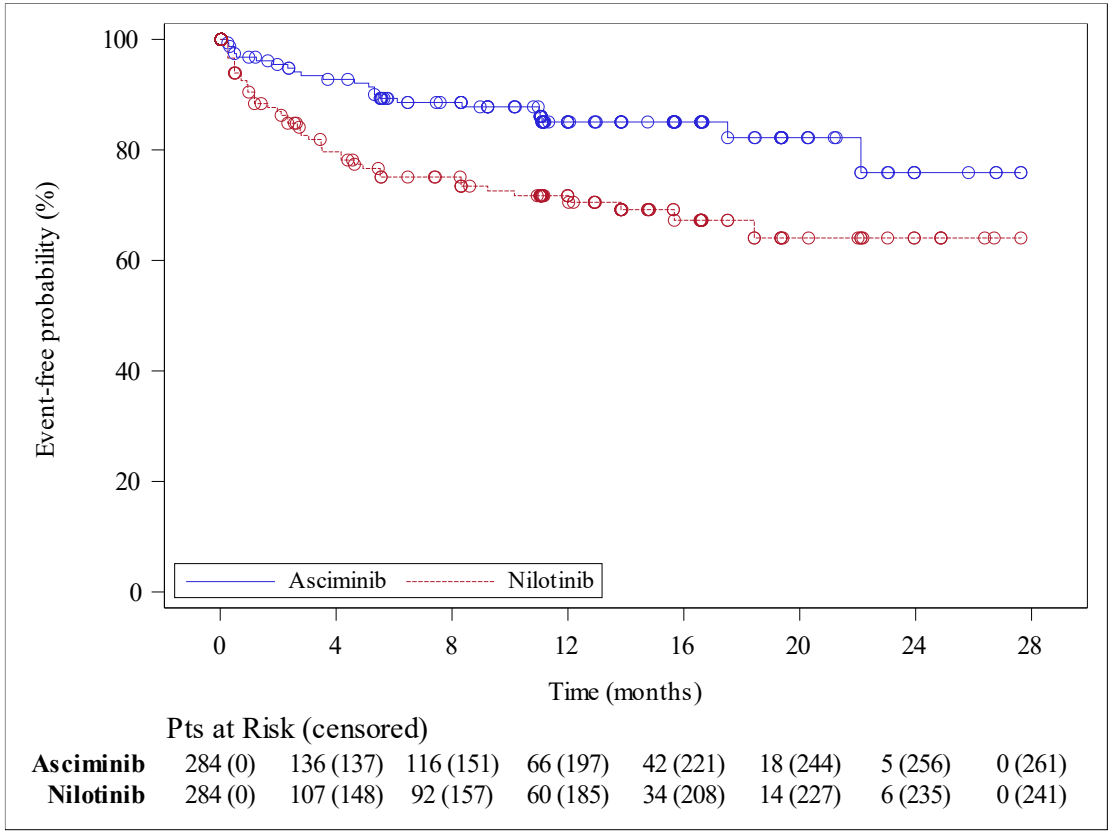
Headache - Severity (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.5 PRO-CTCAE - Severity: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

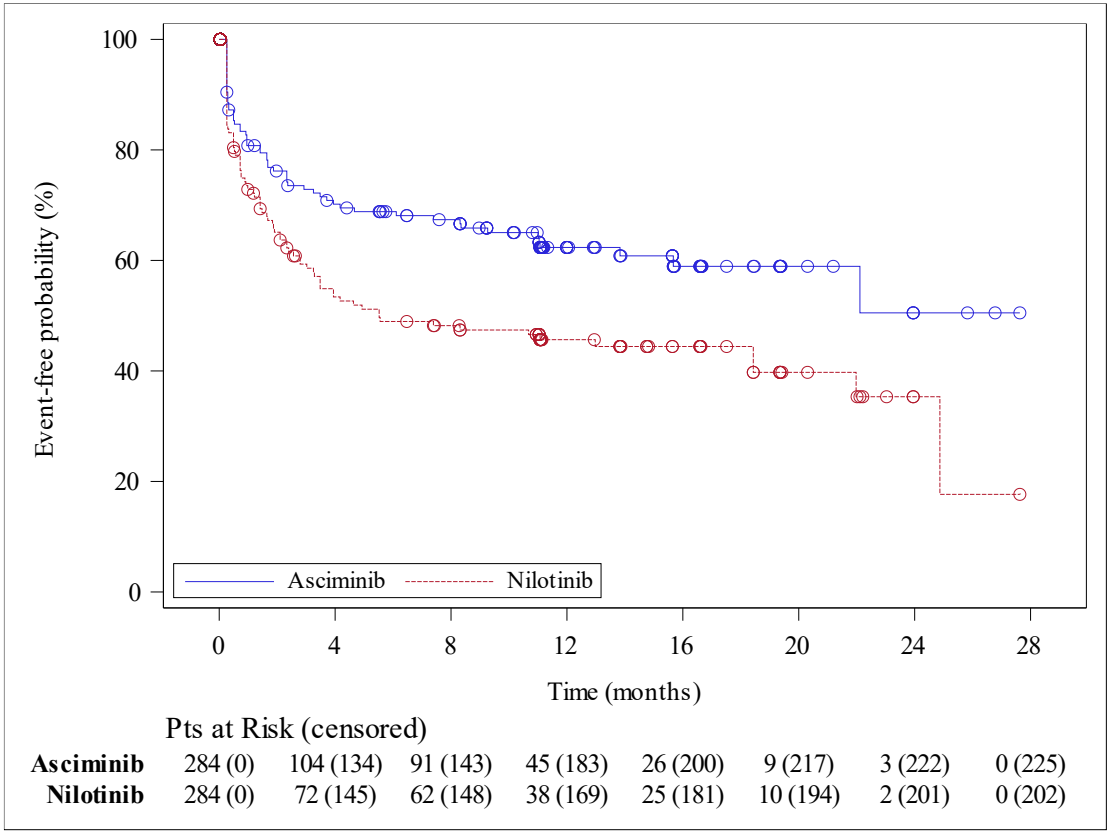
Vomiting - Severity (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.5 PRO-CTCAE - Severity: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

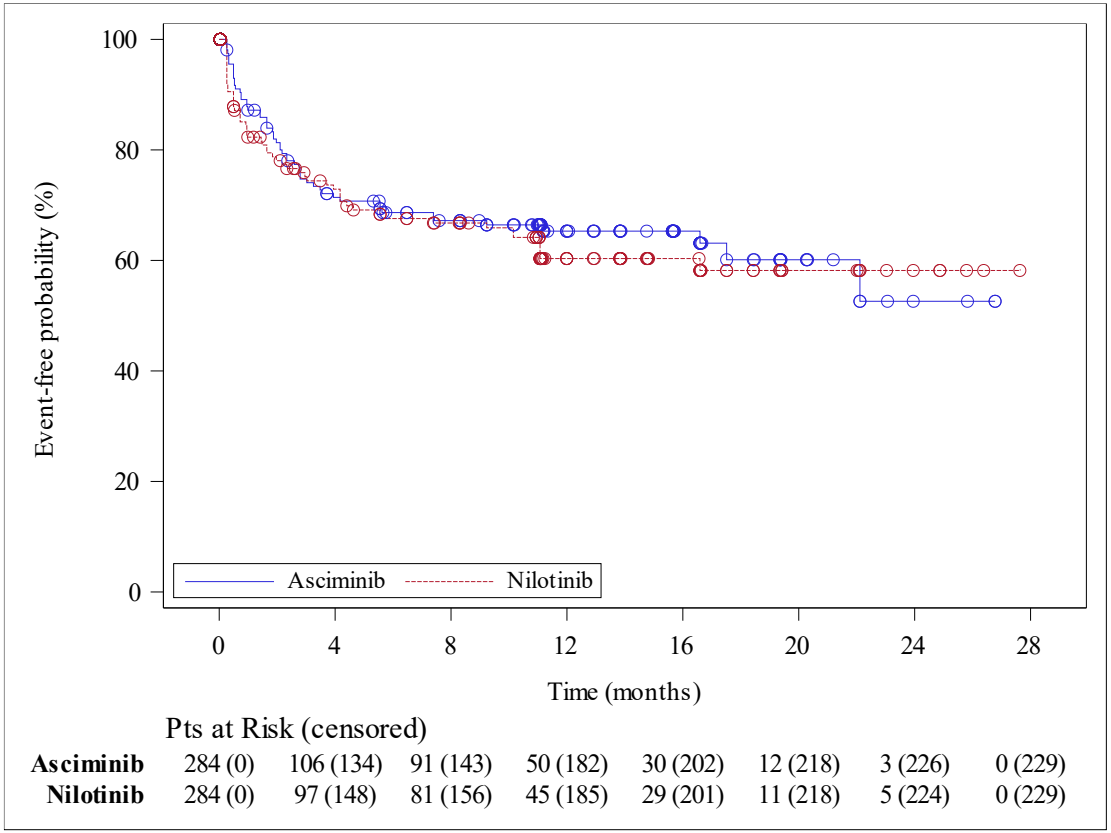
Nausea - Severity (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.5 PRO-CTCAE - Severity: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

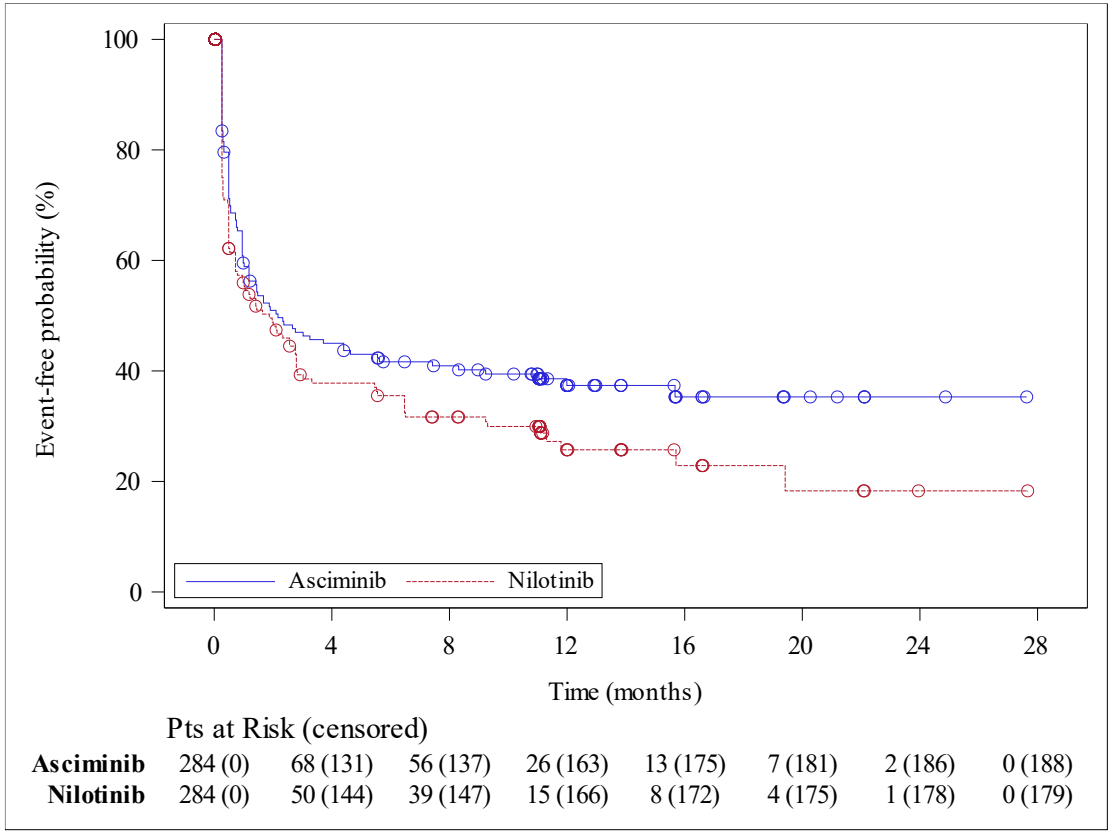
Edema - Severity (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.5 PRO-CTCAE - Severity: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

Muscle Pain - Severity (MID=1)



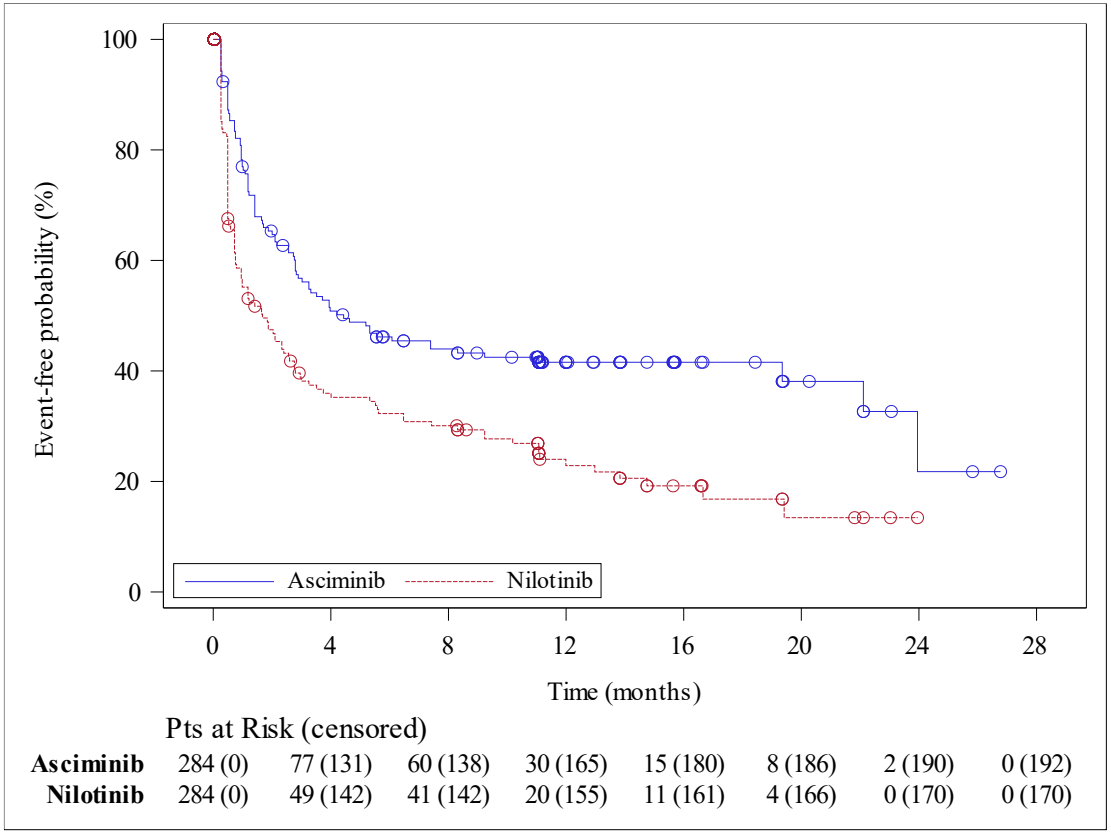
Pts at Risk (censored)

Asciminib	284 (0)	68 (131)	56 (137)	26 (163)	13 (175)	7 (181)	2 (186)	0 (188)
Nilotinib	284 (0)	50 (144)	39 (147)	15 (166)	8 (172)	4 (175)	1 (178)	0 (179)

Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.5 PRO-CTCAE - Severity: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

Pruritus - Severity (MID=1)



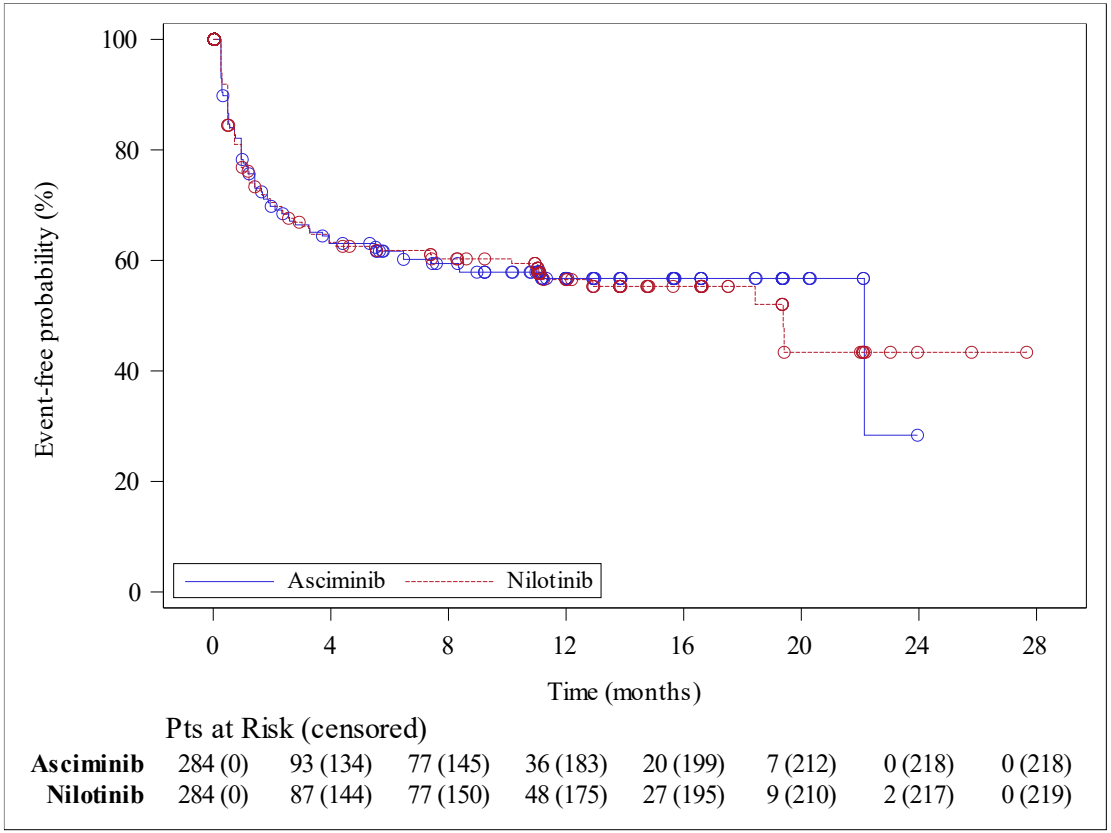
Pts at Risk (censored)

Asciminib	284 (0)	77 (131)	60 (138)	30 (165)	15 (180)	8 (186)	2 (190)	0 (192)
Nilotinib	284 (0)	49 (142)	41 (142)	20 (155)	11 (161)	4 (166)	0 (170)	0 (170)

Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.5 PRO-CTCAE - Severity: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

Increased Sweating - Severity (MID=1)



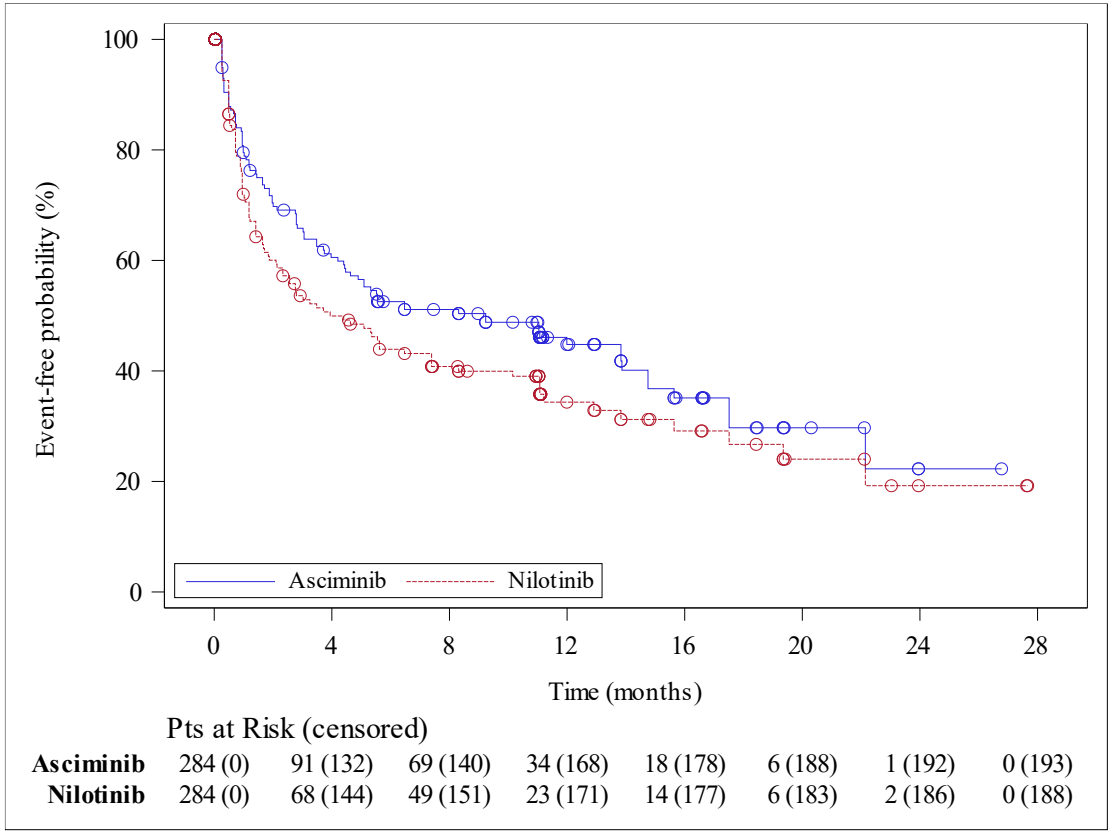
Pts at Risk (censored)

Asciminib	284 (0)	93 (134)	77 (145)	36 (183)	20 (199)	7 (212)	0 (218)	0 (218)
Nilotinib	284 (0)	87 (144)	77 (150)	48 (175)	27 (195)	9 (210)	2 (217)	0 (219)

Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.5 PRO-CTCAE - Severity: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

Cough - Severity (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Table 3-1.6 PRO-CTCAE - Interference: Time to first deterioration (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Fatigue - Interference (MID=1)			
N*	284	284	1.05
Number of patients with events, n (%)	103 (36.3)	90 (31.7)	[0.79; 1.40]
			0.505
Percentiles (months) [95% CI]			
25th	0.7 [0.5; 1.0]	0.5 [0.3; 0.7]	
Median	3.5 [2.4; 7.4]	3.0 [1.1; 11.1]	
75th	22.1 [11.1; N.E.]	N.E. [19.4; N.E.]	
Headache - Interference (MID=1)			
N*	284	284	0.73
Number of patients with events, n (%)	82 (28.9)	90 (31.7)	[0.54; 0.99]
			0.055
Percentiles (months) [95% CI]			
25th	1.9 [1.0; 2.3]	0.5 [0.3; 1.1]	
Median	10.2 [4.4; 22.1]	3.0 [2.1; 7.4]	
75th	N.E. [22.1; N.E.]	N.E. [N.E.; N.E.]	

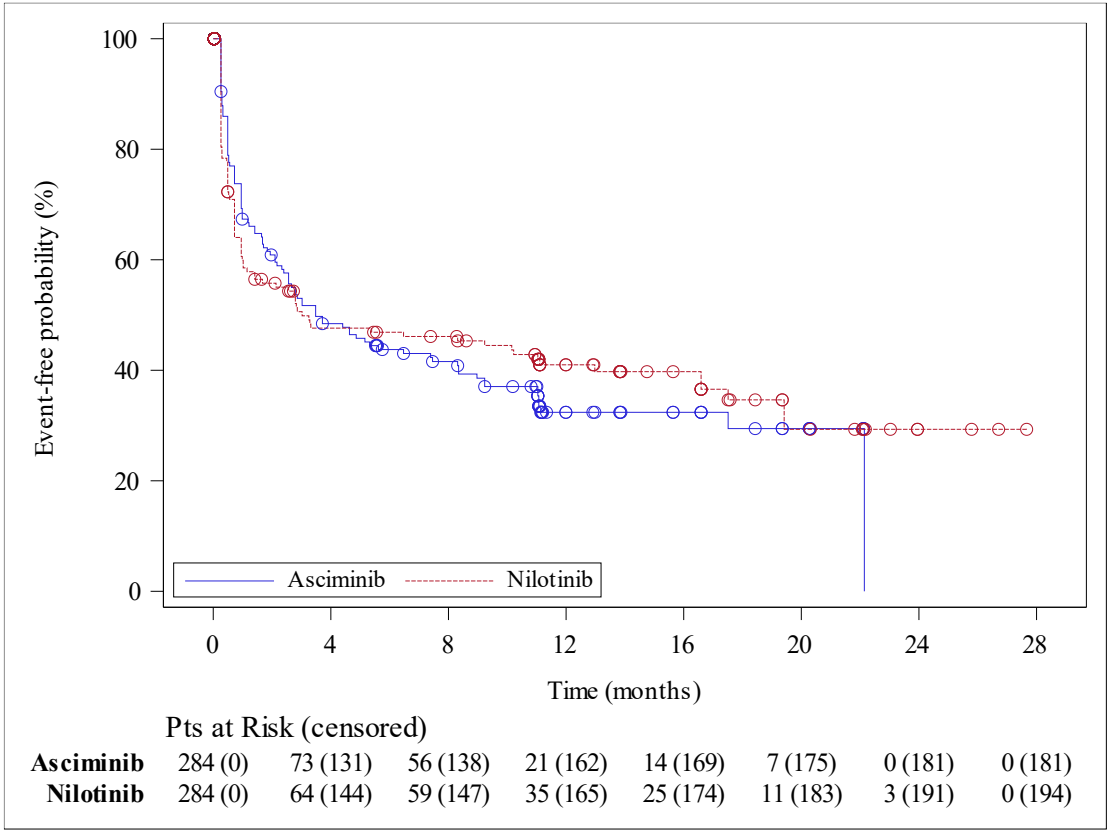
	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Edema - Interference (MID=1)			
N*	284	284	0.85
Number of patients with events, n (%)	42 (14.8)	44 (15.5)	[0.55; 1.30]
			0.450
Percentiles (months) [95% CI]			
25th	9.2 [3.5; 22.1]	4.2 [2.8; 11.1]	
Median	N.E. [22.1; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Muscle Pain - Interference (MID=1)			
N*	284	284	0.94
Number of patients with events, n (%)	91 (32.0)	85 (29.9)	[0.70; 1.26]
			0.751
Percentiles (months) [95% CI]			
25th	0.6 [0.5; 1.0]	0.5 [0.3; 0.7]	
Median	3.9 [2.1; 11.0]	2.8 [1.6; 13.9]	
75th	N.E. [N.E.; N.E.]	N.E. [18.4; N.E.]	
Cough - Interference (MID=1)			

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
N*	284	284	0.79
Number of patients with events, n (%)	61 (21.5)	64 (22.5)	[0.56; 1.13]
			0.273
Percentiles (months) [95% CI]			
25th	3.5 [2.0; 11.0]	2.8 [1.4; 4.6]	
Median	17.5 [13.9; N.E.]	15.7 [11.1; N.E.]	
75th	N.E. [22.1; N.E.]	N.E. [N.E.; N.E.]	

MID: Minimal important difference
HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factor ELTS Score (IRT) and covariates baseline score and treatment arm.
P-Values are from a stratified logrank test with stratification factor ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 3-1.6 PRO-CTCAE - Interference: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

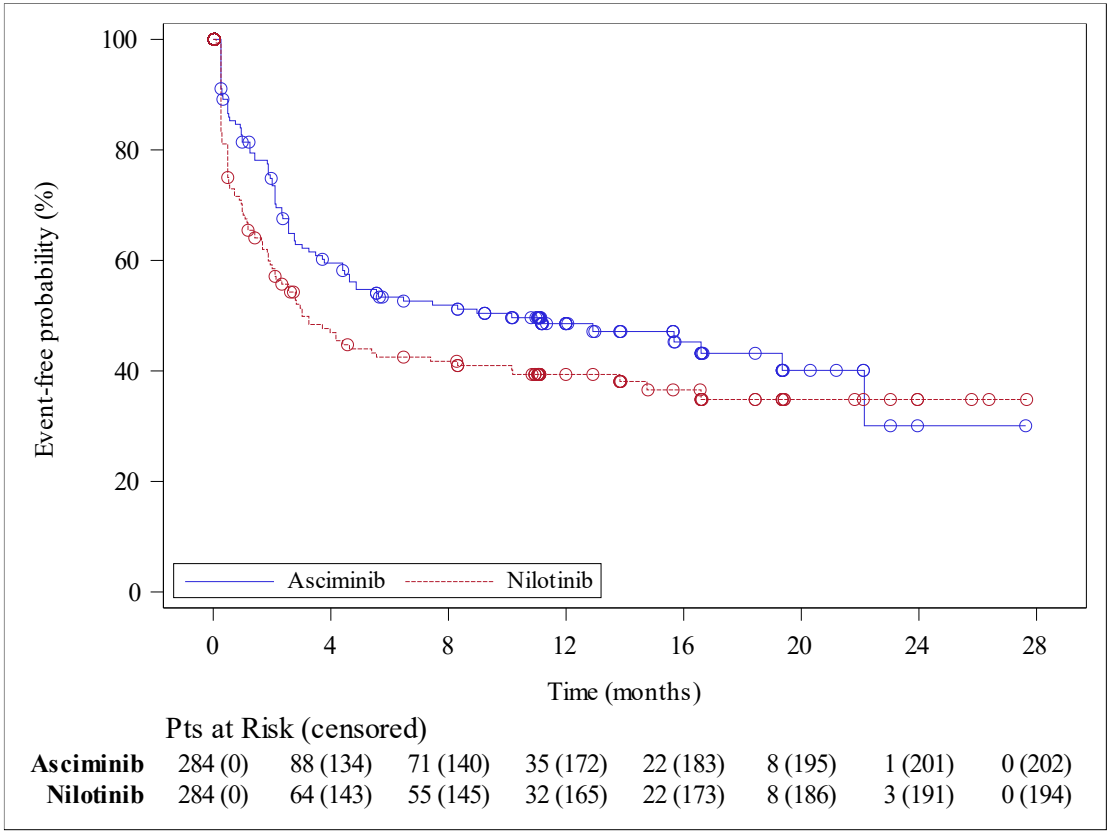
Fatigue - Interference (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.6 PRO-CTCAE - Interference: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

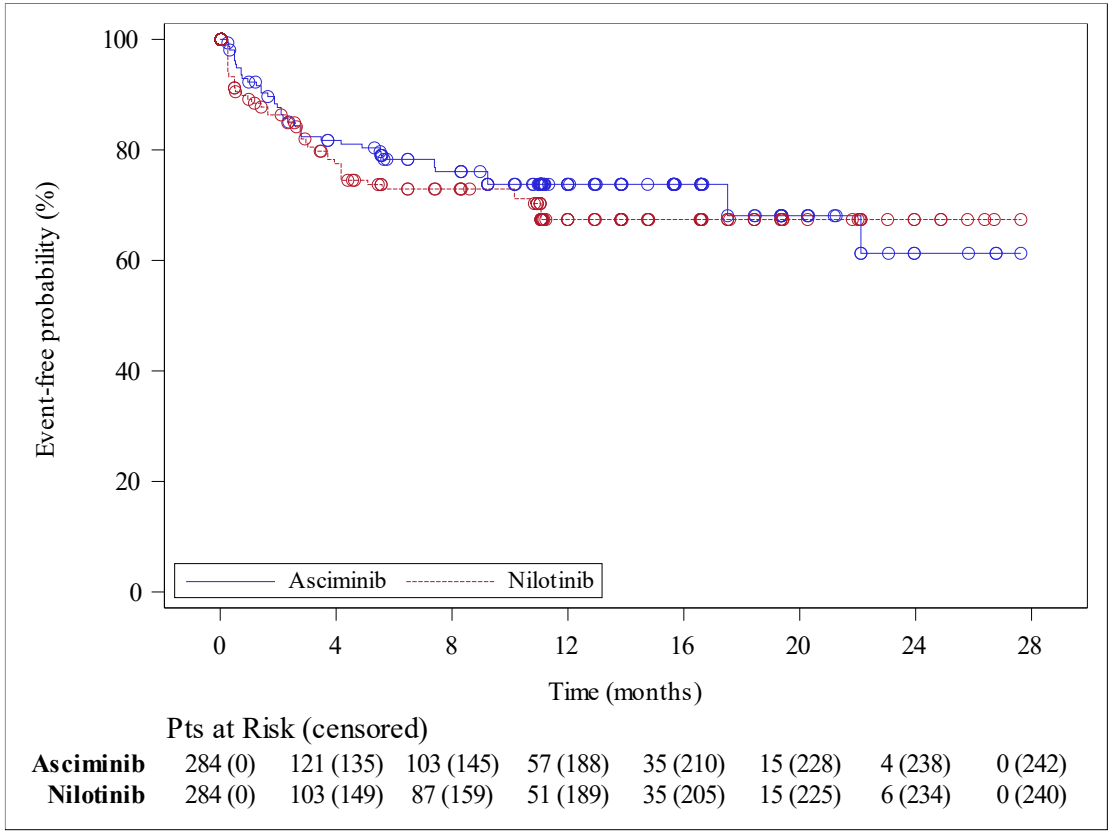
Headache - Interference (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.6 PRO-CTCAE - Interference: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

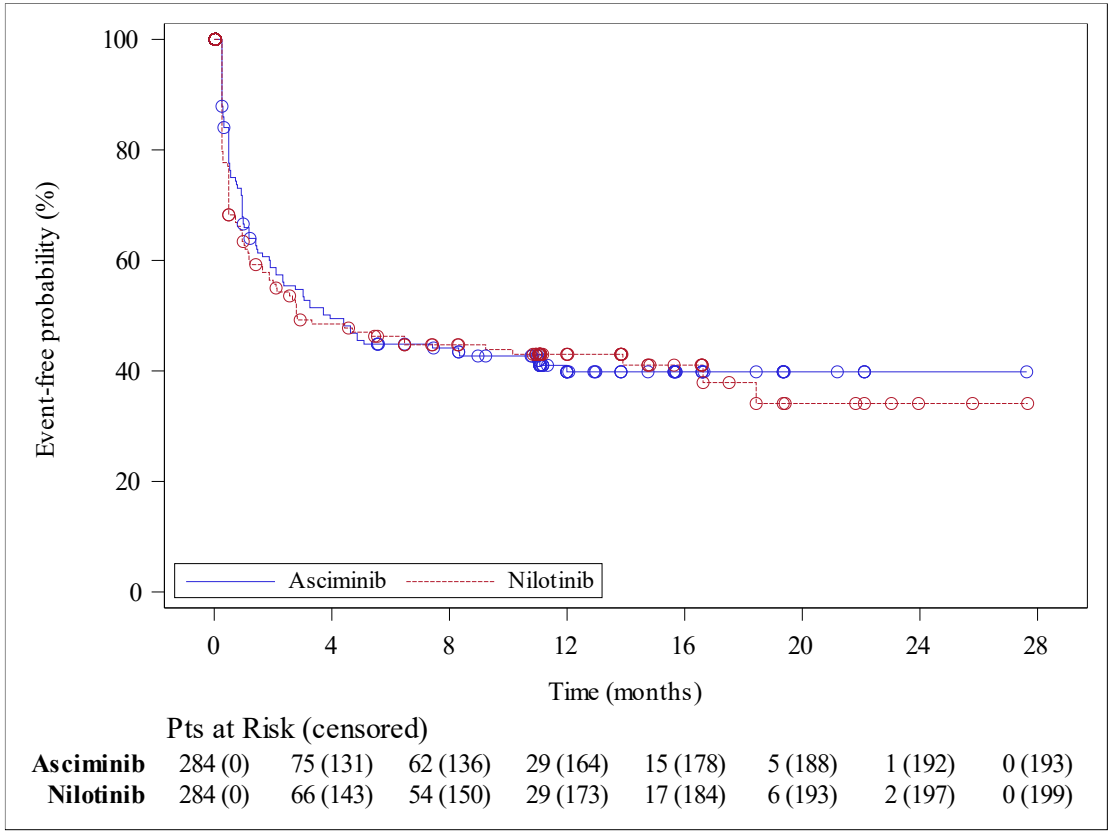
Edema - Interference (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.6 PRO-CTCAE - Interference: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

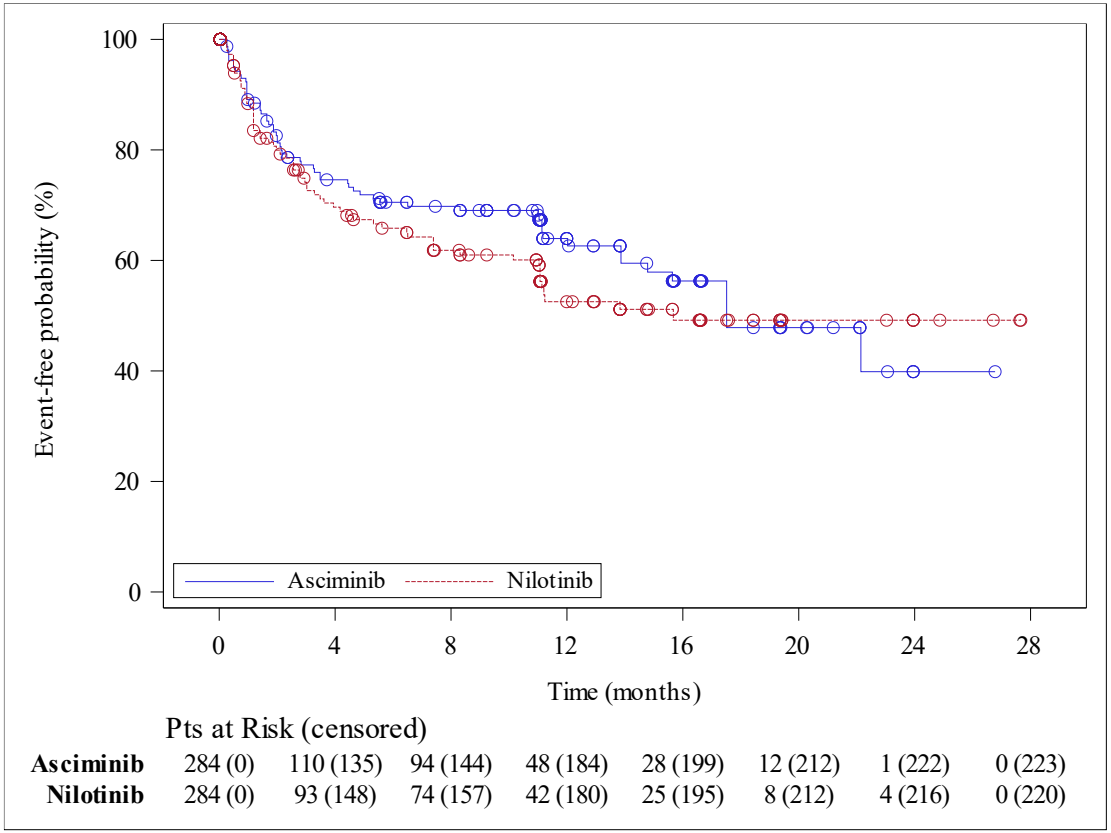
Muscle Pain - Interference (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-1.6 PRO-CTCAE - Interference: Time to first deterioration: Kaplan-Meier plot (Full Analysis Set)

Cough - Interference (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Table 3-2.1 EORTC QLQ-C30: Time to first deterioration analysis by subgroups (Full Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Global health status/QoL (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.232)							
Low	43/171 (25.1)	11.2 [11.0; 22.1]	41/172 (23.8)	22.0 [10.7; N.E.]	1.11	[0.72; 1.70]	0.627
Intermediate	12/75 (16.0)	22.1 [11.1; N.E.]	16/75 (21.3)	N.E. [5.5; N.E.]	0.57	[0.27; 1.22]	0.160
High	4/38 (10.5)	N.E. [11.1; N.E.]	6/37 (16.2)	N.E. [5.6; N.E.]	0.39	[0.11; 1.41]	0.206
Sex							
(Interaction test: p = 0.630)							
Female	23/107 (21.5)	11.2 [11.1; N.E.]	25/126 (19.8)	22.0 [5.7; N.E.]	0.99	[0.56; 1.75]	0.962
Male	36/177 (20.3)	22.1 [11.1; N.E.]	38/158 (24.1)	N.E. [10.9; N.E.]	0.82	[0.52; 1.30]	0.407

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Race							
(Interaction test: p = 0.900)							
Asian	13/40 (32.5)	11.2 [11.0; N.E.]	18/46 (39.1)	10.9 [5.5; N.E.]	0.74	[0.36; 1.54]	0.403
White	44/227 (19.4)	22.1 [11.1; N.E.]	44/217 (20.3)	22.0 [11.1; N.E.]	0.94	[0.61; 1.43]	0.698
Other	2/17 (11.8)	N.E. [0.9; N.E.]	1/21 (4.8)	N.E. [1.0; N.E.]	2.03	[0.03; 143.02]	0.244
Age groups							
(Interaction test: p = 0.642)							
18 - < 65 years	52/237 (21.9)	22.1 [11.1; N.E.]	57/247 (23.1)	22.0 [11.1; N.E.]	0.93	[0.63; 1.35]	0.701
65 - < 75 years	5/38 (13.2)	22.1 [11.1; N.E.]	4/24 (16.7)	N.E. [0.9; N.E.]	0.29	[0.04; 1.98]	0.567
>= 75 years	2/9 (22.2)	N.E. [1.0; N.E.]	2/13 (15.4)	1.0 [1.0; N.E.]	0.88	[0.08; 9.40]	0.701
Geographic region							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.801)							
Europe excluding Germany	28/138 (20.3)	22.1 [11.2; N.E.]	33/141 (23.4)	22.0 [10.8; N.E.]	0.86	[0.51; 1.43]	0.606
Germany	10/72 (13.9)	11.1 [2.8; N.E.]	6/53 (11.3)	N.E. [0.9; N.E.]	0.56	[0.18; 1.74]	0.403
Others	21/74 (28.4)	11.2 [11.0; N.E.]	24/90 (26.7)	N.E. [5.7; N.E.]	0.99	[0.55; 1.81]	0.813
Physical functioning (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.063)							
Low	26/171 (15.2)	N.E. [11.2; N.E.]	38/172 (22.1)	N.E. [11.1; N.E.]	0.64	[0.39; 1.05]	0.081
Intermediate	15/75 (20.0)	N.E. [11.1; N.E.]	9/75 (12.0)	N.E. [N.E.; N.E.]	1.75	[0.76; 4.04]	0.315
High	8/38 (21.1)	N.E. [8.9; N.E.]	3/37 (8.1)	N.E. [N.E.; N.E.]	2.01	[0.52; 7.75]	0.226

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Sex							
(Interaction test: p = 0.760)							
Female	24/107 (22.4)	11.2 [11.1; N.E.]	26/126 (20.6)	11.8 [5.7; N.E.]	1.02	[0.58; 1.78]	0.961
Male	25/177 (14.1)	N.E. [N.E.; N.E.]	24/158 (15.2)	N.E. [N.E.; N.E.]	0.88	[0.50; 1.54]	0.663
Race							
(Interaction test: p = 0.457)							
Asian	17/40 (42.5)	11.1 [2.0; N.E.]	14/46 (30.4)	N.E. [1.9; N.E.]	1.21	[0.58; 2.52]	0.584
White	30/227 (13.2)	N.E. [N.E.; N.E.]	35/217 (16.1)	N.E. [N.E.; N.E.]	0.78	[0.47; 1.27]	0.282
Other	2/17 (11.8)	N.E. [0.9; N.E.]	1/21 (4.8)	11.1 [N.E.; N.E.]	1.94	[0.04; 87.12]	0.343
Age groups							
(Interaction test: p = 0.427)							
18 - < 65 years	44/237	N.E. [11.2; N.E.]	45/247	N.E. [11.8; N.E.]	0.95	[0.63; 1.45]	0.853

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(18.6)		(18.2)				
65 - < 75 years	3/38	N.E. [N.E.; N.E.]	5/24	N.E. [0.9; N.E.]	0.28	[0.07; 1.21]	0.071
	(7.9)		(20.8)				
>= 75 years	2/9	N.E. [1.0; N.E.]	0/13	N.E. [N.E.; N.E.]	3.29	[0.09; 121.85]	0.199
	(22.2)						
Geographic region							
(Interaction test: p = 0.112)							
Europe excluding Germany	21/138	N.E. [11.2; N.E.]	26/141	N.E. [11.8; N.E.]	0.80	[0.45; 1.43]	0.440
	(15.2)		(18.4)				
Germany	6/72	N.E. [11.1; N.E.]	7/53	5.6 [1.0; N.E.]	0.38	[0.11; 1.28]	0.137
	(8.3)		(13.2)				
Others	22/74	N.E. [5.6; N.E.]	17/90	N.E. [N.E.; N.E.]	1.44	[0.75; 2.75]	0.257
	(29.7)		(18.9)				
Role functioning (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.964)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Low	42/171 (24.6)	11.2 [5.6; N.E.]	37/172 (21.5)	11.8 [11.1; N.E.]	1.14	[0.73; 1.78]	0.498
Intermediate	17/75 (22.7)	N.E. [2.8; N.E.]	18/75 (24.0)	22.1 [5.5; N.E.]	1.07	[0.54; 2.12]	0.959
High	5/38 (13.2)	N.E. [N.E.; N.E.]	4/37 (10.8)	N.E. [5.7; N.E.]	0.83	[0.22; 3.13]	0.915
Sex							
(Interaction test: p = 0.711)							
Female	28/107 (26.2)	11.2 [2.7; N.E.]	28/126 (22.2)	11.8 [5.7; N.E.]	1.22	[0.72; 2.08]	0.549
Male	36/177 (20.3)	22.1 [11.1; N.E.]	31/158 (19.6)	22.1 [22.1; N.E.]	1.06	[0.65; 1.75]	0.666
Race							
(Interaction test: p = 0.868)							
Asian	12/40 (30.0)	N.E. [5.7; N.E.]	15/46 (32.6)	11.1 [5.6; N.E.]	0.89	[0.41; 1.93]	0.809
White	50/227	22.1 [11.1; N.E.]	42/217	22.1 [11.8; N.E.]	1.16	[0.76; 1.76]	0.442

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(22.0)		(19.4)				
Other	2/17	N.E. [1.8; N.E.]	2/21	N.E. [2.8; N.E.]	0.60	[0.07; 4.88]	0.692
	(11.8)		(9.5)				
Age groups							
(Interaction test: p = 0.157)							
18 - < 65 years	59/237	22.1 [11.0; N.E.]	52/247	22.3 [11.1; N.E.]	1.19	[0.82; 1.74]	0.264
	(24.9)		(21.1)				
65 - < 75 years	3/38	N.E. [N.E.; N.E.]	5/24	N.E. [0.9; N.E.]	0.30	[0.07; 1.34]	0.056
	(7.9)		(20.8)				
>= 75 years	2/9	N.E. [1.0; N.E.]	2/13	22.1 [1.9; N.E.]	14.16	[0.12; 1696.0]	0.541
	(22.2)		(15.4)				
Geographic region							
(Interaction test: p = 0.230)							
Europe excluding Germany	32/138	22.5 [11.1; N.E.]	31/141	22.1 [11.1; N.E.]	1.08	[0.65; 1.79]	0.689
	(23.2)		(22.0)				
Germany	11/72	22.1 [1.9; N.E.]	9/53	2.7 [0.9; N.E.]	0.36	[0.12; 1.02]	0.222
	(15.3)		(17.0)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Others	21/74 (28.4)	N.E. [5.7; N.E.]	19/90 (21.1)	22.3 [11.1; N.E.]	1.30	[0.69; 2.45]	0.406
Emotional functioning (MID=10)							
Stratification factor: ELTS based on randomization data from IRT (Interaction test: p = 0.520)							
Low	26/171 (15.2)	N.E. [11.2; N.E.]	39/172 (22.7)	11.8 [5.6; N.E.]	0.58	[0.35; 0.95]	0.088
Intermediate	17/75 (22.7)	11.1 [11.1; N.E.]	14/75 (18.7)	22.0 [11.0; N.E.]	0.99	[0.48; 2.03]	0.777
High	4/38 (10.5)	N.E. [11.1; N.E.]	6/37 (16.2)	N.E. [11.0; N.E.]	0.42	[0.11; 1.55]	0.223
Sex (Interaction test: p = 0.749)							
Female	20/107 (18.7)	N.E. [11.1; N.E.]	26/126 (20.6)	11.8 [5.6; N.E.]	0.71	[0.39; 1.28]	0.356
Male	27/177	N.E. [11.1; N.E.]	33/158	22.0 [11.1; N.E.]	0.61	[0.36; 1.02]	0.211

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(15.3)		(20.9)				
Race							
(Interaction test: p = 0.328)							
Asian	8/40	N.E. [N.E.; N.E.]	15/46	N.E. [2.8; N.E.]	0.43	[0.18; 1.03]	0.089
	(20.0)		(32.6)				
White	35/227	N.E. [11.2; N.E.]	43/217	22.0 [11.1; N.E.]	0.70	[0.45; 1.10]	0.205
	(15.4)		(19.8)				
Other	4/17	11.2 [0.9; N.E.]	1/21	N.E. [5.6; N.E.]	3.79	[0.09; 152.79]	0.212
	(23.5)		(4.8)				
Age groups							
(Interaction test: p = 0.696)							
18 - < 65 years	40/237	N.E. [11.2; N.E.]	54/247	N.E. [11.1; N.E.]	0.64	[0.42; 0.97]	0.142
	(16.9)		(21.9)				
65 - < 75 years	5/38	N.E. [11.1; N.E.]	4/24	22.0 [2.8; N.E.]	1.06	[0.22; 5.08]	0.851
	(13.2)		(16.7)				
>= 75 years	2/9	N.E. [1.0; N.E.]	1/13	N.E. [1.0; N.E.]	13.27	[0.09; 1969.7]	0.739
	(22.2)		(7.7)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = 0.985)							
Europe excluding Germany	26/138 (18.8)	N.E. [11.1; N.E.]	31/141 (22.0)	N.E. [10.7; N.E.]	0.72	[0.43; 1.23]	0.431
Germany	4/72 (5.6)	N.E. [11.1; N.E.]	4/53 (7.5)	N.E. [2.7; N.E.]	0.73	[0.17; 3.19]	0.662
Others	17/74 (23.0)	11.2 [11.2; N.E.]	24/90 (26.7)	N.E. [11.0; N.E.]	0.67	[0.35; 1.26]	0.334
Cognitive functioning (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.760)							
Low	42/171 (24.6)	11.1 [11.0; N.E.]	49/172 (28.5)	11.1 [2.9; N.E.]	0.84	[0.56; 1.28]	0.436
Intermediate	23/75 (30.7)	10.8 [4.2; N.E.]	20/75 (26.7)	11.1 [2.8; N.E.]	1.06	[0.58; 1.94]	0.822
High	10/38	N.E. [2.8; N.E.]	8/37	N.E. [2.8; N.E.]	1.01	[0.40; 2.58]	0.993

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(26.3)		(21.6)				
Sex							
(Interaction test: p = 0.043)							
Female	38/107	5.6 [2.0; 11.1]	33/126	11.1 [2.9; 11.8]	1.38	[0.85; 2.22]	0.165
	(35.5)		(26.2)				
Male	37/177	22.1 [11.1; N.E.]	44/158	11.1 [2.8; N.E.]	0.69	[0.45; 1.07]	0.112
	(20.9)		(27.8)				
Race							
(Interaction test: p = 0.698)							
Asian	16/40	11.1 [2.8; N.E.]	17/46	11.1 [2.8; N.E.]	0.94	[0.47; 1.89]	0.846
	(40.0)		(37.0)				
White	56/227	11.1 [5.6; 22.1]	55/217	11.1 [5.6; N.E.]	0.93	[0.64; 1.35]	0.708
	(24.7)		(25.3)				
Other	3/17	N.E. [0.9; N.E.]	5/21	5.6 [1.0; N.E.]	1.08	[0.15; 7.87]	0.409
	(17.6)		(23.8)				
Age groups							
(Interaction test: p = 0.346)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
18 - < 65 years	64/237 (27.0)	11.1 [11.0; 22.1]	71/247 (28.7)	11.1 [5.6; 11.8]	0.88	[0.63; 1.24]	0.519
65 - < 75 years	7/38 (18.4)	N.E. [2.8; N.E.]	5/24 (20.8)	N.E. [2.8; N.E.]	0.81	[0.25; 2.65]	0.723
>= 75 years	4/9 (44.4)	2.8 [1.6; N.E.]	1/13 (7.7)	N.E. [2.8; N.E.]	4.98	[0.14; 177.70]	0.105
Geographic region (Interaction test: p = 0.934)							
Europe excluding Germany	34/138 (24.6)	11.2 [11.1; N.E.]	39/141 (27.7)	11.1 [5.6; N.E.]	0.88	[0.55; 1.40]	0.603
Germany	14/72 (19.4)	8.3 [1.8; 22.1]	9/53 (17.0)	2.8 [0.9; N.E.]	0.70	[0.27; 1.81]	0.845
Others	27/74 (36.5)	11.1 [2.8; N.E.]	29/90 (32.2)	11.1 [2.8; N.E.]	0.98	[0.57; 1.68]	0.910
Social functioning (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.948)							
Low	35/171 (20.5)	22.1 [11.2; N.E.]	41/172 (23.8)	N.E. [5.6; N.E.]	0.74	[0.47; 1.17]	0.265
Intermediate	16/75 (21.3)	N.E. [2.8; N.E.]	17/75 (22.7)	N.E. [2.8; N.E.]	0.82	[0.41; 1.62]	0.581
High	7/38 (18.4)	N.E. [8.9; N.E.]	6/37 (16.2)	N.E. [2.7; N.E.]	0.84	[0.28; 2.51]	0.747
Sex							
(Interaction test: p = 0.695)							
Female	23/107 (21.5)	N.E. [11.2; N.E.]	27/126 (21.4)	N.E. [2.8; N.E.]	0.84	[0.48; 1.47]	0.440
Male	35/177 (19.8)	22.1 [11.1; N.E.]	37/158 (23.4)	N.E. [11.0; N.E.]	0.76	[0.47; 1.21]	0.343
Race							
(Interaction test: p = 0.509)							
Asian	15/40 (37.5)	N.E. [2.8; N.E.]	15/46 (32.6)	N.E. [2.8; N.E.]	0.88	[0.43; 1.82]	0.736

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
White	41/227 (18.1)	22.1 [11.2; N.E.]	48/217 (22.1)	N.E. [5.6; N.E.]	0.70	[0.46; 1.07]	0.162
Other	2/17 (11.8)	N.E. [0.9; N.E.]	1/21 (4.8)	N.E. [2.8; N.E.]	2.68	[0.06; 128.64]	0.343
Age groups (Interaction test: p = 0.768)							
18 - < 65 years	52/237 (21.9)	22.1 [11.2; N.E.]	58/247 (23.5)	N.E. [6.0; N.E.]	0.79	[0.54; 1.16]	0.367
65 - < 75 years	5/38 (13.2)	N.E. [2.8; N.E.]	5/24 (20.8)	N.E. [1.2; N.E.]	0.43	[0.12; 1.59]	0.186
>= 75 years	1/9 (11.1)	N.E. [1.0; N.E.]	1/13 (7.7)	N.E. [1.0; N.E.]	1.55	[0.00; 874.00]	0.739
Geographic region (Interaction test: p = 0.068)							
Europe excluding Germany	30/138 (21.7)	22.5 [11.1; N.E.]	37/141 (26.2)	11.3 [3.0; N.E.]	0.73	[0.45; 1.20]	0.274
Germany	5/72	22.1 [N.E.; N.E.]	7/53	N.E. [1.0; N.E.]	0.21	[0.05; 0.82]	0.024

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(6.9)		(13.2)				
Others	23/74	N.E. [5.6; N.E.]	20/90	N.E. [11.1; N.E.]	1.18	[0.64; 2.18]	0.579
	(31.1)		(22.2)				
Fatigue (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.294)							
Low	30/171	N.E. [11.2; N.E.]	41/172	11.8 [5.6; N.E.]	0.68	[0.42; 1.09]	0.164
	(17.5)		(23.8)				
Intermediate	15/75	22.1 [11.1; N.E.]	10/75	N.E. [22.0; N.E.]	1.22	[0.54; 2.74]	0.520
	(20.0)		(13.3)				
High	5/38	N.E. [11.1; N.E.]	7/37	N.E. [2.7; N.E.]	0.48	[0.14; 1.68]	0.199
	(13.2)		(18.9)				
Sex							
(Interaction test: p = 0.376)							
Female	21/107	22.1 [11.2; N.E.]	24/126	N.E. [5.6; N.E.]	0.94	[0.52; 1.71]	0.695
	(19.6)		(19.0)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Male	29/177 (16.4)	N.E. [11.1; N.E.]	34/158 (21.5)	22.1 [22.0; N.E.]	0.63	[0.38; 1.05]	0.224
Race							
(Interaction test: p = 0.884)							
Asian	9/40 (22.5)	N.E. [N.E.; N.E.]	15/46 (32.6)	N.E. [2.7; N.E.]	0.48	[0.21; 1.13]	0.111
White	37/227 (16.3)	N.E. [11.2; N.E.]	43/217 (19.8)	22.0 [11.8; N.E.]	0.73	[0.47; 1.14]	0.211
Other	4/17 (23.5)	8.3 [0.9; N.E.]	0/21	N.E. [N.E.; N.E.]	6.75	[0.15; 300.69]	0.074
Age groups							
(Interaction test: p = 0.826)							
18 - < 65 years	42/237 (17.7)	N.E. [11.2; N.E.]	52/247 (21.1)	22.1 [11.8; N.E.]	0.73	[0.49; 1.11]	0.218
65 - < 75 years	6/38 (15.8)	N.E. [2.8; N.E.]	6/24 (25.0)	22.0 [1.9; N.E.]	0.48	[0.12; 1.89]	0.495
>= 75 years	2/9	22.1 [1.6; N.E.]	0/13	N.E. [N.E.; N.E.]	10.18	[0.12; 884.59]	0.199

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(22.2)						
Geographic region							
(Interaction test: p = 0.635)							
Europe excluding Germany	25/138	22.1 [11.2; N.E.]	33/141	22.1 [5.6; N.E.]	0.68	[0.40; 1.15]	0.149
	(18.1)		(23.4)				
Germany	7/72	N.E. [5.6; N.E.]	6/53	22.0 [1.9; N.E.]	0.41	[0.11; 1.50]	0.491
	(9.7)		(11.3)				
Others	18/74	N.E. [11.0; N.E.]	19/90	N.E. [11.1; N.E.]	0.87	[0.45; 1.70]	0.810
	(24.3)		(21.1)				
Nausea and vomiting (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.639)							
Low	23/171	N.E. [N.E.; N.E.]	28/172	22.2 [22.0; N.E.]	0.83	[0.48; 1.45]	0.509
	(13.5)		(16.3)				
Intermediate	8/75	22.1 [22.1; N.E.]	13/75	N.E. [11.1; N.E.]	0.55	[0.23; 1.34]	0.114
	(10.7)		(17.3)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
High	8/38 (21.1)	22.1 [11.1; N.E.]	6/37 (16.2)	N.E. [11.0; N.E.]	0.84	[0.28; 2.48]	0.886
Sex							
(Interaction test: p = 0.998)							
Female	20/107 (18.7)	22.1 [22.1; N.E.]	24/126 (19.0)	22.0 [11.1; N.E.]	0.78	[0.43; 1.44]	0.433
Male	19/177 (10.7)	N.E. [N.E.; N.E.]	23/158 (14.6)	N.E. [N.E.; N.E.]	0.69	[0.38; 1.28]	0.219
Race							
(Interaction test: p = 0.641)							
Asian	13/40 (32.5)	N.E. [5.6; N.E.]	15/46 (32.6)	N.E. [5.5; N.E.]	0.91	[0.42; 1.96]	0.841
White	25/227 (11.0)	22.1 [22.1; N.E.]	32/217 (14.7)	22.2 [22.0; N.E.]	0.68	[0.40; 1.16]	0.127
Other	1/17 (5.9)	N.E. [2.8; N.E.]	0/21	N.E. [N.E.; N.E.]	1.40	[0.01; 222.25]	0.527
Age groups							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.484)							
18 - < 65 years	34/237 (14.3)	N.E. [N.E.; N.E.]	44/247 (17.8)	N.E. [22.0; N.E.]	0.70	[0.44; 1.10]	0.107
65 - < 75 years	3/38 (7.9)	22.1 [11.1; N.E.]	2/24 (8.3)	22.2 [22.2; N.E.]	1.26	[0.11; 14.42]	0.850
>= 75 years	2/9 (22.2)	22.1 [1.0; N.E.]	1/13 (7.7)	N.E. [1.0; N.E.]	0.71	[0.04; 11.79]	0.695
Geographic region							
(Interaction test: p = 0.237)							
Europe excluding Germany	18/138 (13.0)	22.1 [22.1; N.E.]	24/141 (17.0)	22.2 [22.0; N.E.]	0.68	[0.36; 1.28]	0.210
Germany	3/72 (4.2)	N.E. [11.1; N.E.]	5/53 (9.4)	N.E. [2.8; N.E.]	0.20	[0.04; 1.08]	0.029
Others	18/74 (24.3)	N.E. [11.1; N.E.]	18/90 (20.0)	N.E. [N.E.; N.E.]	1.09	[0.56; 2.13]	0.815
Pain (MID=10)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.224)							
Low	42/171 (24.6)	11.2 [5.6; N.E.]	52/172 (30.2)	5.6 [2.8; N.E.]	0.72	[0.48; 1.08]	0.141
Intermediate	22/75 (29.3)	11.1 [1.0; N.E.]	17/75 (22.7)	16.4 [2.8; N.E.]	1.38	[0.73; 2.60]	0.475
High	12/38 (31.6)	N.E. [1.0; N.E.]	10/37 (27.0)	5.7 [2.0; N.E.]	1.24	[0.53; 2.88]	0.921
Sex							
(Interaction test: p = 0.115)							
Female	37/107 (34.6)	2.9 [1.8; N.E.]	35/126 (27.8)	5.6 [2.8; N.E.]	1.22	[0.76; 1.96]	0.560
Male	39/177 (22.0)	N.E. [11.1; N.E.]	44/158 (27.8)	11.1 [2.8; N.E.]	0.74	[0.48; 1.14]	0.156
Race							
(Interaction test: p = 0.720)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Asian	19/40 (47.5)	11.0 [1.8; N.E.]	20/46 (43.5)	5.6 [1.9; N.E.]	0.88	[0.47; 1.65]	0.639
White	54/227 (23.8)	11.2 [5.6; N.E.]	57/217 (26.3)	11.1 [2.8; N.E.]	0.87	[0.60; 1.26]	0.398
Other	3/17 (17.6)	N.E. [0.9; N.E.]	2/21 (9.5)	N.E. [1.0; N.E.]	0.50	[0.03; 7.55]	0.937
Age groups (Interaction test: p = 0.521)							
18 - < 65 years	67/237 (28.3)	11.1 [5.6; N.E.]	71/247 (28.7)	11.1 [2.8; N.E.]	0.95	[0.68; 1.33]	0.661
65 - < 75 years	6/38 (15.8)	N.E. [5.6; N.E.]	7/24 (29.2)	5.7 [2.8; N.E.]	0.47	[0.13; 1.65]	0.199
>= 75 years	3/9 (33.3)	1.0 [1.0; N.E.]	1/13 (7.7)	N.E. [1.0; N.E.]	2.12	[0.19; 23.50]	0.485
Geographic region (Interaction test: p = 0.221)							
Europe excluding Germany	31/138	N.E. [11.1; N.E.]	40/141	16.4 [2.8; N.E.]	0.69	[0.43; 1.10]	0.124

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(22.5)		(28.4)				
Germany	12/72	1.9 [1.0; N.E.]	8/53	2.8 [1.0; N.E.]	1.20	[0.45; 3.22]	0.568
	(16.7)		(15.1)				
Others	33/74	5.6 [1.9; N.E.]	31/90	11.1 [2.8; N.E.]	1.14	[0.69; 1.87]	0.681
	(44.6)		(34.4)				
Dyspnoea (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.302)							
Low	30/171	22.1 [22.1; N.E.]	36/172	N.E. [11.1; N.E.]	0.83	[0.51; 1.36]	0.559
	(17.5)		(20.9)				
Intermediate	10/75	N.E. [11.1; N.E.]	13/75	N.E. [11.0; N.E.]	0.66	[0.29; 1.51]	0.304
	(13.3)		(17.3)				
High	5/38	N.E. [11.1; N.E.]	1/37	N.E. [N.E.; N.E.]	4.23	[0.49; 36.35]	0.161
	(13.2)		(2.7)				
Sex							
(Interaction test: p = 0.566)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Female	23/107 (21.5)	22.1 [11.1; N.E.]	25/126 (19.8)	11.8 [11.1; N.E.]	1.04	[0.58; 1.83]	0.845
Male	22/177 (12.4)	22.1 [22.1; N.E.]	25/158 (15.8)	N.E. [N.E.; N.E.]	0.76	[0.43; 1.36]	0.409
Race							
(Interaction test: p = 0.899)							
Asian	10/40 (25.0)	N.E. [N.E.; N.E.]	11/46 (23.9)	N.E. [11.1; N.E.]	0.96	[0.40; 2.34]	0.961
White	33/227 (14.5)	22.1 [22.1; N.E.]	37/217 (17.1)	N.E. [11.8; N.E.]	0.80	[0.50; 1.29]	0.431
Other	2/17 (11.8)	N.E. [0.9; N.E.]	2/21 (9.5)	N.E. [1.0; N.E.]	0.23	[0.02; 3.03]	0.567
Age groups							
(Interaction test: p = 0.801)							
18 - < 65 years	38/237 (16.0)	22.1 [22.1; N.E.]	48/247 (19.4)	N.E. [11.3; N.E.]	0.79	[0.52; 1.22]	0.331
65 - < 75 years	5/38	N.E. [5.6; N.E.]	2/24	N.E. [2.8; N.E.]	1.15	[0.21; 6.27]	0.940

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(13.2)		(8.3)				
>= 75 years	2/9 (22.2)	N.E. [1.9; N.E.]	0/13	N.E. [N.E.; N.E.]	1.83	[0.02; 199.10]	0.199
Geographic region							
(Interaction test: p = 0.615)							
Europe excluding Germany	24/138 (17.4)	N.E. [N.E.; N.E.]	31/141 (22.0)	N.E. [11.1; N.E.]	0.72	[0.42; 1.23]	0.283
Germany	5/72 (6.9)	22.1 [N.E.; N.E.]	4/53 (7.5)	N.E. [2.8; N.E.]	0.74	[0.15; 3.68]	0.738
Others	16/74 (21.6)	22.1 [N.E.; N.E.]	15/90 (16.7)	N.E. [N.E.; N.E.]	1.08	[0.53; 2.22]	0.775
Insomnia (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.597)							
Low	31/171 (18.1)	22.5 [11.2; N.E.]	39/172 (22.7)	22.0 [5.6; N.E.]	0.72	[0.44; 1.16]	0.267

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Intermediate	14/75 (18.7)	22.1 [11.1; N.E.]	19/75 (25.3)	11.2 [1.9; N.E.]	0.63	[0.31; 1.28]	0.088
High	10/38 (26.3)	11.1 [5.6; N.E.]	6/37 (16.2)	N.E. [5.6; N.E.]	1.16	[0.42; 3.24]	0.578
Sex							
(Interaction test: p = 0.126)							
Female	25/107 (23.4)	11.2 [5.6; N.E.]	25/126 (19.8)	22.2 [5.8; N.E.]	1.06	[0.60; 1.87]	0.907
Male	30/177 (16.9)	22.1 [11.1; N.E.]	39/158 (24.7)	22.0 [5.6; N.E.]	0.57	[0.35; 0.92]	0.033
Race							
(Interaction test: p = 0.591)							
Asian	11/40 (27.5)	N.E. [11.1; N.E.]	14/46 (30.4)	11.2 [2.0; N.E.]	0.78	[0.35; 1.75]	0.630
White	41/227 (18.1)	22.1 [11.1; N.E.]	48/217 (22.1)	22.0 [5.6; N.E.]	0.67	[0.44; 1.03]	0.090
Other	3/17	N.E. [1.0; N.E.]	2/21	N.E. [1.0; N.E.]	0.65	[0.10; 4.09]	0.729

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(17.6)		(9.5)				
Age groups							
(Interaction test: p = 0.475)							
18 - < 65 years	46/237	22.1 [11.1; N.E.]	57/247	22.0 [11.1; N.E.]	0.72	[0.48; 1.06]	0.097
	(19.4)		(23.1)				
65 - < 75 years	8/38	N.E. [2.8; N.E.]	5/24	22.2 [1.2; N.E.]	1.38	[0.39; 4.86]	0.531
	(21.1)		(20.8)				
>= 75 years	1/9	N.E. [1.9; N.E.]	2/13	1.9 [1.0; N.E.]	0.56	[0.00; 126.83]	0.116
	(11.1)		(15.4)				
Geographic region							
(Interaction test: p = 0.618)							
Europe excluding Germany	32/138	11.2 [11.1; N.E.]	38/141	22.0 [5.6; N.E.]	0.66	[0.41; 1.09]	0.075
	(23.2)		(27.0)				
Germany	4/72	N.E. [11.1; N.E.]	5/53	N.E. [1.9; N.E.]	0.34	[0.08; 1.41]	0.101
	(5.6)		(9.4)				
Others	19/74	N.E. [11.0; N.E.]	21/90	N.E. [11.2; N.E.]	0.97	[0.51; 1.84]	0.982
	(25.7)		(23.3)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Appetite loss (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.171)							
Low	22/171 (12.9)	22.1 [22.1; N.E.]	20/172 (11.6)	N.E. [22.2; N.E.]	1.14	[0.62; 2.10]	0.600
Intermediate	6/75 (8.0)	N.E. [N.E.; N.E.]	12/75 (16.0)	N.E. [11.1; N.E.]	0.43	[0.16; 1.16]	0.063
High	3/38 (7.9)	N.E. [N.E.; N.E.]	7/37 (18.9)	16.6 [5.6; N.E.]	0.40	[0.09; 1.73]	0.072
Sex							
(Interaction test: p = 0.777)							
Female	17/107 (15.9)	N.E. [11.2; N.E.]	22/126 (17.5)	22.2 [11.1; N.E.]	0.90	[0.47; 1.72]	0.492
Male	14/177 (7.9)	22.1 [22.1; N.E.]	17/158 (10.8)	N.E. [22.1; N.E.]	0.73	[0.36; 1.48]	0.366
Race							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.256)							
Asian	6/40 (15.0)	N.E. [N.E.; N.E.]	13/46 (28.3)	N.E. [2.8; N.E.]	0.39	[0.15; 1.04]	0.057
White	22/227 (9.7)	22.1 [22.1; N.E.]	24/217 (11.1)	22.2 [22.1; N.E.]	0.92	[0.52; 1.66]	0.633
Other	3/17 (17.6)	N.E. [2.0; N.E.]	2/21 (9.5)	11.1 [2.8; N.E.]	2.16	[0.18; 25.80]	0.588
Age groups							
(Interaction test: p = 0.157)							
18 - < 65 years	26/237 (11.0)	22.1 [22.1; N.E.]	32/247 (13.0)	N.E. [N.E.; N.E.]	0.82	[0.49; 1.38]	0.437
65 - < 75 years	2/38 (5.3)	N.E. [N.E.; N.E.]	5/24 (20.8)	22.2 [1.2; N.E.]	0.25	[0.04; 1.39]	0.088
>= 75 years	3/9 (33.3)	2.8 [1.0; N.E.]	2/13 (15.4)	12.5 [2.8; N.E.]	1.89	[0.18; 19.47]	0.629
Geographic region							
(Interaction test: p = 0.876)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Europe excluding Germany	13/138 (9.4)	N.E. [N.E.; N.E.]	17/141 (12.1)	22.2 [22.1; N.E.]	0.85	[0.41; 1.77]	0.506
Germany	3/72 (4.2)	22.1 [N.E.; N.E.]	4/53 (7.5)	N.E. [5.6; N.E.]	0.38	[0.07; 2.15]	0.209
Others	15/74 (20.3)	N.E. [N.E.; N.E.]	18/90 (20.0)	N.E. [N.E.; N.E.]	0.74	[0.37; 1.49]	0.580
Constipation (MID=10)							
Stratification factor: ELTS based on randomization data from IRT (Interaction test: p = 0.998)							
Low	27/171 (15.8)	N.E. [11.2; N.E.]	39/172 (22.7)	11.8 [11.0; N.E.]	0.62	[0.38; 1.02]	0.089
Intermediate	13/75 (17.3)	22.1 [11.1; N.E.]	16/75 (21.3)	N.E. [2.8; N.E.]	0.63	[0.30; 1.32]	0.204
High	4/38 (10.5)	N.E. [N.E.; N.E.]	5/37 (13.5)	N.E. [5.6; N.E.]	0.65	[0.17; 2.42]	0.495
Sex							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.844)							
Female	17/107 (15.9)	21.4 [11.2; N.E.]	27/126 (21.4)	11.8 [5.6; N.E.]	0.60	[0.33; 1.11]	0.102
Male	27/177 (15.3)	N.E. [11.3; N.E.]	33/158 (20.9)	N.E. [11.1; N.E.]	0.63	[0.38; 1.05]	0.126
Race							
(Interaction test: p = 0.198)							
Asian	7/40 (17.5)	N.E. [11.1; N.E.]	17/46 (37.0)	11.1 [2.0; N.E.]	0.34	[0.14; 0.83]	0.015
White	34/227 (15.0)	22.1 [11.3; N.E.]	42/217 (19.4)	N.E. [11.1; N.E.]	0.71	[0.45; 1.12]	0.136
Other	3/17 (17.6)	N.E. [5.6; N.E.]	1/21 (4.8)	N.E. [5.6; N.E.]	5.07	[0.10; 245.53]	0.110
Age groups							
(Interaction test: p = 0.668)							
18 - < 65 years	37/237 (15.6)	N.E. [11.3; N.E.]	56/247 (22.7)	N.E. [11.1; N.E.]	0.60	[0.39; 0.91]	0.020

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
65 - < 75 years	6/38 (15.8)	N.E. [1.9; N.E.]	3/24 (12.5)	N.E. [1.0; N.E.]	1.00	[0.24; 4.14]	0.939
>= 75 years	1/9 (11.1)	N.E. [1.0; N.E.]	1/13 (7.7)	N.E. [1.0; N.E.]	0.34	[0.00; 23.19]	0.739
Geographic region (Interaction test: p = 0.072)							
Europe excluding Germany	25/138 (18.1)	21.4 [11.2; N.E.]	27/141 (19.1)	N.E. [11.8; N.E.]	0.84	[0.48; 1.46]	0.589
Germany	2/72 (2.8)	N.E. [N.E.; N.E.]	7/53 (13.2)	2.8 [0.9; N.E.]	0.15	[0.03; 0.77]	0.005
Others	17/74 (23.0)	N.E. [11.1; N.E.]	26/90 (28.9)	N.E. [5.6; N.E.]	0.63	[0.34; 1.18]	0.216
Diarrhoea (MID=10)							
Stratification factor: ELTS based on randomization data from IRT (Interaction test: p = 0.626)							
Low	22/171	N.E. [N.E.; N.E.]	37/172	22.2 [10.8; N.E.]	0.65	[0.38; 1.10]	0.033

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(12.9)		(21.5)				
Intermediate	11/75	N.E. [N.E.; N.E.]	12/75	N.E. [11.1; N.E.]	0.84	[0.37; 1.90]	0.588
	(14.7)		(16.0)				
High	6/38	22.0 [11.1; N.E.]	4/37	N.E. [N.E.; N.E.]	1.10	[0.31; 3.92]	0.867
	(15.8)		(10.8)				
Sex							
(Interaction test: p = 0.332)							
Female	16/107	N.E. [11.2; N.E.]	19/126	22.2 [22.2; N.E.]	0.90	[0.45; 1.77]	0.583
	(15.0)		(15.1)				
Male	23/177	N.E. [22.0; N.E.]	34/158	N.E. [11.1; N.E.]	0.61	[0.36; 1.04]	0.039
	(13.0)		(21.5)				
Race							
(Interaction test: p = 0.975)							
Asian	7/40	N.E. [11.1; N.E.]	11/46	N.E. [5.6; N.E.]	0.70	[0.27; 1.82]	0.276
	(17.5)		(23.9)				
White	30/227	N.E. [22.0; N.E.]	40/217	22.2 [11.1; N.E.]	0.73	[0.46; 1.19]	0.138
	(13.2)		(18.4)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Other	2/17 (11.8)	N.E. [2.8; N.E.]	2/21 (9.5)	N.E. [1.6; N.E.]	0.38	[0.05; 2.76]	0.149
Age groups (Interaction test: p = 0.613)							
18 - < 65 years	34/237 (14.3)	N.E. [22.0; N.E.]	50/247 (20.2)	N.E. [N.E.; N.E.]	0.70	[0.45; 1.09]	0.044
65 - < 75 years	5/38 (13.2)	N.E. [1.9; N.E.]	2/24 (8.3)	22.2 [22.2; N.E.]	3.24	[0.34; 30.58]	0.322
>= 75 years	0/9	N.E. [N.E.; N.E.]	1/13 (7.7)	N.E. [1.0; N.E.]	0.17	[0.00; 18.51]	0.221
Geographic region (Interaction test: p = 0.314)							
Europe excluding Germany	22/138 (15.9)	N.E. [11.2; N.E.]	31/141 (22.0)	22.2 [11.1; N.E.]	0.75	[0.43; 1.31]	0.221
Germany	3/72 (4.2)	22.0 [22.0; N.E.]	6/53 (11.3)	N.E. [1.9; N.E.]	0.16	[0.03; 0.91]	0.010

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Others	14/74 (18.9)	N.E. [11.1; N.E.]	16/90 (17.8)	N.E. [N.E.; N.E.]	0.95	[0.45; 1.97]	0.641
Financial difficulties (MID=10)							
Stratification factor: ELTS based on randomization data from IRT (Interaction test: p = 0.141)							
Low	24/171 (14.0)	N.E. [11.2; N.E.]	25/172 (14.5)	22.2 [22.2; N.E.]	1.05	[0.60; 1.83]	0.865
Intermediate	14/75 (18.7)	N.E. [11.1; N.E.]	8/75 (10.7)	26.4 [22.3; N.E.]	2.42	[0.92; 6.35]	0.072
High	2/38 (5.3)	N.E. [N.E.; N.E.]	4/37 (10.8)	N.E. [N.E.; N.E.]	0.31	[0.06; 1.71]	0.192
Sex (Interaction test: p = 0.441)							
Female	16/107 (15.0)	N.E. [11.2; N.E.]	13/126 (10.3)	N.E. [22.2; N.E.]	1.47	[0.69; 3.14]	0.357
Male	24/177	N.E. [N.E.; N.E.]	24/158	22.3 [22.3; N.E.]	1.04	[0.58; 1.86]	0.875

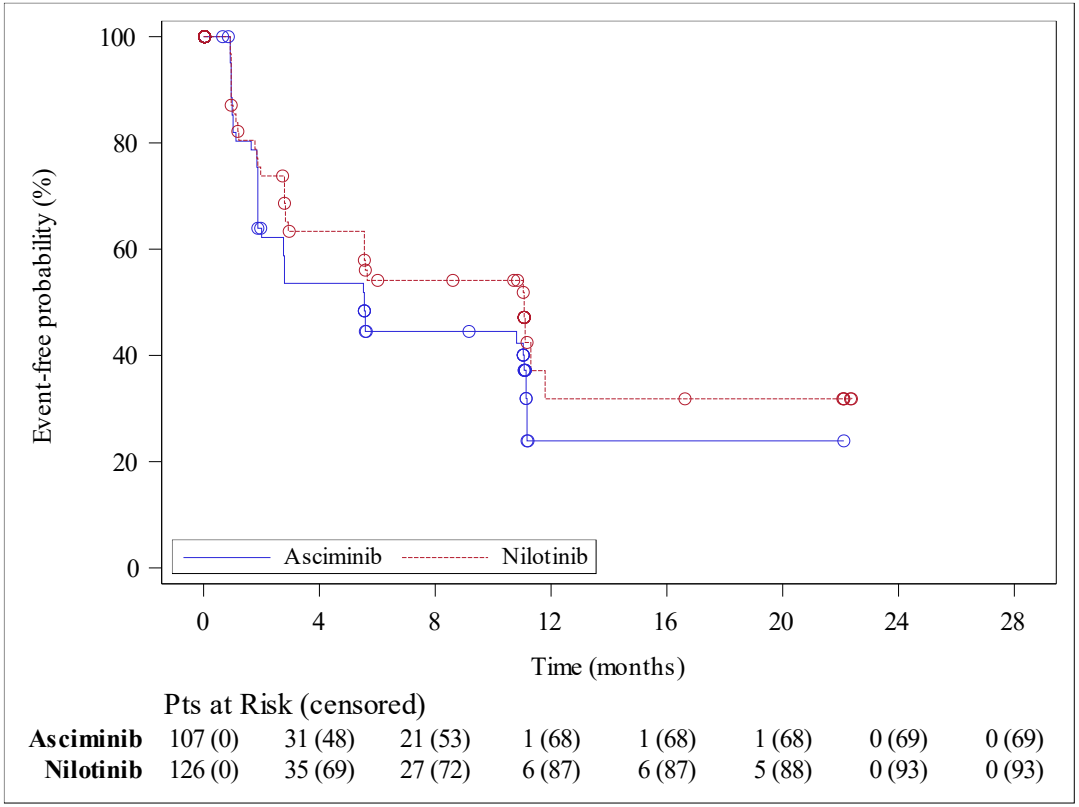
	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(13.6)		(15.2)				
Race							
(Interaction test: p = 0.502)							
Asian	12/40	N.E. [5.6; N.E.]	10/46	22.3 [22.3; N.E.]	1.27	[0.53; 3.06]	0.413
	(30.0)		(21.7)				
White	25/227	N.E. [N.E.; N.E.]	26/217	26.4 [22.2; N.E.]	0.98	[0.56; 1.73]	0.968
	(11.0)		(12.0)				
Other	3/17	N.E. [1.0; N.E.]	1/21	N.E. [2.8; N.E.]	3.38	[0.12; 98.70]	0.212
	(17.6)		(4.8)				
Age groups							
(Interaction test: p = 0.693)							
18 - < 65 years	35/237	N.E. [N.E.; N.E.]	33/247	22.3 [22.2; N.E.]	1.23	[0.76; 2.00]	0.388
	(14.8)		(13.4)				
65 - < 75 years	3/38	N.E. [N.E.; N.E.]	4/24	26.4 [1.8; N.E.]	1.13	[0.12; 11.05]	0.397
	(7.9)		(16.7)				
>= 75 years	2/9	N.E. [1.0; N.E.]	0/13	N.E. [N.E.; N.E.]	3.00	[0.04; 207.39]	0.182
	(22.2)						

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = 0.667)							
Europe excluding Germany	18/138 (13.0)	N.E. [N.E.; N.E.]	18/141 (12.8)	N.E. [22.2; N.E.]	1.05	[0.54; 2.04]	0.838
Germany	4/72 (5.6)	N.E. [N.E.; N.E.]	5/53 (9.4)	26.4 [1.0; N.E.]	0.70	[0.17; 2.93]	0.572
Others	18/74 (24.3)	N.E. [N.E.; N.E.]	14/90 (15.6)	22.3 [N.E.; N.E.]	1.45	[0.71; 2.98]	0.252

MID: Minimally important difference
N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
If there are not at least 10 patients in every subgroup or not more than 10 events per subgroup per treatment arm, no subgroup analyses were performed for the corresponding attribute.
If there are not more than 10 events per subgroup per treatment arm, no Cox PH hazard analysis is carried out.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variables ELTS Score (IRT) and covariates treatment arm and baseline PRO score.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variables ELTS Score (IRT).
For the subgroup of Stratification factor: ELTS based on IRT randomisation data not stratification factor was included in the Cox PH model and an unstratitfied log-rank test was applied
The reference group in the (stratified) Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/2025-05-15

Figure 3-2.1 EORTC QLQ-C30: Time to first deterioration analysis by subgroups: Kaplan-Meier plot by subgroups (Full Analysis Set)

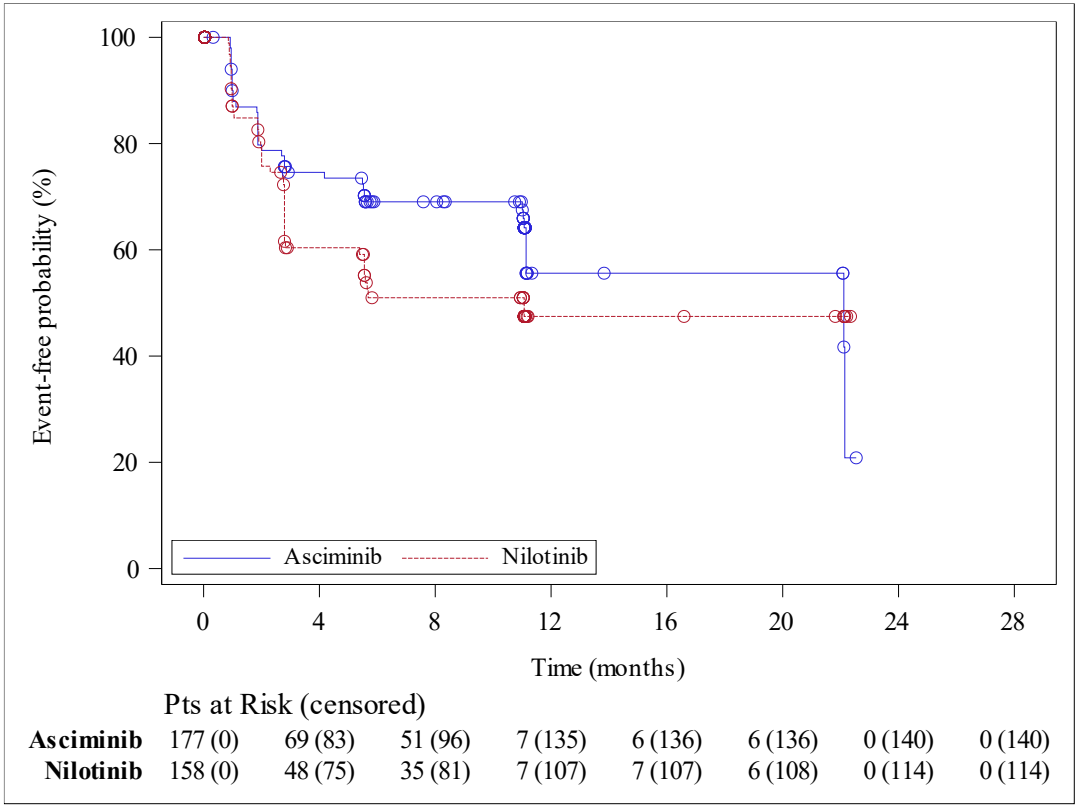
Cognitive functioning (MID=10): Sex: Female



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Figure 3-2.1 EORTC QLQ-C30: Time to first deterioration analysis by subgroups: Kaplan-Meier plot by subgroups (Full Analysis Set)

Cognitive functioning (MID=10): Sex: Male



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Table 3-2.2 EORTC QLQ-CML24: Time to first deterioration analysis by subgroups (Full Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Body Image Problems (MID=15)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.653)							
Low	35/171 (20.5)	N.E. [11.0; N.E.]	30/172 (17.4)	N.E. [22.1; N.E.]	1.22	[0.75; 1.99]	0.347
Intermediate	18/75 (24.0)	11.1 [5.6; N.E.]	21/75 (28.0)	10.9 [2.8; N.E.]	0.85	[0.45; 1.60]	0.391
High	9/38 (23.7)	N.E. [5.6; N.E.]	6/37 (16.2)	N.E. [5.6; N.E.]	0.82	[0.29; 2.36]	0.890
Sex							
(Interaction test: p = 0.786)							
Female	30/107 (28.0)	11.0 [2.8; N.E.]	29/126 (23.0)	11.1 [3.0; N.E.]	1.09	[0.64; 1.84]	0.785
Male	32/177 (18.1)	N.E. [11.1; N.E.]	28/158 (17.7)	N.E. [22.1; N.E.]	1.01	[0.60; 1.68]	0.977

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Race							
(Interaction test: p = 0.857)							
Asian	15/40 (37.5)	11.1 [2.8; N.E.]	13/46 (28.3)	N.E. [2.8; N.E.]	1.13	[0.54; 2.40]	0.724
White	45/227 (19.8)	N.E. [11.1; N.E.]	41/217 (18.9)	22.1 [11.1; N.E.]	1.02	[0.66; 1.56]	0.978
Other	2/17 (11.8)	N.E. [1.8; N.E.]	3/21 (14.3)	11.1 [2.8; N.E.]	2.11	[0.05; 82.83]	0.343
Age groups							
(Interaction test: p = 0.698)							
18 - < 65 years	54/237 (22.8)	N.E. [11.1; N.E.]	54/247 (21.9)	22.1 [11.1; N.E.]	1.00	[0.68; 1.47]	0.866
65 - < 75 years	5/38 (13.2)	N.E. [5.6; N.E.]	2/24 (8.3)	N.E. [0.9; N.E.]	4.74	[0.54; 41.95]	0.532
>= 75 years	3/9 (33.3)	2.8 [1.0; N.E.]	1/13 (7.7)	N.E. [1.9; N.E.]	1.45	[0.12; 17.57]	0.455
Geographic region							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.692)							
Europe excluding Germany	29/138 (21.0)	N.E. [11.1; N.E.]	32/141 (22.7)	16.6 [6.0; N.E.]	0.95	[0.57; 1.59]	0.588
Germany	11/72 (15.3)	11.1 [2.8; N.E.]	6/53 (11.3)	N.E. [1.0; N.E.]	0.79	[0.27; 2.32]	0.984
Others	22/74 (29.7)	N.E. [5.5; N.E.]	19/90 (21.1)	N.E. [11.1; N.E.]	1.23	[0.66; 2.29]	0.440
Impact on Daily Life (MID=15)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.356)							
Low	30/171 (17.5)	N.E. [11.2; N.E.]	34/172 (19.8)	N.E. [11.3; N.E.]	0.82	[0.50; 1.35]	0.667
Intermediate	7/75 (9.3)	N.E. [N.E.; N.E.]	16/75 (21.3)	16.6 [5.8; N.E.]	0.38	[0.15; 0.92]	0.022
High	5/38 (13.2)	N.E. [11.1; N.E.]	4/37 (10.8)	N.E. [2.8; N.E.]	0.56	[0.14; 2.18]	0.651

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Sex							
(Interaction test: p = 0.597)							
Female	19/107 (17.8)	N.E. [11.2; N.E.]	31/126 (24.6)	11.1 [2.8; N.E.]	0.63	[0.36; 1.13]	0.094
Male	23/177 (13.0)	N.E. [N.E.; N.E.]	23/158 (14.6)	N.E. [N.E.; N.E.]	0.75	[0.42; 1.36]	0.661
Race							
(Interaction test: p = 0.129)							
Asian	12/40 (30.0)	N.E. [2.8; N.E.]	10/46 (21.7)	N.E. [11.1; N.E.]	1.31	[0.56; 3.07]	0.447
White	28/227 (12.3)	N.E. [N.E.; N.E.]	41/217 (18.9)	N.E. [11.3; N.E.]	0.56	[0.35; 0.92]	0.036
Other	2/17 (11.8)	N.E. [1.8; N.E.]	3/21 (14.3)	11.1 [1.0; N.E.]	0.32	[0.02; 5.17]	0.624
Age groups							
(Interaction test: p = 0.743)							
18 - < 65 years	38/237	N.E. [11.2; N.E.]	50/247	N.E. [11.3; N.E.]	0.67	[0.44; 1.04]	0.162

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(16.0)		(20.2)				
65 - < 75 years	3/38	N.E. [N.E.; N.E.]	4/24	N.E. [0.9; N.E.]	0.08	[0.00; 1.44]	0.175
	(7.9)		(16.7)				
>= 75 years	1/9	N.E. [1.0; N.E.]	0/13	N.E. [N.E.; N.E.]	27.00	[0.00; 6.53E6]	0.480
	(11.1)						
Geographic region							
(Interaction test: p = 0.118)							
Europe excluding Germany	20/138	N.E. [11.2; N.E.]	34/141	11.8 [5.8; N.E.]	0.54	[0.31; 0.95]	0.035
	(14.5)		(24.1)				
Germany	3/72	N.E. [N.E.; N.E.]	3/53	N.E. [11.0; N.E.]	0.49	[0.08; 2.87]	0.600
	(4.2)		(5.7)				
Others	19/74	N.E. [11.0; N.E.]	17/90	N.E. [N.E.; N.E.]	1.18	[0.61; 2.30]	0.511
	(25.7)		(18.9)				
Impact on Worry/Mood (MID=15)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.891)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Low	18/171 (10.5)	N.E. [N.E.; N.E.]	15/172 (8.7)	N.E. [N.E.; N.E.]	1.17	[0.59; 2.34]	0.561
Intermediate	10/75 (13.3)	N.E. [11.1; N.E.]	7/75 (9.3)	N.E. [N.E.; N.E.]	1.29	[0.49; 3.41]	0.500
High	3/38 (7.9)	N.E. [N.E.; N.E.]	2/37 (5.4)	N.E. [N.E.; N.E.]	0.79	[0.13; 4.86]	0.956
Sex							
(Interaction test: p = 0.056)							
Female	16/107 (15.0)	N.E. [11.2; N.E.]	8/126 (6.3)	N.E. [N.E.; N.E.]	2.15	[0.91; 5.06]	0.067
Male	15/177 (8.5)	N.E. [N.E.; N.E.]	16/158 (10.1)	N.E. [N.E.; N.E.]	0.76	[0.37; 1.55]	0.606
Race							
(Interaction test: p = 0.306)							
Asian	10/40 (25.0)	N.E. [11.0; N.E.]	5/46 (10.9)	N.E. [N.E.; N.E.]	1.91	[0.63; 5.72]	0.140
White	18/227	N.E. [N.E.; N.E.]	18/217	N.E. [N.E.; N.E.]	0.91	[0.47; 1.75]	0.892

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(7.9)		(8.3)				
Other	3/17	11.0 [2.8; N.E.]	1/21	N.E. [5.6; N.E.]	2.99	[0.09; 95.46]	0.267
	(17.6)		(4.8)				
Age groups							
(Interaction test: p = 0.875)							
18 - < 65 years	30/237	N.E. [N.E.; N.E.]	23/247	N.E. [N.E.; N.E.]	1.23	[0.71; 2.14]	0.264
	(12.7)		(9.3)				
65 - < 75 years	1/38	N.E. [N.E.; N.E.]	1/24	N.E. [0.9; N.E.]	0.58	[0.03; 10.86]	0.485
	(2.6)		(4.2)				
>= 75 years	0/9	N.E. [N.E.; N.E.]	0/13	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.
Geographic region							
(Interaction test: p = 0.106)							
Europe excluding Germany	14/138	N.E. [N.E.; N.E.]	12/141	N.E. [N.E.; N.E.]	1.17	[0.54; 2.54]	0.568
	(10.1)		(8.5)				
Germany	2/72	N.E. [N.E.; N.E.]	4/53	N.E. [1.9; N.E.]	0.08	[0.01; 0.77]	0.028
	(2.8)		(7.5)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Others	15/74 (20.3)	N.E. [N.E.; N.E.]	8/90 (8.9)	N.E. [N.E.; N.E.]	1.92	[0.80; 4.60]	0.090
Symptom Burden (MID=15)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.599)							
Low	7/171 (4.1)	N.E. [N.E.; N.E.]	18/172 (10.5)	N.E. [N.E.; N.E.]	0.40	[0.16; 0.96]	0.035
Intermediate	4/75 (5.3)	N.E. [22.1; N.E.]	7/75 (9.3)	N.E. [N.E.; N.E.]	0.50	[0.15; 1.71]	0.250
High	2/38 (5.3)	N.E. [N.E.; N.E.]	1/37 (2.7)	N.E. [11.2; N.E.]	1.22	[0.11; 13.97]	0.768
Sex							
(Interaction test: p = 0.720)							
Female	7/107 (6.5)	N.E. [N.E.; N.E.]	17/126 (13.5)	N.E. [11.3; N.E.]	0.42	[0.17; 1.02]	0.046
Male	6/177	N.E. [22.1; N.E.]	9/158	N.E. [N.E.; N.E.]	0.53	[0.18; 1.51]	0.276

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(3.4)		(5.7)				
Race							
(Interaction test: p = 0.900)							
Asian	4/40	N.E. [N.E.; N.E.]	9/46	N.E. [11.2; N.E.]	0.52	[0.16; 1.72]	0.285
	(10.0)		(19.6)				
White	7/227	N.E. [N.E.; N.E.]	17/217	N.E. [N.E.; N.E.]	0.36	[0.15; 0.89]	0.023
	(3.1)		(7.8)				
Other	2/17	N.E. [0.9; N.E.]	0/21	N.E. [N.E.; N.E.]	1.78	[0.01; 242.14]	0.343
	(11.8)						
Age groups							
(Interaction test: p = 1.000)							
18 - < 65 years	13/237	N.E. [22.1; N.E.]	23/247	N.E. [N.E.; N.E.]	0.55	[0.28; 1.10]	0.110
	(5.5)		(9.3)				
65 - < 75 years	0/38	N.E. [N.E.; N.E.]	3/24	N.E. [0.9; N.E.]	0.01	[0.00; 6.84]	0.015
			(12.5)				
>= 75 years	0/9	N.E. [N.E.; N.E.]	0/13	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = 0.800)							
Europe excluding Germany	6/138 (4.3)	N.E. [N.E.; N.E.]	14/141 (9.9)	N.E. [N.E.; N.E.]	0.42	[0.16; 1.10]	0.071
Germany	1/72 (1.4)	N.E. [N.E.; N.E.]	2/53 (3.8)	N.E. [5.4; N.E.]	0.05	[0.00; 4.29]	0.212
Others	6/74 (8.1)	N.E. [N.E.; N.E.]	10/90 (11.1)	N.E. [11.2; N.E.]	0.62	[0.22; 1.78]	0.408
Satisfaction with Care and Information (MID=15)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.786)							
Low	24/171 (14.0)	N.E. [11.2; N.E.]	21/172 (12.2)	N.E. [N.E.; N.E.]	1.13	[0.63; 2.02]	0.516
Intermediate	18/75 (24.0)	11.2 [8.3; N.E.]	14/75 (18.7)	N.E. [3.0; N.E.]	1.11	[0.55; 2.25]	0.772
High	10/38	N.E. [2.8; N.E.]	4/37	N.E. [2.8; N.E.]	1.76	[0.55; 5.64]	0.378

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(26.3)		(10.8)				
Sex							
(Interaction test: p = 0.845)							
Female	25/107	11.2 [6.1; N.E.]	19/126	N.E. [N.E.; N.E.]	1.10	[0.60; 2.01]	0.453
	(23.4)		(15.1)				
Male	27/177	N.E. [11.2; N.E.]	20/158	N.E. [N.E.; N.E.]	1.20	[0.67; 2.14]	0.551
	(15.3)		(12.7)				
Race							
(Interaction test: p = 0.557)							
Asian	18/40	5.6 [2.8; N.E.]	10/46	N.E. [2.8; N.E.]	1.49	[0.67; 3.34]	0.101
	(45.0)		(21.7)				
White	32/227	N.E. [11.2; N.E.]	25/217	N.E. [N.E.; N.E.]	1.18	[0.70; 2.01]	0.593
	(14.1)		(11.5)				
Other	2/17	N.E. [1.0; N.E.]	4/21	5.6 [1.9; N.E.]	0.20	[0.02; 2.02]	0.151
	(11.8)		(19.0)				
Age groups							
(Interaction test: p = 0.273)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
18 - < 65 years	46/237 (19.4)	N.E. [11.2; N.E.]	33/247 (13.4)	N.E. [N.E.; N.E.]	1.36	[0.86; 2.13]	0.126
65 - < 75 years	5/38 (13.2)	N.E. [2.8; N.E.]	5/24 (20.8)	5.6 [0.9; N.E.]	0.59	[0.17; 2.10]	0.305
>= 75 years	1/9 (11.1)	N.E. [2.8; N.E.]	1/13 (7.7)	N.E. [1.0; N.E.]	0.71	[0.03; 17.62]	0.515
Geographic region (Interaction test: p = 0.247)							
Europe excluding Germany	20/138 (14.5)	13.1 [11.2; N.E.]	21/141 (14.9)	N.E. [N.E.; N.E.]	0.85	[0.46; 1.58]	0.521
Germany	6/72 (8.3)	N.E. [6.1; N.E.]	2/53 (3.8)	N.E. [11.1; N.E.]	2.16	[0.42; 11.09]	0.391
Others	26/74 (35.1)	11.0 [5.6; N.E.]	16/90 (17.8)	N.E. [N.E.; N.E.]	1.55	[0.82; 2.94]	0.074
Satisfaction with Social Life (MID=15)							
Stratification factor: ELTS based on randomization data from IRT							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.547)							
Low	43/171 (25.1)	11.1 [2.9; N.E.]	42/172 (24.4)	22.1 [3.0; N.E.]	0.99	[0.65; 1.52]	0.786
Intermediate	25/75 (33.3)	5.6 [1.9; N.E.]	24/75 (32.0)	2.8 [1.9; 16.6]	1.14	[0.64; 2.03]	0.987
High	11/38 (28.9)	11.1 [2.8; N.E.]	4/37 (10.8)	N.E. [1.9; N.E.]	1.83	[0.58; 5.75]	0.298
Sex							
(Interaction test: p = 0.405)							
Female	34/107 (31.8)	11.0 [2.8; 11.2]	27/126 (21.4)	11.3 [3.0; N.E.]	1.32	[0.79; 2.21]	0.171
Male	45/177 (25.4)	11.1 [5.6; N.E.]	43/158 (27.2)	16.6 [2.8; N.E.]	0.96	[0.63; 1.47]	0.672
Race							
(Interaction test: p = 0.844)							
Asian	20/40 (50.0)	5.6 [1.8; N.E.]	14/46 (30.4)	11.3 [2.3; N.E.]	1.45	[0.71; 2.95]	0.142

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
White	55/227 (24.2)	11.1 [5.6; N.E.]	52/217 (24.0)	16.6 [2.8; N.E.]	1.04	[0.71; 1.53]	0.899
Other	4/17 (23.5)	11.1 [0.9; N.E.]	4/21 (19.0)	5.6 [1.0; N.E.]	0.42	[0.07; 2.62]	0.107
Age groups (Interaction test: p = 0.827)							
18 - < 65 years	70/237 (29.5)	11.1 [5.6; 11.2]	65/247 (26.3)	11.3 [2.9; N.E.]	1.08	[0.76; 1.51]	0.476
65 - < 75 years	7/38 (18.4)	N.E. [2.8; N.E.]	4/24 (16.7)	N.E. [0.9; N.E.]	2.50	[0.57; 11.00]	0.802
>= 75 years	2/9 (22.2)	N.E. [1.0; N.E.]	1/13 (7.7)	N.E. [1.0; N.E.]	1.62	[0.14; 18.31]	0.861
Geographic region (Interaction test: p = 0.265)							
Europe excluding Germany	40/138 (29.0)	11.1 [2.9; N.E.]	38/141 (27.0)	11.1 [2.8; N.E.]	1.26	[0.80; 1.98]	0.751
Germany	9/72	N.E. [1.0; N.E.]	9/53	2.8 [1.0; N.E.]	0.45	[0.14; 1.50]	0.448

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Others	(12.5) 30/74 (40.5)	5.6 [2.8; N.E.]	(17.0) 23/90 (25.6)	N.E. [2.8; N.E.]	1.14	[0.65; 1.99]	0.294

MID: Minimally important difference
N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
If there are not at least 10 patients in every subgroup or not more than 10 events per subgroup per treatment arm, no subgroup analyses were performed for the corresponding attribute.
If there are not more than 10 events per subgroup per treatment arm, no Cox PH hazard analysis is carried out.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variables ELTS Score (IRT) and covariates treatment arm and baseline PRO score.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variables ELTS Score (IRT).
For the subgroup of Stratification factor: ELTS based on IRT randomisation data not stratification factor was included in the Cox PH model and an unstratitfied log-rank test was applied
The reference group in the (stratified) Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
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Table 3-2.3 FACIT GP5: Time to first deterioration analysis by subgroups (Full Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
V4 (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.843)							
Low	61/171 (35.7)	2.1 [1.0; 4.4]	63/172 (36.6)	1.0 [0.5; 3.0]	0.91	[0.64; 1.29]	0.748
Intermediate	24/75 (32.0)	5.4 [1.2; N.E.]	25/75 (33.3)	2.8 [0.5; 19.4]	0.76	[0.44; 1.34]	0.458
High	18/38 (47.4)	1.7 [0.5; 4.6]	12/37 (32.4)	1.8 [0.3; 7.4]	0.77	[0.37; 1.61]	0.838
Sex							
(Interaction test: p = 0.659)							
Female	39/107 (36.4)	1.6 [0.5; 4.2]	46/126 (36.5)	1.2 [0.5; 2.8]	0.83	[0.54; 1.27]	0.485
Male	64/177 (36.2)	2.7 [1.7; 8.3]	54/158 (34.2)	1.9 [0.7; 8.3]	0.92	[0.64; 1.33]	0.870

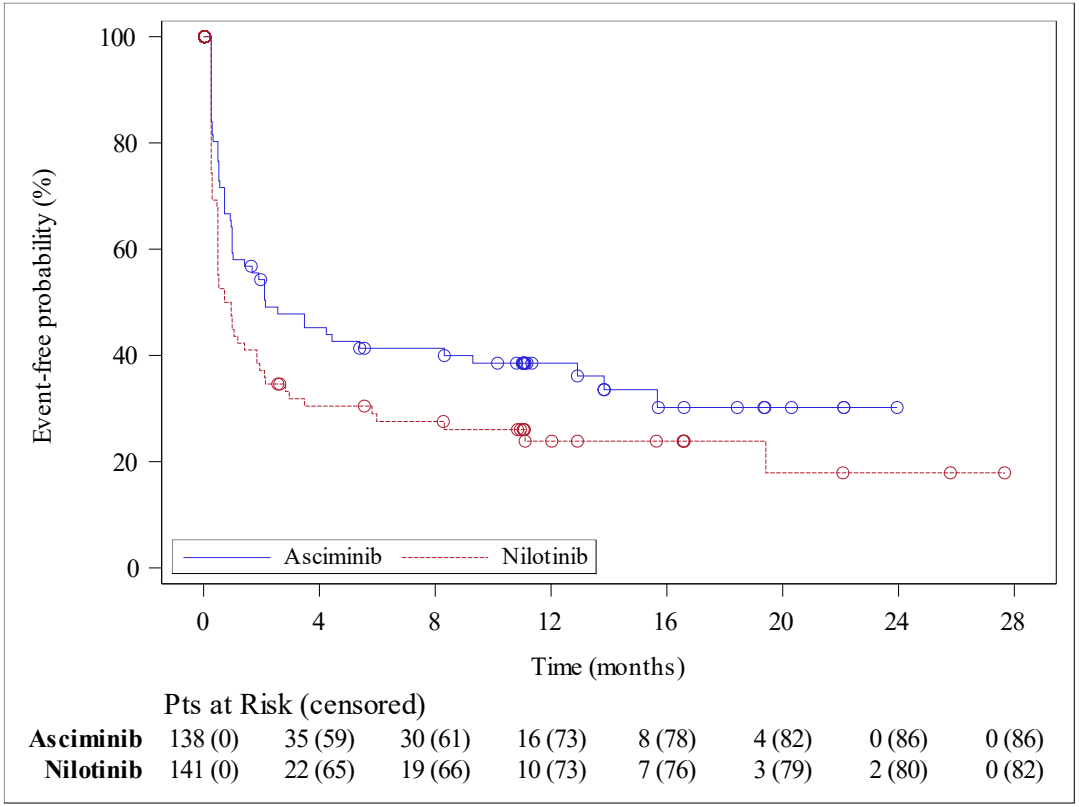
	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Race							
(Interaction test: p = 0.339)							
Asian	19/40 (47.5)	2.8 [1.0; N.E.]	19/46 (41.3)	8.3 [1.4; N.E.]	1.16	[0.59; 2.28]	0.799
White	79/227 (34.8)	2.1 [1.0; 4.4]	75/217 (34.6)	1.0 [0.5; 2.1]	0.77	[0.56; 1.06]	0.234
Other	5/17 (29.4)	2.1 [0.5; N.E.]	6/21 (28.6)	1.0 [0.1; N.E.]	0.15	[0.02; 1.34]	0.102
Age groups							
(Interaction test: p = 0.531)							
18 - < 65 years	91/237 (38.4)	1.9 [1.2; 4.2]	89/247 (36.0)	1.8 [0.7; 3.5]	0.91	[0.68; 1.22]	0.881
65 - < 75 years	10/38 (26.3)	2.1 [0.7; N.E.]	8/24 (33.3)	2.0 [0.3; N.E.]	0.58	[0.22; 1.58]	0.365
>= 75 years	2/9 (22.2)	N.E. [0.3; N.E.]	3/13 (23.1)	0.7 [0.5; N.E.]	1.62	[0.14; 18.31]	0.397
Geographic region							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.005)							
Europe excluding Germany	52/138 (37.7)	2.1 [1.0; 9.3]	59/141 (41.8)	0.8 [0.5; 1.8]	0.66	[0.45; 0.97]	0.047
Germany	15/72 (20.8)	1.9 [0.5; 7.4]	12/53 (22.6)	0.3 [0.3; 0.8]	0.36	[0.15; 0.87]	0.035
Others	36/74 (48.6)	1.9 [1.0; 11.0]	29/90 (32.2)	11.1 [2.8; N.E.]	1.50	[0.91; 2.48]	0.065

MID: Minimally important difference
N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
If there are not at least 10 patients in every subgroup or not more than 10 events per subgroup per treatment arm, no subgroup analyses were performed for the corresponding attribute.
If there are not more than 10 events per subgroup per treatment arm, no Cox PH hazard analysis is carried out.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variables ELTS Score (IRT) and covariates treatment arm and baseline PRO score.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variables ELTS Score (IRT).
For the subgroup of Stratification factor: ELTS based on IRT randomisation data not stratification factor was included in the Cox PH model and an unstratitfied log-rank test was applied
The reference group in the (stratified) Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
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Figure 3-2.3 FACIT GP5: Time to first deterioration analysis by subgroups: Kaplan-Meier plot by subgroups (Full Analysis Set)

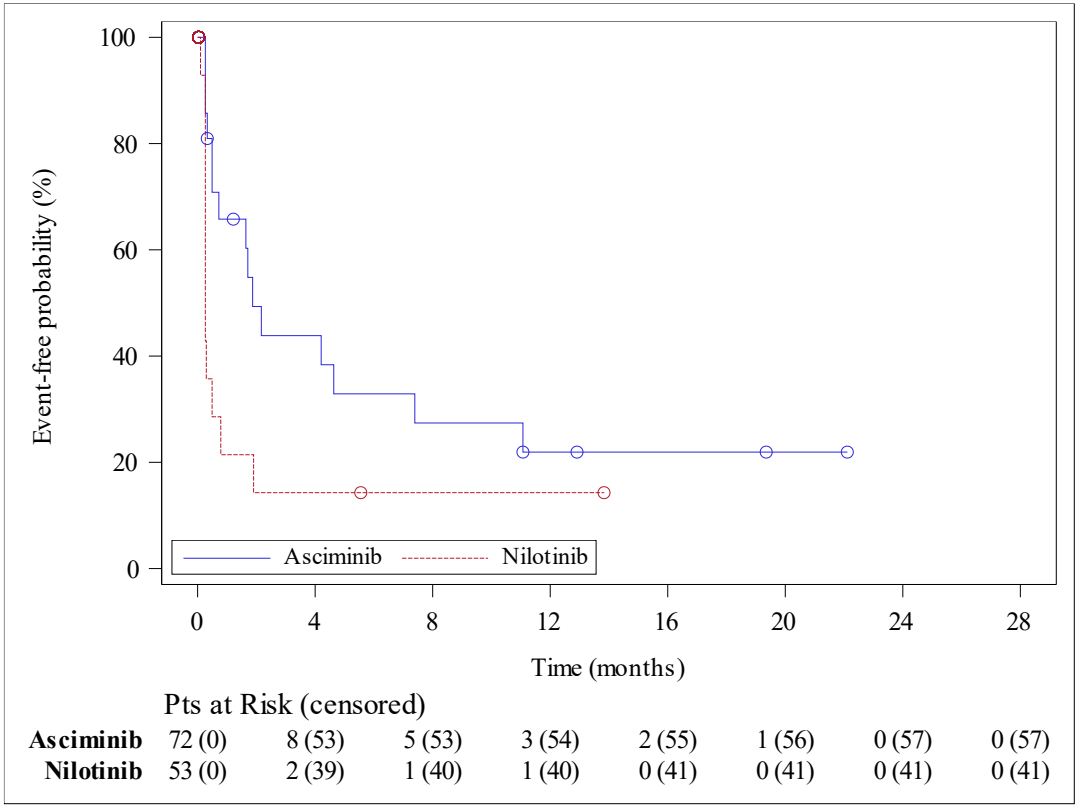
V4 (MID=1): Geographic region: Europe excluding Germany



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Figure 3-2.3 FACIT GP5: Time to first deterioration analysis by subgroups: Kaplan-Meier plot by subgroups (Full Analysis Set)

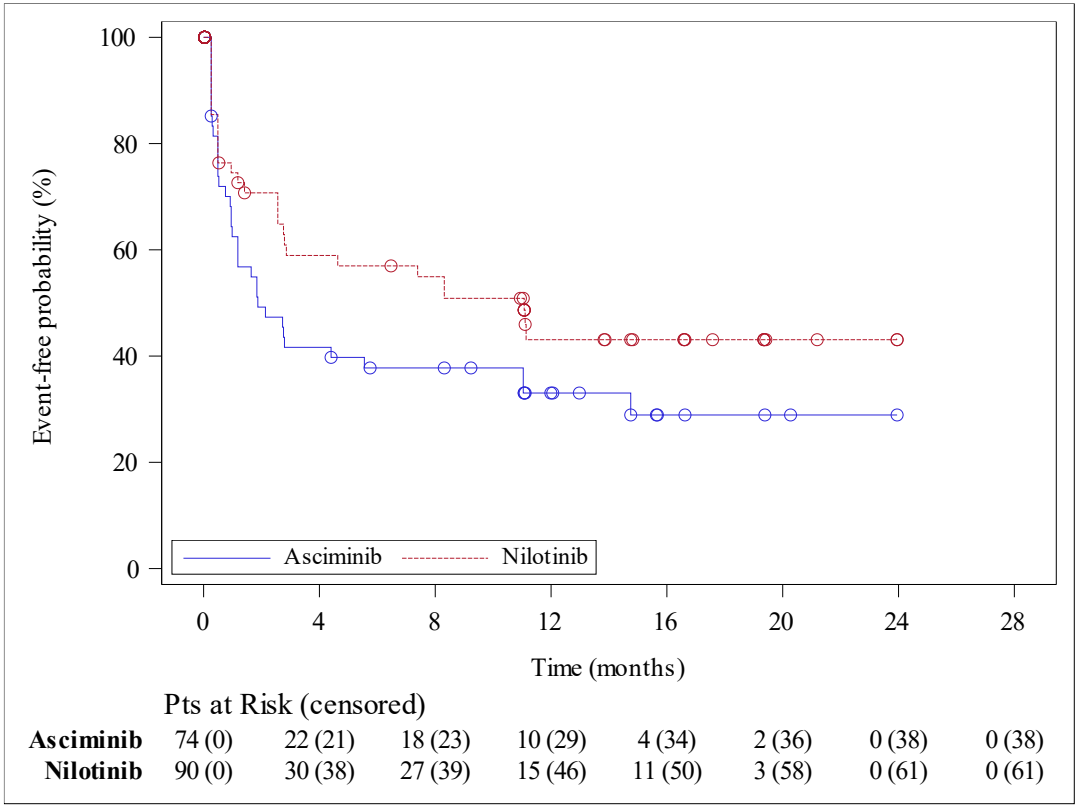
V4 (MID=1): Geographic region: Germany



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Figure 3-2.3 FACIT GP5: Time to first deterioration analysis by subgroups: Kaplan-Meier plot by subgroups (Full Analysis Set)

V4 (MID=1): Geographic region: Others



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Table 3-2.4 PRO-CTCAE - Frequency: Time to first deterioration analysis by subgroups (Full Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Headache - Frequency (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.698)							
Low	55/171 (32.2)	4.2 [2.0; 5.6]	72/172 (41.9)	1.1 [0.7; 2.8]	0.61	[0.43; 0.87]	0.010
Intermediate	26/75 (34.7)	2.5 [1.0; N.E.]	27/75 (36.0)	1.9 [0.5; 6.5]	0.80	[0.47; 1.38]	0.412
High	18/38 (47.4)	3.7 [1.0; 9.0]	13/37 (35.1)	0.7 [0.3; 3.9]	0.56	[0.27; 1.16]	0.191
Sex							
(Interaction test: p = 0.725)							
Female	40/107 (37.4)	1.9 [0.5; 5.5]	51/126 (40.5)	1.0 [0.5; 2.6]	0.69	[0.45; 1.05]	0.085
Male	59/177 (33.3)	4.4 [2.1; 10.2]	61/158 (38.6)	1.4 [0.7; 3.9]	0.63	[0.44; 0.90]	0.024

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Race							
(Interaction test: p = 0.176)							
Asian	17/40 (42.5)	5.6 [1.0; N.E.]	28/46 (60.9)	2.0 [0.5; 4.4]	0.50	[0.27; 0.92]	0.019
White	79/227 (34.8)	2.6 [1.9; 4.6]	77/217 (35.5)	1.1 [0.7; 2.8]	0.75	[0.54; 1.03]	0.148
Other	3/17 (17.6)	N.E. [0.5; N.E.]	7/21 (33.3)	0.5 [0.1; 3.7]	0.23	[0.04; 1.25]	0.068
Age groups							
(Interaction test: p = 0.214)							
18 - < 65 years	84/237 (35.4)	3.7 [2.1; 5.6]	102/247 (41.3)	1.2 [0.7; 2.6]	0.63	[0.47; 0.85]	0.004
65 - < 75 years	11/38 (28.9)	3.4 [1.2; N.E.]	8/24 (33.3)	1.7 [0.3; 19.4]	0.64	[0.24; 1.73]	0.426
>= 75 years	4/9 (44.4)	0.3 [0.3; N.E.]	2/13 (15.4)	3.9 [1.1; N.E.]	5.96	[0.47; 76.09]	0.202
Geographic region							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.384)							
Europe excluding Germany	52/138 (37.7)	2.8 [1.4; 7.4]	58/141 (41.1)	1.1 [0.6; 4.0]	0.70	[0.48; 1.03]	0.130
Germany	14/72 (19.4)	4.6 [2.1; N.E.]	11/53 (20.8)	0.4 [0.3; 9.2]	0.36	[0.13; 0.94]	0.048
Others	33/74 (44.6)	2.6 [1.0; N.E.]	43/90 (47.8)	2.1 [0.7; 2.8]	0.71	[0.45; 1.12]	0.091
Rash - Presence/Absence (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.262)							
Low	48/171 (28.1)	9.2 [3.9; N.E.]	51/172 (29.7)	5.5 [1.4; N.E.]	0.72	[0.49; 1.07]	0.489
Intermediate	19/75 (25.3)	N.E. [4.2; N.E.]	28/75 (37.3)	2.3 [1.1; 3.0]	0.42	[0.23; 0.75]	0.003
High	13/38 (34.2)	11.2 [3.7; N.E.]	11/37 (29.7)	2.8 [0.5; N.E.]	0.38	[0.16; 0.86]	0.073

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Sex							
(Interaction test: p = 0.153)							
Female	41/107 (38.3)	2.4 [1.6; 10.2]	41/126 (32.5)	2.7 [0.9; 6.5]	0.79	[0.51; 1.24]	0.810
Male	39/177 (22.0)	N.E. [9.0; N.E.]	49/158 (31.0)	3.3 [1.6; 19.4]	0.47	[0.31; 0.72]	0.001
Race							
(Interaction test: p = 0.836)							
Asian	14/40 (35.0)	12.0 [3.1; N.E.]	19/46 (41.3)	3.9 [1.4; N.E.]	0.41	[0.20; 0.86]	0.103
White	64/227 (28.2)	8.3 [4.2; N.E.]	65/217 (30.0)	2.7 [1.4; 6.5]	0.62	[0.44; 0.88]	0.052
Other	2/17 (11.8)	N.E. [0.3; N.E.]	6/21 (28.6)	2.5 [0.5; N.E.]	0.57	[0.10; 3.22]	0.223
Age groups							
(Interaction test: p = 0.850)							
18 - < 65 years	71/237	10.2 [4.6; N.E.]	81/247	2.8 [1.6; 5.6]	0.57	[0.41; 0.79]	0.019

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(30.0)		(32.8)				
65 - < 75 years	7/38	N.E. [2.1; N.E.]	7/24	5.6 [0.5; N.E.]	0.52	[0.18; 1.51]	0.227
	(18.4)		(29.2)				
>= 75 years	2/9	N.E. [1.2; N.E.]	2/13	0.7 [0.3; N.E.]	0.13	[0.00; 5.13]	0.039
	(22.2)		(15.4)				
Geographic region							
(Interaction test: p = 0.825)							
Europe excluding Germany	44/138	8.3 [3.9; N.E.]	47/141	3.0 [1.4; 13.0]	0.60	[0.40; 0.92]	0.136
	(31.9)		(33.3)				
Germany	10/72	N.E. [1.9; N.E.]	10/53	1.8 [0.3; N.E.]	0.47	[0.18; 1.22]	0.074
	(13.9)		(18.9)				
Others	26/74	12.0 [5.1; N.E.]	33/90	2.8 [1.4; N.E.]	0.49	[0.28; 0.85]	0.056
	(35.1)		(36.7)				
Diarrhea - Frequency (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.736)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Low	56/171 (32.7)	2.1 [1.5; 5.3]	64/172 (37.2)	2.6 [1.4; 4.6]	0.91	[0.63; 1.31]	0.551
Intermediate	25/75 (33.3)	3.5 [1.8; N.E.]	19/75 (25.3)	9.2 [1.4; N.E.]	1.15	[0.64; 2.10]	0.565
High	15/38 (39.5)	2.9 [1.0; N.E.]	9/37 (24.3)	3.5 [1.4; N.E.]	1.16	[0.50; 2.65]	0.726
Sex							
(Interaction test: p = 0.766)							
Female	34/107 (31.8)	2.9 [1.2; N.E.]	41/126 (32.5)	2.8 [1.5; 10.2]	0.92	[0.57; 1.48]	0.695
Male	62/177 (35.0)	2.3 [1.6; 5.1]	51/158 (32.3)	3.0 [1.4; 9.2]	1.03	[0.71; 1.50]	0.881
Race							
(Interaction test: p = 0.748)							
Asian	21/40 (52.5)	4.2 [1.2; 17.5]	19/46 (41.3)	5.6 [1.0; N.E.]	1.05	[0.55; 2.01]	0.833
White	70/227	2.3 [1.6; 7.4]	68/217	2.8 [1.9; 8.3]	0.96	[0.69; 1.34]	0.795

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(30.8)		(31.3)				
Other	5/17	2.1 [0.3; N.E.]	5/21	1.4 [0.3; N.E.]	1.12	[0.24; 5.23]	0.933
	(29.4)		(23.8)				
Age groups							
(Interaction test: p = 0.773)							
18 - < 65 years	80/237	2.4 [1.7; 5.6]	84/247	2.8 [1.9; 8.3]	0.97	[0.71; 1.32]	0.757
	(33.8)		(34.0)				
65 - < 75 years	12/38	3.5 [1.0; 17.5]	6/24	4.7 [0.3; N.E.]	1.41	[0.51; 3.92]	0.518
	(31.6)		(25.0)				
>= 75 years	4/9	1.2 [0.3; N.E.]	2/13	2.6 [0.7; N.E.]	1.69	[0.27; 10.49]	0.636
	(44.4)		(15.4)				
Geographic region							
(Interaction test: p = 0.009)							
Europe excluding Germany	52/138	1.7 [1.0; 3.0]	49/141	2.8 [1.4; 10.2]	1.23	[0.83; 1.82]	0.334
	(37.7)		(34.8)				
Germany	8/72	N.E. [2.8; N.E.]	11/53	1.1 [0.3; 9.2]	0.20	[0.06; 0.63]	0.006
	(11.1)		(20.8)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Others	36/74 (48.6)	2.4 [1.2; 11.1]	32/90 (35.6)	3.5 [1.9; N.E.]	1.29	[0.79; 2.10]	0.324
Vomiting - Frequency (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.745)							
Low	14/171 (8.2)	N.E. [N.E.; N.E.]	31/172 (18.0)	N.E. [18.4; N.E.]	0.40	[0.21; 0.76]	0.004
Intermediate	7/75 (9.3)	N.E. [17.5; N.E.]	10/75 (13.3)	N.E. [N.E.; N.E.]	0.45	[0.16; 1.24]	0.186
High	3/38 (7.9)	N.E. [N.E.; N.E.]	6/37 (16.2)	N.E. [3.0; N.E.]	0.28	[0.07; 1.21]	0.067
Sex							
(Interaction test: p = 0.379)							
Female	12/107 (11.2)	N.E. [22.1; N.E.]	29/126 (23.0)	N.E. [4.6; N.E.]	0.34	[0.17; 0.68]	0.001
Male	12/177	N.E. [N.E.; N.E.]	18/158	N.E. [N.E.; N.E.]	0.54	[0.26; 1.13]	0.095

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(6.8)		(11.4)				
Race							
(Interaction test: p = 0.767)							
Asian	7/40	N.E. [17.5; N.E.]	14/46	N.E. [4.6; N.E.]	0.45	[0.18; 1.13]	0.077
	(17.5)		(30.4)				
White	16/227	N.E. [N.E.; N.E.]	28/217	N.E. [N.E.; N.E.]	0.45	[0.24; 0.84]	0.011
	(7.0)		(12.9)				
Other	1/17	N.E. [2.8; N.E.]	5/21	15.7 [1.2; N.E.]	0.87	[0.05; 13.95]	0.857
	(5.9)		(23.8)				
Age groups							
(Interaction test: p = 0.989)							
18 - < 65 years	21/237	N.E. [N.E.; N.E.]	44/247	N.E. [18.4; N.E.]	0.40	[0.24; 0.68]	<0.001
	(8.9)		(17.8)				
65 - < 75 years	2/38	N.E. [N.E.; N.E.]	3/24	N.E. [0.5; N.E.]	0.32	[0.05; 2.09]	0.201
	(5.3)		(12.5)				
>= 75 years	1/9	22.1 [N.E.; N.E.]	0/13	N.E. [N.E.; N.E.]	2.99	[0.03; 275.43]	0.317
	(11.1)						

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = 0.953)							
Europe excluding Germany	11/138 (8.0)	N.E. [N.E.; N.E.]	21/141 (14.9)	N.E. [18.4; N.E.]	0.44	[0.21; 0.91]	0.024
Germany	1/72 (1.4)	N.E. [N.E.; N.E.]	1/53 (1.9)	N.E. [N.E.; N.E.]	0.55	[0.03; 8.78]	0.666
Others	12/74 (16.2)	N.E. [17.5; N.E.]	25/90 (27.8)	15.7 [4.2; N.E.]	0.38	[0.19; 0.79]	0.006
Nausea - Frequency (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.445)							
Low	36/171 (21.1)	25.8 [11.0; N.E.]	50/172 (29.1)	5.5 [1.7; N.E.]	0.65	[0.42; 1.00]	0.056
Intermediate	13/75 (17.3)	22.1 [15.7; N.E.]	22/75 (29.3)	4.9 [1.9; N.E.]	0.38	[0.19; 0.78]	0.006
High	12/38	N.E. [1.7; N.E.]	8/37	11.1 [1.9; N.E.]	0.79	[0.32; 1.94]	0.887

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(31.6)		(21.6)				
Sex							
(Interaction test: p = 0.880)							
Female	31/107	13.8 [3.0; N.E.]	41/126	2.3 [1.2; 5.6]	0.57	[0.35; 0.93]	0.047
	(29.0)		(32.5)				
Male	30/177	25.8 [25.8; N.E.]	39/158	18.4 [3.9; N.E.]	0.64	[0.39; 1.03]	0.050
	(16.9)		(24.7)				
Race							
(Interaction test: p = 0.906)							
Asian	13/40	N.E. [2.3; N.E.]	17/46	11.0 [1.2; N.E.]	0.70	[0.34; 1.46]	0.382
	(32.5)		(37.0)				
White	46/227	22.1 [15.7; N.E.]	59/217	4.6 [2.3; N.E.]	0.58	[0.39; 0.86]	0.007
	(20.3)		(27.2)				
Other	2/17	N.E. [0.5; N.E.]	4/21	18.4 [0.3; N.E.]	0.52	[0.07; 3.86]	0.596
	(11.8)		(19.0)				
Age groups							
(Interaction test: p = 0.318)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
18 - < 65 years	53/237 (22.4)	25.8 [13.8; N.E.]	72/247 (29.1)	8.3 [3.0; N.E.]	0.65	[0.45; 0.93]	0.020
65 - < 75 years	6/38 (15.8)	N.E. [8.3; N.E.]	7/24 (29.2)	1.7 [0.3; N.E.]	0.19	[0.05; 0.69]	0.015
>= 75 years	2/9 (22.2)	22.1 [0.5; N.E.]	1/13 (7.7)	N.E. [0.7; N.E.]	0.71	[0.04; 11.79]	0.695
Geographic region (Interaction test: p = 0.595)							
Europe excluding Germany	31/138 (22.5)	22.1 [15.7; N.E.]	45/141 (31.9)	3.9 [1.4; 18.4]	0.51	[0.32; 0.82]	0.004
Germany	9/72 (12.5)	25.8 [2.3; N.E.]	9/53 (17.0)	3.9 [0.3; N.E.]	0.60	[0.22; 1.62]	0.273
Others	21/74 (28.4)	N.E. [11.0; N.E.]	26/90 (28.9)	N.E. [3.0; N.E.]	0.79	[0.44; 1.42]	0.492
Edema - Frequency (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.731)							
Low	36/171 (21.1)	N.E. [8.3; N.E.]	43/172 (25.0)	15.7 [11.1; N.E.]	0.85	[0.55; 1.33]	0.462
Intermediate	16/75 (21.3)	22.1 [17.5; N.E.]	13/75 (17.3)	N.E. [9.2; N.E.]	1.20	[0.57; 2.52]	0.701
High	13/38 (34.2)	16.6 [0.5; N.E.]	7/37 (18.9)	N.E. [0.3; N.E.]	1.06	[0.42; 2.67]	0.802
Sex							
(Interaction test: p = 0.946)							
Female	34/107 (31.8)	5.6 [2.1; N.E.]	36/126 (28.6)	10.2 [2.8; N.E.]	1.00	[0.62; 1.61]	0.876
Male	31/177 (17.5)	22.1 [17.5; N.E.]	27/158 (17.1)	N.E. [15.7; N.E.]	1.00	[0.59; 1.67]	0.953
Race							
(Interaction test: p = 0.385)							
Asian	15/40 (37.5)	N.E. [3.5; N.E.]	20/46 (43.5)	4.6 [1.0; N.E.]	0.67	[0.34; 1.32]	0.232

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
White	45/227 (19.8)	22.1 [17.5; N.E.]	39/217 (18.0)	24.9 [12.0; N.E.]	1.06	[0.69; 1.63]	0.882
Other	5/17 (29.4)	2.8 [0.3; N.E.]	4/21 (19.0)	15.7 [0.3; N.E.]	1.38	[0.29; 6.54]	0.440
Age groups (Interaction test: p = 0.835)							
18 - < 65 years	55/237 (23.2)	22.1 [11.1; N.E.]	59/247 (23.9)	16.6 [11.1; N.E.]	0.88	[0.61; 1.28]	0.521
65 - < 75 years	9/38 (23.7)	N.E. [1.6; N.E.]	4/24 (16.7)	N.E. [0.3; N.E.]	1.02	[0.29; 3.57]	0.764
>= 75 years	1/9 (11.1)	22.1 [N.E.; N.E.]	0/13	N.E. [N.E.; N.E.]	2.99	[0.03; 275.43]	0.317
Geographic region (Interaction test: p = 0.921)							
Europe excluding Germany	30/138 (21.7)	22.1 [17.5; N.E.]	30/141 (21.3)	24.9 [11.3; N.E.]	0.97	[0.58; 1.62]	0.813
Germany	8/72	22.1 [2.8; N.E.]	6/53	N.E. [1.8; N.E.]	0.74	[0.24; 2.32]	0.813

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(11.1)		(11.3)				
Others	27/74	11.1 [3.5; N.E.]	27/90	15.7 [3.0; N.E.]	1.07	[0.62; 1.85]	0.771
	(36.5)		(30.0)				
Muscle Pain - Frequency (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.780)							
Low	59/171	1.9 [1.0; 4.9]	64/172	1.1 [0.5; 2.8]	0.87	[0.61; 1.25]	0.545
	(34.5)		(37.2)				
Intermediate	31/75	1.0 [0.7; 1.6]	28/75	1.2 [0.3; 3.5]	1.05	[0.63; 1.76]	0.912
	(41.3)		(37.3)				
High	15/38	1.0 [0.5; N.E.]	12/37	1.9 [0.5; 2.8]	0.85	[0.40; 1.83]	0.643
	(39.5)		(32.4)				
Sex							
(Interaction test: p = 0.704)							
Female	43/107	1.0 [0.5; 2.0]	50/126	1.0 [0.5; 2.1]	0.88	[0.58; 1.33]	0.444
	(40.2)		(39.7)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Male	62/177 (35.0)	1.7 [1.0; 5.6]	54/158 (34.2)	2.8 [0.5; 10.2]	0.98	[0.68; 1.41]	0.981
Race (Interaction test: p = 0.165)							
Asian	18/40 (45.0)	4.9 [0.8; N.E.]	29/46 (63.0)	1.1 [0.5; 2.8]	0.59	[0.32; 1.08]	0.033
White	81/227 (35.7)	1.2 [0.9; 1.9]	71/217 (32.7)	1.2 [0.5; 2.8]	1.01	[0.73; 1.40]	0.866
Other	6/17 (35.3)	0.5 [0.3; 7.4]	4/21 (19.0)	N.E. [0.3; N.E.]	1.69	[0.31; 9.26]	0.349
Age groups (Interaction test: p = 0.555)							
18 - < 65 years	87/237 (36.7)	1.7 [1.0; 3.3]	92/247 (37.2)	1.2 [0.7; 2.8]	0.91	[0.68; 1.23]	0.587
65 - < 75 years	13/38 (34.2)	1.2 [0.5; 8.3]	10/24 (41.7)	1.9 [0.3; 2.8]	0.72	[0.29; 1.81]	0.411
>= 75 years	5/9	1.0 [0.3; N.E.]	2/13	1.1 [0.3; N.E.]	0.55	[0.06; 4.67]	0.863

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(55.6)		(15.4)				
Geographic region							
(Interaction test: p = 0.559)							
Europe excluding Germany	55/138	1.4 [1.0; 2.3]	50/141	1.4 [0.7; 11.1]	1.08	[0.74; 1.60]	0.612
	(39.9)		(35.5)				
Germany	14/72	1.2 [0.5; 8.3]	10/53	0.4 [0.3; N.E.]	0.71	[0.28; 1.80]	0.524
	(19.4)		(18.9)				
Others	36/74	1.4 [0.7; 10.2]	44/90	1.6 [0.5; 2.8]	0.80	[0.51; 1.25]	0.177
	(48.6)		(48.9)				
Increased Sweating - Frequency (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.643)							
Low	44/171	8.4 [2.6; N.E.]	49/172	11.1 [3.3; N.E.]	0.99	[0.66; 1.49]	0.984
	(25.7)		(28.5)				
Intermediate	21/75	11.1 [1.2; N.E.]	17/75	19.4 [1.9; N.E.]	1.29	[0.67; 2.45]	0.534
	(28.0)		(22.7)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
High	11/38 (28.9)	13.8 [6.5; N.E.]	5/37 (13.5)	N.E. [7.4; N.E.]	1.63	[0.56; 4.76]	0.403
Sex							
(Interaction test: p = 0.898)							
Female	33/107 (30.8)	5.5 [1.0; N.E.]	34/126 (27.0)	10.7 [2.1; N.E.]	1.21	[0.74; 1.97]	0.400
Male	43/177 (24.3)	22.1 [8.3; N.E.]	37/158 (23.4)	19.4 [10.2; N.E.]	1.14	[0.73; 1.78]	0.739
Race							
(Interaction test: p = 0.274)							
Asian	11/40 (27.5)	N.E. [2.8; N.E.]	18/46 (39.1)	11.1 [1.8; N.E.]	0.63	[0.29; 1.34]	0.230
White	61/227 (26.9)	8.4 [3.1; N.E.]	48/217 (22.1)	19.4 [7.4; N.E.]	1.30	[0.89; 1.90]	0.166
Other	4/17 (23.5)	N.E. [0.3; N.E.]	5/21 (23.8)	4.3 [1.0; N.E.]	2.30	[0.48; 11.12]	0.923
Age groups							

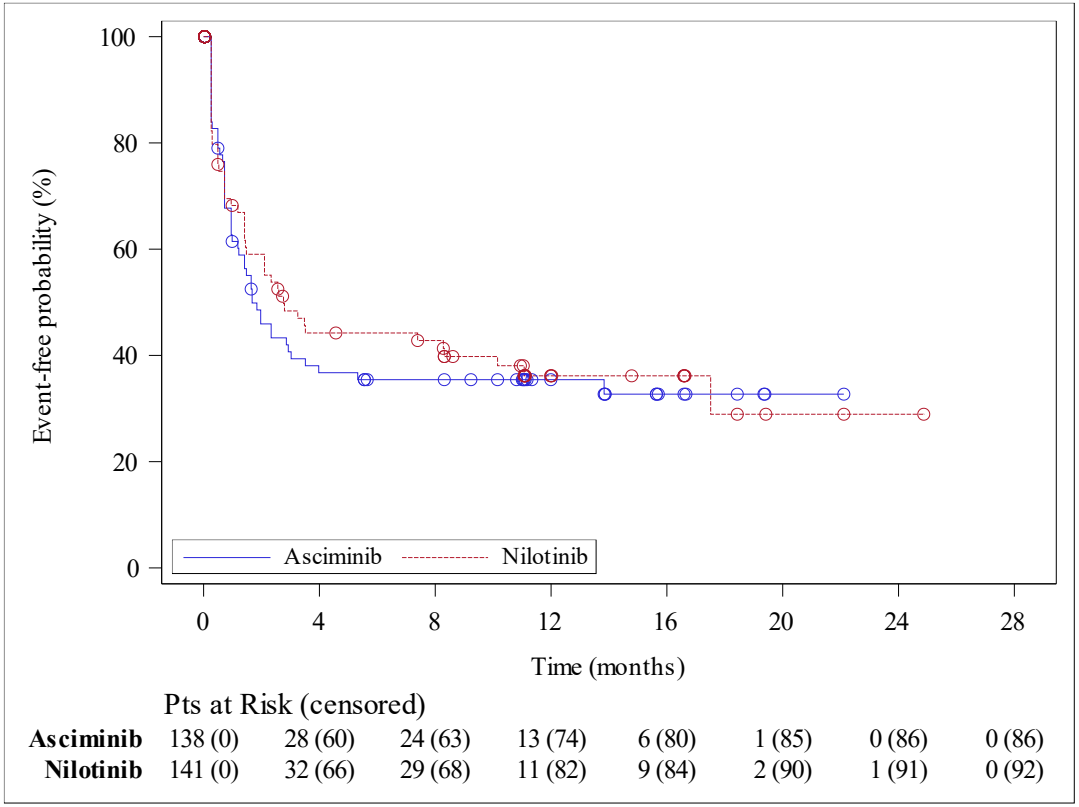
	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.320)							
18 - < 65 years	65/237 (27.4)	13.8 [3.7; N.E.]	64/247 (25.9)	12.9 [8.3; N.E.]	1.10	[0.78; 1.56]	0.540
65 - < 75 years	9/38 (23.7)	11.1 [1.4; N.E.]	4/24 (16.7)	19.4 [0.3; N.E.]	1.37	[0.36; 5.24]	0.502
>= 75 years	2/9 (22.2)	N.E. [2.1; N.E.]	3/13 (23.1)	1.0 [0.7; N.E.]	0.06	[0.00; 2.62]	0.025
Geographic region							
(Interaction test: p = 0.567)							
Europe excluding Germany	41/138 (29.7)	8.3 [1.9; N.E.]	39/141 (27.7)	11.1 [6.0; N.E.]	1.21	[0.77; 1.88]	0.358
Germany	13/72 (18.1)	6.5 [1.6; N.E.]	9/53 (17.0)	1.4 [0.3; N.E.]	0.65	[0.26; 1.64]	0.522
Others	22/74 (29.7)	N.E. [5.5; N.E.]	23/90 (25.6)	N.E. [8.3; N.E.]	1.04	[0.58; 1.88]	1.000

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			

MID: Minimally important difference
N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
If there are not at least 10 patients in every subgroup or not more than 10 events per subgroup per treatment arm, no subgroup analyses were performed for the corresponding attribute.
If there are not more than 10 events per subgroup per treatment arm, no Cox PH hazard analysis is carried out.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variables ELTS Score (IRT) and covariates treatment arm and baseline PRO score.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variables ELTS Score (IRT).
For the subgroup of Stratification factor: ELTS based on IRT randomisation data not stratification factor was included in the Cox PH model and an unstratitfied log-rank test was applied
The reference group in the (stratified) Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/2025-05-15

Figure 3-2.4 PRO-CTCAE - Frequency: Time to first deterioration analysis by subgroups: Kaplan-Meier plot by subgroups (Full Analysis Set)

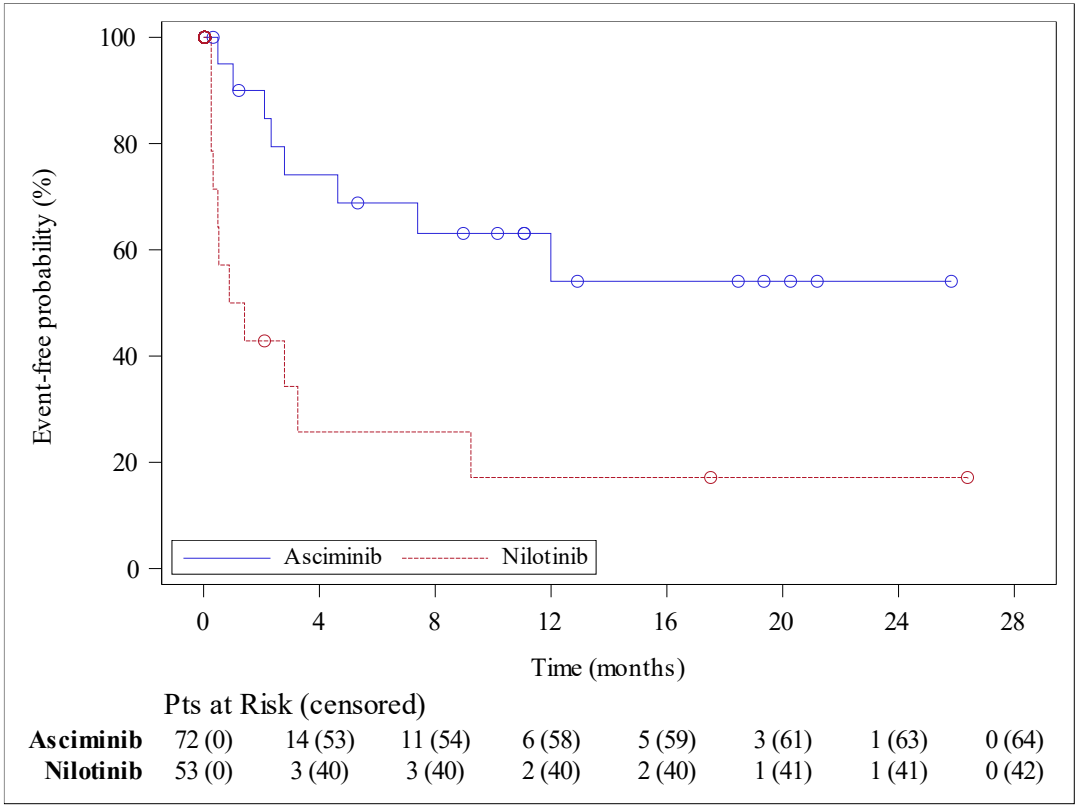
Diarrhea - Frequency (MID=1): Geographic region: Europe excluding Germany



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Figure 3-2.4 PRO-CTCAE - Frequency: Time to first deterioration analysis by subgroups: Kaplan-Meier plot by subgroups (Full Analysis Set)

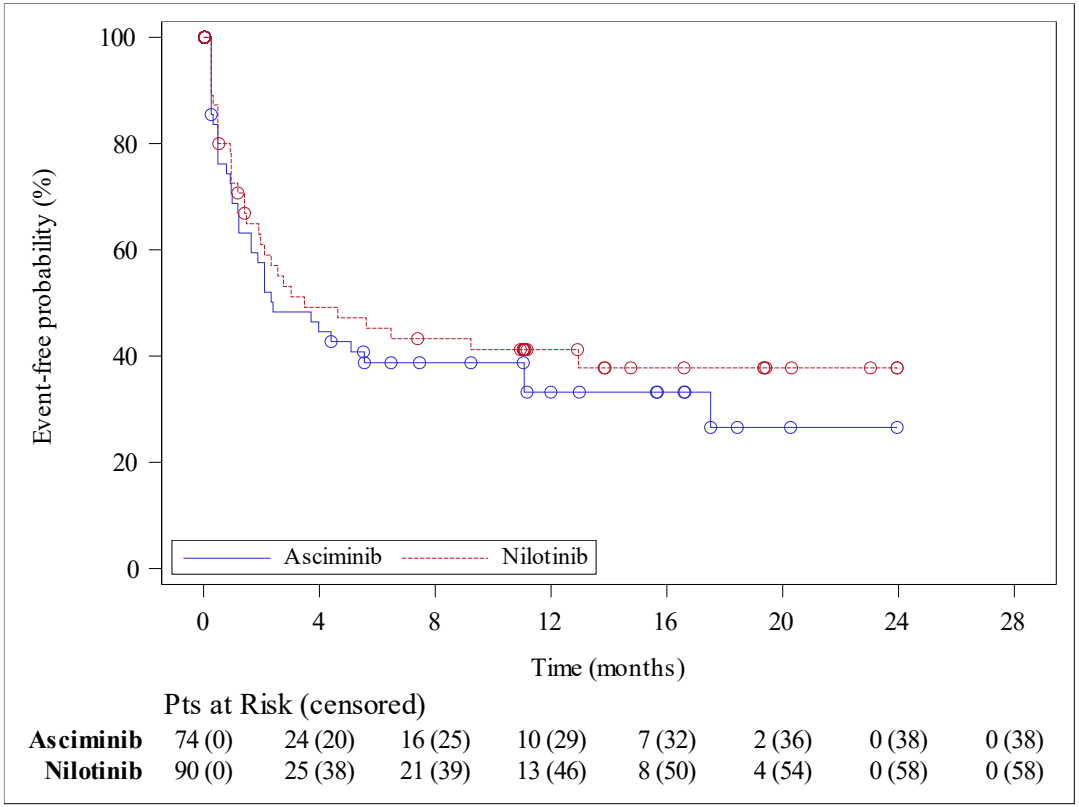
Diarrhea - Frequency (MID=1): Geographic region: Germany



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Figure 3-2.4 PRO-CTCAE - Frequency: Time to first deterioration analysis by subgroups: Kaplan-Meier plot by subgroups (Full Analysis Set)

Diarrhea - Frequency (MID=1): Geographic region: Others



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Table 3-2.5 PRO-CTCAE - Severity: Time to first deterioration analysis by subgroups (Full Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Fatigue - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.639)							
Low	60/171 (35.1)	1.8 [1.0; 5.9]	62/172 (36.0)	2.3 [1.0; 5.4]	0.98	[0.69; 1.41]	0.692
Intermediate	26/75 (34.7)	7.4 [2.3; 17.5]	27/75 (36.0)	2.8 [0.7; 5.6]	0.70	[0.41; 1.21]	0.155
High	13/38 (34.2)	11.1 [1.0; N.E.]	9/37 (24.3)	12.9 [0.3; N.E.]	0.67	[0.28; 1.59]	0.609
Sex							
(Interaction test: p = 0.990)							
Female	42/107 (39.3)	1.8 [1.0; 9.2]	45/126 (35.7)	2.8 [1.0; 5.6]	0.93	[0.60; 1.45]	0.961
Male	57/177 (32.2)	5.9 [2.1; 11.1]	53/158 (33.5)	2.6 [0.7; 6.5]	0.89	[0.61; 1.30]	0.603

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Race							
(Interaction test: p = 0.491)							
Asian	20/40 (50.0)	1.9 [1.0; N.E.]	23/46 (50.0)	5.5 [0.7; 11.1]	0.75	[0.40; 1.41]	0.681
White	74/227 (32.6)	5.6 [1.9; 11.1]	72/217 (33.2)	1.9 [1.0; 3.5]	0.83	[0.59; 1.15]	0.353
Other	5/17 (29.4)	2.1 [0.3; N.E.]	3/21 (14.3)	N.E. [0.3; N.E.]	0.39	[0.01; 11.08]	0.148
Age groups							
(Interaction test: p = 0.697)							
18 - < 65 years	86/237 (36.3)	2.8 [1.4; 9.0]	89/247 (36.0)	2.8 [1.1; 5.5]	0.89	[0.66; 1.20]	0.863
65 - < 75 years	9/38 (23.7)	15.7 [1.0; N.E.]	8/24 (33.3)	0.7 [0.3; N.E.]	0.83	[0.30; 2.32]	0.570
>= 75 years	4/9 (44.4)	8.3 [0.5; N.E.]	1/13 (7.7)	N.E. [0.5; N.E.]	1.25	[0.08; 19.72]	0.610
Geographic region							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.511)							
Europe excluding Germany	49/138 (35.5)	5.6 [1.6; 17.5]	54/141 (38.3)	1.9 [1.0; 3.9]	0.76	[0.51; 1.13]	0.292
Germany	15/72 (20.8)	8.3 [0.3; 13.0]	9/53 (17.0)	1.9 [0.3; N.E.]	0.72	[0.28; 1.86]	0.850
Others	35/74 (47.3)	2.6 [1.1; 15.7]	35/90 (38.9)	5.6 [1.0; 12.9]	1.13	[0.69; 1.83]	0.568
Headache - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.821)							
Low	57/171 (33.3)	2.8 [1.8; 5.6]	65/172 (37.8)	1.7 [1.0; 4.0]	0.77	[0.54; 1.10]	0.305
Intermediate	23/75 (30.7)	4.2 [1.0; N.E.]	27/75 (36.0)	2.3 [0.5; 5.3]	0.68	[0.39; 1.19]	0.174
High	17/38 (44.7)	3.7 [1.6; N.E.]	13/37 (35.1)	1.0 [0.3; 5.3]	0.60	[0.29; 1.25]	0.201

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Sex							
(Interaction test: p = 0.488)							
Female	42/107 (39.3)	1.9 [0.5; 4.2]	49/126 (38.9)	1.7 [0.5; 3.3]	0.82	[0.54; 1.25]	0.446
Male	55/177 (31.1)	4.6 [2.6; 22.1]	56/158 (35.4)	2.0 [0.9; 8.3]	0.68	[0.46; 0.99]	0.090
Race							
(Interaction test: p = 0.139)							
Asian	18/40 (45.0)	5.6 [1.0; N.E.]	27/46 (58.7)	1.9 [0.5; 5.1]	0.60	[0.32; 1.09]	0.084
White	77/227 (33.9)	2.6 [1.9; 4.5]	71/217 (32.7)	1.7 [0.8; 4.2]	0.81	[0.59; 1.13]	0.504
Other	2/17 (11.8)	N.E. [0.5; N.E.]	7/21 (33.3)	1.8 [0.1; 5.3]	0.22	[0.03; 1.63]	0.094
Age groups							
(Interaction test: p = 0.141)							
18 - < 65 years	82/237	3.5 [2.1; 7.4]	95/247	1.6 [0.9; 3.5]	0.71	[0.53; 0.97]	0.057

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(34.6)		(38.5)				
65 - < 75 years	11/38	3.4 [1.2; N.E.]	8/24	2.8 [0.3; N.E.]	0.69	[0.24; 1.99]	0.623
	(28.9)		(33.3)				
>= 75 years	4/9	0.3 [0.3; N.E.]	2/13	9.3 [1.1; N.E.]	5.48	[0.29; 104.41]	0.202
	(44.4)		(15.4)				
Geographic region							
(Interaction test: p = 0.629)							
Europe excluding Germany	49/138	3.5 [1.9; 12.9]	53/141	1.6 [0.7; 7.4]	0.70	[0.47; 1.04]	0.238
	(35.5)		(37.6)				
Germany	15/72	4.4 [2.1; 9.0]	10/53	0.5 [0.3; N.E.]	0.42	[0.15; 1.14]	0.227
	(20.8)		(18.9)				
Others	33/74	2.4 [1.0; N.E.]	42/90	2.3 [1.0; 5.1]	0.78	[0.49; 1.23]	0.241
	(44.6)		(46.7)				
Vomiting - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.903)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Low	14/171 (8.2)	N.E. [N.E.; N.E.]	29/172 (16.9)	N.E. [18.4; N.E.]	0.45	[0.24; 0.85]	0.011
Intermediate	6/75 (8.0)	N.E. [17.5; N.E.]	9/75 (12.0)	N.E. [N.E.; N.E.]	0.44	[0.15; 1.32]	0.190
High	3/38 (7.9)	N.E. [N.E.; N.E.]	5/37 (13.5)	N.E. [3.5; N.E.]	0.39	[0.09; 1.75]	0.210
Sex							
(Interaction test: p = 0.966)							
Female	12/107 (11.2)	N.E. [22.1; N.E.]	24/126 (19.0)	N.E. [9.2; N.E.]	0.46	[0.23; 0.93]	0.025
Male	11/177 (6.2)	N.E. [N.E.; N.E.]	19/158 (12.0)	N.E. [N.E.; N.E.]	0.47	[0.22; 0.99]	0.039
Race							
(Interaction test: p = 0.844)							
Asian	6/40 (15.0)	N.E. [17.5; N.E.]	12/46 (26.1)	N.E. [12.0; N.E.]	0.54	[0.20; 1.50]	0.216
White	16/227	N.E. [N.E.; N.E.]	27/217	N.E. [N.E.; N.E.]	0.47	[0.25; 0.88]	0.016

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(7.0)		(12.4)				
Other	1/17	N.E. [2.8; N.E.]	4/21	17.1 [1.2; N.E.]	0.87	[0.05; 13.95]	0.857
	(5.9)		(19.0)				
Age groups							
(Interaction test: p = 0.955)							
18 - < 65 years	20/237	N.E. [N.E.; N.E.]	41/247	N.E. [18.4; N.E.]	0.43	[0.25; 0.74]	0.002
	(8.4)		(16.6)				
65 - < 75 years	2/38	N.E. [N.E.; N.E.]	2/24	N.E. [0.5; N.E.]	0.63	[0.08; 5.12]	0.555
	(5.3)		(8.3)				
>= 75 years	1/9	22.1 [N.E.; N.E.]	0/13	N.E. [N.E.; N.E.]	2.99	[0.03; 275.43]	0.317
	(11.1)						
Geographic region							
(Interaction test: p = 0.965)							
Europe excluding Germany	11/138	N.E. [N.E.; N.E.]	20/141	N.E. [18.4; N.E.]	0.46	[0.22; 0.97]	0.036
	(8.0)		(14.2)				
Germany	1/72	N.E. [N.E.; N.E.]	1/53	N.E. [N.E.; N.E.]	0.55	[0.03; 8.78]	0.666
	(1.4)		(1.9)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Others	11/74 (14.9)	N.E. [17.5; N.E.]	22/90 (24.4)	N.E. [9.2; N.E.]	0.43	[0.20; 0.91]	0.025
Nausea - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT (Interaction test: p = 0.537)							
Low	35/171 (20.5)	N.E. [11.0; N.E.]	51/172 (29.7)	5.5 [2.3; 24.9]	0.65	[0.42; 1.00]	0.047
Intermediate	13/75 (17.3)	22.1 [13.8; N.E.]	22/75 (29.3)	5.6 [2.1; N.E.]	0.37	[0.18; 0.76]	0.006
High	11/38 (28.9)	N.E. [1.9; N.E.]	9/37 (24.3)	3.5 [1.9; N.E.]	0.72	[0.30; 1.75]	0.492
Sex (Interaction test: p = 0.704)							
Female	30/107 (28.0)	15.7 [3.5; N.E.]	41/126 (32.5)	3.3 [1.7; 10.7]	0.64	[0.40; 1.04]	0.084
Male	29/177	N.E. [N.E.; N.E.]	41/158	18.4 [3.5; N.E.]	0.57	[0.35; 0.92]	0.013

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(16.4)		(25.9)				
Race							
(Interaction test: p = 0.942)							
Asian	11/40	N.E. [11.1; N.E.]	16/46	N.E. [1.9; N.E.]	0.68	[0.31; 1.47]	0.311
	(27.5)		(34.8)				
White	46/227	N.E. [13.8; N.E.]	62/217	4.6 [2.4; 18.4]	0.57	[0.38; 0.83]	0.003
	(20.3)		(28.6)				
Other	2/17	N.E. [0.5; N.E.]	4/21	18.4 [0.3; N.E.]	0.50	[0.07; 3.76]	0.648
	(11.8)		(19.0)				
Age groups							
(Interaction test: p = 0.567)							
18 - < 65 years	51/237	N.E. [15.7; N.E.]	75/247	5.5 [3.0; 22.0]	0.60	[0.42; 0.86]	0.004
	(21.5)		(30.4)				
65 - < 75 years	5/38	N.E. [8.3; N.E.]	6/24	7.4 [0.3; N.E.]	0.27	[0.06; 1.18]	0.054
	(13.2)		(25.0)				
>= 75 years	3/9	22.1 [0.5; N.E.]	1/13	N.E. [0.7; N.E.]	0.42	[0.02; 8.07]	0.695
	(33.3)		(7.7)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = 0.391)							
Europe excluding Germany	30/138 (21.7)	22.1 [13.8; N.E.]	47/141 (33.3)	3.9 [1.7; 18.4]	0.47	[0.30; 0.76]	0.002
Germany	9/72 (12.5)	N.E. [2.3; N.E.]	10/53 (18.9)	3.3 [0.3; N.E.]	0.56	[0.22; 1.44]	0.246
Others	20/74 (27.0)	N.E. [11.1; N.E.]	25/90 (27.8)	N.E. [3.5; N.E.]	0.82	[0.46; 1.49]	0.524
Edema - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.945)							
Low	31/171 (18.1)	N.E. [N.E.; N.E.]	34/172 (19.8)	N.E. [16.6; N.E.]	0.93	[0.57; 1.51]	0.758
Intermediate	14/75 (18.7)	22.1 [17.5; N.E.]	14/75 (18.7)	N.E. [5.6; N.E.]	0.90	[0.43; 1.88]	0.634
High	10/38	16.6 [2.8; N.E.]	7/37	N.E. [0.3; N.E.]	0.71	[0.27; 1.87]	0.642

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(26.3)		(18.9)				
Sex							
(Interaction test: p = 0.953)							
Female	31/107	7.4 [3.0; N.E.]	33/126	10.2 [3.7; N.E.]	0.91	[0.55; 1.51]	0.789
	(29.0)		(26.2)				
Male	24/177	N.E. [22.1; N.E.]	22/158	N.E. [N.E.; N.E.]	0.93	[0.52; 1.67]	0.785
	(13.6)		(13.9)				
Race							
(Interaction test: p = 0.379)							
Asian	11/40	N.E. [7.4; N.E.]	17/46	10.2 [2.3; N.E.]	0.54	[0.25; 1.17]	0.118
	(27.5)		(37.0)				
White	40/227	N.E. [17.5; N.E.]	34/217	N.E. [N.E.; N.E.]	1.03	[0.65; 1.64]	0.920
	(17.6)		(15.7)				
Other	4/17	11.1 [0.5; N.E.]	4/21	7.4 [0.3; N.E.]	0.92	[0.21; 3.97]	0.834
	(23.5)		(19.0)				
Age groups							
(Interaction test: p = 0.902)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
18 - < 65 years	48/237 (20.3)	22.1 [17.5; N.E.]	49/247 (19.8)	N.E. [16.6; N.E.]	0.90	[0.60; 1.35]	0.664
65 - < 75 years	7/38 (18.4)	N.E. [2.0; N.E.]	5/24 (20.8)	N.E. [0.3; N.E.]	0.59	[0.18; 2.01]	0.402
>= 75 years	0/9	N.E. [N.E.; N.E.]	1/13 (7.7)	N.E. [0.5; N.E.]	0.57	[0.00; 107.73]	0.221
Geographic region (Interaction test: p = 0.873)							
Europe excluding Germany	26/138 (18.8)	N.E. [17.5; N.E.]	27/141 (19.1)	N.E. [16.6; N.E.]	0.87	[0.51; 1.51]	0.621
Germany	7/72 (9.7)	22.1 [9.2; N.E.]	6/53 (11.3)	N.E. [1.8; N.E.]	0.68	[0.21; 2.20]	0.677
Others	22/74 (29.7)	N.E. [7.4; N.E.]	22/90 (24.4)	N.E. [5.6; N.E.]	0.94	[0.52; 1.73]	0.928
Muscle Pain - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.427)							
Low	55/171 (32.2)	2.8 [1.2; 9.2]	67/172 (39.0)	1.2 [0.5; 2.8]	0.73	[0.51; 1.05]	0.076
Intermediate	28/75 (37.3)	1.4 [0.8; 4.4]	26/75 (34.7)	2.8 [0.5; 15.7]	1.04	[0.61; 1.78]	0.988
High	13/38 (34.2)	N.E. [0.5; N.E.]	12/37 (32.4)	2.1 [0.5; 2.8]	0.63	[0.29; 1.40]	0.232
Sex							
(Interaction test: p = 0.754)							
Female	39/107 (36.4)	1.2 [0.5; 5.6]	50/126 (39.7)	1.4 [0.5; 2.6]	0.75	[0.49; 1.15]	0.125
Male	57/177 (32.2)	3.3 [1.4; 12.0]	55/158 (34.8)	2.8 [0.5; 6.5]	0.85	[0.58; 1.23]	0.355
Race							
(Interaction test: p = 0.414)							
Asian	16/40 (40.0)	11.0 [1.0; N.E.]	28/46 (60.9)	1.8 [0.5; 2.8]	0.56	[0.29; 1.06]	0.021

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
White	74/227 (32.6)	1.9 [1.0; 4.4]	71/217 (32.7)	1.4 [0.7; 3.0]	0.86	[0.62; 1.20]	0.369
Other	6/17 (35.3)	0.5 [0.3; 7.4]	6/21 (28.6)	3.8 [0.3; N.E.]	1.49	[0.25; 8.73]	0.761
Age groups (Interaction test: p = 0.322)							
18 - < 65 years	80/237 (33.8)	2.4 [1.0; 9.2]	94/247 (38.1)	1.4 [0.7; 2.8]	0.77	[0.57; 1.04]	0.069
65 - < 75 years	11/38 (28.9)	2.9 [0.7; N.E.]	9/24 (37.5)	2.1 [0.3; 2.8]	0.42	[0.14; 1.23]	0.104
>= 75 years	5/9 (55.6)	1.0 [0.3; N.E.]	2/13 (15.4)	15.7 [0.7; N.E.]	2.84	[0.24; 33.24]	0.261
Geographic region (Interaction test: p = 0.637)							
Europe excluding Germany	49/138 (35.5)	2.1 [1.2; 12.0]	50/141 (35.5)	2.6 [0.8; 6.5]	0.89	[0.60; 1.33]	0.634
Germany	13/72	2.2 [0.5; N.E.]	11/53	0.4 [0.3; 5.5]	0.66	[0.28; 1.55]	0.304

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(18.1)		(20.8)				
Others	34/74	2.7 [0.8; 15.7]	44/90	2.0 [0.5; 2.8]	0.74	[0.47; 1.17]	0.092
	(45.9)		(48.9)				
Pruritus - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.192)							
Low	55/171	3.7 [2.1; 8.3]	72/172	1.6 [0.8; 3.3]	0.63	[0.44; 0.90]	0.014
	(32.2)		(41.9)				
Intermediate	25/75	5.2 [2.8; N.E.]	27/75	1.9 [0.5; 13.0]	0.54	[0.31; 0.95]	0.072
	(33.3)		(36.0)				
High	12/38	N.E. [1.2; N.E.]	15/37	0.8 [0.5; 2.6]	0.33	[0.15; 0.70]	0.003
	(31.6)		(40.5)				
Sex							
(Interaction test: p = 0.878)							
Female	38/107	2.9 [1.4; 19.4]	51/126	1.0 [0.7; 2.3]	0.57	[0.37; 0.88]	0.010
	(35.5)		(40.5)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Male	54/177 (30.5)	6.1 [3.3; N.E.]	63/158 (39.9)	2.0 [1.0; 4.0]	0.57	[0.39; 0.82]	0.007
Race							
(Interaction test: p = 0.436)							
Asian	13/40 (32.5)	N.E. [2.8; N.E.]	24/46 (52.2)	1.8 [0.5; 8.3]	0.39	[0.20; 0.79]	0.014
White	72/227 (31.7)	4.0 [2.2; 9.2]	82/217 (37.8)	1.7 [0.8; 3.3]	0.62	[0.44; 0.85]	0.004
Other	7/17 (41.2)	1.9 [0.3; 5.6]	8/21 (38.1)	0.8 [0.3; 2.6]	0.76	[0.19; 2.97]	0.597
Age groups							
(Interaction test: p = 0.269)							
18 - < 65 years	80/237 (33.8)	4.0 [2.7; 9.2]	102/247 (41.3)	1.7 [1.0; 2.8]	0.59	[0.44; 0.80]	0.001
65 - < 75 years	9/38 (23.7)	24.0 [2.8; N.E.]	9/24 (37.5)	2.6 [0.3; 5.6]	0.34	[0.12; 0.94]	0.031
>= 75 years	3/9	2.1 [1.0; N.E.]	3/13	0.5 [N.E.; N.E.]	0.05	[0.00; 2.45]	0.014

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(33.3)		(23.1)				
Geographic region							
(Interaction test: p = 0.357)							
Europe excluding Germany	49/138	4.0 [2.1; 11.1]	61/141	2.1 [0.8; 3.5]	0.58	[0.39; 0.86]	0.007
	(35.5)		(43.3)				
Germany	12/72	19.4 [1.2; N.E.]	12/53	0.7 [0.3; 2.0]	0.39	[0.16; 0.96]	0.033
	(16.7)		(22.6)				
Others	31/74	3.3 [2.6; N.E.]	41/90	1.9 [0.7; 5.3]	0.64	[0.40; 1.04]	0.080
	(41.9)		(45.6)				
Increased Sweating - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.834)							
Low	40/171	22.1 [3.3; N.E.]	44/172	18.4 [3.9; N.E.]	0.98	[0.64; 1.51]	0.953
	(23.4)		(25.6)				
Intermediate	18/75	N.E. [1.7; N.E.]	15/75	19.4 [3.0; N.E.]	1.15	[0.57; 2.29]	0.740
	(24.0)		(20.0)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
High	8/38 (21.1)	N.E. [6.5; N.E.]	6/37 (16.2)	N.E. [7.4; N.E.]	0.87	[0.30; 2.51]	0.823
Sex							
(Interaction test: p = 0.280)							
Female	27/107 (25.2)	N.E. [2.8; N.E.]	34/126 (27.0)	11.0 [1.9; N.E.]	0.85	[0.51; 1.43]	0.753
Male	39/177 (22.0)	22.1 [8.3; N.E.]	31/158 (19.6)	19.4 [18.4; N.E.]	1.22	[0.76; 1.96]	0.518
Race							
(Interaction test: p = 0.113)							
Asian	7/40 (17.5)	N.E. [N.E.; N.E.]	16/46 (34.8)	12.9 [2.3; N.E.]	0.47	[0.19; 1.15]	0.109
White	55/227 (24.2)	22.1 [3.9; N.E.]	44/217 (20.3)	19.4 [11.1; N.E.]	1.23	[0.82; 1.83]	0.291
Other	4/17 (23.5)	N.E. [0.3; N.E.]	5/21 (23.8)	3.3 [0.3; N.E.]	1.31	[0.32; 5.42]	0.740
Age groups							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.716)							
18 - < 65 years	58/237 (24.5)	22.1 [7.4; N.E.]	58/247 (23.5)	19.4 [11.0; N.E.]	1.04	[0.72; 1.49]	0.782
65 - < 75 years	6/38 (15.8)	N.E. [3.3; N.E.]	5/24 (20.8)	19.4 [0.3; N.E.]	0.61	[0.17; 2.28]	0.601
>= 75 years	2/9 (22.2)	N.E. [1.0; N.E.]	2/13 (15.4)	1.0 [0.7; N.E.]	0.17	[0.01; 2.00]	0.116
Geographic region							
(Interaction test: p = 0.896)							
Europe excluding Germany	38/138 (27.5)	N.E. [2.8; N.E.]	38/141 (27.0)	18.4 [3.9; N.E.]	1.09	[0.69; 1.73]	0.724
Germany	11/72 (15.3)	11.1 [1.6; N.E.]	6/53 (11.3)	N.E. [0.3; N.E.]	1.07	[0.37; 3.14]	0.749
Others	17/74 (23.0)	N.E. [N.E.; N.E.]	21/90 (23.3)	N.E. [11.0; N.E.]	0.86	[0.45; 1.64]	0.590
Cough - Severity (MID=1)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.579)							
Low	51/171 (29.8)	9.2 [4.4; 14.8]	67/172 (39.0)	2.8 [1.4; 6.5]	0.75	[0.52; 1.08]	0.021
Intermediate	25/75 (33.3)	8.3 [2.0; 17.5]	18/75 (24.0)	13.8 [1.8; N.E.]	1.06	[0.57; 1.96]	0.623
High	15/38 (39.5)	11.1 [1.4; N.E.]	11/37 (29.7)	4.6 [1.6; N.E.]	0.81	[0.36; 1.79]	0.536
Sex							
(Interaction test: p = 0.254)							
Female	41/107 (38.3)	3.5 [1.4; 9.2]	42/126 (33.3)	3.9 [1.8; 10.2]	0.93	[0.59; 1.45]	0.789
Male	50/177 (28.2)	13.8 [5.6; N.E.]	54/158 (34.2)	4.6 [1.7; 11.1]	0.74	[0.50; 1.10]	0.042
Race							
(Interaction test: p = 0.666)							

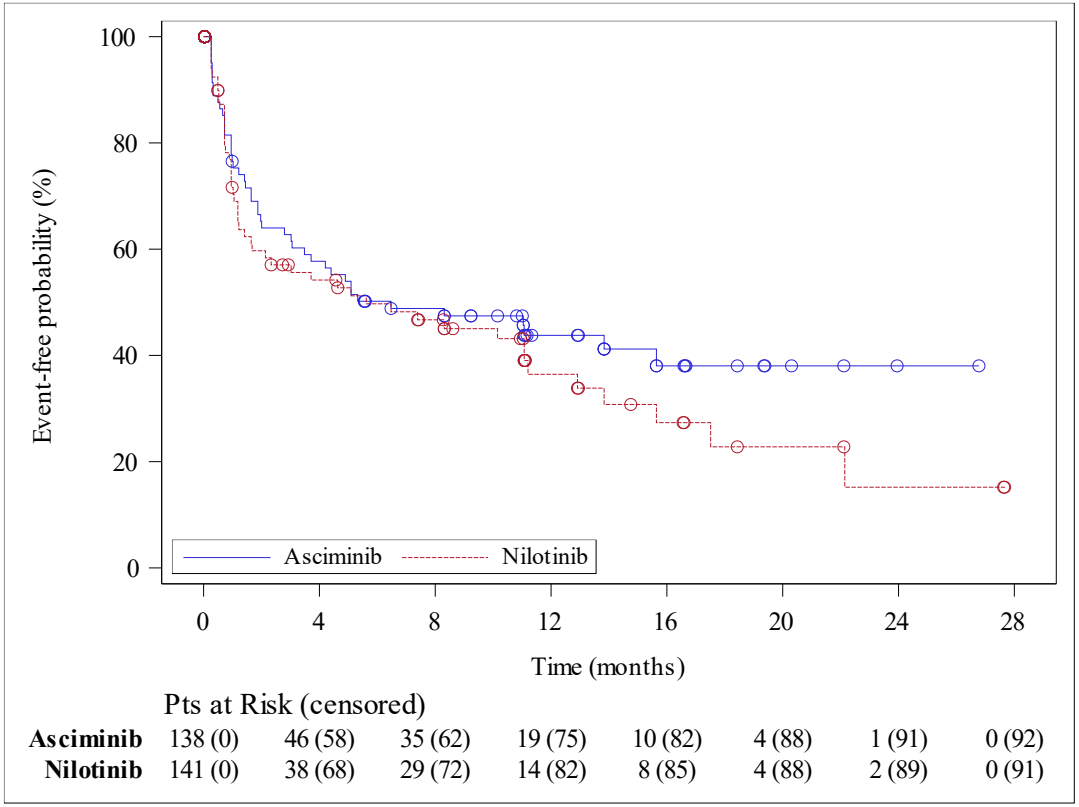
	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Asian	19/40 (47.5)	11.0 [2.8; N.E.]	24/46 (52.2)	4.4 [1.9; 7.4]	0.87	[0.45; 1.66]	0.307
White	68/227 (30.0)	9.2 [4.4; 14.8]	69/217 (31.8)	3.3 [1.4; 10.2]	0.76	[0.54; 1.07]	0.081
Other	4/17 (23.5)	2.8 [0.5; N.E.]	3/21 (14.3)	N.E. [0.3; N.E.]	0.17	[0.02; 1.93]	0.841
Age groups (Interaction test: p = 0.100)							
18 - < 65 years	79/237 (33.3)	6.5 [4.2; 13.8]	88/247 (35.6)	3.9 [2.1; 7.4]	0.85	[0.62; 1.16]	0.092
65 - < 75 years	8/38 (21.1)	14.8 [4.9; N.E.]	7/24 (29.2)	2.0 [0.5; N.E.]	0.23	[0.07; 0.74]	0.017
>= 75 years	4/9 (44.4)	2.8 [1.0; N.E.]	1/13 (7.7)	22.1 [N.E.; N.E.]	1.59	[0.00; 28200]	0.056
Geographic region (Interaction test: p = 0.036)							
Europe excluding Germany	46/138	6.5 [3.0; N.E.]	50/141	5.6 [1.6; 11.2]	0.81	[0.54; 1.21]	0.315

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(33.3)		(35.5)				
Germany	13/72	13.8 [1.7; N.E.]	13/53	0.5 [0.5; 1.7]	0.34	[0.14; 0.83]	0.005
	(18.1)		(24.5)				
Others	32/74	9.2 [4.0; 17.5]	33/90	5.4 [2.8; 19.4]	1.07	[0.65; 1.79]	0.801
	(43.2)		(36.7)				

MID: Minimally important difference
N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
If there are not at least 10 patients in every subgroup or not more than 10 events per subgroup per treatment arm, no subgroup analyses were performed for the corresponding attribute.
If there are not more than 10 events per subgroup per treatment arm, no Cox PH hazard analysis is carried out.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variables ELTS Score (IRT) and covariates treatment arm and baseline PRO score.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variables ELTS Score (IRT).
For the subgroup of Stratification factor: ELTS based on IRT randomisation data not stratification factor was included in the Cox PH model and an unstratitfied log-rank test was applied
The reference group in the (stratified) Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/2025-05-15

Figure 3-2.5 PRO-CTCAE - Severity: Time to first deterioration analysis by subgroups: Kaplan-Meier plot by subgroups (Full Analysis Set)

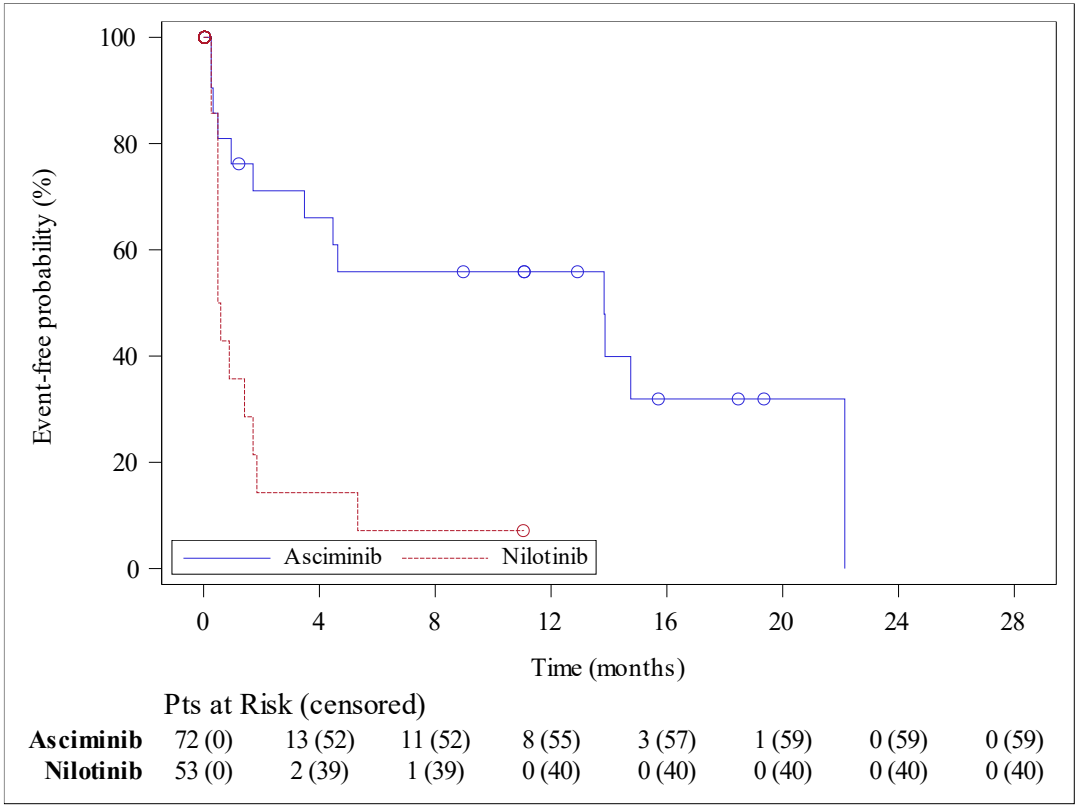
Cough - Severity (MID=1): Geographic region: Europe excluding Germany



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Figure 3-2.5 PRO-CTCAE - Severity: Time to first deterioration analysis by subgroups: Kaplan-Meier plot by subgroups (Full Analysis Set)

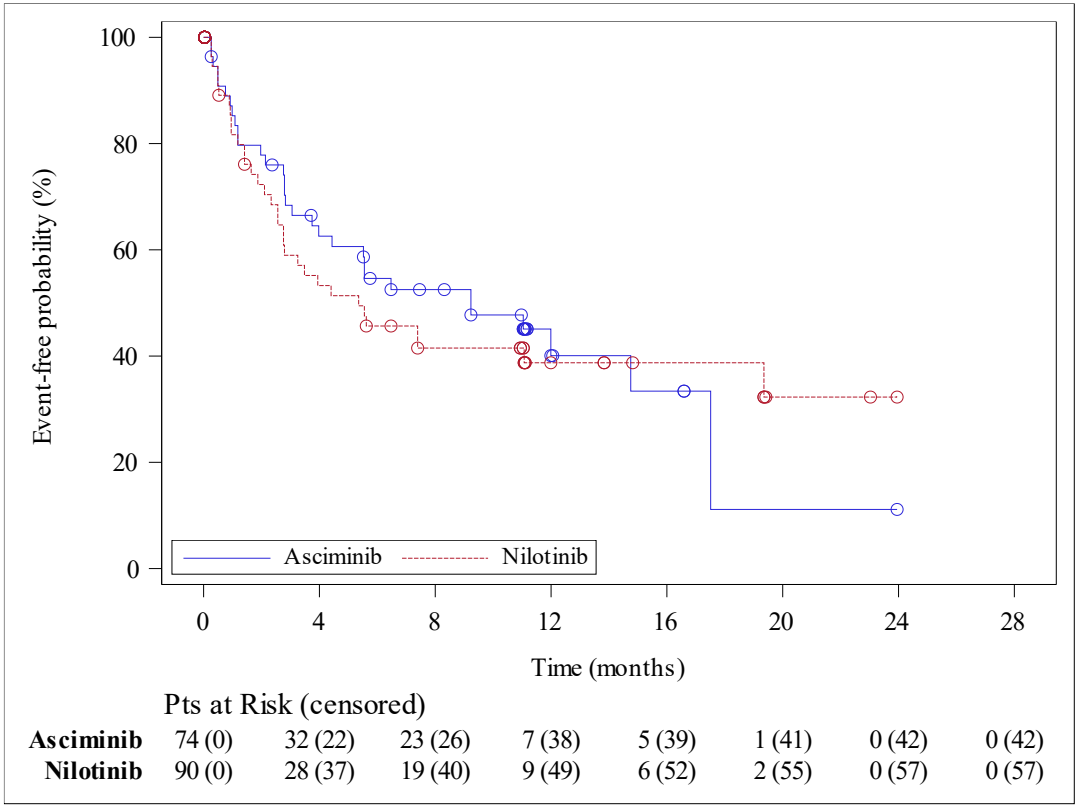
Cough - Severity (MID=1): Geographic region: Germany



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Figure 3-2.5 PRO-CTCAE - Severity: Time to first deterioration analysis by subgroups: Kaplan-Meier plot by subgroups (Full Analysis Set)

Cough - Severity (MID=1): Geographic region: Others



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Table 3-2.6 PRO-CTCAE - Interference: Time to first deterioration analysis by subgroups (Full Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Fatigue - Interference (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.719)							
Low	63/171 (36.8)	2.8 [1.4; 5.2]	55/172 (32.0)	2.8 [1.0; 16.6]	1.15	[0.80; 1.65]	0.261
Intermediate	27/75 (36.0)	4.4 [1.7; 11.1]	27/75 (36.0)	8.3 [0.7; 13.0]	1.00	[0.58; 1.71]	0.857
High	13/38 (34.2)	N.E. [2.9; N.E.]	8/37 (21.6)	11.0 [0.5; N.E.]	0.78	[0.32; 1.89]	0.714
Sex							
(Interaction test: p = 0.628)							
Female	43/107 (40.2)	2.8 [1.0; 5.3]	41/126 (32.5)	2.8 [1.0; 11.0]	1.16	[0.74; 1.80]	0.410
Male	60/177 (33.9)	4.6 [2.4; 11.0]	49/158 (31.0)	3.3 [0.7; 19.4]	1.02	[0.69; 1.50]	0.763

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Race							
(Interaction test: p = 0.790)							
Asian	21/40 (52.5)	3.7 [1.0; 11.0]	23/46 (50.0)	4.7 [0.5; 16.6]	0.99	[0.53; 1.85]	0.717
White	78/227 (34.4)	3.7 [2.2; 8.3]	63/217 (29.0)	3.0 [1.0; 13.0]	1.10	[0.79; 1.54]	0.485
Other	4/17 (23.5)	2.8 [0.5; N.E.]	4/21 (19.0)	N.E. [0.3; N.E.]	0.42	[0.06; 2.90]	0.924
Age groups							
(Interaction test: p = 0.673)							
18 - < 65 years	92/237 (38.8)	3.5 [2.1; 6.5]	81/247 (32.8)	3.3 [1.1; 11.0]	1.09	[0.81; 1.48]	0.293
65 - < 75 years	9/38 (23.7)	5.6 [1.0; N.E.]	7/24 (29.2)	1.1 [0.3; N.E.]	0.76	[0.26; 2.21]	0.610
>= 75 years	2/9 (22.2)	N.E. [0.5; N.E.]	2/13 (15.4)	16.6 [0.7; N.E.]	11.34	[0.07; 1861.5]	0.464
Geographic region							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.604)							
Europe excluding Germany	53/138 (38.4)	3.5 [1.0; 8.3]	47/141 (33.3)	2.8 [1.0; 16.6]	1.11	[0.74; 1.66]	0.448
Germany	17/72 (23.6)	3.5 [1.6; 9.0]	9/53 (17.0)	1.9 [0.3; N.E.]	0.63	[0.24; 1.64]	0.779
Others	33/74 (44.6)	4.4 [2.4; 17.5]	34/90 (37.8)	8.3 [1.0; 19.4]	1.02	[0.62; 1.66]	0.981
Headache - Interference (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.960)							
Low	51/171 (29.8)	4.9 [2.8; 15.7]	61/172 (35.5)	2.3 [1.7; 4.2]	0.72	[0.49; 1.04]	0.122
Intermediate	16/75 (21.3)	N.E. [6.5; N.E.]	19/75 (25.3)	8.3 [2.6; N.E.]	0.68	[0.35; 1.33]	0.257
High	15/38 (39.5)	4.4 [1.9; N.E.]	10/37 (27.0)	4.6 [0.5; N.E.]	0.82	[0.37; 1.84]	0.694

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Sex							
(Interaction test: p = 0.638)							
Female	40/107 (37.4)	3.0 [1.9; 8.3]	45/126 (35.7)	2.3 [1.2; 3.3]	0.78	[0.51; 1.20]	0.317
Male	42/177 (23.7)	22.1 [7.5; N.E.]	45/158 (28.5)	8.3 [2.1; N.E.]	0.69	[0.45; 1.05]	0.104
Race							
(Interaction test: p = 0.414)							
Asian	16/40 (40.0)	8.3 [1.9; N.E.]	24/46 (52.2)	2.9 [1.0; 10.2]	0.67	[0.36; 1.28]	0.170
White	64/227 (28.2)	9.0 [3.8; 19.4]	61/217 (28.1)	3.0 [2.1; 14.8]	0.80	[0.56; 1.14]	0.299
Other	2/17 (11.8)	N.E. [0.5; N.E.]	5/21 (23.8)	2.6 [0.1; N.E.]	0.20	[0.03; 1.47]	0.165
Age groups							
(Interaction test: p = 0.461)							
18 - < 65 years	70/237	8.3 [3.8; N.E.]	85/247	2.8 [1.9; 5.4]	0.68	[0.50; 0.94]	0.024

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(29.5)		(34.4)				
65 - < 75 years	9/38	16.6 [2.3; N.E.]	3/24	N.E. [0.9; N.E.]	1.78	[0.43; 7.45]	0.357
	(23.7)		(12.5)				
>= 75 years	3/9	19.4 [0.3; N.E.]	2/13	14.8 [1.1; N.E.]	0.43	[0.04; 4.84]	0.485
	(33.3)		(15.4)				
Geographic region							
(Interaction test: p = 0.390)							
Europe excluding Germany	43/138	11.2 [3.0; N.E.]	46/141	3.0 [1.7; 16.6]	0.76	[0.50; 1.16]	0.304
	(31.2)		(32.6)				
Germany	12/72	9.0 [4.4; N.E.]	10/53	2.3 [0.3; 5.6]	0.29	[0.11; 0.75]	0.010
	(16.7)		(18.9)				
Others	27/74	8.3 [2.4; N.E.]	34/90	4.2 [1.9; 13.8]	0.77	[0.47; 1.28]	0.318
	(36.5)		(37.8)				
Edema - Interference (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.394)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Low	23/171 (13.5)	N.E. [N.E.; N.E.]	29/172 (16.9)	N.E. [N.E.; N.E.]	0.79	[0.46; 1.36]	0.397
Intermediate	13/75 (17.3)	22.1 [17.5; N.E.]	9/75 (12.0)	N.E. [N.E.; N.E.]	1.26	[0.52; 3.05]	0.536
High	6/38 (15.8)	N.E. [N.E.; N.E.]	6/37 (16.2)	N.E. [0.3; N.E.]	0.45	[0.14; 1.39]	0.252
Sex							
(Interaction test: p = 0.630)							
Female	22/107 (20.6)	22.1 [17.5; N.E.]	27/126 (21.4)	N.E. [5.1; N.E.]	0.76	[0.43; 1.36]	0.356
Male	20/177 (11.3)	N.E. [N.E.; N.E.]	17/158 (10.8)	N.E. [N.E.; N.E.]	1.02	[0.53; 1.94]	0.964
Race							
(Interaction test: p = 0.265)							
Asian	10/40 (25.0)	17.5 [17.5; N.E.]	16/46 (34.8)	N.E. [3.0; N.E.]	0.49	[0.21; 1.11]	0.083
White	28/227	N.E. [22.1; N.E.]	26/217	N.E. [N.E.; N.E.]	0.95	[0.55; 1.63]	0.848

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(12.3)		(12.0)				
Other	4/17	7.4 [0.5; N.E.]	2/21	N.E. [0.3; N.E.]	2.06	[0.30; 13.90]	0.394
	(23.5)		(9.5)				
Age groups							
(Interaction test: p = 0.866)							
18 - < 65 years	36/237	N.E. [N.E.; N.E.]	40/247	N.E. [N.E.; N.E.]	0.85	[0.54; 1.33]	0.476
	(15.2)		(16.2)				
65 - < 75 years	5/38	N.E. [5.6; N.E.]	3/24	N.E. [0.3; N.E.]	0.84	[0.19; 3.64]	0.820
	(13.2)		(12.5)				
>= 75 years	1/9	22.1 [N.E.; N.E.]	1/13	N.E. [1.1; N.E.]	0.57	[0.00; 107.73]	0.221
	(11.1)		(7.7)				
Geographic region							
(Interaction test: p = 0.698)							
Europe excluding Germany	20/138	N.E. [22.1; N.E.]	21/141	N.E. [N.E.; N.E.]	0.88	[0.47; 1.65]	0.708
	(14.5)		(14.9)				
Germany	5/72	N.E. [9.2; N.E.]	2/53	N.E. [N.E.; N.E.]	0.73	[0.12; 4.65]	0.911
	(6.9)		(3.8)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Others	17/74 (23.0)	N.E. [17.5; N.E.]	21/90 (23.3)	N.E. [5.6; N.E.]	0.73	[0.38; 1.40]	0.396
Muscle Pain - Interference (MID=1)							
Stratification factor: ELTS based on randomization data from IRT (Interaction test: p = 0.061)							
Low	48/171 (28.1)	5.1 [3.0; N.E.]	55/172 (32.0)	2.6 [1.0; 16.6]	0.78	[0.53; 1.15]	0.246
Intermediate	29/75 (38.7)	1.4 [0.8; 2.8]	19/75 (25.3)	13.9 [0.9; N.E.]	1.64	[0.92; 2.94]	0.087
High	14/38 (36.8)	4.6 [0.8; N.E.]	11/37 (29.7)	2.7 [0.5; N.E.]	0.64	[0.29; 1.42]	0.386
Sex (Interaction test: p = 0.573)							
Female	40/107 (37.4)	1.5 [0.7; 4.9]	40/126 (31.7)	2.1 [1.0; 2.8]	1.06	[0.68; 1.65]	0.822
Male	51/177	5.1 [3.3; N.E.]	45/158	9.2 [1.1; N.E.]	0.91	[0.61; 1.36]	0.757

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(28.8)		(28.5)				
Race							
(Interaction test: p = 0.228)							
Asian	21/40	2.9 [1.0; 11.0]	22/46	2.5 [0.5; N.E.]	0.95	[0.52; 1.74]	0.904
	(52.5)		(47.8)				
White	64/227	4.4 [2.1; N.E.]	60/217	2.8 [1.2; 16.6]	0.87	[0.61; 1.24]	0.519
	(28.2)		(27.6)				
Other	6/17	0.5 [0.3; 7.4]	3/21	N.E. [0.3; N.E.]	1.90	[0.32; 11.41]	0.322
	(35.3)		(14.3)				
Age groups							
(Interaction test: p = 0.557)							
18 - < 65 years	76/237	4.4 [2.3; 12.0]	74/247	4.7 [1.6; 18.4]	0.93	[0.67; 1.28]	0.715
	(32.1)		(30.0)				
65 - < 75 years	10/38	6.4 [1.0; N.E.]	9/24	2.4 [0.3; 4.4]	0.48	[0.17; 1.34]	0.383
	(26.3)		(37.5)				
>= 75 years	5/9	1.5 [0.5; N.E.]	2/13	0.7 [0.5; N.E.]	0.10	[0.00; 3.88]	0.586
	(55.6)		(15.4)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = 0.360)							
Europe excluding Germany	43/138 (31.2)	4.4 [1.9; N.E.]	43/141 (30.5)	5.4 [1.2; N.E.]	0.91	[0.59; 1.41]	0.789
Germany	13/72 (18.1)	3.1 [0.5; N.E.]	10/53 (18.9)	0.5 [0.3; N.E.]	0.68	[0.27; 1.69]	0.347
Others	35/74 (47.3)	3.0 [1.0; 7.4]	32/90 (35.6)	3.3 [1.0; N.E.]	1.13	[0.70; 1.83]	0.617
Cough - Interference (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.548)							
Low	31/171 (18.1)	22.1 [17.5; N.E.]	41/172 (23.8)	15.7 [10.2; N.E.]	0.74	[0.46; 1.18]	0.191
Intermediate	21/75 (28.0)	14.8 [6.5; 17.5]	15/75 (20.0)	N.E. [3.5; N.E.]	1.00	[0.51; 1.97]	0.659
High	9/38	N.E. [11.1; N.E.]	8/37	11.0 [2.8; N.E.]	0.59	[0.23; 1.54]	0.351

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(23.7)		(21.6)				
Sex							
(Interaction test: p = 0.206)							
Female	31/107	13.9 [4.9; 17.5]	29/126	11.1 [7.4; N.E.]	0.95	[0.56; 1.60]	0.727
	(29.0)		(23.0)				
Male	30/177	22.1 [17.5; N.E.]	35/158	N.E. [7.4; N.E.]	0.65	[0.40; 1.07]	0.078
	(16.9)		(22.2)				
Race							
(Interaction test: p = 0.431)							
Asian	13/40	17.5 [5.3; N.E.]	14/46	N.E. [7.4; N.E.]	0.83	[0.38; 1.83]	0.875
	(32.5)		(30.4)				
White	44/227	22.1 [13.9; N.E.]	47/217	13.8 [8.3; N.E.]	0.72	[0.47; 1.09]	0.120
	(19.4)		(21.7)				
Other	4/17	2.8 [0.5; N.E.]	3/21	15.7 [2.8; N.E.]	3.38	[0.35; 32.25]	0.124
	(23.5)		(14.3)				
Age groups							
(Interaction test: p = 0.043)							

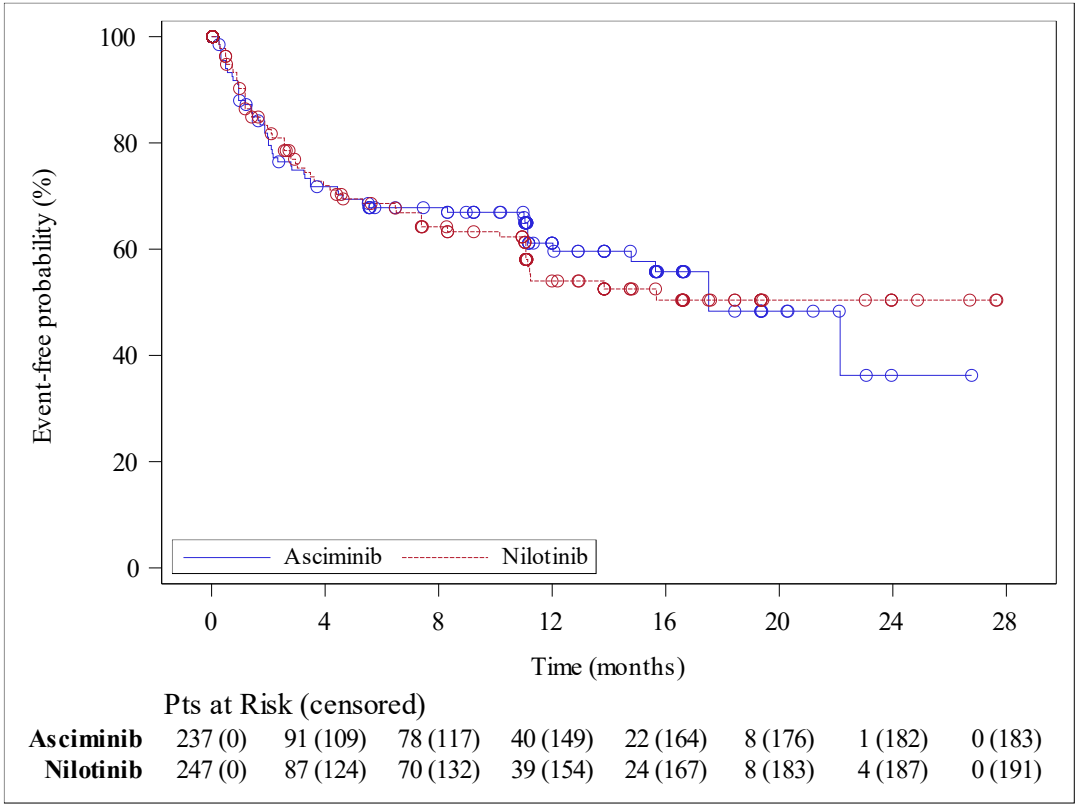
	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
18 - < 65 years	54/237 (22.8)	17.5 [12.0; N.E.]	56/247 (22.7)	N.E. [11.1; N.E.]	0.90	[0.62; 1.31]	0.688
65 - < 75 years	3/38 (7.9)	N.E. [13.9; N.E.]	5/24 (20.8)	N.E. [0.3; N.E.]	0.17	[0.03; 0.88]	0.036
>= 75 years	4/9 (44.4)	6.5 [1.0; N.E.]	3/13 (23.1)	0.8 [0.5; N.E.]	0.18	[0.02; 1.84]	0.071
Geographic region (Interaction test: p = 0.181)							
Europe excluding Germany	27/138 (19.6)	N.E. [13.9; N.E.]	35/141 (24.8)	13.8 [6.5; N.E.]	0.65	[0.39; 1.09]	0.110
Germany	11/72 (15.3)	13.9 [4.5; N.E.]	9/53 (17.0)	2.1 [0.7; N.E.]	0.48	[0.17; 1.37]	0.139
Others	23/74 (31.1)	17.5 [12.0; 17.5]	20/90 (22.2)	N.E. [11.1; N.E.]	1.22	[0.66; 2.27]	0.456

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			

MID: Minimally important difference
N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
If there are not at least 10 patients in every subgroup or not more than 10 events per subgroup per treatment arm, no subgroup analyses were performed for the corresponding attribute.
If there are not more than 10 events per subgroup per treatment arm, no Cox PH hazard analysis is carried out.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variables ELTS Score (IRT) and covariates treatment arm and baseline PRO score.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variables ELTS Score (IRT).
For the subgroup of Stratification factor: ELTS based on IRT randomisation data not stratification factor was included in the Cox PH model and an unstratitfied log-rank test was applied
The reference group in the (stratified) Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/2025-05-15

Figure 3-2.6 PRO-CTCAE - Interference: Time to first deterioration analysis by subgroups: Kaplan-Meier plot by subgroups (Full Analysis Set)

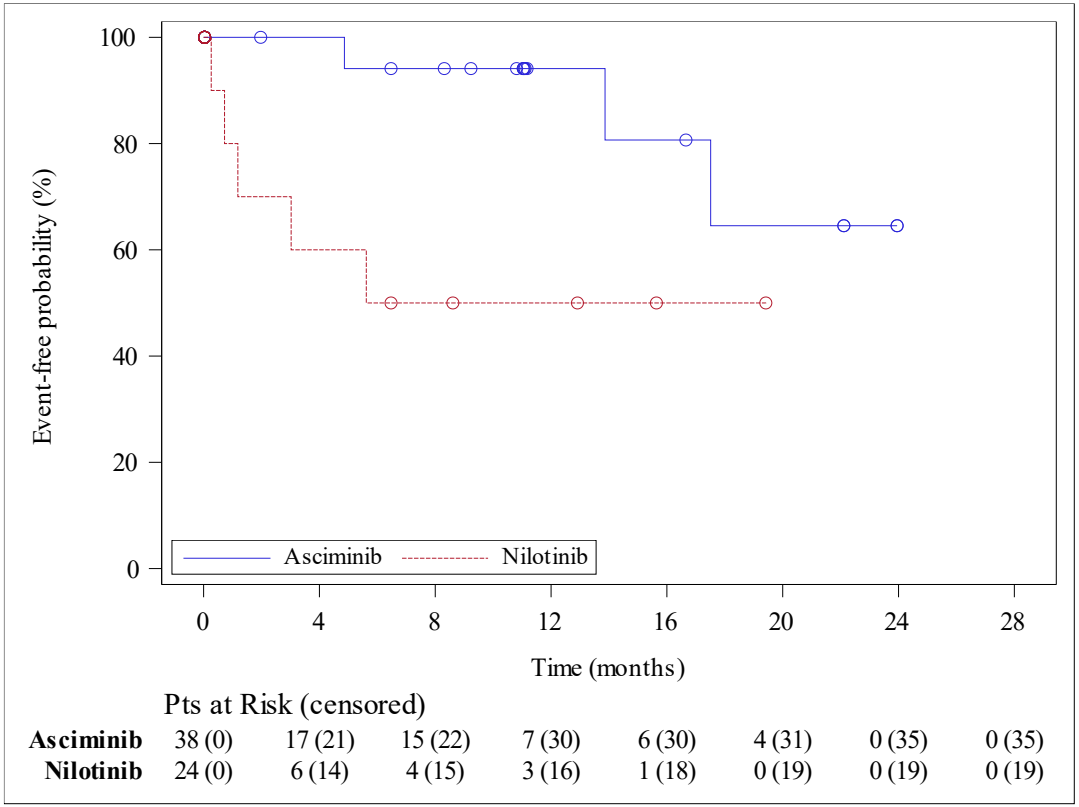
Cough - Interference (MID=1): Age groups: 18 - < 65 years



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Figure 3-2.6 PRO-CTCAE - Interference: Time to first deterioration analysis by subgroups: Kaplan-Meier plot by subgroups (Full Analysis Set)

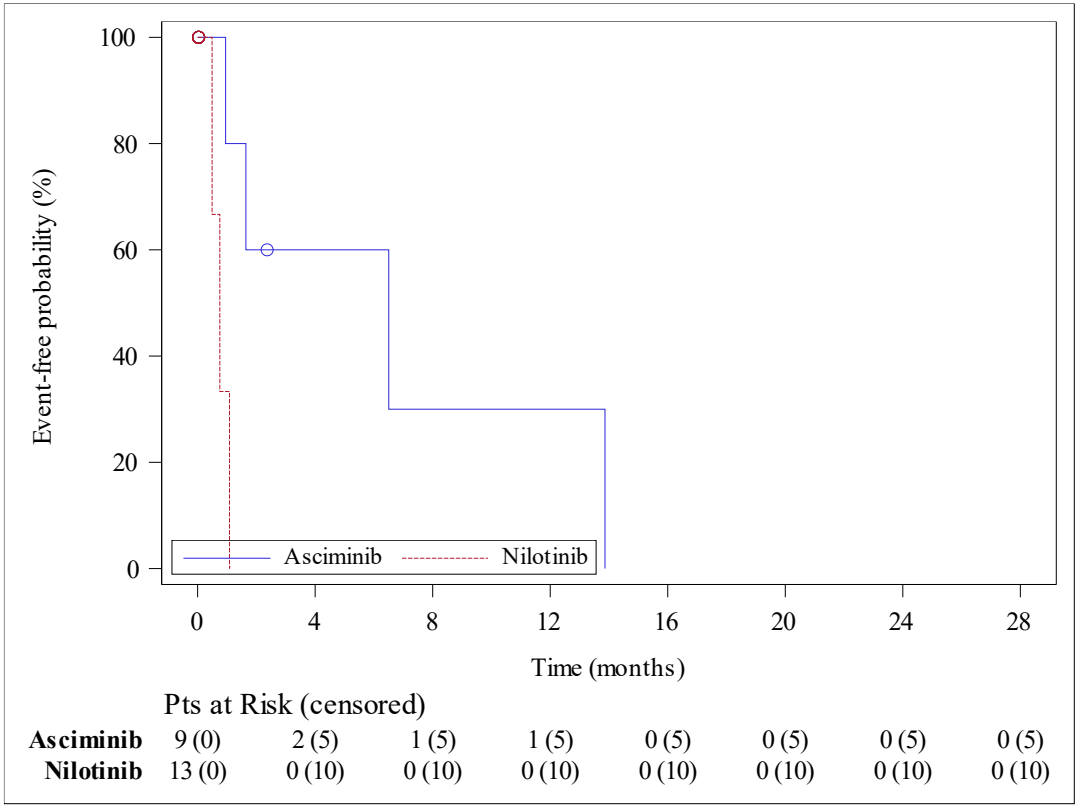
Cough - Interference (MID=1): Age groups: 65 - < 75 years



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Figure 3-2.6 PRO-CTCAE - Interference: Time to first deterioration analysis by subgroups: Kaplan-Meier plot by subgroups (Full Analysis Set)

Cough - Interference (MID=1): Age groups: >= 75 years



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Table 3-3.1: MMRM - EORTC QLQ-C30 (Full Analysis Set)

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
EORTC QLQ-C30: Appetite loss									
Baseline	168	9.8 (17.1)			165	8.8 (16.5)			
Week 4	255	6.1 (13.2)	151	-4.3 (1.0)	232	8.5 (14.5)	132	-2.2 (1.0)	-2.0 [-4.7; 0.6] 0.132
Week 8	175	3.9 (11.5)	114	-5.0 (1.0)	150	6.8 (13.2)	94	-3.1 (1.1)	-1.9 [-4.8; 1.0] 0.197
Week 12	230	4.7 (13.3)	143	-4.1 (1.1)	210	7.3 (15.2)	130	-2.6 (1.2)	-1.4 [-4.5; 1.7] 0.365
Week 24	210	3.2 (8.7)	134	-5.2 (1.1)	191	6.4 (14.6)	120	-2.6 (1.1)	-2.6 [-5.5; 0.2] 0.071
Week 48	188	4.5 (12.9)	114	-5.7 (1.1)	164	5.6 (13.4)	109	-3.3 (1.1)	-2.4 [-5.3; 0.5] 0.102
Overall treatment effect			163	-4.9 (0.8)			155	-2.8 (0.9)	-2.1 [-4.2; 0.0] 0.055
EORTC QLQ-C30: Cognitive functioning									
Baseline	168	92.3 (11.7)			165	91.2 (11.6)			
Week 4	255	93.3 (10.7)	151	1.9 (0.8)	232	90.4 (13.3)	132	1.1 (0.9)	0.8 [-1.4; 3.0] 0.485
Week 8	175	91.1 (12.3)	114	0.3 (1.0)	150	88.6 (13.5)	94	-1.1 (1.1)	1.4 [-1.5; 4.2] 0.345
Week 12	230	91.6 (12.6)	143	0.1 (1.0)	210	87.8 (14.9)	130	-1.5 (1.0)	1.6 [-1.1; 4.3] 0.249
Week 24	210	91.3 (13.0)	134	-0.3 (1.1)	191	87.4 (15.8)	120	-3.8 (1.2)	3.5 [0.4; 6.6] 0.027

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 48	188	89.9 (14.0)	114	-1.1 (1.2)	164	88.5 (14.7)	109	-2.3 (1.2)	1.1 [-2.0; 4.3] 0.477
Overall treatment effect			163	0.2 (0.8)			155	-1.5 (0.9)	1.7 [-0.5; 3.8] 0.124
EORTC QLQ-C30: Constipation									
Baseline	168	6.7 (14.6)			165	10.6 (17.7)			
Week 4	255	6.3 (14.0)	151	-1.3 (1.3)	232	11.1 (18.8)	132	2.2 (1.4)	-3.4 [-6.9; 0.0] 0.051
Week 8	175	6.4 (15.1)	114	-1.1 (1.4)	150	11.3 (18.0)	94	1.6 (1.5)	-2.7 [-6.6; 1.2] 0.175
Week 12	230	5.8 (14.1)	143	-1.5 (1.3)	210	11.3 (19.3)	130	1.8 (1.4)	-3.3 [-6.9; 0.3] 0.074
Week 24	210	4.8 (12.5)	134	-2.5 (1.3)	191	11.6 (18.5)	120	2.0 (1.3)	-4.5 [-7.9; -1.1] 0.010
Week 48	188	5.9 (13.9)	114	-1.1 (1.5)	164	11.6 (18.7)	109	2.9 (1.5)	-4.1 [-8.0; -0.1] 0.045
Overall treatment effect			163	-1.5 (1.0)			155	2.1 (1.0)	-3.6 [-6.1; -1.1] 0.005
EORTC QLQ-C30: Diarrhoea									
Baseline	168	7.4 (16.3)			165	5.0 (12.1)			
Week 4	255	6.5 (13.0)	151	-1.1 (1.0)	232	5.5 (12.3)	132	0.8 (1.1)	-1.9 [-4.7; 0.8] 0.171
Week 8	175	7.0 (13.8)	114	0.1 (1.3)	150	5.7 (14.2)	94	1.3 (1.4)	-1.2 [-4.8; 2.4] 0.518
Week 12	230	7.0 (13.2)	143	-0.9 (1.0)	210	6.2 (12.1)	130	1.4 (1.0)	-2.3 [-5.0; 0.4] 0.097

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 24	210	8.5 (14.6)	134	0.9 (1.1)	191	6.3 (13.8)	120	1.9 (1.2)	-1.0 [-4.1; 2.1] 0.513
Week 48	188	7.2 (14.5)	114	-0.8 (1.1)	164	5.0 (12.4)	109	1.1 (1.2)	-1.9 [-5.0; 1.2] 0.232
Overall treatment effect			163	-0.3 (0.8)			155	1.3 (0.8)	-1.7 [-3.7; 0.4] 0.117
EORTC QLQ-C30: Dyspnoea									
Baseline	168	10.4 (17.2)			165	12.3 (18.8)			
Week 4	255	10.7 (16.5)	151	-3.0 (1.3)	232	13.8 (19.0)	132	0.3 (1.3)	-3.4 [-6.8; 0.1] 0.056
Week 8	175	8.4 (15.5)	114	-4.2 (1.3)	150	11.2 (15.2)	94	-2.4 (1.4)	-1.8 [-5.3; 1.7] 0.312
Week 12	230	7.2 (13.7)	143	-4.7 (1.1)	210	9.8 (15.7)	130	-3.9 (1.2)	-0.8 [-3.9; 2.3] 0.616
Week 24	210	8.1 (14.9)	134	-3.9 (1.2)	191	9.2 (15.4)	120	-4.4 (1.2)	0.5 [-2.6; 3.6] 0.750
Week 48	188	9.0 (15.4)	114	-3.9 (1.3)	164	8.7 (15.1)	109	-3.7 (1.4)	-0.3 [-3.8; 3.3] 0.888
Overall treatment effect			163	-3.9 (0.9)			155	-2.8 (1.0)	-1.1 [-3.6; 1.3] 0.358
EORTC QLQ-C30: Emotional functioning									
Baseline	168	84.3 (15.5)			165	82.5 (14.0)			
Week 4	255	87.1 (14.1)	151	4.8 (1.0)	232	85.0 (13.7)	132	3.3 (1.0)	1.5 [-1.1; 4.1] 0.262
Week 8	175	87.1 (14.8)	114	4.6 (1.2)	150	84.2 (15.5)	94	1.6 (1.3)	3.0 [-0.3; 6.2] 0.074

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 12	230	86.7 (13.5)	143	3.2 (1.0)	210	84.4 (14.8)	130	2.3 (1.1)	0.9 [-1.9; 3.7] 0.510
Week 24	210	87.1 (14.6)	134	4.6 (1.0)	191	84.5 (14.5)	120	1.5 (1.1)	3.1 [0.2; 5.9] 0.033
Week 48	188	86.5 (15.5)	114	3.1 (1.2)	164	85.5 (14.7)	109	2.3 (1.2)	0.9 [-2.3; 4.1] 0.596
Overall treatment effect			163	4.1 (0.8)			155	2.2 (0.9)	1.9 [-0.3; 4.0] 0.087
EORTC QLQ-C30: Fatigue									
Baseline	168	22.7 (19.8)			165	24.2 (19.5)			
Week 4	255	20.3 (16.7)	151	-5.3 (1.2)	232	25.0 (18.6)	132	-1.1 (1.3)	-4.3 [-7.6; -1.0] 0.011
Week 8	175	21.1 (18.9)	114	-4.3 (1.4)	150	23.7 (18.3)	94	-3.5 (1.5)	-0.7 [-4.6; 3.1] 0.707
Week 12	230	17.9 (16.1)	143	-6.0 (1.3)	210	20.6 (17.0)	130	-4.6 (1.4)	-1.4 [-5.0; 2.2] 0.435
Week 24	210	17.6 (18.2)	134	-7.1 (1.3)	191	21.7 (18.2)	120	-3.7 (1.4)	-3.4 [-6.9; 0.1] 0.058
Week 48	188	19.9 (17.7)	114	-3.8 (1.4)	164	20.4 (18.4)	109	-5.0 (1.5)	1.2 [-2.8; 5.1] 0.564
Overall treatment effect			163	-5.3 (1.0)			155	-3.6 (1.1)	-1.7 [-4.4; 1.0] 0.210
EORTC QLQ-C30: Financial difficulties									
Baseline	168	11.2 (19.9)			165	9.8 (17.8)			
Week 4	255	9.5 (17.5)	151	-1.7 (1.2)	232	9.5 (17.9)	132	-3.4 (1.3)	1.6 [-1.7; 5.0] 0.331

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 8	175	10.3 (18.4)	114	-0.8 (1.5)	150	11.0 (18.7)	94	-2.3 (1.6)	1.5 [-2.6; 5.5] 0.470
Week 12	230	9.7 (17.7)	143	-0.9 (1.4)	210	9.3 (18.5)	130	-2.2 (1.5)	1.3 [-2.5; 5.2] 0.495
Week 24	210	7.4 (14.4)	134	-3.0 (1.3)	191	8.6 (17.5)	120	-3.4 (1.4)	0.4 [-3.1; 3.9] 0.834
Week 48	188	7.7 (16.4)	114	-3.1 (1.4)	164	8.2 (17.3)	109	-2.6 (1.5)	-0.4 [-4.3; 3.4] 0.824
Overall treatment effect			163	-1.9 (1.1)			155	-2.8 (1.2)	0.9 [-2.1; 3.8] 0.555
EORTC QLQ-C30: Nausea and vomiting									
Baseline	168	4.8 (9.9)			165	3.6 (8.4)			
Week 4	255	2.4 (6.8)	151	-1.9 (0.7)	232	4.5 (9.7)	132	0.9 (0.8)	-2.8 [-4.8; -0.8] 0.007
Week 8	175	2.5 (7.2)	114	-1.4 (0.7)	150	3.4 (7.5)	94	0.4 (0.8)	-1.8 [-3.8; 0.2] 0.070
Week 12	230	2.4 (6.7)	143	-1.7 (0.6)	210	2.8 (6.1)	130	-0.7 (0.6)	-1.0 [-2.5; 0.5] 0.204
Week 24	210	2.6 (8.5)	134	-0.7 (0.8)	191	3.7 (8.9)	120	0.5 (0.9)	-1.2 [-3.5; 1.1] 0.300
Week 48	188	2.7 (7.2)	114	-1.2 (0.7)	164	4.0 (9.6)	109	-0.1 (0.7)	-1.1 [-3.0; 0.8] 0.266
Overall treatment effect			163	-1.4 (0.5)			155	0.2 (0.5)	-1.6 [-2.9; -0.2] 0.024
EORTC QLQ-C30: Pain									
Baseline	168	12.5 (15.9)			165	11.7 (16.3)			
Week 4	255	12.5 (15.3)	151	0.1 (1.2)	232	13.3 (16.9)	132	1.0 (1.3)	-0.8 [-4.2; 2.5] 0.622

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 8	175	12.6 (17.5)	114	-0.4 (1.3)	150	12.5 (15.7)	94	-0.9 (1.4)	0.5 [-3.2; 4.1] 0.792
Week 12	230	10.8 (16.2)	143	-1.5 (1.2)	210	10.7 (13.9)	130	-1.2 (1.2)	-0.2 [-3.5; 3.0] 0.899
Week 24	210	8.9 (15.4)	134	-3.8 (1.1)	191	11.9 (16.2)	120	-0.9 (1.2)	-2.9 [-6.1; 0.2] 0.064
Week 48	188	11.0 (14.6)	114	-1.4 (1.2)	164	9.7 (13.5)	109	-3.1 (1.2)	1.7 [-1.5; 4.9] 0.306
Overall treatment effect			163	-1.4 (0.9)			155	-1.0 (0.9)	-0.4 [-2.7; 2.0] 0.755
EORTC QLQ-C30: Physical functioning									
Baseline	168	89.6 (12.3)			165	90.0 (11.6)			
Week 4	255	90.9 (11.0)	151	1.3 (0.7)	232	89.6 (10.9)	132	1.1 (0.8)	0.2 [-1.7; 2.1] 0.828
Week 8	175	90.9 (12.1)	114	1.3 (0.8)	150	91.4 (9.4)	94	2.9 (0.9)	-1.6 [-3.8; 0.7] 0.178
Week 12	230	92.1 (10.4)	143	2.7 (0.8)	210	91.6 (10.4)	130	2.5 (0.8)	0.2 [-1.8; 2.2] 0.845
Week 24	210	92.2 (11.9)	134	2.5 (0.8)	191	91.2 (10.7)	120	2.7 (0.9)	-0.2 [-2.5; 2.0] 0.833
Week 48	188	91.6 (11.8)	114	2.3 (0.9)	164	92.9 (9.4)	109	3.0 (0.9)	-0.8 [-3.2; 1.6] 0.523
Overall treatment effect			163	2.0 (0.7)			155	2.4 (0.7)	-0.4 [-2.2; 1.3] 0.628
EORTC QLQ-C30: Global health status/QoL									
Baseline	168	72.6 (19.7)			165	72.4 (19.3)			

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 4	255	75.3 (16.2)	151	4.9 (1.2)	232	72.7 (17.8)	132	3.8 (1.3)	1.0 [-2.3; 4.4] 0.546
Week 8	175	73.6 (18.2)	114	2.2 (1.5)	150	74.6 (17.5)	94	5.2 (1.6)	-3.0 [-7.1; 1.1] 0.147
Week 12	230	76.7 (18.0)	143	5.4 (1.4)	210	75.4 (16.6)	130	4.5 (1.4)	0.9 [-2.8; 4.6] 0.647
Week 24	210	77.1 (17.8)	134	5.0 (1.4)	191	75.6 (17.0)	120	4.9 (1.4)	0.1 [-3.6; 3.8] 0.968
Week 48	188	78.2 (17.6)	114	5.9 (1.5)	164	77.6 (16.6)	109	5.8 (1.6)	0.0 [-4.1; 4.2] 0.984
Overall treatment effect			163	4.7 (1.1)			155	4.9 (1.1)	-0.2 [-3.0; 2.6] 0.890
EORTC QLQ-C30: Role functioning									
Baseline	168	87.7 (17.6)			165	85.2 (18.9)			
Week 4	255	89.4 (15.1)	151	3.8 (1.2)	232	84.1 (18.9)	132	0.4 (1.3)	3.4 [0.1; 6.7] 0.043
Week 8	175	88.4 (17.6)	114	2.4 (1.4)	150	85.9 (17.3)	94	2.5 (1.5)	-0.2 [-4.0; 3.7] 0.929
Week 12	230	89.7 (16.6)	143	3.2 (1.2)	210	88.5 (14.6)	130	4.3 (1.3)	-1.1 [-4.4; 2.2] 0.518
Week 24	210	90.6 (15.8)	134	3.7 (1.2)	191	87.8 (17.2)	120	4.1 (1.3)	-0.5 [-3.7; 2.8] 0.778
Week 48	188	90.0 (15.3)	114	2.4 (1.3)	164	89.7 (16.0)	109	5.3 (1.3)	-2.8 [-6.3; 0.6] 0.109
Overall treatment effect			163	3.1 (1.0)			155	3.3 (1.0)	-0.2 [-2.8; 2.4] 0.863
EORTC QLQ-C30: Social functioning									

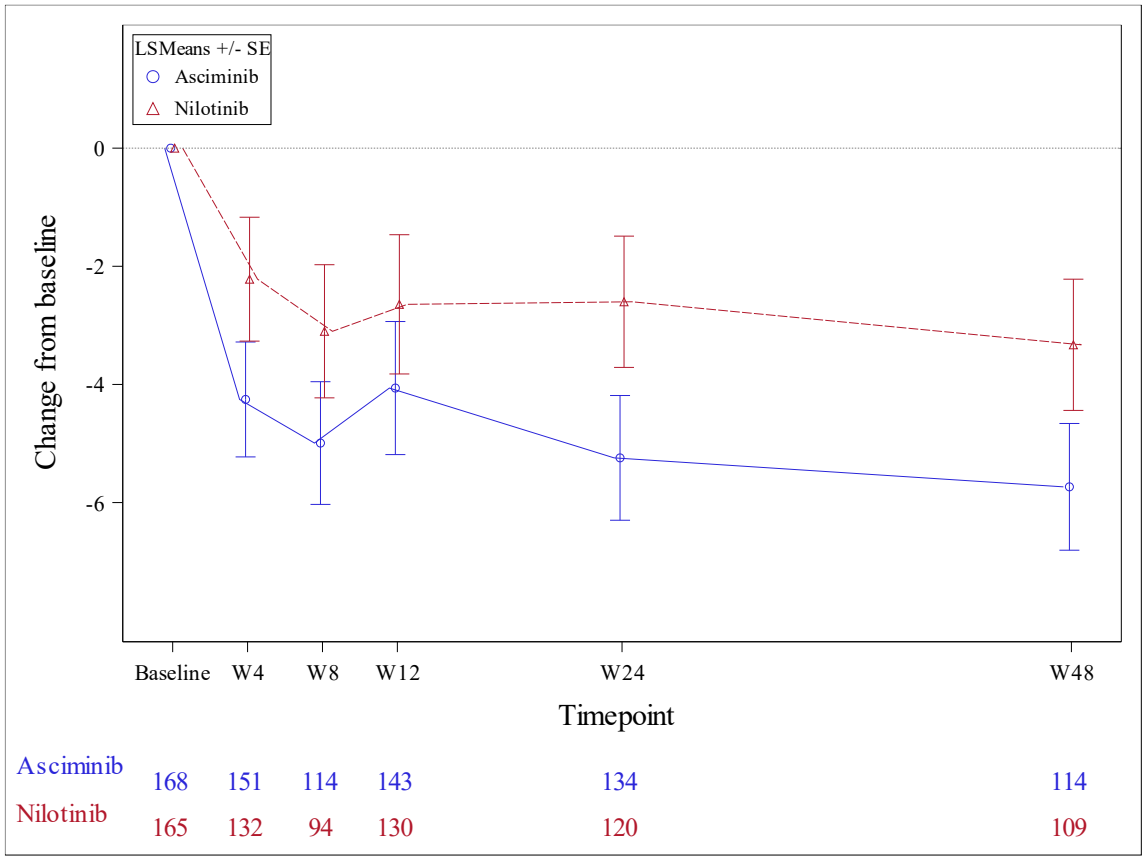
	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Baseline	168	90.5 (15.2)			165	89.1 (16.2)			
Week 4	255	91.5 (13.5)	151	2.1 (1.2)	232	85.9 (18.3)	132	-1.4 (1.3)	3.5 [0.3; 6.7] 0.031
Week 8	175	91.1 (14.7)	114	1.1 (1.3)	150	86.7 (15.6)	94	-0.2 (1.4)	1.3 [-2.2; 4.8] 0.472
Week 12	230	91.8 (13.9)	143	1.5 (1.2)	210	87.8 (16.1)	130	0.7 (1.2)	0.8 [-2.3; 4.0] 0.604
Week 24	210	92.7 (14.0)	134	1.8 (1.3)	191	88.6 (15.9)	120	0.6 (1.4)	1.2 [-2.3; 4.7] 0.511
Week 48	188	92.8 (13.7)	114	3.2 (1.2)	164	90.0 (15.0)	109	0.9 (1.3)	2.4 [-0.9; 5.6] 0.150
Overall treatment effect			163	1.9 (1.0)			155	0.1 (1.0)	1.8 [-0.7; 4.3] 0.150
EORTC QLQ-C30: Insomnia									
Baseline	168	17.1 (20.1)			165	16.8 (20.7)			
Week 4	255	14.2 (19.1)	151	-4.1 (1.5)	232	16.1 (19.8)	132	-1.5 (1.6)	-2.5 [-6.6; 1.5] 0.222
Week 8	175	12.9 (18.2)	114	-5.2 (1.5)	150	17.0 (20.1)	94	-0.7 (1.6)	-4.5 [-8.6; -0.4] 0.031
Week 12	230	12.6 (17.6)	143	-5.9 (1.3)	210	15.0 (19.0)	130	-2.5 (1.4)	-3.4 [-7.0; 0.1] 0.055
Week 24	210	12.4 (17.7)	134	-5.2 (1.5)	191	16.6 (20.2)	120	-0.9 (1.6)	-4.3 [-8.5; -0.1] 0.044
Week 48	188	14.1 (19.0)	114	-2.6 (1.5)	164	12.7 (16.5)	109	-4.5 (1.6)	1.9 [-2.2; 6.0] 0.358
Overall treatment effect			163	-4.6 (1.1)			155	-2.0 (1.1)	-2.6 [-5.3; 0.2] 0.067

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value

N[a]: Number of patients with non-missing values at the timepoint
N[b]: Number of patients with non-missing values at baseline and at the timepoint after baseline
CI: Confidence Interval
MMRM: Mixed Model for Repeated Measures
LS Mean: Least Square Mean
SE: Standard Error
SD: Standard Deviation
N.E.: Not Estimable
.....
The column 'Mean (SD)' contains the raw mean and SD of the score at the respective timepoint, the column 'LS mean (SE)' contains the model based LS mean and SE of the change from baseline of the score at the respective timepoint. The difference in the comparison is the difference of the LS mean changes from baseline between Asciminib and Nilotinib.
EORTC QLQ-C30 scores range from 0-100, with higher scores representing a higher response level.
The mixed model includes the PRO change from baseline as the dependent variable, treatment arm, study visit, baseline PRO and the stratification factors as recorded in the IRT system as covariates, and treatment arm*study visit interaction as fixed effects with study visit being treated as a repeated effect (repeated by subject).
Models were run using a UN covariance matrix.
Data Cut/15MAY2025

Figure 3-3.1 MMRM - EORTC QLQ-C30 (Full Analysis Set)

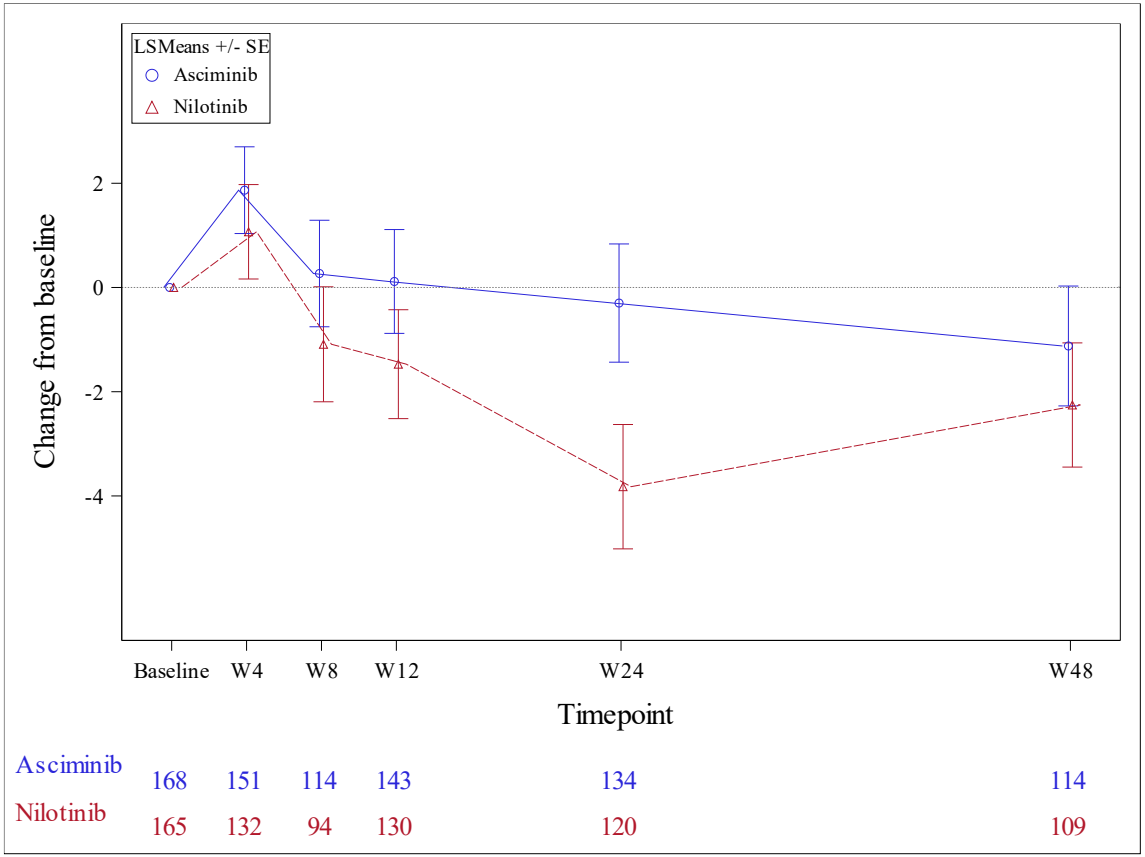
EORTC QLQ-C30: Appetite loss



Data Cut/15MAY2025

Figure 3-3.1 MMRM - EORTC QLQ-C30 (Full Analysis Set)

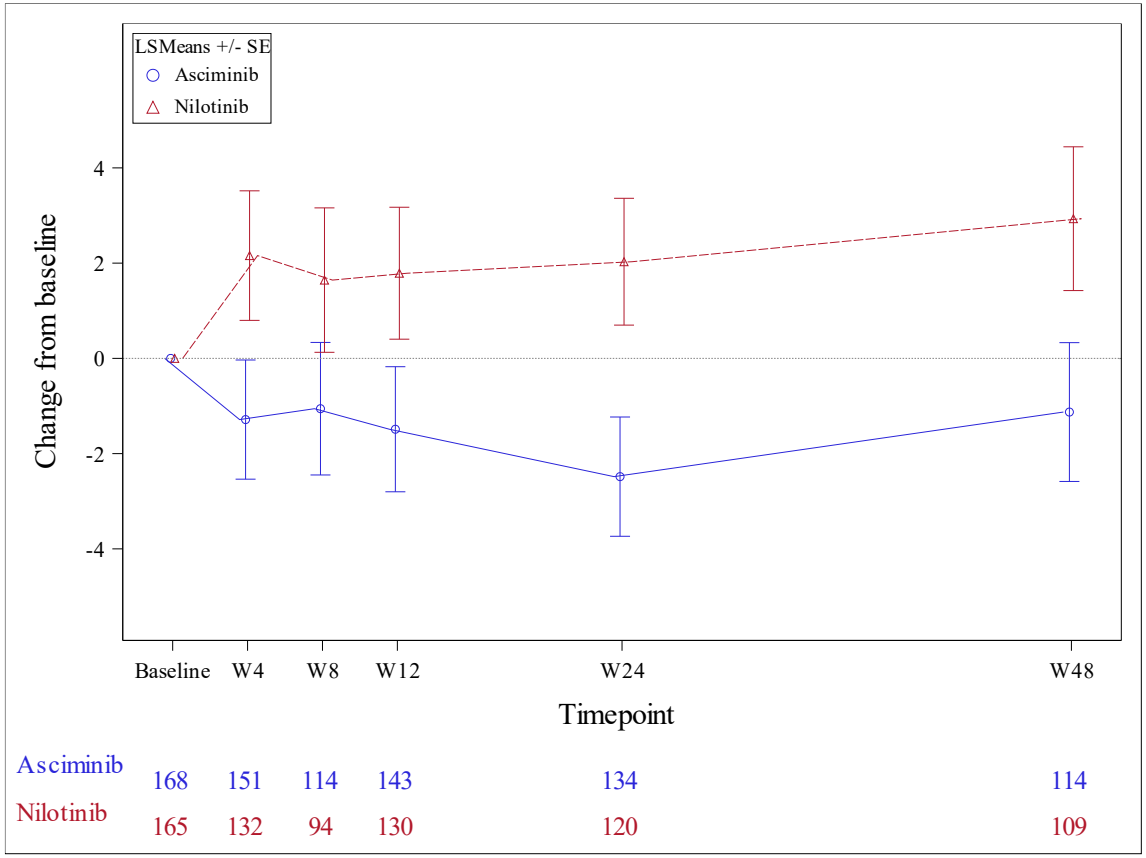
EORTC QLQ-C30: Cognitive functioning



Data Cut/15MAY2025

Figure 3-3.1 MMRM - EORTC QLQ-C30 (Full Analysis Set)

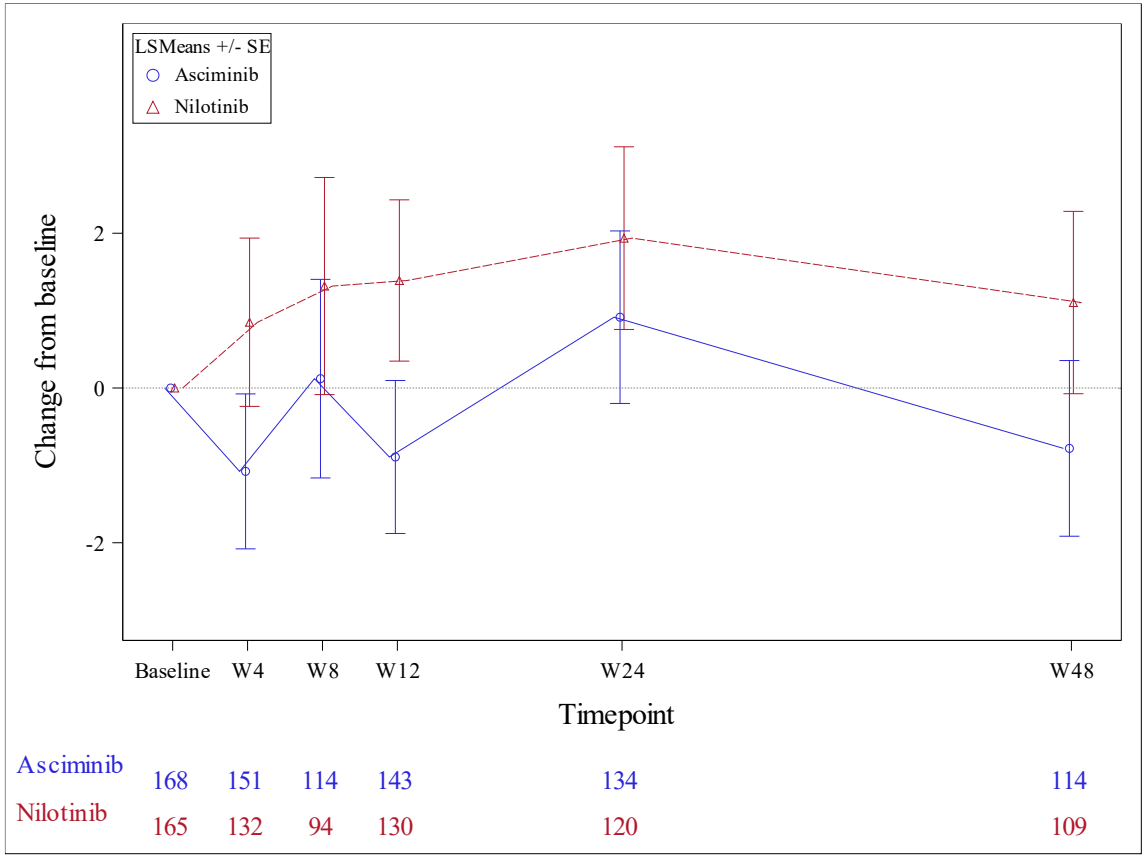
EORTC QLQ-C30: Constipation



Data Cut/15MAY2025

Figure 3-3.1 MMRM - EORTC QLQ-C30 (Full Analysis Set)

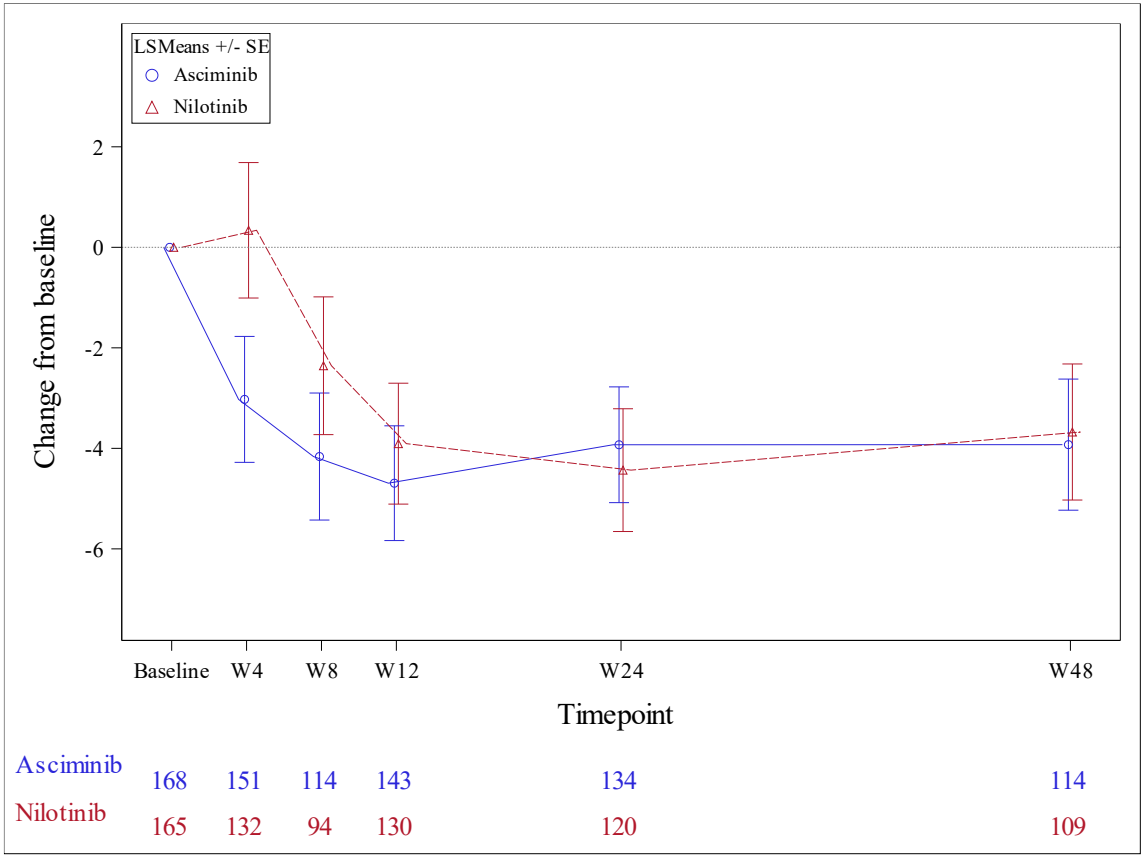
EORTC QLQ-C30: Diarrhoea



Data Cut/15MAY2025

Figure 3-3.1 MMRM - EORTC QLQ-C30 (Full Analysis Set)

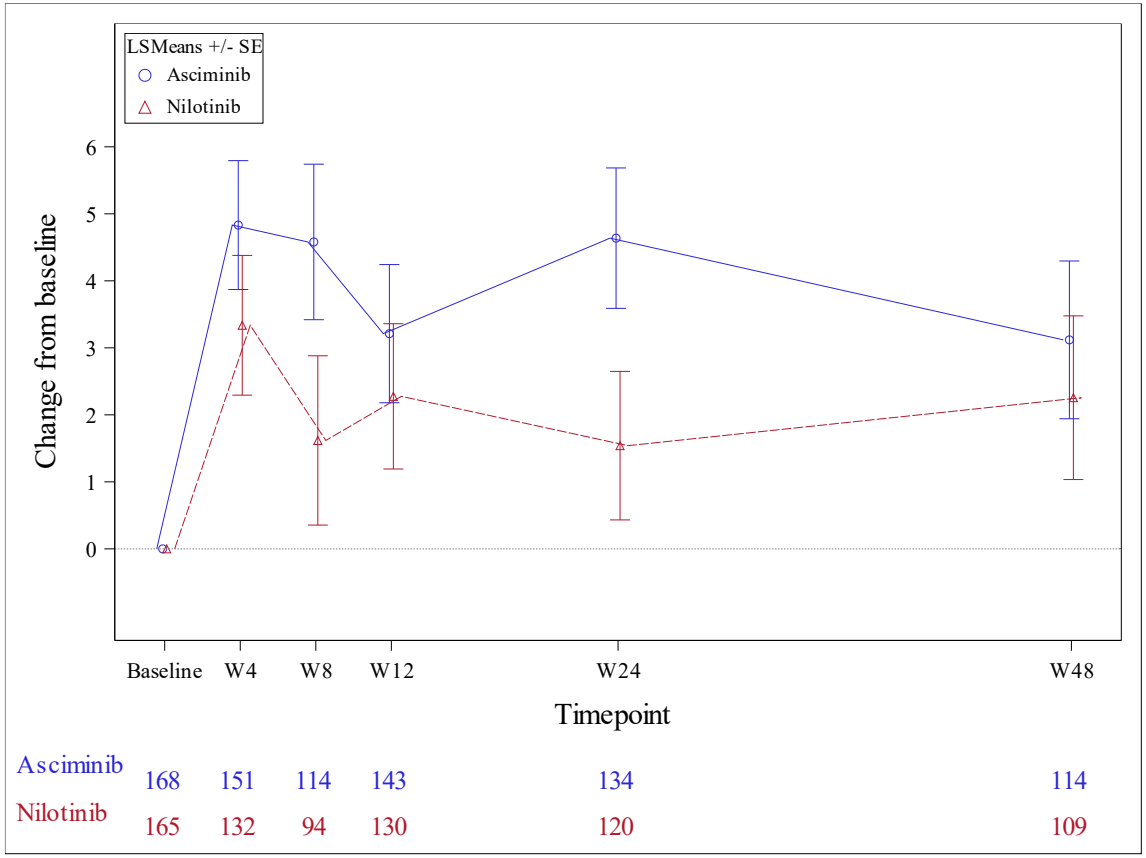
EORTC QLQ-C30: Dyspnoea



Data Cut/15MAY2025

Figure 3-3.1 MMRM - EORTC QLQ-C30 (Full Analysis Set)

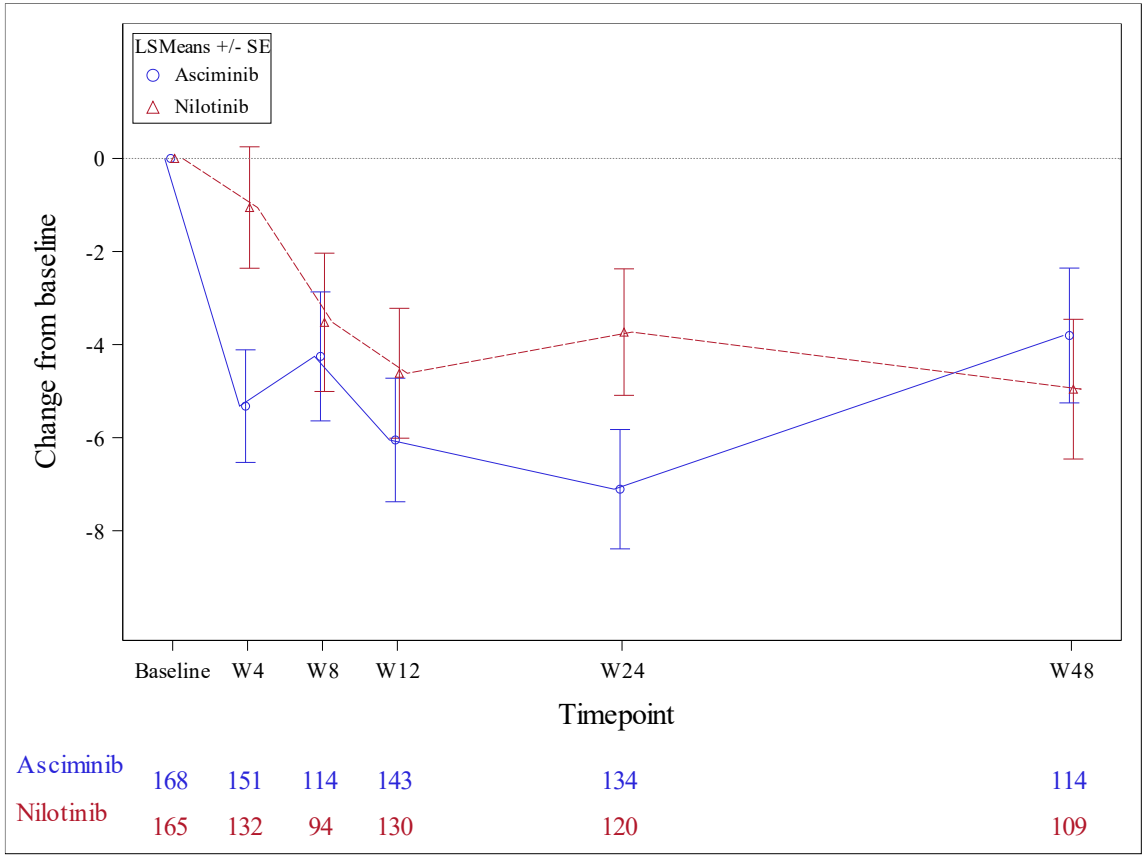
EORTC QLQ-C30: Emotional functioning



Data Cut/15MAY2025

Figure 3-3.1 MMRM - EORTC QLQ-C30 (Full Analysis Set)

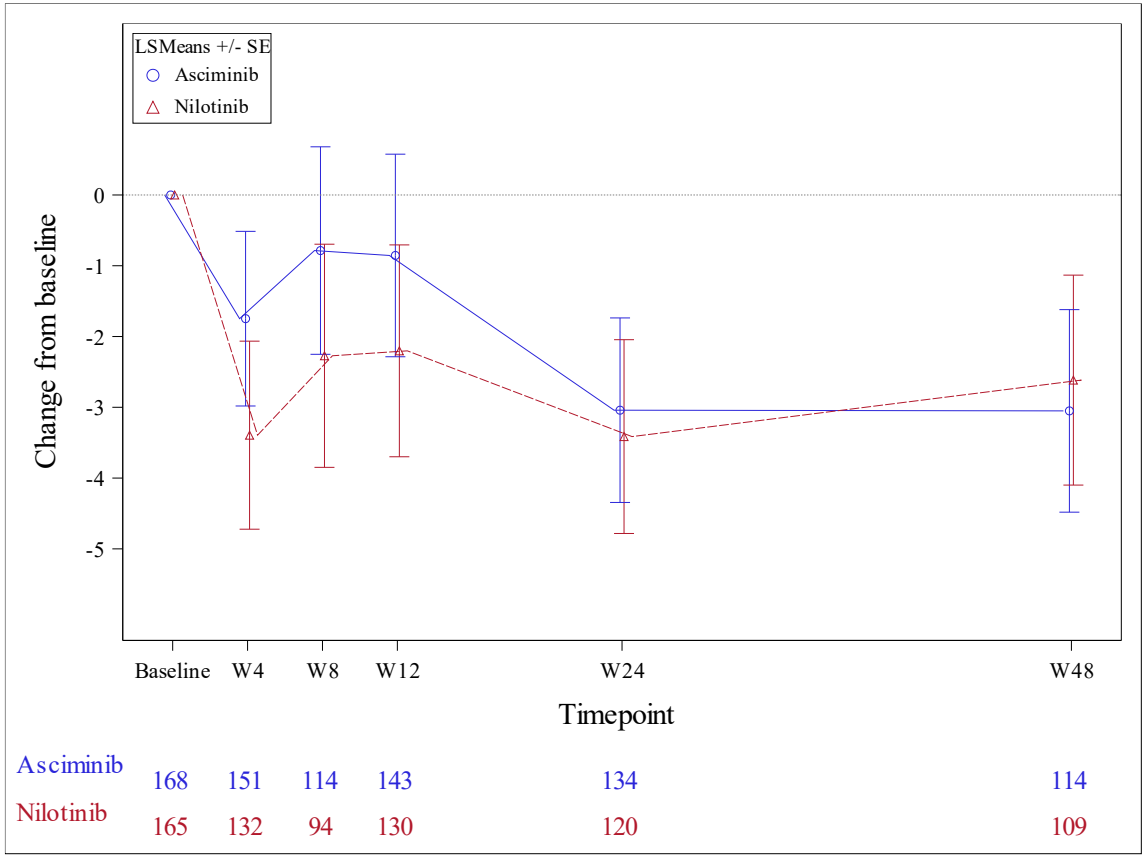
EORTC QLQ-C30: Fatigue



Data Cut/15MAY2025

Figure 3-3.1 MMRM - EORTC QLQ-C30 (Full Analysis Set)

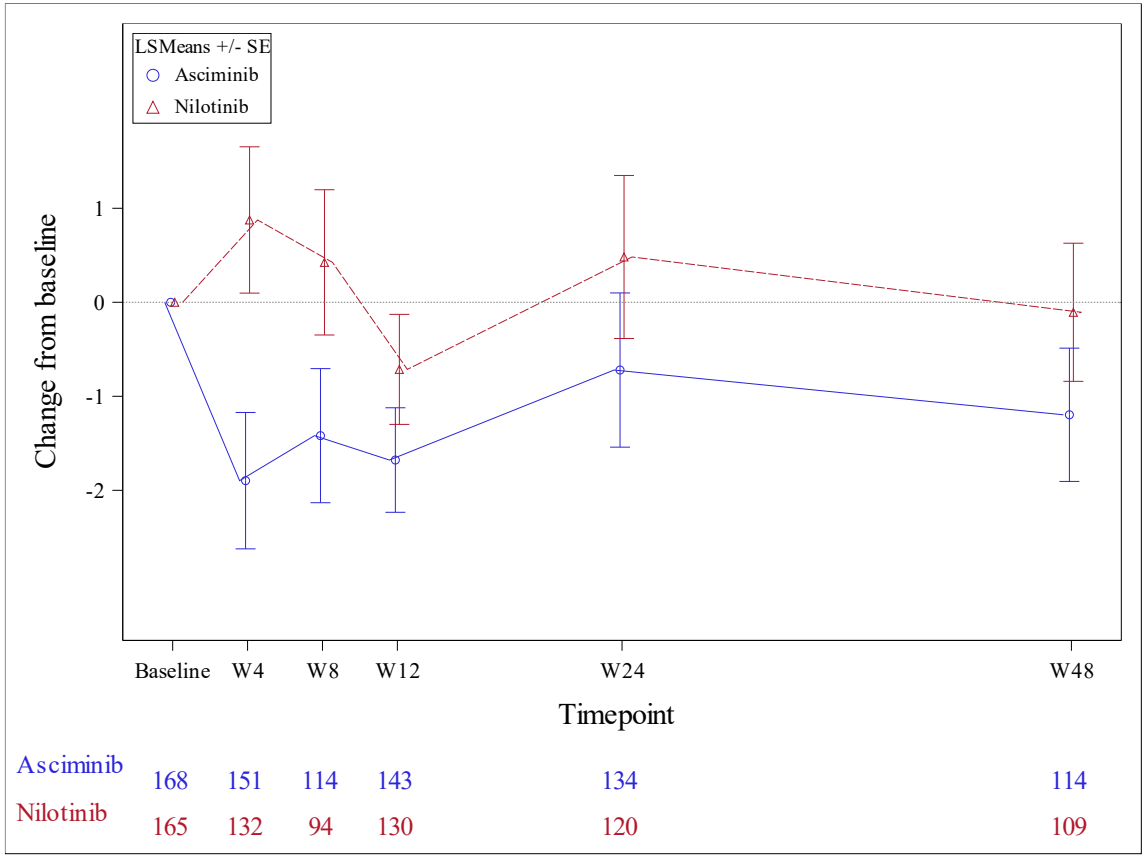
EORTC QLQ-C30: Financial difficulties



Data Cut/15MAY2025

Figure 3-3.1 MMRM - EORTC QLQ-C30 (Full Analysis Set)

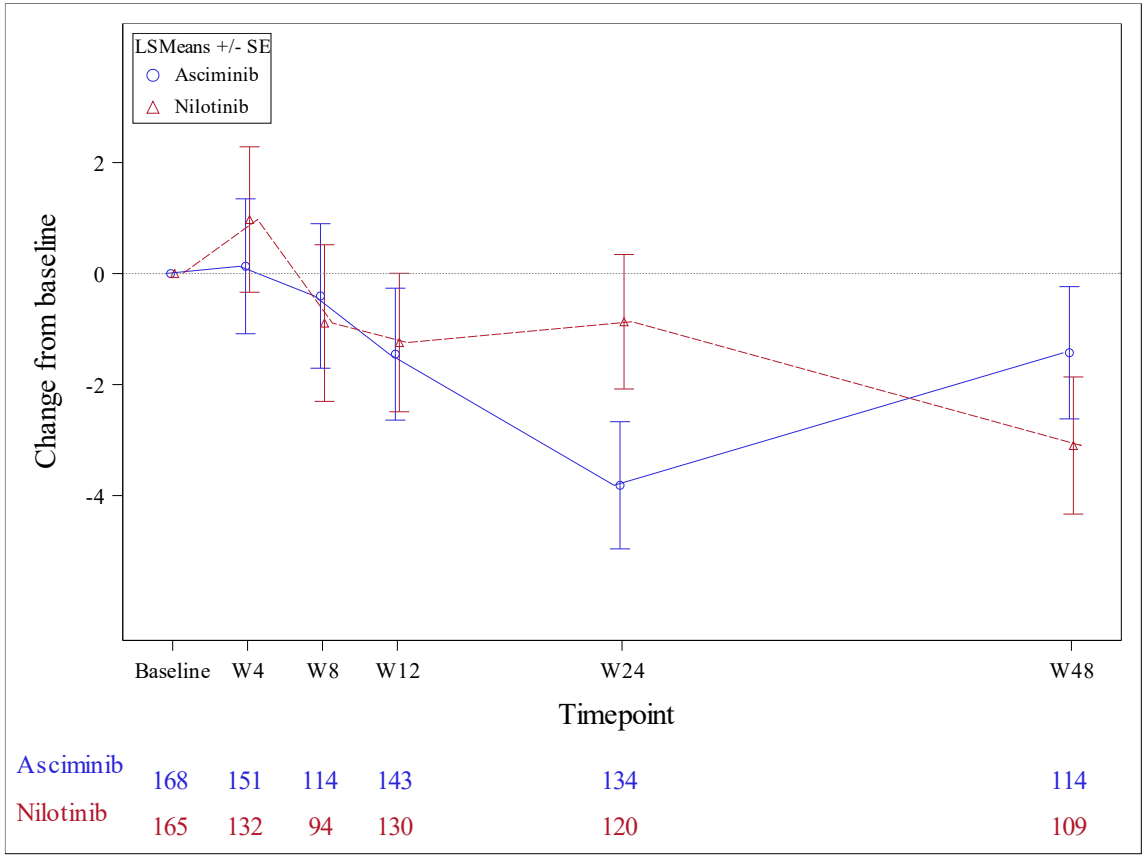
EORTC QLQ-C30: Nausea and vomiting



Data Cut/15MAY2025

Figure 3-3.1 MMRM - EORTC QLQ-C30 (Full Analysis Set)

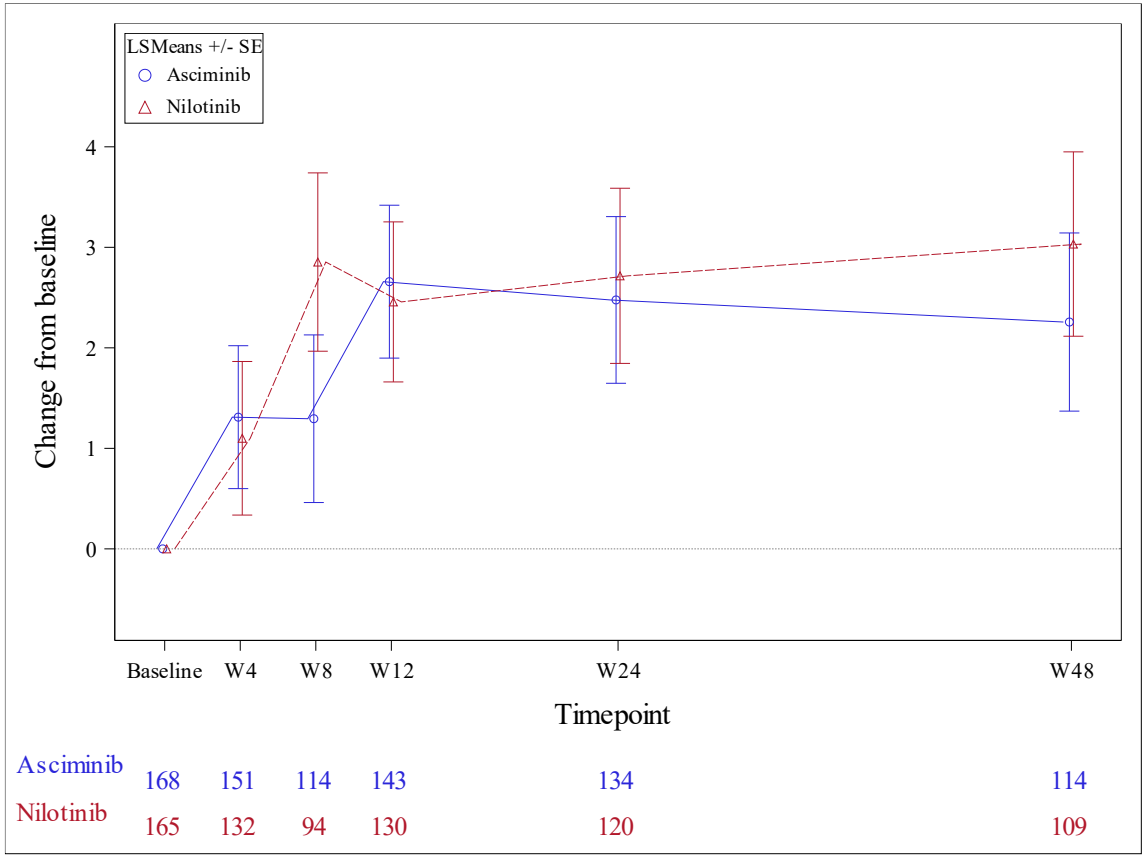
EORTC QLQ-C30: Pain



Data Cut/15MAY2025

Figure 3-3.1 MMRM - EORTC QLQ-C30 (Full Analysis Set)

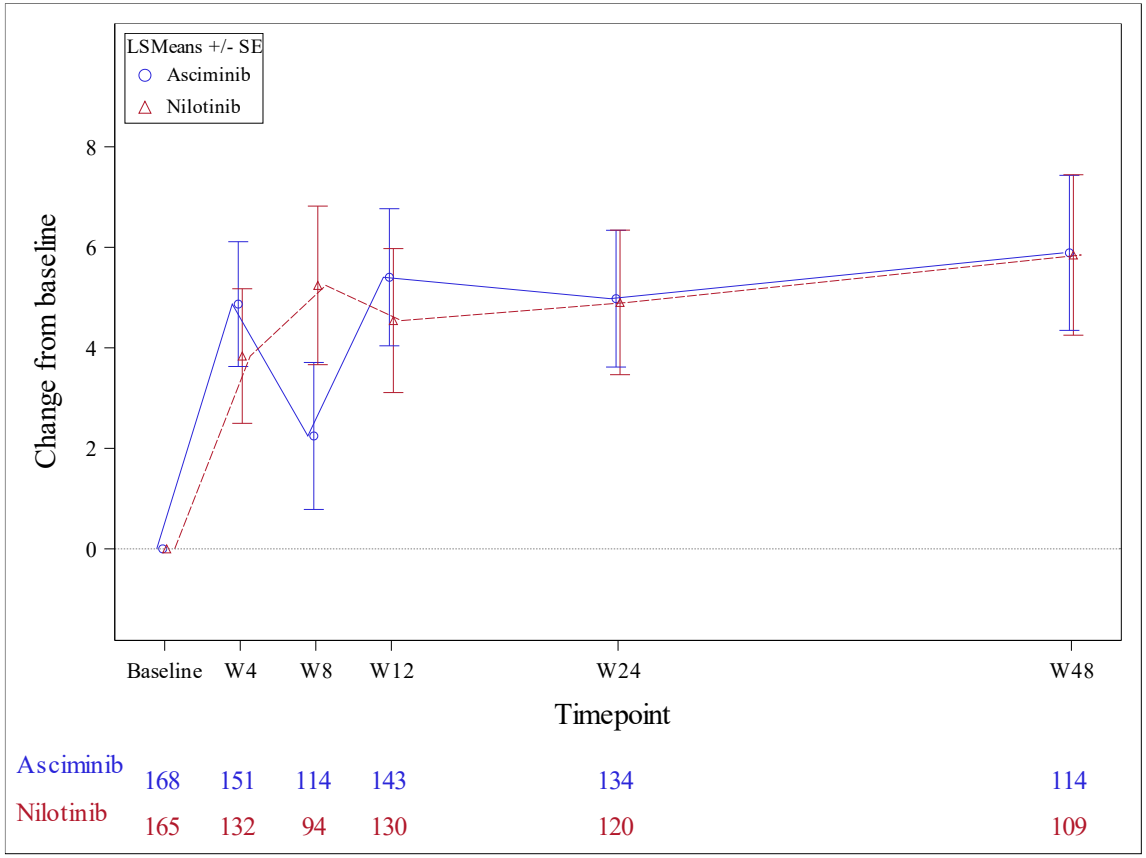
EORTC QLQ-C30: Physical functioning



Data Cut/15MAY2025

Figure 3-3.1 MMRM - EORTC QLQ-C30 (Full Analysis Set)

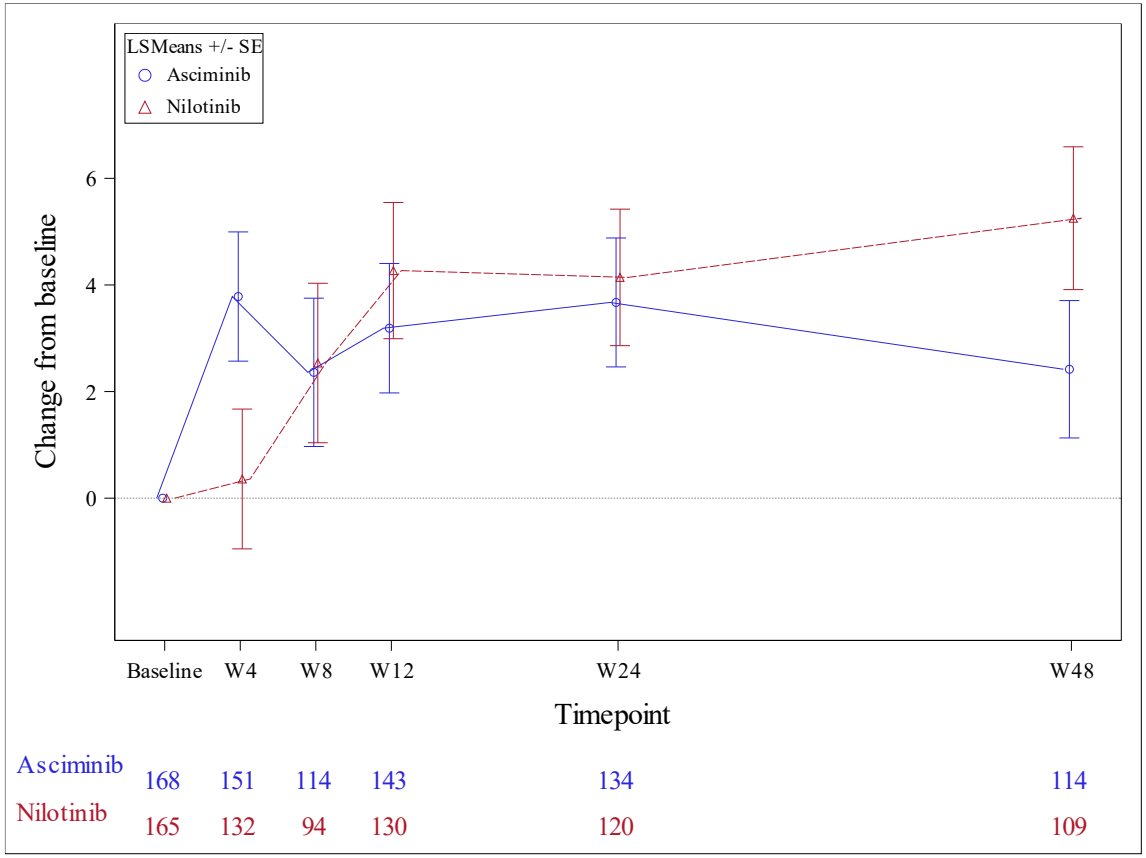
EORTC QLQ-C30: Global health status/QoL



Data Cut/15MAY2025

Figure 3-3.1 MMRM - EORTC QLQ-C30 (Full Analysis Set)

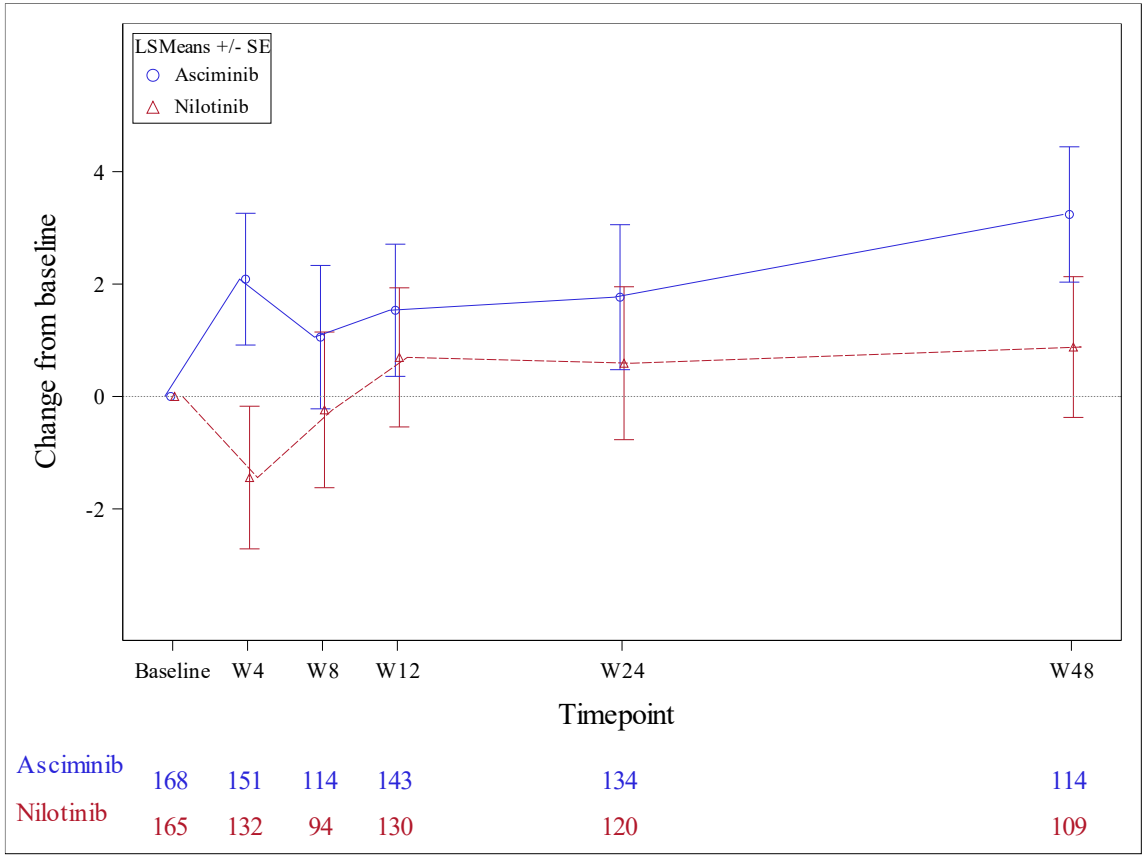
EORTC QLQ-C30: Role functioning



Data Cut/15MAY2025

Figure 3-3.1 MMRM - EORTC QLQ-C30 (Full Analysis Set)

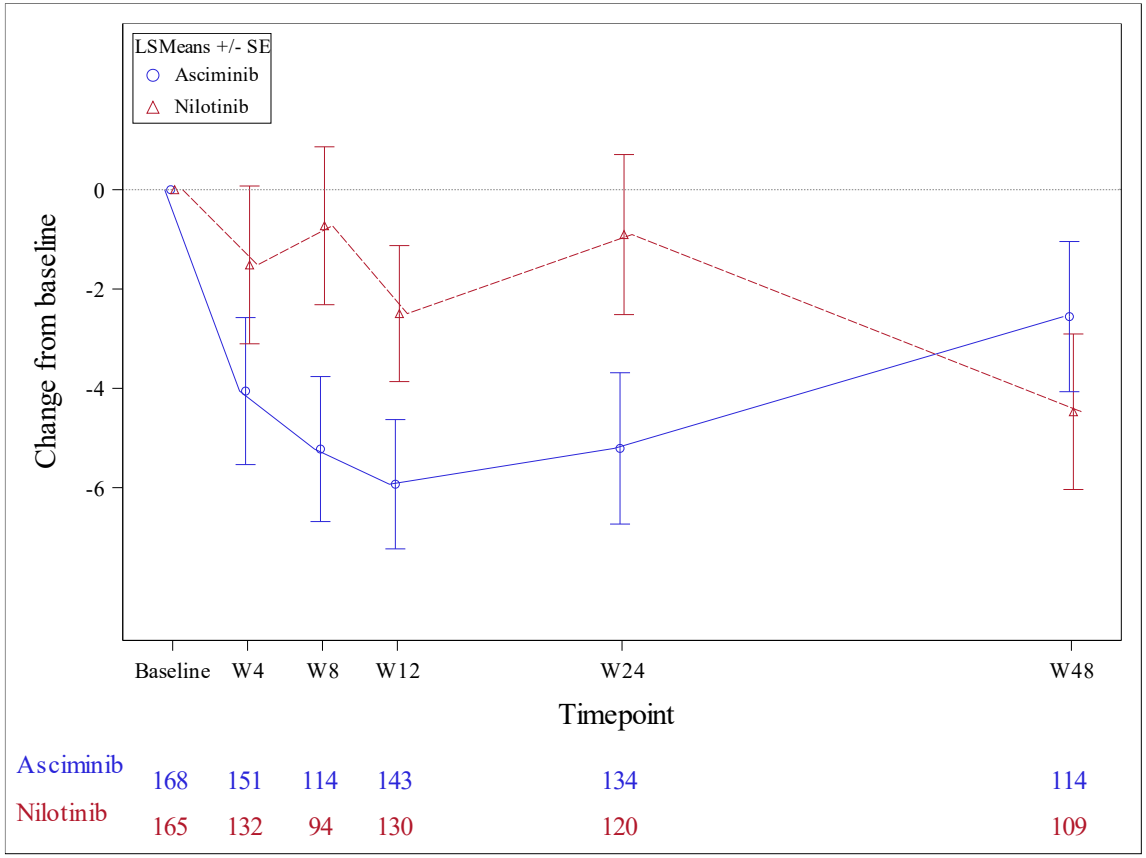
EORTC QLQ-C30: Social functioning



Data Cut/15MAY2025

Figure 3-3.1 MMRM - EORTC QLQ-C30 (Full Analysis Set)

EORTC QLQ-C30: Insomnia



Data Cut/15MAY2025

Table 3-3.2: MMRM - EORTC QLQ-CML24 (Full Analysis Set)

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
EORTC QLQ-CML24: Body Image Problems									
Baseline	161	13.4 (19.8)			157	14.5 (20.4)			
Week 4	251	10.7 (16.8)	145	-4.4 (1.3)	227	14.6 (18.7)	127	-0.5 (1.4)	-4.0 [-7.5; -0.4] 0.029
Week 8	171	13.3 (18.8)	108	-2.5 (1.5)	149	16.8 (20.6)	91	-1.0 (1.6)	-1.5 [-5.8; 2.7] 0.477
Week 12	224	11.6 (18.5)	133	-1.6 (1.6)	207	14.5 (18.8)	124	-1.0 (1.6)	-0.6 [-4.9; 3.6] 0.776
Week 24	209	11.4 (16.2)	130	-3.1 (1.5)	188	15.6 (20.0)	113	0.3 (1.6)	-3.5 [-7.5; 0.6] 0.092
Week 48	186	11.3 (17.4)	110	-2.3 (1.6)	164	12.5 (17.6)	105	-4.3 (1.7)	1.9 [-2.5; 6.3] 0.390
Overall treatment effect			157	-2.8 (1.1)			147	-1.3 (1.1)	-1.5 [-4.3; 1.3] 0.284
EORTC QLQ-CML24: Impact on Daily Life									
Baseline	161	17.0 (16.8)			157	19.1 (17.2)			
Week 4	251	13.3 (13.1)	145	-5.1 (1.1)	227	18.4 (15.6)	127	-1.3 (1.2)	-3.7 [-6.8; -0.6] 0.018
Week 8	171	14.3 (14.6)	108	-3.5 (1.2)	149	18.2 (15.4)	91	-2.0 (1.3)	-1.5 [-4.8; 1.8] 0.378
Week 12	224	11.5 (13.8)	133	-5.3 (1.2)	207	17.4 (15.9)	124	-0.9 (1.2)	-4.4 [-7.5; -1.3] 0.006
Week 24	209	10.8 (14.1)	130	-6.0 (1.2)	188	15.8 (15.0)	113	-3.0 (1.3)	-2.9 [-6.3; 0.4] 0.088

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 48	186	12.2 (14.1)	110	-4.4 (1.2)	164	15.0 (14.4)	105	-2.6 (1.3)	-1.8 [-5.2; 1.5] 0.287
Overall treatment effect			157	-4.9 (0.9)			147	-2.0 (1.0)	-2.9 [-5.3; -0.4] 0.024
EORTC QLQ-CML24: Satisfaction with Care and Information									
Baseline	161	63.0 (17.1)			157	58.9 (21.7)			
Week 4	251	65.1 (16.3)	145	2.5 (1.4)	227	64.3 (16.3)	127	3.8 (1.5)	-1.3 [-5.0; 2.5] 0.499
Week 8	171	62.3 (17.3)	108	-1.0 (1.8)	149	60.7 (19.5)	91	-1.2 (2.0)	0.2 [-5.0; 5.4] 0.948
Week 12	224	61.4 (18.5)	133	0.8 (1.6)	207	61.5 (19.3)	124	-0.9 (1.7)	1.7 [-2.7; 6.1] 0.445
Week 24	209	60.5 (21.3)	130	-1.8 (1.8)	188	61.6 (18.2)	113	1.8 (1.9)	-3.6 [-8.5; 1.3] 0.145
Week 48	186	62.8 (17.7)	110	0.5 (1.7)	164	62.0 (18.6)	105	3.1 (1.8)	-2.6 [-7.3; 2.0] 0.268
Overall treatment effect			157	0.2 (1.1)			147	1.3 (1.2)	-1.1 [-4.1; 1.9] 0.458
EORTC QLQ-CML24: Symptom Burden									
Baseline	161	10.8 (9.7)			157	12.2 (9.8)			
Week 4	251	10.5 (7.9)	145	-1.6 (0.6)	227	13.4 (9.2)	127	0.2 (0.7)	-1.8 [-3.4; -0.2] 0.032
Week 8	171	11.3 (9.2)	108	-1.0 (0.7)	149	13.7 (9.9)	91	0.1 (0.8)	-1.1 [-3.1; 0.9] 0.298
Week 12	224	10.2 (9.0)	133	-1.6 (0.7)	207	13.4 (10.1)	124	0.2 (0.7)	-1.8 [-3.7; 0.1] 0.060

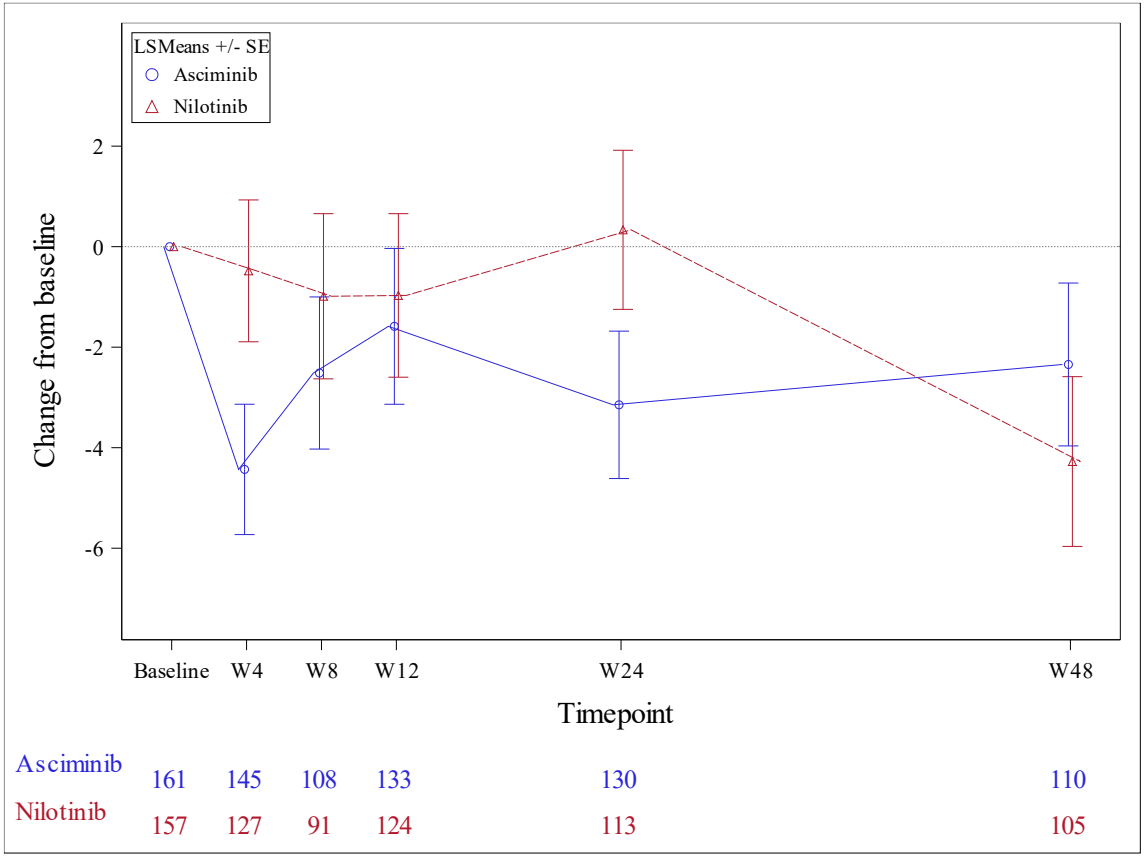
	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 24	209	10.0 (9.7)	130	-1.5 (0.7)	188	14.2 (10.5)	113	1.5 (0.8)	-3.1 [-5.0; -1.1] 0.002
Week 48	186	10.4 (10.3)	110	-1.2 (0.8)	164	13.0 (9.9)	105	0.6 (0.9)	-1.9 [-4.1; 0.4] 0.098
Overall treatment effect			157	-1.4 (0.6)			147	0.5 (0.6)	-1.9 [-3.5; -0.3] 0.019
EORTC QLQ-CML24: Satisfaction with Social Life									
Baseline	161	57.0 (19.6)			157	53.5 (22.5)			
Week 4	251	55.7 (20.1)	145	-2.6 (1.7)	227	55.4 (19.8)	127	0.0 (1.8)	-2.6 [-7.2; 2.0] 0.263
Week 8	171	54.1 (20.6)	108	-2.6 (2.1)	149	49.3 (23.2)	91	-8.1 (2.3)	5.6 [-0.4; 11.5] 0.065
Week 12	224	56.8 (20.4)	133	1.3 (1.8)	207	52.2 (22.3)	124	-4.8 (1.9)	6.1 [1.3; 11.0] 0.013
Week 24	209	54.3 (22.0)	130	-4.0 (2.0)	188	53.2 (22.2)	113	-0.3 (2.1)	-3.7 [-9.2; 1.8] 0.188
Week 48	186	56.7 (20.3)	110	-2.8 (2.1)	164	54.3 (21.6)	105	0.0 (2.2)	-2.8 [-8.5; 2.9] 0.328
Overall treatment effect			157	-2.1 (1.3)			147	-2.6 (1.4)	0.5 [-3.0; 4.1] 0.775
EORTC QLQ-CML24: Impact on Worry/Mood									
Baseline	161	17.6 (14.5)			157	20.9 (14.6)			
Week 4	251	14.2 (12.7)	145	-5.1 (0.9)	227	18.4 (13.6)	127	-2.7 (1.0)	-2.3 [-4.9; 0.3] 0.078
Week 8	171	15.0 (12.9)	108	-5.0 (1.0)	149	18.2 (13.1)	91	-2.3 (1.1)	-2.7 [-5.5; 0.0] 0.049

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 12	224	12.4 (11.9)	133	-6.2 (1.0)	207	16.9 (14.2)	124	-3.6 (1.0)	-2.6 [-5.2; 0.1] 0.061
Week 24	209	13.2 (13.5)	130	-5.7 (1.1)	188	17.2 (15.1)	113	-4.1 (1.2)	-1.6 [-4.7; 1.4] 0.296
Week 48	186	13.2 (14.2)	110	-4.9 (1.1)	164	16.0 (13.5)	105	-3.8 (1.2)	-1.2 [-4.2; 1.9] 0.448
Overall treatment effect			157	-5.4 (0.8)			147	-3.3 (0.9)	-2.1 [-4.2; 0.0] 0.052

N[a]: Number of patients with non-missing values at the timepoint
N[b]: Number of patients with non-missing values at baseline and at the timepoint after baseline
CI: Confidence Interval
MMRM: Mixed Model for Repeated Measures
LS Mean: Least Square Mean
SE: Standard Error
SD: Standard Deviation
N.E.: Not Estimable
.....
The column 'Mean (SD)' contains the raw mean and SD of the score at the respective timepoint, the column 'LS mean (SE)' contains the model based LS mean and SE of the change from baseline of the score at the respective timepoint. The difference in the comparison is the difference of the LS mean changes from baseline between Asciminib and Nilotinib.
EORTC QLQ-CML24 scores range from 0-100, with higher scores representing a higher response level.
The mixed model includes the PRO change from baseline as the dependent variable, treatment arm, study visit, baseline PRO and the stratification factors as recorded in the IRT system as covariates, and treatment arm*study visit interaction as fixed effects with study visit being treated as a repeated effect (repeated by subject).
Models were run using a UN covariance matrix.
Data Cut/15MAY2025

Figure 3-3.2 MMRM - EORTC QLQ-CML24 (Full Analysis Set)

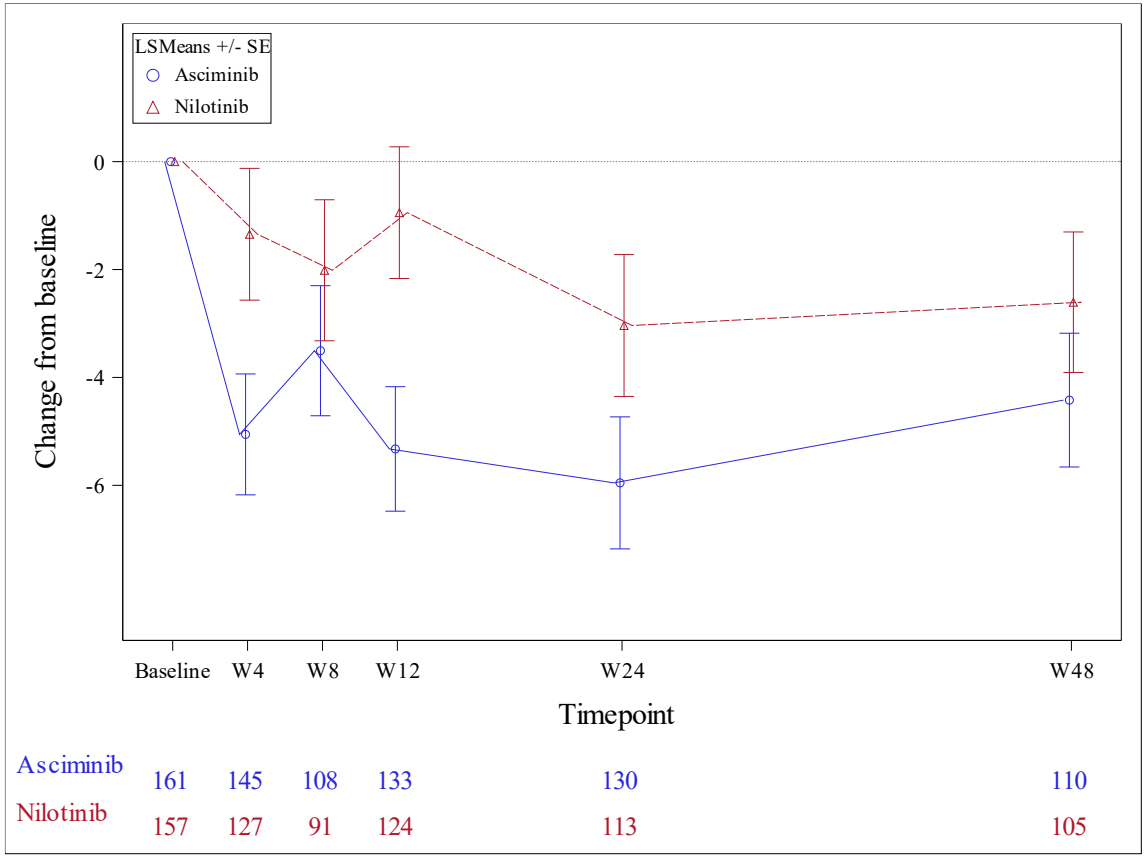
EORTC QLQ-CML24: Body Image Problems



Data Cut/15MAY2025

Figure 3-3.2 MMRM - EORTC QLQ-CML24 (Full Analysis Set)

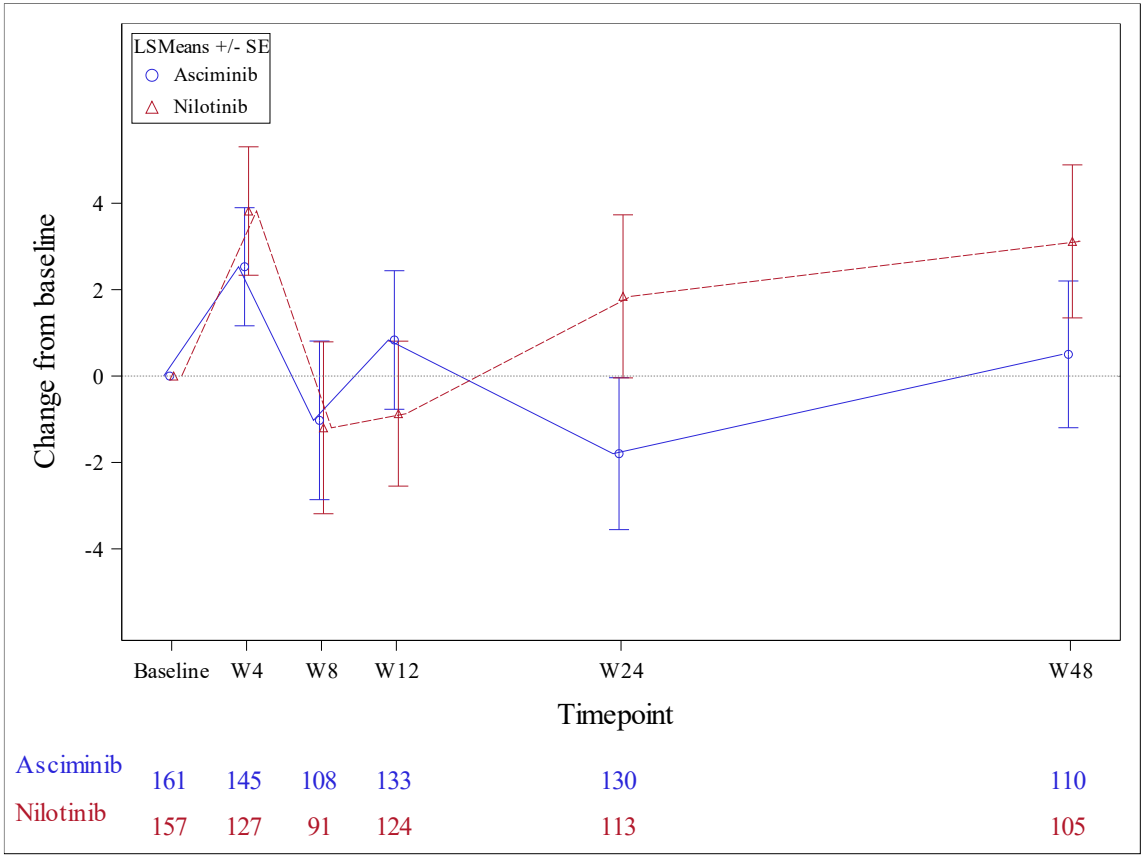
EORTC QLQ-CML24: Impact on Daily Life



Data Cut/15MAY2025

Figure 3-3.2 MMRM - EORTC QLQ-CML24 (Full Analysis Set)

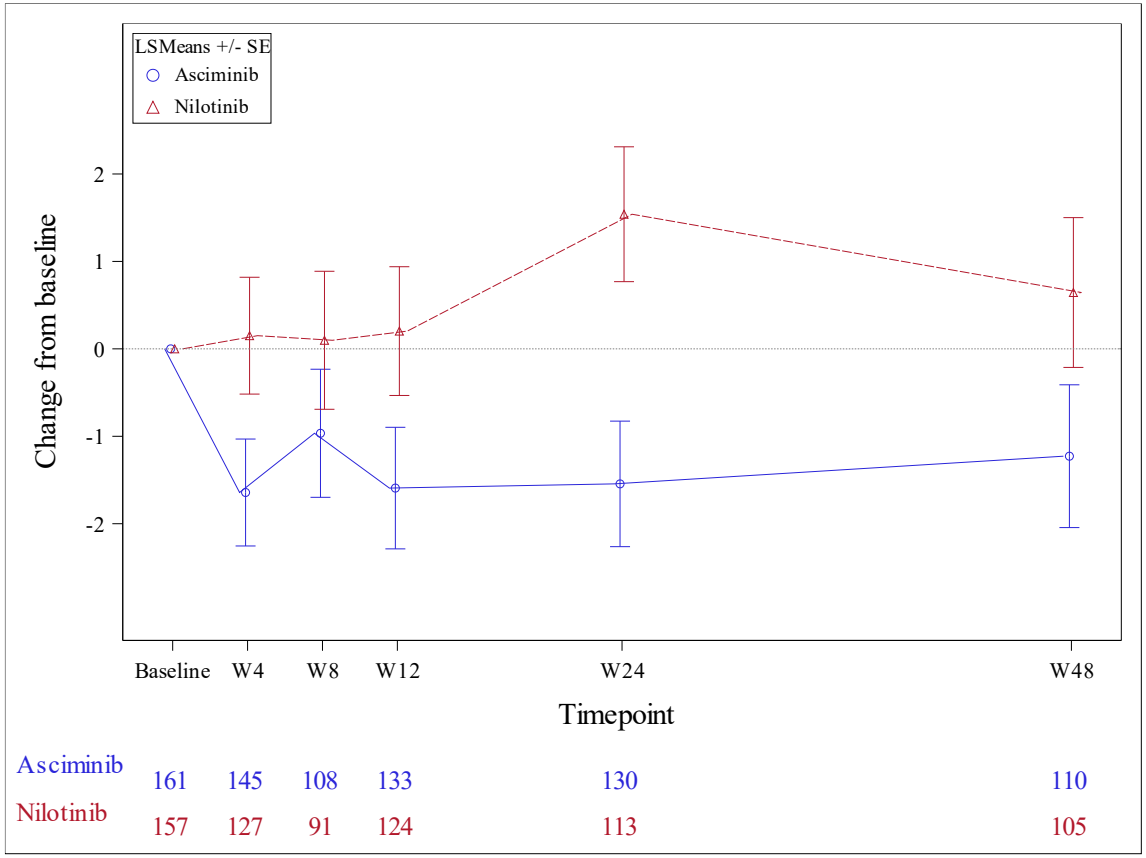
EORTC QLQ-CML24: Satisfaction with Care and Information



Data Cut/15MAY2025

Figure 3-3.2 MMRM - EORTC QLQ-CML24 (Full Analysis Set)

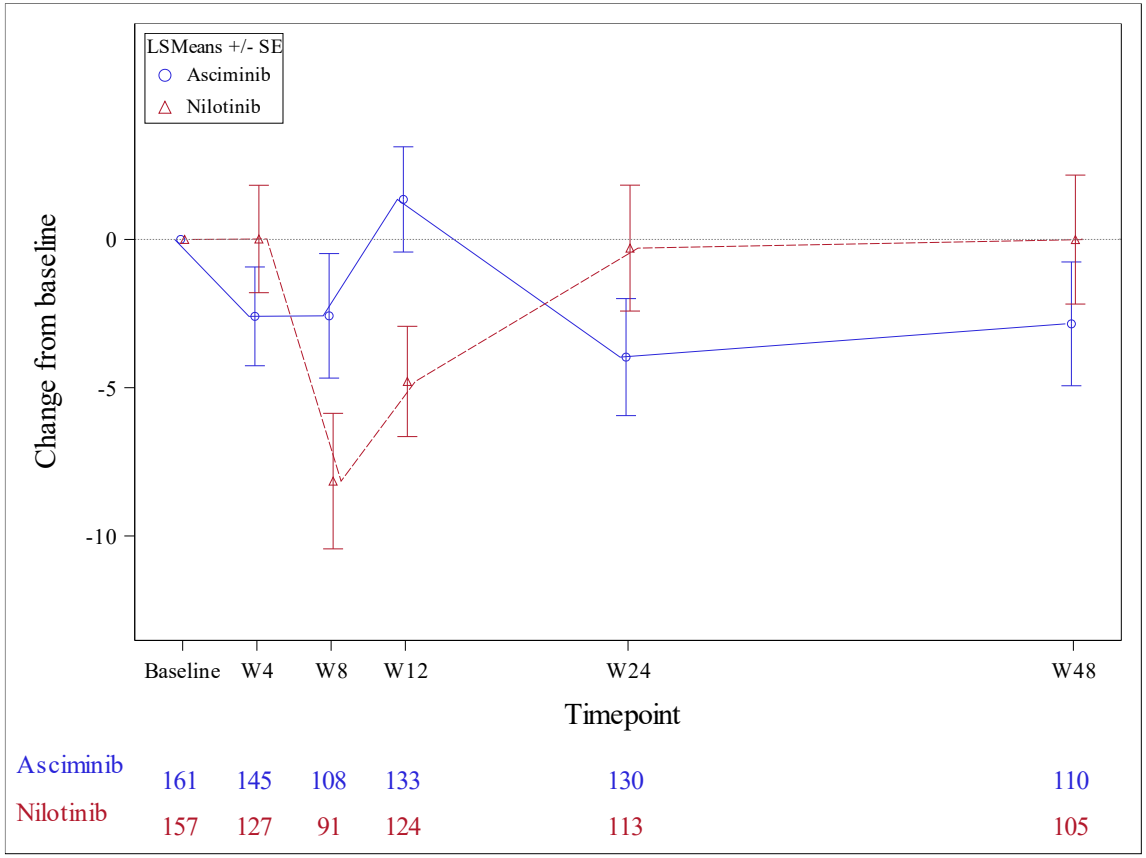
EORTC QLQ-CML24: Symptom Burden



Data Cut/15MAY2025

Figure 3-3.2 MMRM - EORTC QLQ-CML24 (Full Analysis Set)

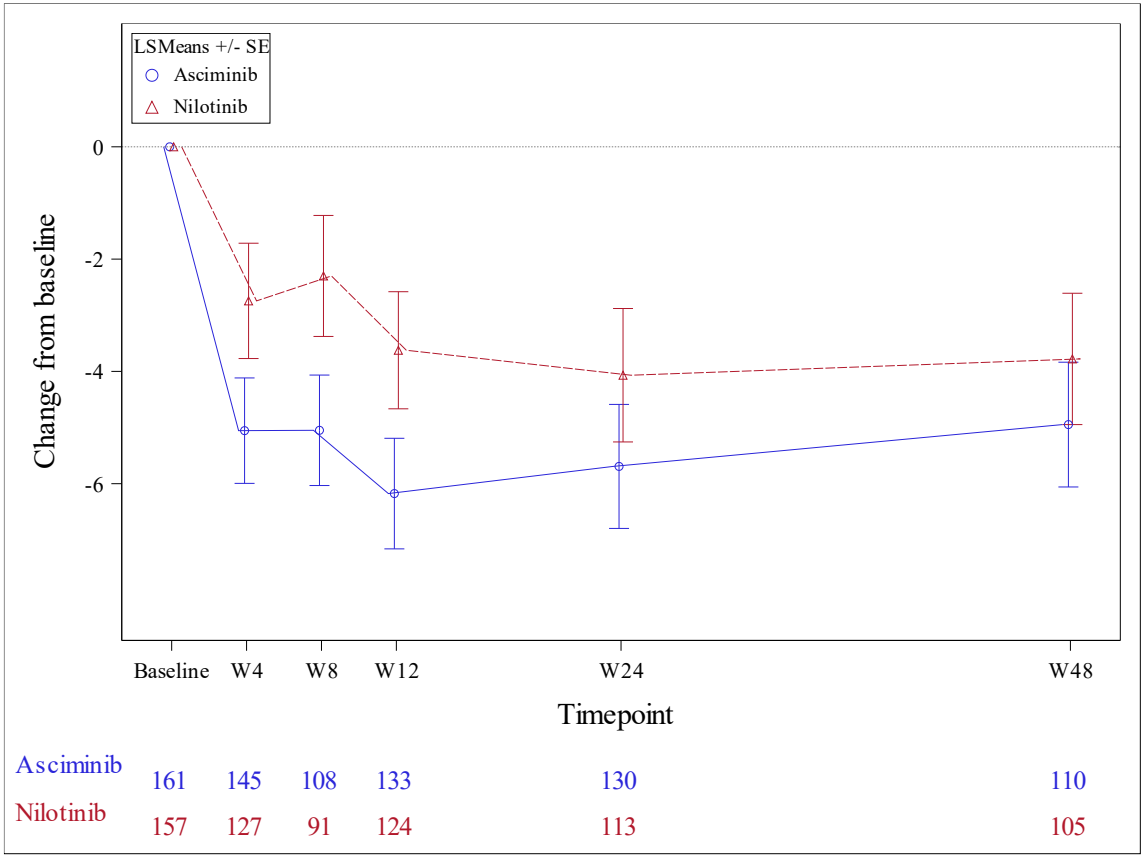
EORTC QLQ-CML24: Satisfaction with Social Life



Data Cut/15MAY2025

Figure 3-3.2 MMRM - EORTC QLQ-CML24 (Full Analysis Set)

EORTC QLQ-CML24: Impact on Worry/Mood



Data Cut/15MAY2025

Table 3-3.3: MMRM - FACT-ITEM GP5 (Full Analysis Set)

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
FACIT GP5									
Baseline	156	0.4 (0.7)			152	0.5 (0.9)			
Week 1	193	0.7 (0.9)	102	0.3 (0.1)	185	1.0 (1.1)	92	0.4 (0.1)	-0.1 [-0.4; 0.2] 0.540
Week 2	203	0.6 (0.9)	110	0.1 (0.1)	203	1.0 (1.0)	118	0.4 (0.1)	-0.3 [-0.6; -0.1] 0.013
Week 3	179	0.5 (0.8)	94	0.1 (0.1)	173	1.0 (1.0)	101	0.3 (0.1)	-0.3 [-0.5; 0.0] 0.033
Week 4	215	0.5 (0.7)	129	0.0 (0.1)	182	0.8 (0.9)	107	0.3 (0.1)	-0.3 [-0.5; 0.0] 0.015
Week 5	191	0.5 (0.7)	101	0.0 (0.1)	167	0.9 (1.0)	91	0.3 (0.1)	-0.2 [-0.4; 0.0] 0.015
Week 6	175	0.5 (0.7)	98	0.0 (0.1)	167	0.8 (0.8)	93	0.2 (0.1)	-0.2 [-0.4; 0.0] 0.028
Week 7	177	0.5 (0.8)	94	0.1 (0.1)	155	0.8 (0.8)	87	0.2 (0.1)	-0.1 [-0.4; 0.1] 0.147
Week 8	153	0.6 (0.9)	87	0.2 (0.1)	133	0.9 (0.9)	76	0.4 (0.1)	-0.2 [-0.4; 0.0] 0.087
Week 9	178	0.6 (0.8)	104	0.1 (0.1)	156	0.9 (0.8)	86	0.3 (0.1)	-0.2 [-0.4; 0.0] 0.073
Week 10	167	0.5 (0.8)	94	0.1 (0.1)	162	0.9 (0.9)	84	0.2 (0.1)	-0.1 [-0.3; 0.1] 0.261
Week 11	176	0.5 (0.7)	98	0.1 (0.1)	155	0.9 (1.0)	88	0.4 (0.1)	-0.3 [-0.5; 0.0] 0.017
Week 12	189	0.6 (0.9)	109	0.1 (0.1)	179	0.9 (1.0)	102	0.4 (0.1)	-0.2 [-0.5; 0.0] 0.025
Week 13	173	0.5 (0.8)	103	0.1 (0.1)	151	0.9 (0.9)	81	0.3 (0.1)	-0.2 [-0.4; 0.0] 0.065

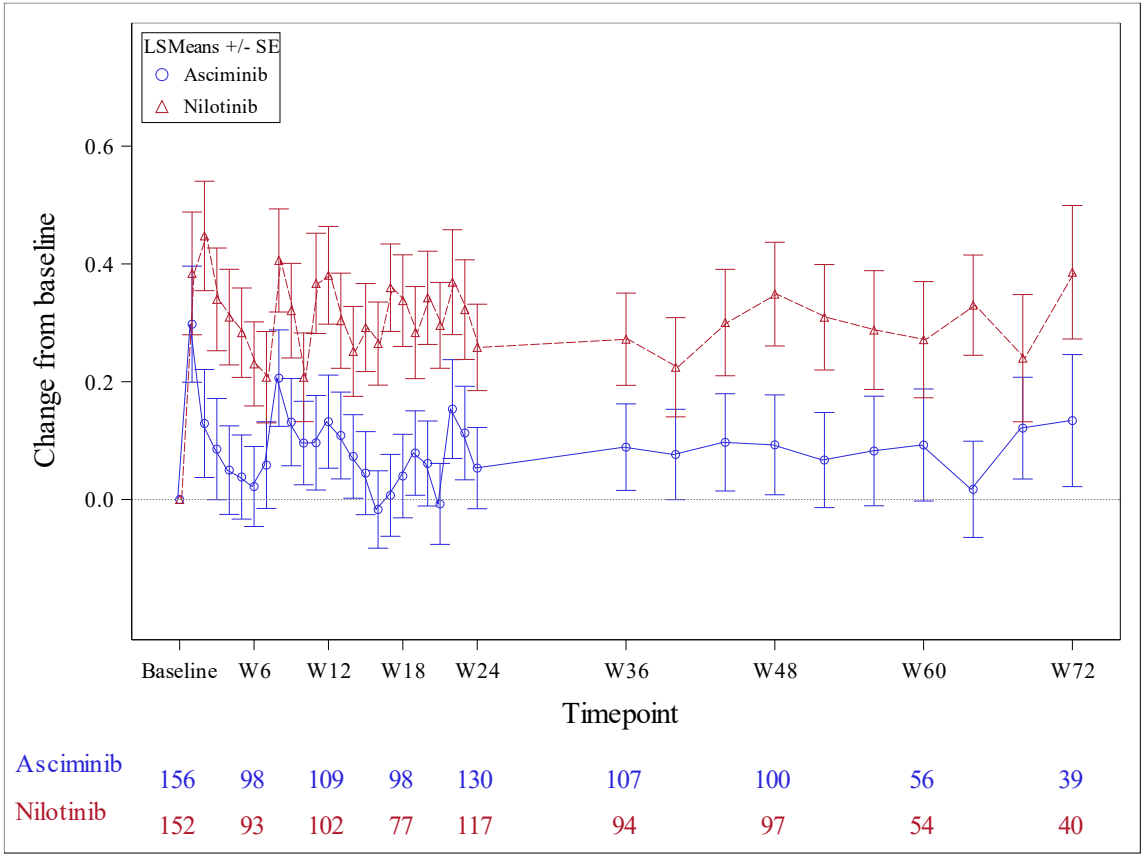
	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 14	159	0.5 (0.7)	88	0.1 (0.1)	139	0.9 (0.9)	75	0.3 (0.1)	-0.2 [-0.4; 0.0] 0.075
Week 15	163	0.4 (0.6)	91	0.0 (0.1)	149	0.9 (1.0)	82	0.3 (0.1)	-0.2 [-0.4; -0.1] 0.012
Week 16	164	0.4 (0.7)	93	0.0 (0.1)	149	0.9 (0.9)	80	0.3 (0.1)	-0.3 [-0.5; -0.1] 0.002
Week 17	162	0.4 (0.6)	90	0.0 (0.1)	145	0.9 (1.0)	79	0.4 (0.1)	-0.4 [-0.5; -0.2] <0.001
Week 18	164	0.4 (0.7)	98	0.0 (0.1)	144	0.9 (0.9)	77	0.3 (0.1)	-0.3 [-0.5; -0.1] 0.003
Week 19	161	0.5 (0.7)	90	0.1 (0.1)	141	0.9 (1.0)	72	0.3 (0.1)	-0.2 [-0.4; 0.0] 0.046
Week 20	163	0.4 (0.7)	92	0.1 (0.1)	140	0.9 (1.0)	73	0.3 (0.1)	-0.3 [-0.5; -0.1] 0.007
Week 21	162	0.4 (0.6)	89	0.0 (0.1)	146	0.8 (0.9)	80	0.3 (0.1)	-0.3 [-0.5; -0.1] 0.002
Week 22	148	0.6 (0.8)	85	0.2 (0.1)	145	0.8 (0.9)	76	0.4 (0.1)	-0.2 [-0.4; 0.0] 0.071
Week 23	161	0.5 (0.8)	93	0.1 (0.1)	153	0.9 (1.0)	82	0.3 (0.1)	-0.2 [-0.4; 0.0] 0.063
Week 24	215	0.5 (0.8)	130	0.1 (0.1)	205	0.8 (0.9)	117	0.3 (0.1)	-0.2 [-0.4; 0.0] 0.034
Week 36	188	0.4 (0.7)	107	0.1 (0.1)	160	0.8 (0.8)	94	0.3 (0.1)	-0.2 [-0.4; 0.0] 0.076
Week 40	124	0.4 (0.6)	72	0.1 (0.1)	93	0.7 (0.8)	57	0.2 (0.1)	-0.1 [-0.4; 0.1] 0.179
Week 44	114	0.4 (0.7)	62	0.1 (0.1)	84	0.8 (0.8)	50	0.3 (0.1)	-0.2 [-0.4; 0.0] 0.088
Week 48	169	0.5 (0.9)	100	0.1 (0.1)	148	0.8 (0.9)	97	0.3 (0.1)	-0.3 [-0.5; 0.0] 0.032
Week 52	95	0.5 (0.7)	50	0.1 (0.1)	72	0.7 (0.7)	39	0.3 (0.1)	-0.2 [-0.5; 0.0] 0.040

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 56	86	0.5 (0.7)	43	0.1 (0.1)	70	0.8 (0.9)	36	0.3 (0.1)	-0.2 [-0.5; 0.1] 0.128
Week 60	113	0.5 (0.7)	56	0.1 (0.1)	88	0.7 (0.9)	54	0.3 (0.1)	-0.2 [-0.4; 0.1] 0.184
Week 64	74	0.5 (0.7)	35	0.0 (0.1)	53	0.7 (0.6)	32	0.3 (0.1)	-0.3 [-0.5; -0.1] 0.007
Week 68	70	0.4 (0.6)	41	0.1 (0.1)	43	0.7 (0.7)	23	0.2 (0.1)	-0.1 [-0.4; 0.1] 0.381
Week 72	79	0.5 (0.7)	39	0.1 (0.1)	67	0.8 (0.8)	40	0.4 (0.1)	-0.3 [-0.6; 0.1] 0.111
Overall treatment effect			155	0.1 (0.1)			147	0.3 (0.1)	-0.2 [-0.4; -0.1] 0.003

N[a]: Number of patients with non-missing values at the timepoint
N[b]: Number of patients with non-missing values at baseline and at the timepoint after baseline
CI: Confidence Interval
MMRM: Mixed Model for Repeated Measures
LS Mean: Least Square Mean
SE: Standard Error
SD: Standard Deviation
N.E.: Not Estimable
.....
The column 'Mean (SD)' contains the raw mean and SD of the score at the respective timepoint, the column 'LS mean (SE)' contains the model based LS mean and SE of the change from baseline of the score at the respective timepoint. The difference in the comparison is the difference of the LS mean changes from baseline between Asciminib and Nilotinib.
FACT-ITEM GP5 V4 score ranges from 0='Not at all' to 4='Very much' with higher scores therefore indicating a stronger toxicity of cancer treatment.
The mixed model includes the PRO change from baseline as the dependent variable, treatment arm, study visit, and the stratification factors as recorded in the IRT system as covariates, and treatment arm*study visit interaction as fixed effects with study visit being treated as a repeated effect (repeated by subject).
Models were run using a CSH covariance matrix.
Data Cut/15MAY2025

Figure 3-3.3 MMRM - FACT-ITEM GP5 (Full Analysis Set)

FACIT GP5



Data Cut/15MAY2025

Table 3-3.4: MMRM - PRO-CTCAE (Full Analysis Set)

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
PRO-CTCAE: Nausea - Frequency									
Baseline	157	0.3 (0.7)			154	0.3 (0.8)			
Week 1	195	0.4 (0.7)	103	0.1 (0.1)	186	0.6 (0.9)	93	0.2 (0.1)	-0.1 [-0.4; 0.1] 0.219
Week 2	205	0.4 (0.8)	111	-0.1 (0.1)	206	0.5 (0.8)	120	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.171
Week 3	180	0.3 (0.6)	94	-0.1 (0.1)	173	0.4 (0.7)	102	-0.1 (0.1)	-0.1 [-0.2; 0.1] 0.340
Week 4	215	0.2 (0.6)	130	-0.1 (0.1)	184	0.4 (0.8)	107	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.264
Week 5	191	0.2 (0.5)	101	-0.2 (0.0)	167	0.4 (0.7)	92	0.0 (0.0)	-0.2 [-0.3; -0.1] 0.005
Week 6	176	0.2 (0.5)	99	-0.2 (0.1)	167	0.4 (0.7)	94	0.0 (0.1)	-0.2 [-0.3; 0.0] 0.034
Week 7	180	0.2 (0.5)	95	-0.1 (0.1)	156	0.3 (0.6)	87	-0.1 (0.1)	-0.1 [-0.2; 0.1] 0.286
Week 8	153	0.2 (0.6)	89	-0.1 (0.1)	133	0.3 (0.7)	76	0.0 (0.1)	-0.2 [-0.4; 0.0] 0.110
Week 9	180	0.2 (0.6)	104	-0.1 (0.0)	157	0.3 (0.6)	87	0.0 (0.1)	-0.1 [-0.2; 0.1] 0.357
Week 10	168	0.1 (0.5)	94	-0.1 (0.1)	162	0.3 (0.7)	84	-0.1 (0.1)	-0.1 [-0.3; 0.1] 0.217
Week 11	178	0.2 (0.4)	98	-0.2 (0.0)	156	0.3 (0.6)	89	-0.1 (0.0)	0.0 [-0.2; 0.1] 0.556
Week 12	191	0.2 (0.6)	111	-0.1 (0.1)	180	0.3 (0.6)	103	-0.1 (0.1)	0.0 [-0.2; 0.1] 0.853

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 13	174	0.2 (0.7)	103	-0.1 (0.1)	150	0.2 (0.6)	80	-0.1 (0.1)	0.1 [-0.1; 0.2] 0.527
Week 14	162	0.2 (0.5)	90	-0.1 (0.1)	140	0.3 (0.6)	77	-0.1 (0.1)	0.0 [-0.1; 0.2] 0.856
Week 15	166	0.1 (0.4)	93	-0.1 (0.0)	149	0.3 (0.5)	83	0.0 (0.1)	-0.1 [-0.2; 0.0] 0.175
Week 16	165	0.1 (0.4)	93	-0.1 (0.0)	149	0.3 (0.6)	81	-0.1 (0.1)	0.0 [-0.2; 0.1] 0.515
Week 17	163	0.2 (0.5)	90	-0.1 (0.1)	145	0.3 (0.7)	80	0.0 (0.1)	-0.1 [-0.3; 0.0] 0.158
Week 18	165	0.1 (0.4)	98	-0.1 (0.0)	145	0.3 (0.6)	77	0.0 (0.1)	-0.1 [-0.2; 0.0] 0.196
Week 19	162	0.2 (0.5)	90	-0.1 (0.1)	141	0.3 (0.7)	73	-0.1 (0.1)	0.0 [-0.2; 0.1] 0.667
Week 20	165	0.2 (0.5)	92	-0.1 (0.1)	140	0.3 (0.7)	73	0.0 (0.1)	-0.1 [-0.3; 0.0] 0.113
Week 21	164	0.1 (0.5)	90	-0.1 (0.1)	147	0.3 (0.6)	80	-0.1 (0.1)	0.0 [-0.2; 0.1] 0.567
Week 22	149	0.2 (0.5)	85	-0.1 (0.1)	145	0.3 (0.6)	77	0.0 (0.1)	-0.1 [-0.2; 0.1] 0.338
Week 23	162	0.1 (0.4)	93	-0.2 (0.0)	154	0.2 (0.6)	83	-0.1 (0.0)	0.0 [-0.2; 0.1] 0.472
Week 24	218	0.2 (0.6)	132	-0.1 (0.1)	205	0.3 (0.7)	118	-0.1 (0.1)	0.0 [-0.1; 0.1] 0.993
Week 36	189	0.2 (0.6)	107	0.0 (0.1)	160	0.4 (0.8)	95	0.0 (0.1)	-0.1 [-0.2; 0.1] 0.486
Week 40	125	0.2 (0.5)	72	-0.1 (0.1)	93	0.3 (0.6)	58	0.0 (0.1)	-0.1 [-0.2; 0.1] 0.496
Week 44	115	0.2 (0.5)	62	-0.1 (0.1)	84	0.3 (0.7)	50	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.600
Week 48	169	0.2 (0.6)	100	-0.1 (0.1)	149	0.3 (0.6)	97	0.0 (0.1)	-0.1 [-0.2; 0.1] 0.329

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 52	97	0.2 (0.5)	51	-0.1 (0.1)	74	0.4 (0.6)	40	0.1 (0.1)	-0.1 [-0.4; 0.1] 0.178
Week 56	88	0.2 (0.4)	44	-0.1 (0.1)	70	0.2 (0.5)	37	-0.1 (0.1)	0.0 [-0.2; 0.2] 0.866
Week 60	113	0.2 (0.6)	55	0.0 (0.1)	89	0.3 (0.7)	54	-0.1 (0.1)	0.1 [-0.1; 0.3] 0.250
Week 64	75	0.1 (0.4)	35	0.0 (0.1)	53	0.3 (0.6)	32	0.1 (0.1)	-0.1 [-0.3; 0.2] 0.583
Week 68	70	0.2 (0.4)	41	-0.1 (0.1)	43	0.3 (0.6)	23	-0.1 (0.1)	0.1 [-0.2; 0.3] 0.631
Week 72	80	0.2 (0.7)	39	0.0 (0.1)	68	0.3 (0.7)	40	-0.1 (0.1)	0.1 [-0.2; 0.3] 0.466
Overall treatment effect			156	-0.1 (0.0)			148	0.0 (0.0)	-0.1 [-0.1; 0.0] 0.191
PRO-CTCAE: Nausea - Severity									
Baseline	157	0.3 (0.6)			154	0.3 (0.6)			
Week 1	195	0.3 (0.7)	103	0.1 (0.1)	186	0.6 (0.9)	93	0.2 (0.1)	-0.1 [-0.3; 0.1] 0.290
Week 2	205	0.3 (0.7)	111	0.0 (0.1)	206	0.4 (0.7)	120	0.0 (0.1)	-0.1 [-0.2; 0.1] 0.391
Week 3	180	0.2 (0.6)	94	-0.1 (0.1)	173	0.3 (0.7)	102	-0.1 (0.1)	0.0 [-0.2; 0.1] 0.784
Week 4	215	0.2 (0.5)	130	-0.1 (0.0)	184	0.3 (0.7)	107	0.0 (0.1)	-0.1 [-0.2; 0.0] 0.193
Week 5	191	0.2 (0.5)	101	-0.1 (0.1)	167	0.4 (0.7)	92	0.0 (0.1)	-0.2 [-0.3; 0.0] 0.015
Week 6	176	0.2 (0.5)	99	-0.1 (0.0)	167	0.3 (0.7)	94	0.0 (0.1)	-0.1 [-0.3; 0.0] 0.044
Week 7	180	0.2 (0.5)	95	-0.1 (0.0)	156	0.3 (0.6)	87	0.0 (0.1)	-0.1 [-0.2; 0.1] 0.304

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 8	153	0.2 (0.6)	89	-0.1 (0.1)	133	0.3 (0.7)	76	0.1 (0.1)	-0.1 [-0.3; 0.0] 0.097
Week 9	180	0.2 (0.5)	104	-0.1 (0.1)	157	0.3 (0.6)	87	0.0 (0.1)	-0.1 [-0.2; 0.0] 0.180
Week 10	168	0.1 (0.4)	94	-0.1 (0.1)	162	0.3 (0.7)	84	0.0 (0.1)	-0.1 [-0.3; 0.0] 0.138
Week 11	178	0.2 (0.4)	98	-0.1 (0.0)	156	0.2 (0.6)	89	-0.1 (0.0)	0.0 [-0.2; 0.1] 0.540
Week 12	191	0.2 (0.6)	111	-0.1 (0.1)	180	0.3 (0.5)	103	0.0 (0.1)	0.0 [-0.2; 0.1] 0.541
Week 13	174	0.2 (0.5)	103	-0.1 (0.0)	150	0.2 (0.5)	80	-0.1 (0.1)	0.0 [-0.1; 0.1] 0.825
Week 14	162	0.2 (0.5)	90	-0.1 (0.1)	140	0.2 (0.5)	77	-0.1 (0.1)	0.0 [-0.1; 0.2] 0.710
Week 15	166	0.1 (0.4)	93	-0.1 (0.0)	149	0.3 (0.6)	83	0.0 (0.1)	-0.1 [-0.2; 0.0] 0.168
Week 16	165	0.1 (0.4)	93	-0.1 (0.0)	149	0.3 (0.6)	81	0.0 (0.1)	-0.1 [-0.2; 0.1] 0.236
Week 17	163	0.2 (0.4)	90	-0.1 (0.0)	145	0.2 (0.6)	80	0.0 (0.1)	-0.1 [-0.2; 0.1] 0.275
Week 18	165	0.1 (0.4)	98	-0.1 (0.0)	145	0.3 (0.6)	77	0.0 (0.1)	-0.1 [-0.3; 0.0] 0.091
Week 19	162	0.2 (0.5)	90	-0.1 (0.1)	141	0.3 (0.7)	73	0.0 (0.1)	0.0 [-0.2; 0.1] 0.642
Week 20	165	0.1 (0.4)	92	-0.1 (0.0)	140	0.3 (0.6)	73	0.0 (0.1)	-0.1 [-0.2; 0.0] 0.088
Week 21	164	0.1 (0.4)	90	-0.1 (0.1)	147	0.2 (0.5)	80	0.0 (0.1)	0.0 [-0.2; 0.1] 0.560
Week 22	149	0.2 (0.5)	85	-0.1 (0.1)	145	0.3 (0.6)	77	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.351
Week 23	162	0.1 (0.4)	93	-0.1 (0.0)	154	0.2 (0.5)	83	-0.1 (0.0)	0.0 [-0.2; 0.1] 0.443

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 24	218	0.2 (0.5)	132	-0.1 (0.0)	205	0.3 (0.6)	118	-0.1 (0.0)	0.0 [-0.1; 0.1] 0.934
Week 36	189	0.2 (0.6)	107	0.0 (0.1)	160	0.4 (0.8)	95	0.1 (0.1)	-0.1 [-0.3; 0.1] 0.303
Week 40	125	0.1 (0.4)	72	-0.1 (0.0)	93	0.3 (0.5)	58	0.0 (0.1)	-0.1 [-0.2; 0.1] 0.415
Week 44	115	0.2 (0.4)	62	-0.1 (0.1)	84	0.3 (0.7)	50	-0.1 (0.1)	0.0 [-0.2; 0.1] 0.606
Week 48	169	0.2 (0.5)	100	-0.1 (0.0)	149	0.3 (0.6)	97	0.0 (0.1)	-0.1 [-0.2; 0.1] 0.402
Week 52	97	0.2 (0.4)	51	-0.1 (0.1)	74	0.3 (0.5)	40	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.195
Week 56	88	0.2 (0.5)	44	0.0 (0.1)	70	0.3 (0.6)	37	0.0 (0.1)	0.0 [-0.2; 0.2] 0.917
Week 60	113	0.2 (0.6)	55	0.0 (0.1)	89	0.3 (0.7)	54	-0.1 (0.1)	0.1 [-0.1; 0.3] 0.225
Week 64	75	0.1 (0.4)	35	0.0 (0.1)	53	0.2 (0.6)	32	0.1 (0.1)	-0.1 [-0.3; 0.2] 0.645
Week 68	70	0.1 (0.4)	41	-0.1 (0.1)	43	0.3 (0.5)	23	-0.1 (0.1)	0.0 [-0.2; 0.2] 0.835
Week 72	80	0.2 (0.5)	39	-0.1 (0.1)	68	0.2 (0.5)	40	-0.1 (0.1)	0.1 [-0.1; 0.2] 0.437
Overall treatment effect			156	-0.1 (0.0)			148	0.0 (0.0)	-0.1 [-0.1; 0.0] 0.156
PRO-CTCAE: Vomiting - Frequency									
Baseline	157	0.1 (0.4)			154	0.1 (0.3)			
Week 1	195	0.0 (0.2)	103	0.0 (0.0)	186	0.1 (0.3)	93	0.0 (0.0)	0.0 [-0.1; 0.1] 0.492
Week 2	205	0.0 (0.2)	111	0.0 (0.0)	206	0.1 (0.5)	120	0.1 (0.0)	-0.1 [-0.2; 0.0] 0.135

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 3	180	0.0 (0.3)	94	0.0 (0.0)	173	0.1 (0.4)	102	0.0 (0.0)	0.0 [-0.1; 0.1] 0.433
Week 4	215	0.0 (0.2)	130	-0.1 (0.0)	184	0.1 (0.4)	107	0.0 (0.0)	0.0 [-0.1; 0.0] 0.196
Week 5	191	0.0 (0.1)	101	0.0 (0.0)	167	0.1 (0.3)	92	0.0 (0.0)	-0.1 [-0.1; 0.0] 0.155
Week 6	176	0.0 (0.1)	99	-0.1 (0.0)	167	0.1 (0.3)	94	0.0 (0.0)	0.0 [-0.1; 0.0] 0.239
Week 7	180	0.0 (0.2)	95	0.0 (0.0)	156	0.0 (0.2)	87	-0.1 (0.0)	0.0 [0.0; 0.1] 0.588
Week 8	153	0.0 (0.2)	89	0.0 (0.0)	133	0.0 (0.3)	76	0.0 (0.0)	0.0 [-0.1; 0.0] 0.578
Week 9	180	0.0 (0.2)	104	0.0 (0.0)	157	0.1 (0.4)	87	0.0 (0.0)	-0.1 [-0.2; 0.0] 0.046
Week 10	168	0.0 (0.1)	94	0.0 (0.0)	162	0.1 (0.4)	84	0.0 (0.0)	-0.1 [-0.1; 0.0] 0.172
Week 11	178	0.0 (0.1)	98	0.0 (0.0)	156	0.0 (0.2)	89	0.0 (0.0)	0.0 [-0.1; 0.0] 0.585
Week 12	191	0.1 (0.3)	111	0.0 (0.0)	180	0.1 (0.3)	103	0.0 (0.0)	0.0 [-0.1; 0.1] 0.889
Week 13	174	0.1 (0.4)	103	0.0 (0.0)	150	0.0 (0.2)	80	0.0 (0.0)	0.0 [-0.1; 0.1] 0.738
Week 14	162	0.0 (0.1)	90	-0.1 (0.0)	140	0.1 (0.3)	77	0.0 (0.0)	0.0 [-0.1; 0.0] 0.089
Week 15	166	0.0 (0.1)	93	0.0 (0.0)	149	0.1 (0.3)	83	0.0 (0.0)	-0.1 [-0.1; 0.0] 0.111
Week 16	165	0.0 (0.1)	93	0.0 (0.0)	149	0.1 (0.4)	81	0.0 (0.0)	-0.1 [-0.2; 0.0] 0.076
Week 17	163	0.0 (0.2)	90	0.0 (0.0)	145	0.0 (0.2)	80	0.0 (0.0)	0.0 [-0.1; 0.0] 0.259
Week 18	165	0.0 (0.0)	98	-0.1 (0.0)	145	0.0 (0.3)	77	0.0 (0.0)	-0.1 [-0.1; 0.0] 0.114

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 19	162	0.0 (0.2)	90	0.0 (0.0)	141	0.0 (0.1)	73	0.0 (0.0)	0.0 [-0.1; 0.0] 0.771
Week 20	165	0.0 (0.2)	92	0.0 (0.0)	140	0.1 (0.3)	73	0.0 (0.0)	0.0 [-0.1; 0.0] 0.279
Week 21	164	0.0 (0.2)	90	0.0 (0.0)	147	0.0 (0.3)	80	0.0 (0.0)	0.0 [-0.1; 0.1] 0.711
Week 22	149	0.0 (0.1)	85	0.0 (0.0)	145	0.0 (0.2)	77	0.0 (0.0)	0.0 [-0.1; 0.0] 0.172
Week 23	162	0.0 (0.1)	93	0.0 (0.0)	154	0.0 (0.2)	83	0.0 (0.0)	0.0 [-0.1; 0.1] 0.963
Week 24	218	0.0 (0.3)	132	0.0 (0.0)	205	0.1 (0.3)	118	0.0 (0.0)	0.0 [-0.1; 0.1] 0.741
Week 36	189	0.0 (0.3)	107	0.0 (0.0)	160	0.1 (0.4)	95	0.0 (0.0)	0.0 [-0.1; 0.0] 0.289
Week 40	125	0.0 (0.2)	72	0.0 (0.0)	93	0.1 (0.3)	58	0.0 (0.0)	0.0 [-0.1; 0.1] 0.648
Week 44	115	0.0 (0.1)	62	0.0 (0.0)	84	0.0 (0.2)	50	0.0 (0.0)	0.0 [-0.1; 0.1] 0.987
Week 48	169	0.1 (0.4)	100	0.0 (0.0)	149	0.1 (0.4)	97	0.0 (0.0)	0.0 [-0.1; 0.1] 0.985
Week 52	97	0.1 (0.4)	51	0.0 (0.1)	74	0.1 (0.3)	40	0.0 (0.1)	0.0 [-0.2; 0.1] 0.968
Week 56	88	0.0 (0.2)	44	0.0 (0.0)	70	0.1 (0.3)	37	-0.1 (0.0)	0.1 [0.0; 0.1] 0.079
Week 60	113	0.1 (0.3)	55	0.0 (0.0)	89	0.1 (0.3)	54	0.0 (0.0)	0.0 [-0.1; 0.2] 0.619
Week 64	75	0.0 (0.2)	35	0.0 (0.0)	53	0.0 (0.3)	32	0.0 (0.0)	0.0 [-0.1; 0.1] 0.904
Week 68	70	0.0 (0.1)	41	0.0 (0.0)	43	0.1 (0.3)	23	0.0 (0.0)	-0.1 [-0.2; 0.1] 0.284
Week 72	80	0.0 (0.2)	39	0.0 (0.0)	68	0.1 (0.3)	40	0.0 (0.0)	0.0 [-0.1; 0.1] 0.492

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Overall treatment effect			156	0.0 (0.0)			148	0.0 (0.0)	0.0 [-0.1; 0.0] 0.299
PRO-CTCAE: Vomiting - Severity									
Baseline	157	0.1 (0.4)			154	0.1 (0.3)			
Week 1	195	0.0 (0.3)	103	0.0 (0.0)	186	0.1 (0.4)	93	0.0 (0.0)	0.0 [-0.1; 0.1] 0.464
Week 2	205	0.0 (0.2)	111	0.0 (0.0)	206	0.1 (0.4)	120	0.1 (0.0)	-0.1 [-0.2; 0.0] 0.264
Week 3	180	0.0 (0.3)	94	0.0 (0.0)	173	0.1 (0.5)	102	0.0 (0.0)	0.0 [-0.1; 0.1] 0.888
Week 4	215	0.0 (0.2)	130	0.0 (0.0)	184	0.1 (0.5)	107	0.0 (0.0)	-0.1 [-0.1; 0.0] 0.056
Week 5	191	0.0 (0.1)	101	0.0 (0.0)	167	0.1 (0.3)	92	0.0 (0.0)	0.0 [-0.1; 0.0] 0.155
Week 6	176	0.0 (0.1)	99	0.0 (0.0)	167	0.1 (0.3)	94	0.0 (0.0)	0.0 [-0.1; 0.0] 0.443
Week 7	180	0.0 (0.2)	95	0.0 (0.0)	156	0.0 (0.3)	87	0.0 (0.0)	0.0 [-0.1; 0.1] 0.921
Week 8	153	0.0 (0.2)	89	0.0 (0.0)	133	0.0 (0.2)	76	0.0 (0.0)	0.0 [-0.1; 0.0] 0.712
Week 9	180	0.0 (0.2)	104	0.0 (0.0)	157	0.1 (0.3)	87	0.0 (0.0)	-0.1 [-0.1; 0.0] 0.101
Week 10	168	0.0 (0.2)	94	0.0 (0.0)	162	0.1 (0.3)	84	0.0 (0.0)	0.0 [-0.2; 0.1] 0.400
Week 11	178	0.0 (0.1)	98	0.0 (0.0)	156	0.0 (0.2)	89	0.0 (0.0)	0.0 [0.0; 0.0] 0.791
Week 12	191	0.1 (0.4)	111	0.0 (0.0)	180	0.1 (0.3)	103	0.0 (0.0)	0.0 [-0.1; 0.1] 0.943
Week 13	174	0.1 (0.3)	103	0.0 (0.0)	150	0.0 (0.1)	80	0.0 (0.0)	0.0 [0.0; 0.1] 0.377

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 14	162	0.0 (0.1)	90	0.0 (0.0)	140	0.1 (0.2)	77	0.0 (0.0)	0.0 [-0.1; 0.0] 0.170
Week 15	166	0.0 (0.1)	93	0.0 (0.0)	149	0.1 (0.3)	83	0.0 (0.0)	-0.1 [-0.1; 0.0] 0.122
Week 16	165	0.0 (0.1)	93	0.0 (0.0)	149	0.1 (0.5)	81	0.0 (0.0)	-0.1 [-0.2; 0.0] 0.113
Week 17	163	0.0 (0.2)	90	0.0 (0.0)	145	0.0 (0.3)	80	0.0 (0.0)	0.0 [-0.1; 0.1] 0.690
Week 18	165	0.0 (0.0)	98	0.0 (0.0)	145	0.0 (0.3)	77	0.0 (0.0)	0.0 [-0.1; 0.0] 0.142
Week 19	162	0.0 (0.1)	90	0.0 (0.0)	141	0.0 (0.4)	73	0.0 (0.0)	0.0 [-0.1; 0.0] 0.928
Week 20	165	0.0 (0.2)	92	0.0 (0.0)	140	0.1 (0.4)	73	0.0 (0.0)	0.0 [-0.1; 0.1] 0.599
Week 21	164	0.0 (0.1)	90	0.0 (0.0)	147	0.0 (0.2)	80	0.0 (0.0)	0.0 [-0.1; 0.0] 0.374
Week 22	149	0.0 (0.1)	85	0.0 (0.0)	145	0.0 (0.2)	77	0.0 (0.0)	0.0 [-0.1; 0.0] 0.180
Week 23	162	0.0 (0.1)	93	0.0 (0.0)	154	0.0 (0.1)	83	0.0 (0.0)	0.0 [0.0; 0.1] 0.775
Week 24	218	0.1 (0.4)	132	0.0 (0.0)	205	0.1 (0.3)	118	0.0 (0.0)	0.0 [-0.1; 0.1] 0.714
Week 36	189	0.0 (0.3)	107	0.0 (0.0)	160	0.1 (0.5)	95	0.1 (0.0)	-0.1 [-0.2; 0.1] 0.312
Week 40	125	0.0 (0.1)	72	0.0 (0.0)	93	0.1 (0.4)	58	0.1 (0.0)	-0.1 [-0.2; 0.0] 0.272
Week 44	115	0.0 (0.2)	62	0.0 (0.0)	84	0.0 (0.2)	50	0.0 (0.0)	0.0 [-0.1; 0.1] 0.606
Week 48	169	0.1 (0.3)	100	0.0 (0.0)	149	0.1 (0.5)	97	0.0 (0.0)	0.0 [-0.1; 0.1] 0.892
Week 52	97	0.1 (0.3)	51	0.0 (0.0)	74	0.1 (0.3)	40	0.1 (0.0)	-0.1 [-0.2; 0.1] 0.392

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 56	88	0.1 (0.3)	44	0.0 (0.0)	70	0.1 (0.3)	37	-0.1 (0.0)	0.1 [0.0; 0.2] 0.078
Week 60	113	0.1 (0.4)	55	0.0 (0.0)	89	0.1 (0.3)	54	0.0 (0.0)	0.0 [-0.1; 0.1] 0.443
Week 64	75	0.0 (0.2)	35	0.0 (0.0)	53	0.0 (0.3)	32	0.0 (0.0)	0.0 [-0.1; 0.1] 0.867
Week 68	70	0.0 (0.1)	41	0.0 (0.0)	43	0.1 (0.3)	23	0.1 (0.0)	-0.1 [-0.2; 0.1] 0.266
Week 72	80	0.0 (0.2)	39	0.0 (0.0)	68	0.1 (0.3)	40	0.0 (0.0)	0.0 [-0.1; 0.1] 0.983
Overall treatment effect			156	0.0 (0.0)			148	0.0 (0.0)	0.0 [-0.1; 0.0] 0.348
PRO-CTCAE: Diarrhea - Frequency									
Baseline	157	0.5 (0.9)			154	0.5 (0.9)			
Week 1	195	0.6 (1.0)	103	0.1 (0.1)	186	0.6 (1.0)	93	0.1 (0.1)	0.0 [-0.3; 0.3] 0.873
Week 2	205	0.6 (0.9)	111	-0.1 (0.1)	206	0.5 (0.8)	120	0.0 (0.1)	-0.1 [-0.3; 0.2] 0.577
Week 3	180	0.6 (0.8)	94	0.0 (0.1)	173	0.5 (0.9)	102	-0.1 (0.1)	0.1 [-0.2; 0.3] 0.560
Week 4	215	0.5 (0.8)	130	-0.1 (0.1)	184	0.4 (0.7)	107	-0.1 (0.1)	0.0 [-0.1; 0.2] 0.648
Week 5	191	0.4 (0.8)	101	-0.1 (0.1)	167	0.4 (0.8)	92	-0.2 (0.1)	0.1 [-0.1; 0.3] 0.382
Week 6	176	0.4 (0.7)	99	-0.1 (0.1)	167	0.4 (0.8)	94	-0.1 (0.1)	-0.1 [-0.2; 0.1] 0.557
Week 7	180	0.5 (0.8)	95	-0.1 (0.1)	156	0.4 (0.8)	87	-0.1 (0.1)	0.0 [-0.2; 0.2] 0.940
Week 8	153	0.6 (1.0)	89	0.0 (0.1)	133	0.3 (0.7)	76	-0.1 (0.1)	0.1 [-0.1; 0.3] 0.301

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 9	180	0.4 (0.8)	104	-0.1 (0.1)	157	0.4 (0.7)	87	-0.1 (0.1)	0.0 [-0.2; 0.2] 0.720
Week 10	168	0.5 (0.8)	94	-0.1 (0.1)	162	0.5 (0.8)	84	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.239
Week 11	178	0.5 (0.8)	98	-0.1 (0.1)	156	0.5 (0.7)	89	-0.1 (0.1)	0.0 [-0.2; 0.2] 0.953
Week 12	191	0.5 (0.9)	111	-0.1 (0.1)	180	0.4 (0.8)	103	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.355
Week 13	174	0.5 (0.9)	103	0.0 (0.1)	150	0.4 (0.7)	80	-0.1 (0.1)	0.0 [-0.1; 0.2] 0.621
Week 14	162	0.4 (0.7)	90	-0.2 (0.1)	140	0.3 (0.6)	77	-0.2 (0.1)	0.0 [-0.2; 0.1] 0.798
Week 15	166	0.4 (0.7)	93	-0.2 (0.1)	149	0.3 (0.6)	83	-0.2 (0.1)	0.0 [-0.2; 0.1] 0.737
Week 16	165	0.4 (0.7)	93	-0.1 (0.1)	149	0.4 (0.7)	81	-0.1 (0.1)	0.0 [-0.1; 0.2] 0.728
Week 17	163	0.5 (0.8)	90	-0.1 (0.1)	145	0.3 (0.7)	80	-0.1 (0.1)	0.0 [-0.2; 0.2] 0.854
Week 18	165	0.4 (0.8)	98	-0.2 (0.1)	145	0.4 (0.7)	77	-0.1 (0.1)	-0.1 [-0.2; 0.1] 0.433
Week 19	162	0.4 (0.8)	90	-0.2 (0.1)	141	0.3 (0.6)	73	-0.1 (0.1)	0.0 [-0.2; 0.1] 0.644
Week 20	165	0.4 (0.8)	92	-0.1 (0.1)	140	0.3 (0.6)	73	-0.1 (0.1)	0.0 [-0.2; 0.2] 0.868
Week 21	164	0.4 (0.7)	90	-0.2 (0.1)	147	0.3 (0.6)	80	-0.1 (0.1)	-0.1 [-0.2; 0.1] 0.455
Week 22	149	0.5 (0.8)	85	-0.1 (0.1)	145	0.4 (0.7)	77	-0.1 (0.1)	-0.1 [-0.3; 0.2] 0.606
Week 23	162	0.4 (0.8)	93	-0.2 (0.1)	154	0.4 (0.7)	83	-0.1 (0.1)	-0.1 [-0.3; 0.1] 0.451
Week 24	218	0.5 (0.8)	132	-0.1 (0.1)	205	0.4 (0.8)	118	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.417

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 36	189	0.5 (0.9)	107	-0.1 (0.1)	160	0.4 (0.7)	95	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.494
Week 40	125	0.5 (0.9)	72	0.0 (0.1)	93	0.3 (0.6)	58	-0.1 (0.1)	0.1 [-0.1; 0.4] 0.322
Week 44	115	0.5 (0.9)	62	0.0 (0.1)	84	0.5 (0.8)	50	0.0 (0.1)	-0.1 [-0.3; 0.2] 0.666
Week 48	169	0.4 (0.8)	100	-0.2 (0.1)	149	0.3 (0.7)	97	-0.2 (0.1)	0.0 [-0.2; 0.2] 0.890
Week 52	97	0.5 (0.9)	51	0.0 (0.1)	74	0.4 (0.6)	40	-0.1 (0.1)	0.1 [-0.2; 0.3] 0.691
Week 56	88	0.5 (0.8)	44	-0.1 (0.1)	70	0.4 (0.8)	37	0.0 (0.1)	-0.1 [-0.4; 0.1] 0.362
Week 60	113	0.6 (1.0)	55	-0.1 (0.1)	89	0.3 (0.7)	54	-0.1 (0.1)	0.1 [-0.2; 0.3] 0.593
Week 64	75	0.4 (0.8)	35	-0.2 (0.1)	53	0.3 (0.6)	32	-0.2 (0.1)	0.0 [-0.2; 0.2] 0.936
Week 68	70	0.6 (1.0)	41	-0.1 (0.1)	43	0.4 (0.7)	23	-0.1 (0.1)	0.0 [-0.4; 0.3] 0.779
Week 72	80	0.6 (0.9)	39	0.0 (0.1)	68	0.4 (0.8)	40	-0.1 (0.1)	0.1 [-0.2; 0.5] 0.410
Overall treatment effect			156	-0.1 (0.0)			148	-0.1 (0.0)	0.0 [-0.1; 0.1] 0.893
PRO-CTCAE: Cough - Severity									
Baseline	157	0.5 (0.8)			154	0.4 (0.8)			
Week 1	195	0.5 (0.7)	103	0.0 (0.1)	186	0.5 (0.8)	93	-0.2 (0.1)	0.2 [0.0; 0.4] 0.097
Week 2	205	0.4 (0.7)	111	-0.2 (0.1)	206	0.4 (0.7)	120	-0.2 (0.1)	0.0 [-0.2; 0.1] 0.938
Week 3	180	0.4 (0.7)	94	-0.1 (0.1)	173	0.4 (0.7)	102	-0.1 (0.1)	0.0 [-0.2; 0.2] 0.927

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 4	215	0.4 (0.7)	130	-0.1 (0.1)	184	0.5 (0.8)	107	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.394
Week 5	191	0.4 (0.7)	101	-0.1 (0.1)	167	0.4 (0.7)	92	-0.1 (0.1)	0.0 [-0.2; 0.1] 0.686
Week 6	176	0.4 (0.7)	99	-0.1 (0.1)	167	0.4 (0.7)	94	-0.1 (0.1)	0.0 [-0.2; 0.1] 0.575
Week 7	180	0.4 (0.7)	95	-0.1 (0.1)	156	0.5 (0.7)	87	0.0 (0.1)	-0.1 [-0.2; 0.1] 0.480
Week 8	153	0.4 (0.7)	89	-0.2 (0.1)	133	0.4 (0.8)	76	0.0 (0.1)	-0.2 [-0.4; 0.0] 0.093
Week 9	180	0.3 (0.6)	104	-0.2 (0.1)	157	0.4 (0.6)	87	-0.1 (0.1)	-0.1 [-0.2; 0.1] 0.433
Week 10	168	0.3 (0.5)	94	-0.2 (0.1)	162	0.4 (0.6)	84	-0.1 (0.1)	-0.1 [-0.3; 0.0] 0.103
Week 11	178	0.2 (0.5)	98	-0.3 (0.1)	156	0.4 (0.6)	89	-0.1 (0.1)	-0.2 [-0.3; 0.0] 0.024
Week 12	191	0.3 (0.6)	111	-0.1 (0.1)	180	0.4 (0.6)	103	-0.1 (0.1)	0.0 [-0.2; 0.1] 0.624
Week 13	174	0.2 (0.5)	103	-0.3 (0.1)	150	0.3 (0.6)	80	-0.2 (0.1)	-0.1 [-0.2; 0.1] 0.270
Week 14	162	0.3 (0.7)	90	-0.2 (0.1)	140	0.4 (0.7)	77	-0.1 (0.1)	-0.1 [-0.3; 0.1] 0.280
Week 15	166	0.2 (0.5)	93	-0.3 (0.1)	149	0.5 (0.7)	83	-0.1 (0.1)	-0.3 [-0.4; -0.1] <0.001
Week 16	165	0.3 (0.5)	93	-0.2 (0.1)	149	0.4 (0.7)	81	-0.1 (0.1)	-0.1 [-0.3; 0.0] 0.069
Week 17	163	0.2 (0.5)	90	-0.3 (0.1)	145	0.4 (0.7)	80	0.0 (0.1)	-0.3 [-0.4; -0.1] <0.001
Week 18	165	0.2 (0.5)	98	-0.3 (0.1)	145	0.4 (0.6)	77	-0.1 (0.1)	-0.2 [-0.4; -0.1] 0.006
Week 19	162	0.3 (0.6)	90	-0.1 (0.1)	141	0.4 (0.7)	73	-0.1 (0.1)	0.0 [-0.2; 0.2] 0.993

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 20	165	0.3 (0.5)	92	-0.2 (0.1)	140	0.4 (0.7)	73	-0.1 (0.1)	-0.1 [-0.3; 0.0] 0.112
Week 21	164	0.3 (0.5)	90	-0.2 (0.0)	147	0.3 (0.6)	80	-0.2 (0.1)	-0.1 [-0.2; 0.1] 0.250
Week 22	149	0.2 (0.6)	85	-0.3 (0.1)	145	0.3 (0.6)	77	-0.1 (0.1)	-0.1 [-0.3; 0.0] 0.108
Week 23	162	0.2 (0.5)	93	-0.3 (0.1)	154	0.5 (0.7)	83	0.0 (0.1)	-0.2 [-0.4; -0.1] 0.004
Week 24	218	0.3 (0.6)	132	-0.2 (0.1)	205	0.4 (0.7)	118	-0.1 (0.1)	-0.2 [-0.3; 0.0] 0.025
Week 36	189	0.3 (0.6)	107	-0.2 (0.1)	160	0.5 (0.8)	95	0.0 (0.1)	-0.2 [-0.4; 0.0] 0.020
Week 40	125	0.2 (0.5)	72	-0.2 (0.1)	93	0.4 (0.6)	58	-0.1 (0.1)	-0.1 [-0.2; 0.1] 0.349
Week 44	115	0.3 (0.6)	62	-0.1 (0.1)	84	0.5 (0.8)	50	0.1 (0.1)	-0.2 [-0.5; 0.0] 0.102
Week 48	169	0.4 (0.7)	100	-0.1 (0.1)	149	0.4 (0.8)	97	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.291
Week 52	97	0.3 (0.7)	51	-0.1 (0.1)	74	0.4 (0.8)	40	0.1 (0.1)	-0.2 [-0.5; 0.1] 0.227
Week 56	88	0.4 (0.7)	44	-0.2 (0.1)	70	0.5 (0.7)	37	0.0 (0.1)	-0.2 [-0.4; 0.1] 0.190
Week 60	113	0.4 (0.8)	55	-0.1 (0.1)	89	0.5 (0.9)	54	0.0 (0.1)	-0.1 [-0.3; 0.2] 0.509
Week 64	75	0.4 (0.7)	35	-0.1 (0.1)	53	0.4 (0.7)	32	-0.2 (0.1)	0.1 [-0.2; 0.4] 0.491
Week 68	70	0.2 (0.5)	41	-0.2 (0.1)	43	0.5 (0.7)	23	-0.1 (0.1)	-0.1 [-0.3; 0.1] 0.405
Week 72	80	0.4 (0.7)	39	-0.1 (0.1)	68	0.4 (0.7)	40	-0.1 (0.1)	0.0 [-0.3; 0.3] 0.982
Overall treatment effect			156	-0.2 (0.0)			148	-0.1 (0.0)	-0.1 [-0.2; 0.0] 0.022

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
PRO-CTCAE: Cough - Interference									
Baseline	157	0.2 (0.7)			154	0.2 (0.8)			
Week 1	195	0.2 (0.5)	103	-0.1 (0.0)	186	0.2 (0.6)	93	-0.2 (0.0)	0.0 [-0.1; 0.2] 0.523
Week 2	205	0.2 (0.6)	111	-0.1 (0.0)	206	0.2 (0.5)	120	-0.1 (0.0)	0.0 [-0.1; 0.1] 0.981
Week 3	180	0.2 (0.4)	94	-0.2 (0.0)	173	0.2 (0.5)	102	-0.2 (0.0)	0.0 [-0.1; 0.1] 0.615
Week 4	215	0.2 (0.4)	130	-0.1 (0.0)	184	0.2 (0.5)	107	-0.1 (0.0)	0.0 [-0.2; 0.1] 0.482
Week 5	191	0.1 (0.4)	101	-0.2 (0.0)	167	0.2 (0.6)	92	-0.1 (0.0)	-0.1 [-0.2; 0.0] 0.085
Week 6	176	0.2 (0.5)	99	-0.2 (0.0)	167	0.2 (0.6)	94	-0.1 (0.0)	-0.1 [-0.2; 0.0] 0.091
Week 7	180	0.2 (0.5)	95	-0.1 (0.0)	156	0.2 (0.6)	87	-0.1 (0.1)	0.0 [-0.2; 0.1] 0.722
Week 8	153	0.2 (0.5)	89	-0.1 (0.1)	133	0.2 (0.6)	76	0.0 (0.1)	-0.1 [-0.2; 0.1] 0.351
Week 9	180	0.2 (0.5)	104	-0.1 (0.0)	157	0.2 (0.5)	87	-0.1 (0.1)	0.0 [-0.1; 0.2] 0.627
Week 10	168	0.1 (0.3)	94	-0.2 (0.0)	162	0.2 (0.6)	84	-0.1 (0.0)	-0.1 [-0.2; 0.1] 0.290
Week 11	178	0.1 (0.4)	98	-0.1 (0.0)	156	0.2 (0.6)	89	0.0 (0.0)	-0.1 [-0.2; 0.0] 0.143
Week 12	191	0.2 (0.5)	111	-0.1 (0.1)	180	0.2 (0.6)	103	-0.1 (0.1)	-0.1 [-0.2; 0.1] 0.455
Week 13	174	0.1 (0.3)	103	-0.2 (0.0)	150	0.2 (0.5)	80	-0.1 (0.0)	-0.1 [-0.2; 0.0] 0.093
Week 14	162	0.1 (0.4)	90	-0.2 (0.0)	140	0.2 (0.5)	77	-0.1 (0.0)	0.0 [-0.1; 0.1] 0.774

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 15	166	0.1 (0.4)	93	-0.2 (0.0)	149	0.2 (0.6)	83	-0.1 (0.0)	-0.1 [-0.2; 0.0] 0.083
Week 16	165	0.1 (0.3)	93	-0.2 (0.0)	149	0.2 (0.6)	81	-0.1 (0.0)	-0.1 [-0.2; 0.0] 0.128
Week 17	163	0.1 (0.4)	90	-0.2 (0.0)	145	0.2 (0.5)	80	0.0 (0.0)	-0.2 [-0.3; -0.1] <0.001
Week 18	165	0.1 (0.4)	98	-0.2 (0.0)	145	0.2 (0.5)	77	-0.1 (0.1)	-0.1 [-0.3; 0.0] 0.068
Week 19	162	0.1 (0.4)	90	-0.1 (0.1)	141	0.2 (0.6)	73	-0.1 (0.1)	0.0 [-0.2; 0.1] 0.558
Week 20	165	0.1 (0.3)	92	-0.2 (0.0)	140	0.2 (0.7)	73	-0.1 (0.1)	-0.1 [-0.3; 0.0] 0.077
Week 21	164	0.1 (0.3)	90	-0.2 (0.0)	147	0.2 (0.5)	80	-0.1 (0.0)	-0.1 [-0.2; 0.0] 0.024
Week 22	149	0.1 (0.5)	85	-0.2 (0.0)	145	0.2 (0.6)	77	-0.1 (0.1)	-0.1 [-0.2; 0.0] 0.168
Week 23	162	0.1 (0.4)	93	-0.2 (0.0)	154	0.2 (0.6)	83	0.0 (0.0)	-0.2 [-0.3; 0.0] 0.012
Week 24	218	0.1 (0.5)	132	-0.1 (0.0)	205	0.2 (0.6)	118	-0.1 (0.0)	0.0 [-0.2; 0.1] 0.532
Week 36	189	0.2 (0.4)	107	-0.1 (0.0)	160	0.2 (0.6)	95	-0.1 (0.0)	-0.1 [-0.2; 0.1] 0.248
Week 40	125	0.1 (0.3)	72	-0.2 (0.0)	93	0.1 (0.4)	58	-0.2 (0.0)	0.0 [-0.1; 0.1] 0.859
Week 44	115	0.1 (0.5)	62	-0.1 (0.1)	84	0.4 (0.8)	50	0.2 (0.1)	-0.3 [-0.5; -0.1] 0.006
Week 48	169	0.2 (0.4)	100	-0.1 (0.1)	149	0.2 (0.6)	97	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.202
Week 52	97	0.1 (0.5)	51	-0.1 (0.1)	74	0.3 (0.8)	40	0.1 (0.1)	-0.2 [-0.4; 0.0] 0.082
Week 56	88	0.1 (0.4)	44	-0.1 (0.0)	70	0.2 (0.5)	37	-0.1 (0.1)	-0.1 [-0.2; 0.1] 0.215

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 60	113	0.2 (0.5)	55	-0.1 (0.1)	89	0.3 (0.7)	54	0.1 (0.1)	-0.1 [-0.4; 0.1] 0.221
Week 64	75	0.1 (0.4)	35	0.0 (0.1)	53	0.2 (0.6)	32	0.0 (0.1)	0.0 [-0.3; 0.2] 0.855
Week 68	70	0.1 (0.3)	41	-0.1 (0.1)	43	0.2 (0.5)	23	-0.1 (0.1)	0.0 [-0.2; 0.2] 0.993
Week 72	80	0.3 (0.6)	39	0.0 (0.1)	68	0.2 (0.4)	40	-0.1 (0.1)	0.0 [-0.2; 0.3] 0.769
Overall treatment effect			156	-0.1 (0.0)			148	-0.1 (0.0)	-0.1 [-0.1; 0.0] 0.028
PRO-CTCAE: Swelling - Frequency									
Baseline	157	0.3 (0.8)			154	0.2 (0.5)			
Week 1	195	0.4 (0.8)	103	0.1 (0.1)	186	0.3 (0.7)	93	0.1 (0.1)	0.0 [-0.2; 0.2] 0.974
Week 2	205	0.3 (0.8)	111	0.0 (0.1)	206	0.3 (0.7)	120	0.0 (0.1)	0.1 [-0.1; 0.2] 0.552
Week 3	180	0.3 (0.7)	94	-0.1 (0.1)	173	0.3 (0.8)	102	0.0 (0.1)	0.0 [-0.2; 0.1] 0.673
Week 4	215	0.2 (0.7)	130	-0.1 (0.0)	184	0.1 (0.5)	107	-0.2 (0.0)	0.1 [0.0; 0.2] 0.149
Week 5	191	0.3 (0.7)	101	0.0 (0.1)	167	0.3 (0.7)	92	0.0 (0.1)	0.0 [-0.1; 0.2] 0.668
Week 6	176	0.2 (0.6)	99	0.0 (0.0)	167	0.3 (0.7)	94	0.0 (0.1)	0.0 [-0.1; 0.1] 0.923
Week 7	180	0.2 (0.5)	95	0.0 (0.0)	156	0.2 (0.6)	87	-0.1 (0.1)	0.1 [-0.1; 0.2] 0.372
Week 8	153	0.3 (0.8)	89	0.0 (0.1)	133	0.2 (0.5)	76	-0.1 (0.1)	0.2 [0.0; 0.3] 0.090
Week 9	180	0.4 (0.8)	104	0.1 (0.1)	157	0.2 (0.5)	87	-0.1 (0.1)	0.2 [0.1; 0.4] 0.002

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 10	168	0.3 (0.7)	94	0.1 (0.1)	162	0.3 (0.6)	84	0.0 (0.1)	0.1 [-0.1; 0.2] 0.467
Week 11	178	0.3 (0.6)	98	0.1 (0.1)	156	0.3 (0.6)	89	-0.1 (0.1)	0.1 [0.0; 0.3] 0.078
Week 12	191	0.3 (0.8)	111	0.0 (0.1)	180	0.2 (0.6)	103	-0.1 (0.1)	0.2 [0.0; 0.3] 0.055
Week 13	174	0.3 (0.7)	103	0.0 (0.0)	150	0.2 (0.6)	80	0.0 (0.1)	0.1 [-0.1; 0.2] 0.451
Week 14	162	0.3 (0.7)	90	0.0 (0.1)	140	0.2 (0.5)	77	-0.1 (0.1)	0.1 [0.0; 0.3] 0.106
Week 15	166	0.3 (0.7)	93	0.1 (0.1)	149	0.3 (0.7)	83	0.0 (0.1)	0.1 [-0.1; 0.3] 0.308
Week 16	165	0.2 (0.7)	93	0.0 (0.1)	149	0.2 (0.6)	81	-0.1 (0.1)	0.0 [-0.1; 0.2] 0.631
Week 17	163	0.3 (0.7)	90	0.0 (0.1)	145	0.3 (0.7)	80	0.0 (0.1)	0.0 [-0.2; 0.1] 0.523
Week 18	165	0.2 (0.5)	98	-0.1 (0.0)	145	0.3 (0.6)	77	0.1 (0.1)	-0.1 [-0.3; 0.0] 0.070
Week 19	162	0.2 (0.6)	90	-0.1 (0.1)	141	0.3 (0.7)	73	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.241
Week 20	165	0.2 (0.6)	92	-0.1 (0.0)	140	0.3 (0.7)	73	0.0 (0.1)	-0.1 [-0.2; 0.1] 0.279
Week 21	164	0.2 (0.6)	90	0.0 (0.1)	147	0.3 (0.6)	80	0.0 (0.1)	-0.1 [-0.2; 0.1] 0.474
Week 22	149	0.3 (0.6)	85	0.0 (0.1)	145	0.3 (0.7)	77	0.1 (0.1)	-0.1 [-0.2; 0.1] 0.435
Week 23	162	0.3 (0.7)	93	0.0 (0.1)	154	0.4 (0.8)	83	0.1 (0.1)	-0.1 [-0.3; 0.1] 0.310
Week 24	218	0.2 (0.7)	132	0.0 (0.1)	205	0.3 (0.7)	118	0.0 (0.1)	0.0 [-0.2; 0.2] 0.859
Week 36	189	0.3 (0.6)	107	0.0 (0.1)	160	0.3 (0.6)	95	0.0 (0.1)	0.0 [-0.1; 0.2] 0.731

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 40	125	0.2 (0.5)	72	0.0 (0.1)	93	0.3 (0.6)	58	0.1 (0.1)	-0.1 [-0.3; 0.0] 0.176
Week 44	115	0.2 (0.5)	62	0.0 (0.1)	84	0.4 (0.8)	50	0.3 (0.1)	-0.3 [-0.5; -0.1] 0.017
Week 48	169	0.2 (0.6)	100	-0.1 (0.1)	149	0.3 (0.7)	97	0.1 (0.1)	-0.2 [-0.3; 0.0] 0.088
Week 52	97	0.2 (0.6)	51	-0.1 (0.1)	74	0.3 (0.6)	40	0.1 (0.1)	-0.2 [-0.4; 0.0] 0.040
Week 56	88	0.2 (0.6)	44	-0.1 (0.1)	70	0.4 (0.8)	37	0.1 (0.1)	-0.1 [-0.3; 0.1] 0.244
Week 60	113	0.3 (0.7)	55	0.0 (0.1)	89	0.4 (0.8)	54	0.1 (0.1)	-0.1 [-0.3; 0.1] 0.353
Week 64	75	0.3 (0.7)	35	0.0 (0.1)	53	0.3 (0.6)	32	0.1 (0.1)	-0.1 [-0.3; 0.2] 0.515
Week 68	70	0.2 (0.5)	41	-0.1 (0.1)	43	0.3 (0.7)	23	0.1 (0.1)	-0.2 [-0.4; 0.0] 0.070
Week 72	80	0.3 (0.7)	39	-0.1 (0.1)	68	0.5 (0.9)	40	0.3 (0.1)	-0.3 [-0.6; -0.1] 0.012
Overall treatment effect			156	0.0 (0.0)			148	0.0 (0.0)	0.0 [-0.1; 0.1] 0.591
PRO-CTCAE: Swelling - Severity									
Baseline	157	0.2 (0.6)			154	0.1 (0.4)			
Week 1	195	0.2 (0.6)	103	0.0 (0.1)	186	0.2 (0.6)	93	0.1 (0.1)	-0.1 [-0.2; 0.1] 0.532
Week 2	205	0.2 (0.7)	111	0.0 (0.1)	206	0.2 (0.6)	120	0.0 (0.1)	0.0 [-0.1; 0.2] 0.524
Week 3	180	0.2 (0.6)	94	0.0 (0.1)	173	0.2 (0.5)	102	0.0 (0.1)	0.0 [-0.1; 0.2] 0.935
Week 4	215	0.2 (0.6)	130	0.0 (0.0)	184	0.1 (0.3)	107	-0.1 (0.0)	0.1 [0.0; 0.2] 0.166

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 5	191	0.2 (0.6)	101	0.0 (0.0)	167	0.2 (0.6)	92	0.0 (0.1)	0.0 [-0.1; 0.2] 0.600
Week 6	176	0.2 (0.5)	99	-0.1 (0.0)	167	0.2 (0.5)	94	0.0 (0.0)	0.0 [-0.1; 0.1] 0.463
Week 7	180	0.2 (0.5)	95	0.0 (0.0)	156	0.2 (0.5)	87	-0.1 (0.0)	0.1 [-0.1; 0.2] 0.291
Week 8	153	0.2 (0.7)	89	0.0 (0.0)	133	0.1 (0.4)	76	-0.1 (0.1)	0.1 [0.0; 0.2] 0.111
Week 9	180	0.3 (0.6)	104	0.1 (0.0)	157	0.2 (0.5)	87	-0.1 (0.0)	0.1 [0.0; 0.3] 0.021
Week 10	168	0.2 (0.6)	94	0.0 (0.0)	162	0.2 (0.5)	84	0.0 (0.1)	0.1 [-0.1; 0.2] 0.248
Week 11	178	0.2 (0.5)	98	0.0 (0.0)	156	0.2 (0.6)	89	-0.1 (0.1)	0.1 [0.0; 0.2] 0.166
Week 12	191	0.2 (0.6)	111	0.0 (0.0)	180	0.2 (0.4)	103	-0.1 (0.0)	0.1 [0.0; 0.2] 0.104
Week 13	174	0.2 (0.6)	103	0.0 (0.0)	150	0.2 (0.5)	80	0.0 (0.1)	0.1 [-0.1; 0.2] 0.449
Week 14	162	0.2 (0.6)	90	0.0 (0.0)	140	0.1 (0.3)	77	-0.1 (0.0)	0.1 [0.0; 0.2] 0.071
Week 15	166	0.2 (0.6)	93	0.0 (0.0)	149	0.2 (0.5)	83	-0.1 (0.0)	0.0 [-0.1; 0.2] 0.441
Week 16	165	0.2 (0.6)	93	0.0 (0.0)	149	0.2 (0.4)	81	-0.1 (0.0)	0.0 [-0.1; 0.1] 0.766
Week 17	163	0.2 (0.6)	90	0.0 (0.0)	145	0.2 (0.4)	80	0.0 (0.0)	0.0 [-0.1; 0.1] 0.907
Week 18	165	0.2 (0.5)	98	-0.1 (0.0)	145	0.2 (0.5)	77	0.1 (0.0)	-0.1 [-0.2; 0.0] 0.079
Week 19	162	0.2 (0.5)	90	-0.1 (0.0)	141	0.2 (0.5)	73	0.0 (0.0)	0.0 [-0.2; 0.1] 0.449
Week 20	165	0.2 (0.5)	92	-0.1 (0.0)	140	0.3 (0.7)	73	0.0 (0.0)	-0.1 [-0.2; 0.1] 0.283

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 21	164	0.2 (0.6)	90	0.0 (0.0)	147	0.2 (0.5)	80	0.0 (0.1)	0.0 [-0.2; 0.1] 0.761
Week 22	149	0.2 (0.5)	85	0.0 (0.0)	145	0.2 (0.5)	77	0.0 (0.0)	-0.1 [-0.2; 0.1] 0.387
Week 23	162	0.2 (0.5)	93	0.0 (0.1)	154	0.3 (0.6)	83	0.1 (0.1)	-0.1 [-0.2; 0.0] 0.192
Week 24	218	0.2 (0.6)	132	0.0 (0.0)	205	0.2 (0.5)	118	0.0 (0.0)	0.0 [-0.1; 0.2] 0.664
Week 36	189	0.2 (0.5)	107	0.0 (0.0)	160	0.2 (0.5)	95	0.0 (0.0)	0.0 [-0.2; 0.1] 0.629
Week 40	125	0.2 (0.5)	72	0.0 (0.0)	93	0.2 (0.5)	58	0.0 (0.1)	0.0 [-0.2; 0.1] 0.720
Week 44	115	0.2 (0.6)	62	-0.1 (0.1)	84	0.3 (0.7)	50	0.2 (0.1)	-0.3 [-0.5; -0.1] 0.010
Week 48	169	0.2 (0.5)	100	0.0 (0.1)	149	0.2 (0.6)	97	0.1 (0.1)	-0.1 [-0.3; 0.0] 0.061
Week 52	97	0.2 (0.5)	51	-0.1 (0.1)	74	0.2 (0.5)	40	0.0 (0.1)	-0.2 [-0.3; 0.0] 0.043
Week 56	88	0.2 (0.5)	44	-0.1 (0.1)	70	0.3 (0.7)	37	0.0 (0.1)	-0.1 [-0.2; 0.1] 0.243
Week 60	113	0.2 (0.6)	55	0.0 (0.1)	89	0.3 (0.6)	54	0.1 (0.1)	-0.1 [-0.3; 0.0] 0.136
Week 64	75	0.2 (0.6)	35	0.0 (0.1)	53	0.2 (0.5)	32	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.423
Week 68	70	0.1 (0.5)	41	-0.1 (0.1)	43	0.2 (0.5)	23	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.289
Week 72	80	0.3 (0.8)	39	0.0 (0.1)	68	0.4 (0.6)	40	0.2 (0.1)	-0.2 [-0.4; 0.0] 0.058
Overall treatment effect			156	0.0 (0.0)			148	0.0 (0.0)	0.0 [-0.1; 0.1] 0.623
PRO-CTCAE: Swelling - Interference									

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Baseline	157	0.2 (0.6)			154	0.1 (0.5)			
Week 1	195	0.2 (0.5)	103	-0.1 (0.0)	186	0.1 (0.5)	93	0.0 (0.1)	-0.1 [-0.2; 0.1] 0.244
Week 2	205	0.2 (0.6)	111	-0.1 (0.0)	206	0.2 (0.6)	120	0.0 (0.0)	0.0 [-0.2; 0.1] 0.725
Week 3	180	0.2 (0.6)	94	-0.1 (0.0)	173	0.1 (0.4)	102	-0.1 (0.0)	0.0 [-0.1; 0.1] 0.825
Week 4	215	0.1 (0.5)	130	-0.1 (0.0)	184	0.1 (0.3)	107	-0.1 (0.0)	0.1 [0.0; 0.2] 0.084
Week 5	191	0.2 (0.6)	101	0.0 (0.0)	167	0.1 (0.5)	92	-0.1 (0.0)	0.0 [-0.1; 0.2] 0.480
Week 6	176	0.1 (0.4)	99	-0.1 (0.0)	167	0.1 (0.4)	94	-0.1 (0.0)	0.0 [-0.1; 0.1] 0.633
Week 7	180	0.1 (0.5)	95	0.0 (0.0)	156	0.1 (0.3)	87	-0.1 (0.0)	0.1 [0.0; 0.2] 0.177
Week 8	153	0.2 (0.6)	89	-0.1 (0.0)	133	0.1 (0.3)	76	-0.2 (0.0)	0.1 [0.0; 0.2] 0.013
Week 9	180	0.2 (0.6)	104	0.0 (0.0)	157	0.1 (0.3)	87	-0.1 (0.0)	0.2 [0.1; 0.3] 0.004
Week 10	168	0.2 (0.5)	94	0.0 (0.0)	162	0.1 (0.4)	84	-0.1 (0.0)	0.0 [-0.1; 0.1] 0.363
Week 11	178	0.2 (0.5)	98	0.0 (0.0)	156	0.2 (0.5)	89	-0.1 (0.0)	0.1 [0.0; 0.2] 0.097
Week 12	191	0.1 (0.5)	111	0.0 (0.0)	180	0.1 (0.4)	103	-0.1 (0.0)	0.1 [0.0; 0.2] 0.180
Week 13	174	0.2 (0.6)	103	0.0 (0.0)	150	0.1 (0.5)	80	-0.1 (0.0)	0.1 [0.0; 0.2] 0.203
Week 14	162	0.1 (0.5)	90	0.0 (0.0)	140	0.1 (0.4)	77	-0.1 (0.0)	0.1 [0.0; 0.2] 0.080
Week 15	166	0.2 (0.6)	93	0.0 (0.0)	149	0.1 (0.4)	83	-0.1 (0.0)	0.1 [0.0; 0.2] 0.210

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 16	165	0.2 (0.6)	93	-0.1 (0.0)	149	0.1 (0.4)	81	-0.1 (0.0)	0.0 [-0.1; 0.1] 0.506
Week 17	163	0.2 (0.6)	90	-0.1 (0.0)	145	0.1 (0.5)	80	-0.1 (0.0)	0.0 [-0.1; 0.1] 0.961
Week 18	165	0.1 (0.5)	98	-0.1 (0.0)	145	0.2 (0.5)	77	0.0 (0.0)	-0.1 [-0.2; 0.0] 0.151
Week 19	162	0.1 (0.5)	90	-0.1 (0.0)	141	0.1 (0.5)	73	-0.1 (0.0)	0.0 [-0.1; 0.1] 0.693
Week 20	165	0.1 (0.4)	92	-0.1 (0.0)	140	0.2 (0.5)	73	0.0 (0.1)	0.0 [-0.2; 0.1] 0.484
Week 21	164	0.1 (0.5)	90	0.0 (0.1)	147	0.1 (0.4)	80	0.0 (0.1)	0.0 [-0.2; 0.1] 0.906
Week 22	149	0.1 (0.5)	85	-0.1 (0.0)	145	0.1 (0.4)	77	0.0 (0.0)	-0.1 [-0.1; 0.0] 0.271
Week 23	162	0.1 (0.5)	93	0.0 (0.1)	154	0.2 (0.7)	83	0.1 (0.1)	-0.1 [-0.3; 0.0] 0.106
Week 24	218	0.2 (0.6)	132	0.0 (0.0)	205	0.1 (0.4)	118	-0.1 (0.0)	0.1 [-0.1; 0.2] 0.406
Week 36	189	0.1 (0.5)	107	0.0 (0.0)	160	0.1 (0.4)	95	-0.1 (0.0)	0.0 [-0.1; 0.1] 0.688
Week 40	125	0.1 (0.4)	72	-0.1 (0.0)	93	0.1 (0.3)	58	0.0 (0.0)	0.0 [-0.1; 0.1] 0.648
Week 44	115	0.1 (0.4)	62	-0.1 (0.1)	84	0.2 (0.7)	50	0.1 (0.1)	-0.2 [-0.4; 0.0] 0.018
Week 48	169	0.1 (0.5)	100	-0.1 (0.1)	149	0.2 (0.6)	97	0.1 (0.1)	-0.2 [-0.4; -0.1] 0.009
Week 52	97	0.1 (0.4)	51	-0.1 (0.0)	74	0.2 (0.5)	40	0.0 (0.1)	-0.1 [-0.3; 0.0] 0.055
Week 56	88	0.1 (0.5)	44	-0.1 (0.0)	70	0.2 (0.6)	37	0.0 (0.0)	-0.1 [-0.2; 0.0] 0.174
Week 60	113	0.2 (0.6)	55	-0.1 (0.1)	89	0.2 (0.6)	54	0.0 (0.1)	-0.1 [-0.3; 0.0] 0.140

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 64	75	0.1 (0.6)	35	-0.1 (0.1)	53	0.1 (0.4)	32	0.0 (0.1)	0.0 [-0.2; 0.1] 0.753
Week 68	70	0.1 (0.4)	41	-0.1 (0.0)	43	0.1 (0.4)	23	0.0 (0.1)	0.0 [-0.2; 0.1] 0.532
Week 72	80	0.3 (0.7)	39	-0.1 (0.1)	68	0.2 (0.5)	40	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.325
Overall treatment effect			156	-0.1 (0.0)			148	0.0 (0.0)	0.0 [-0.1; 0.1] 0.780
PRO-CTCAE: Itching - Severity									
Baseline	157	0.2 (0.6)			154	0.3 (0.6)			
Week 1	195	0.3 (0.6)	103	0.0 (0.1)	186	0.5 (0.8)	93	0.2 (0.1)	-0.3 [-0.5; -0.1] 0.012
Week 2	205	0.3 (0.7)	111	0.0 (0.1)	206	0.7 (0.9)	120	0.4 (0.1)	-0.4 [-0.6; -0.2] <0.001
Week 3	180	0.2 (0.5)	94	-0.1 (0.1)	173	0.7 (0.9)	102	0.5 (0.1)	-0.6 [-0.8; -0.4] <0.001
Week 4	215	0.3 (0.7)	130	0.0 (0.1)	184	0.6 (0.8)	107	0.4 (0.1)	-0.4 [-0.6; -0.2] <0.001
Week 5	191	0.3 (0.7)	101	0.0 (0.1)	167	0.7 (0.9)	92	0.5 (0.1)	-0.5 [-0.7; -0.3] <0.001
Week 6	176	0.4 (0.7)	99	0.1 (0.1)	167	0.7 (0.9)	94	0.4 (0.1)	-0.3 [-0.5; -0.2] <0.001
Week 7	180	0.3 (0.5)	95	-0.1 (0.1)	156	0.7 (0.9)	87	0.5 (0.1)	-0.5 [-0.7; -0.3] <0.001
Week 8	153	0.3 (0.7)	89	0.1 (0.1)	133	0.8 (0.9)	76	0.6 (0.1)	-0.5 [-0.7; -0.3] <0.001
Week 9	180	0.4 (0.7)	104	0.1 (0.1)	157	0.8 (0.9)	87	0.5 (0.1)	-0.5 [-0.7; -0.3] <0.001
Week 10	168	0.3 (0.7)	94	0.0 (0.1)	162	0.8 (0.9)	84	0.4 (0.1)	-0.4 [-0.6; -0.2] <0.001

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 11	178	0.3 (0.6)	98	0.1 (0.1)	156	0.8 (1.0)	89	0.5 (0.1)	-0.4 [-0.6; -0.2] <0.001
Week 12	191	0.4 (0.7)	111	0.2 (0.1)	180	0.9 (1.0)	103	0.6 (0.1)	-0.4 [-0.6; -0.2] <0.001
Week 13	174	0.3 (0.5)	103	0.0 (0.1)	150	0.8 (0.9)	80	0.5 (0.1)	-0.5 [-0.7; -0.3] <0.001
Week 14	162	0.3 (0.7)	90	0.1 (0.1)	140	0.7 (0.9)	77	0.4 (0.1)	-0.3 [-0.6; -0.1] 0.002
Week 15	166	0.3 (0.6)	93	0.0 (0.1)	149	0.8 (0.9)	83	0.4 (0.1)	-0.4 [-0.6; -0.3] <0.001
Week 16	165	0.3 (0.6)	93	0.0 (0.1)	149	0.8 (0.9)	81	0.4 (0.1)	-0.4 [-0.6; -0.2] <0.001
Week 17	163	0.3 (0.6)	90	0.1 (0.1)	145	0.8 (1.0)	80	0.4 (0.1)	-0.3 [-0.5; -0.1] 0.001
Week 18	165	0.3 (0.6)	98	0.0 (0.1)	145	0.8 (1.0)	77	0.5 (0.1)	-0.4 [-0.6; -0.2] <0.001
Week 19	162	0.3 (0.6)	90	0.1 (0.1)	141	0.8 (0.9)	73	0.5 (0.1)	-0.3 [-0.5; -0.1] 0.001
Week 20	165	0.3 (0.6)	92	0.0 (0.1)	140	0.8 (0.9)	73	0.4 (0.1)	-0.4 [-0.6; -0.2] <0.001
Week 21	164	0.3 (0.6)	90	0.0 (0.1)	147	0.6 (0.9)	80	0.3 (0.1)	-0.2 [-0.4; -0.1] 0.006
Week 22	149	0.4 (0.7)	85	0.1 (0.1)	145	0.7 (1.0)	77	0.4 (0.1)	-0.3 [-0.5; -0.1] 0.003
Week 23	162	0.3 (0.7)	93	0.1 (0.1)	154	0.8 (0.9)	83	0.4 (0.1)	-0.3 [-0.5; -0.1] 0.004
Week 24	218	0.4 (0.7)	132	0.1 (0.1)	205	0.7 (0.9)	118	0.4 (0.1)	-0.3 [-0.5; -0.1] <0.001
Week 36	189	0.3 (0.6)	107	0.1 (0.1)	160	0.7 (0.8)	95	0.4 (0.1)	-0.3 [-0.5; -0.1] 0.002
Week 40	125	0.3 (0.6)	72	0.1 (0.1)	93	0.6 (0.8)	58	0.4 (0.1)	-0.4 [-0.6; -0.2] <0.001

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 44	115	0.4 (0.7)	62	0.1 (0.1)	84	0.7 (0.8)	50	0.6 (0.1)	-0.5 [-0.7; -0.2] 0.001
Week 48	169	0.4 (0.7)	100	0.2 (0.1)	149	0.7 (0.8)	97	0.4 (0.1)	-0.2 [-0.4; 0.0] 0.035
Week 52	97	0.4 (0.6)	51	0.1 (0.1)	74	0.7 (1.0)	40	0.4 (0.1)	-0.3 [-0.7; 0.0] 0.032
Week 56	88	0.4 (0.7)	44	0.2 (0.1)	70	0.8 (0.9)	37	0.4 (0.1)	-0.2 [-0.5; 0.1] 0.187
Week 60	113	0.4 (0.6)	55	0.1 (0.1)	89	0.8 (1.0)	54	0.4 (0.1)	-0.4 [-0.6; -0.1] 0.007
Week 64	75	0.5 (0.7)	35	0.1 (0.1)	53	0.7 (0.9)	32	0.5 (0.1)	-0.3 [-0.6; 0.0] 0.035
Week 68	70	0.4 (0.8)	41	0.1 (0.1)	43	0.7 (0.8)	23	0.5 (0.1)	-0.4 [-0.7; -0.1] 0.017
Week 72	80	0.5 (0.8)	39	0.2 (0.1)	68	0.8 (1.0)	40	0.4 (0.1)	-0.2 [-0.6; 0.1] 0.159
Overall treatment effect			156	0.1 (0.0)			148	0.4 (0.1)	-0.4 [-0.5; -0.2] <0.001
PRO-CTCAE: Headache - Frequency									
Baseline	157	0.6 (0.9)			154	0.7 (1.0)			
Week 1	195	0.7 (1.0)	103	0.2 (0.1)	186	1.2 (1.3)	93	0.5 (0.1)	-0.4 [-0.7; -0.1] 0.019
Week 2	205	0.6 (0.9)	111	0.0 (0.1)	206	0.9 (1.0)	120	0.2 (0.1)	-0.3 [-0.5; 0.0] 0.027
Week 3	180	0.4 (0.8)	94	-0.2 (0.1)	173	0.8 (1.0)	102	0.2 (0.1)	-0.4 [-0.6; -0.2] <0.001
Week 4	215	0.5 (0.8)	130	-0.2 (0.1)	184	0.7 (1.0)	107	0.0 (0.1)	-0.2 [-0.4; 0.0] 0.078
Week 5	191	0.4 (0.8)	101	-0.2 (0.1)	167	0.8 (1.0)	92	0.0 (0.1)	-0.2 [-0.4; 0.0] 0.045

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 6	176	0.4 (0.7)	99	-0.2 (0.1)	167	0.7 (1.0)	94	0.0 (0.1)	-0.2 [-0.4; 0.0] 0.033
Week 7	180	0.5 (0.8)	95	-0.2 (0.1)	156	0.6 (0.9)	87	-0.1 (0.1)	-0.1 [-0.3; 0.1] 0.352
Week 8	153	0.5 (0.8)	89	-0.1 (0.1)	133	0.7 (1.0)	76	0.0 (0.1)	-0.2 [-0.4; 0.0] 0.118
Week 9	180	0.5 (0.8)	104	-0.1 (0.1)	157	0.6 (0.8)	87	-0.2 (0.1)	0.1 [-0.1; 0.3] 0.369
Week 10	168	0.6 (0.8)	94	0.0 (0.1)	162	0.6 (0.9)	84	-0.1 (0.1)	0.1 [-0.1; 0.3] 0.413
Week 11	178	0.5 (0.8)	98	-0.1 (0.1)	156	0.7 (1.0)	89	-0.1 (0.1)	-0.1 [-0.3; 0.1] 0.368
Week 12	191	0.5 (0.8)	111	-0.2 (0.1)	180	0.7 (1.0)	103	0.1 (0.1)	-0.2 [-0.4; 0.0] 0.023
Week 13	174	0.5 (0.8)	103	-0.1 (0.1)	150	0.6 (0.9)	80	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.340
Week 14	162	0.5 (0.8)	90	-0.3 (0.1)	140	0.7 (1.0)	77	0.0 (0.1)	-0.2 [-0.4; 0.0] 0.043
Week 15	166	0.4 (0.8)	93	-0.2 (0.1)	149	0.7 (0.9)	83	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.157
Week 16	165	0.5 (0.9)	93	-0.1 (0.1)	149	0.7 (0.9)	81	-0.1 (0.1)	0.0 [-0.2; 0.2] 0.757
Week 17	163	0.5 (0.8)	90	-0.3 (0.1)	145	0.6 (0.8)	80	-0.1 (0.1)	-0.2 [-0.3; 0.0] 0.045
Week 18	165	0.5 (0.8)	98	-0.1 (0.1)	145	0.7 (0.9)	77	-0.1 (0.1)	0.0 [-0.2; 0.2] 0.778
Week 19	162	0.4 (0.7)	90	-0.2 (0.1)	141	0.7 (1.0)	73	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.291
Week 20	165	0.5 (0.8)	92	-0.2 (0.1)	140	0.7 (0.9)	73	0.0 (0.1)	-0.2 [-0.4; 0.0] 0.083
Week 21	164	0.4 (0.8)	90	-0.2 (0.1)	147	0.6 (0.9)	80	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.170

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 22	149	0.5 (0.8)	85	-0.1 (0.1)	145	0.7 (0.9)	77	0.1 (0.1)	-0.2 [-0.5; 0.0] 0.069
Week 23	162	0.4 (0.8)	93	-0.2 (0.1)	154	0.7 (1.0)	83	0.1 (0.1)	-0.3 [-0.5; -0.1] 0.002
Week 24	218	0.5 (0.8)	132	-0.1 (0.1)	205	0.7 (1.0)	118	0.1 (0.1)	-0.2 [-0.4; 0.0] 0.021
Week 36	189	0.4 (0.7)	107	-0.2 (0.1)	160	0.6 (0.9)	95	-0.1 (0.1)	-0.1 [-0.2; 0.1] 0.586
Week 40	125	0.5 (0.8)	72	0.0 (0.1)	93	0.6 (0.9)	58	0.0 (0.1)	0.0 [-0.3; 0.2] 0.754
Week 44	115	0.5 (0.8)	62	-0.2 (0.1)	84	0.7 (0.9)	50	0.1 (0.1)	-0.3 [-0.5; -0.1] 0.014
Week 48	169	0.6 (0.9)	100	-0.1 (0.1)	149	0.7 (0.9)	97	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.265
Week 52	97	0.5 (0.8)	51	-0.2 (0.1)	74	0.7 (0.9)	40	0.2 (0.1)	-0.4 [-0.7; -0.1] 0.014
Week 56	88	0.4 (0.8)	44	-0.2 (0.1)	70	0.6 (0.8)	37	0.0 (0.1)	-0.2 [-0.5; 0.1] 0.205
Week 60	113	0.6 (0.8)	55	-0.1 (0.1)	89	0.7 (0.9)	54	0.0 (0.1)	-0.1 [-0.4; 0.2] 0.457
Week 64	75	0.6 (0.8)	35	-0.2 (0.1)	53	0.6 (0.7)	32	0.0 (0.1)	-0.2 [-0.4; 0.1] 0.227
Week 68	70	0.6 (0.8)	41	0.0 (0.1)	43	0.7 (1.0)	23	0.0 (0.1)	0.0 [-0.4; 0.3] 0.767
Week 72	80	0.6 (0.9)	39	0.1 (0.1)	68	0.7 (1.0)	40	0.1 (0.1)	0.0 [-0.3; 0.3] 0.974
Overall treatment effect			156	-0.1 (0.0)			148	0.0 (0.0)	-0.2 [-0.3; 0.0] 0.013
PRO-CTCAE: Headache - Severity									
Baseline	157	0.5 (0.8)			154	0.6 (0.9)			

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 1	195	0.6 (0.9)	103	0.1 (0.1)	186	1.1 (1.1)	93	0.5 (0.1)	-0.4 [-0.7; -0.2] 0.002
Week 2	205	0.6 (0.9)	111	-0.1 (0.1)	206	0.8 (0.9)	120	0.1 (0.1)	-0.2 [-0.4; 0.0] 0.049
Week 3	180	0.4 (0.7)	94	-0.3 (0.1)	173	0.7 (0.9)	102	0.1 (0.1)	-0.4 [-0.6; -0.1] <0.001
Week 4	215	0.5 (0.7)	130	-0.1 (0.1)	184	0.6 (0.9)	107	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.393
Week 5	191	0.4 (0.7)	101	-0.2 (0.1)	167	0.7 (0.9)	92	0.0 (0.1)	-0.2 [-0.4; 0.0] 0.081
Week 6	176	0.4 (0.7)	99	-0.2 (0.1)	167	0.6 (0.9)	94	0.0 (0.1)	-0.2 [-0.3; 0.0] 0.088
Week 7	180	0.5 (0.8)	95	-0.2 (0.1)	156	0.6 (0.8)	87	-0.1 (0.1)	-0.1 [-0.3; 0.1] 0.319
Week 8	153	0.5 (0.8)	89	-0.1 (0.1)	133	0.6 (0.9)	76	-0.1 (0.1)	0.0 [-0.2; 0.2] 0.832
Week 9	180	0.5 (0.8)	104	-0.1 (0.1)	157	0.6 (0.9)	87	-0.1 (0.1)	0.1 [-0.1; 0.3] 0.489
Week 10	168	0.5 (0.7)	94	-0.1 (0.1)	162	0.5 (0.9)	84	-0.1 (0.1)	0.1 [-0.1; 0.2] 0.587
Week 11	178	0.5 (0.8)	98	-0.1 (0.1)	156	0.7 (1.0)	89	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.190
Week 12	191	0.4 (0.8)	111	-0.1 (0.1)	180	0.6 (0.9)	103	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.201
Week 13	174	0.4 (0.8)	103	-0.2 (0.1)	150	0.6 (0.9)	80	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.271
Week 14	162	0.4 (0.7)	90	-0.2 (0.1)	140	0.6 (0.9)	77	0.0 (0.1)	-0.2 [-0.4; 0.0] 0.073
Week 15	166	0.4 (0.8)	93	-0.2 (0.1)	149	0.6 (0.9)	83	-0.1 (0.1)	0.0 [-0.2; 0.1] 0.636
Week 16	165	0.5 (0.8)	93	-0.1 (0.1)	149	0.6 (0.8)	81	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.410

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 17	163	0.4 (0.7)	90	-0.3 (0.1)	145	0.6 (0.8)	80	-0.1 (0.1)	-0.2 [-0.3; 0.0] 0.056
Week 18	165	0.4 (0.7)	98	-0.1 (0.1)	145	0.6 (0.9)	77	-0.1 (0.1)	0.0 [-0.2; 0.2] 0.947
Week 19	162	0.4 (0.8)	90	-0.1 (0.1)	141	0.6 (1.0)	73	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.339
Week 20	165	0.4 (0.8)	92	-0.1 (0.1)	140	0.7 (1.0)	73	0.1 (0.1)	-0.2 [-0.4; 0.0] 0.124
Week 21	164	0.4 (0.8)	90	-0.1 (0.1)	147	0.5 (0.9)	80	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.486
Week 22	149	0.5 (0.8)	85	-0.1 (0.1)	145	0.6 (0.9)	77	0.0 (0.1)	-0.2 [-0.4; 0.1] 0.150
Week 23	162	0.4 (0.7)	93	-0.1 (0.1)	154	0.6 (0.9)	83	0.1 (0.1)	-0.2 [-0.4; 0.0] 0.050
Week 24	218	0.5 (0.8)	132	-0.1 (0.1)	205	0.6 (0.9)	118	0.1 (0.1)	-0.2 [-0.4; 0.0] 0.023
Week 36	189	0.4 (0.7)	107	-0.1 (0.1)	160	0.6 (0.8)	95	-0.1 (0.1)	0.0 [-0.2; 0.2] 0.699
Week 40	125	0.4 (0.7)	72	0.0 (0.1)	93	0.6 (0.9)	58	0.1 (0.1)	-0.1 [-0.4; 0.1] 0.385
Week 44	115	0.5 (0.8)	62	-0.2 (0.1)	84	0.7 (0.9)	50	0.1 (0.1)	-0.3 [-0.5; -0.1] 0.014
Week 48	169	0.5 (0.8)	100	-0.1 (0.1)	149	0.6 (0.9)	97	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.263
Week 52	97	0.5 (0.7)	51	-0.2 (0.1)	74	0.6 (0.8)	40	0.0 (0.1)	-0.2 [-0.5; 0.1] 0.144
Week 56	88	0.4 (0.6)	44	-0.2 (0.1)	70	0.5 (0.8)	37	-0.2 (0.1)	0.0 [-0.3; 0.2] 0.811
Week 60	113	0.6 (0.8)	55	0.0 (0.1)	89	0.7 (0.9)	54	0.1 (0.1)	-0.1 [-0.4; 0.2] 0.547
Week 64	75	0.5 (0.9)	35	-0.1 (0.1)	53	0.6 (0.8)	32	0.0 (0.1)	-0.1 [-0.4; 0.2] 0.475

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 68	70	0.6 (0.8)	41	0.0 (0.1)	43	0.5 (0.8)	23	0.0 (0.1)	0.0 [-0.2; 0.3] 0.801
Week 72	80	0.5 (0.8)	39	0.0 (0.1)	68	0.7 (1.0)	40	0.1 (0.1)	-0.1 [-0.3; 0.2] 0.606
Overall treatment effect			156	-0.1 (0.0)			148	0.0 (0.0)	-0.1 [-0.2; 0.0] 0.037
PRO-CTCAE: Headache - Interference									
Baseline	157	0.3 (0.7)			154	0.4 (0.7)			
Week 1	195	0.4 (0.7)	103	0.0 (0.1)	186	0.7 (1.0)	93	0.3 (0.1)	-0.2 [-0.5; 0.0] 0.029
Week 2	205	0.3 (0.7)	111	-0.1 (0.1)	206	0.5 (0.8)	120	0.1 (0.1)	-0.2 [-0.4; 0.0] 0.014
Week 3	180	0.2 (0.5)	94	-0.2 (0.1)	173	0.4 (0.8)	102	0.0 (0.1)	-0.2 [-0.4; 0.0] 0.012
Week 4	215	0.2 (0.6)	130	-0.1 (0.1)	184	0.4 (0.7)	107	0.0 (0.1)	-0.1 [-0.3; 0.0] 0.107
Week 5	191	0.2 (0.6)	101	-0.1 (0.1)	167	0.4 (0.7)	92	0.0 (0.1)	-0.1 [-0.2; 0.0] 0.189
Week 6	176	0.2 (0.5)	99	-0.1 (0.1)	167	0.4 (0.8)	94	0.1 (0.1)	-0.2 [-0.3; 0.0] 0.012
Week 7	180	0.3 (0.7)	95	-0.1 (0.1)	156	0.4 (0.7)	87	0.0 (0.1)	-0.1 [-0.3; 0.0] 0.078
Week 8	153	0.3 (0.7)	89	0.0 (0.1)	133	0.4 (0.8)	76	0.1 (0.1)	-0.1 [-0.3; 0.1] 0.401
Week 9	180	0.3 (0.7)	104	0.0 (0.1)	157	0.4 (0.8)	87	0.0 (0.1)	0.0 [-0.2; 0.1] 0.722
Week 10	168	0.3 (0.6)	94	-0.1 (0.1)	162	0.4 (0.8)	84	0.0 (0.1)	0.0 [-0.2; 0.1] 0.799
Week 11	178	0.3 (0.7)	98	-0.1 (0.1)	156	0.4 (0.8)	89	0.1 (0.1)	-0.1 [-0.3; 0.0] 0.169

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 12	191	0.3 (0.6)	111	-0.1 (0.1)	180	0.4 (0.8)	103	0.0 (0.1)	-0.2 [-0.3; 0.0] 0.058
Week 13	174	0.3 (0.6)	103	-0.1 (0.1)	150	0.4 (0.7)	80	0.1 (0.1)	-0.2 [-0.4; 0.0] 0.028
Week 14	162	0.2 (0.5)	90	-0.1 (0.1)	140	0.4 (0.8)	77	0.1 (0.1)	-0.2 [-0.4; 0.0] 0.025
Week 15	166	0.2 (0.6)	93	-0.1 (0.1)	149	0.4 (0.8)	83	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.217
Week 16	165	0.3 (0.8)	93	0.0 (0.1)	149	0.4 (0.8)	81	0.1 (0.1)	-0.1 [-0.3; 0.1] 0.295
Week 17	163	0.2 (0.6)	90	-0.1 (0.1)	145	0.3 (0.6)	80	0.0 (0.1)	-0.1 [-0.3; 0.0] 0.092
Week 18	165	0.3 (0.6)	98	-0.1 (0.1)	145	0.4 (0.8)	77	0.0 (0.1)	-0.1 [-0.3; 0.0] 0.138
Week 19	162	0.3 (0.7)	90	0.0 (0.1)	141	0.5 (0.9)	73	0.1 (0.1)	-0.1 [-0.3; 0.1] 0.219
Week 20	165	0.3 (0.6)	92	0.0 (0.1)	140	0.5 (0.9)	73	0.2 (0.1)	-0.2 [-0.4; 0.0] 0.039
Week 21	164	0.2 (0.6)	90	0.0 (0.1)	147	0.4 (0.9)	80	0.1 (0.1)	-0.2 [-0.3; 0.0] 0.087
Week 22	149	0.3 (0.7)	85	-0.1 (0.1)	145	0.4 (0.8)	77	0.1 (0.1)	-0.2 [-0.3; 0.0] 0.115
Week 23	162	0.2 (0.6)	93	-0.1 (0.1)	154	0.5 (0.9)	83	0.1 (0.1)	-0.2 [-0.4; 0.0] 0.023
Week 24	218	0.3 (0.7)	132	-0.1 (0.1)	205	0.4 (0.8)	118	0.1 (0.1)	-0.2 [-0.4; -0.1] 0.003
Week 36	189	0.3 (0.6)	107	0.0 (0.1)	160	0.4 (0.8)	95	0.1 (0.1)	-0.1 [-0.3; 0.1] 0.358
Week 40	125	0.2 (0.5)	72	-0.1 (0.1)	93	0.4 (0.7)	58	0.1 (0.1)	-0.2 [-0.4; 0.0] 0.069
Week 44	115	0.3 (0.7)	62	0.0 (0.1)	84	0.5 (0.8)	50	0.2 (0.1)	-0.2 [-0.4; 0.0] 0.036

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 48	169	0.4 (0.7)	100	0.0 (0.1)	149	0.4 (0.8)	97	0.0 (0.1)	0.0 [-0.1; 0.2] 0.793
Week 52	97	0.2 (0.6)	51	0.0 (0.1)	74	0.4 (0.7)	40	0.1 (0.1)	-0.1 [-0.4; 0.2] 0.476
Week 56	88	0.2 (0.6)	44	-0.1 (0.1)	70	0.3 (0.7)	37	0.0 (0.1)	-0.1 [-0.3; 0.1] 0.423
Week 60	113	0.3 (0.7)	55	0.0 (0.1)	89	0.5 (0.9)	54	0.1 (0.1)	-0.1 [-0.3; 0.1] 0.431
Week 64	75	0.3 (0.7)	35	0.0 (0.1)	53	0.4 (0.6)	32	0.1 (0.1)	-0.1 [-0.3; 0.2] 0.583
Week 68	70	0.3 (0.6)	41	0.0 (0.1)	43	0.4 (0.7)	23	0.1 (0.1)	-0.1 [-0.3; 0.2] 0.629
Week 72	80	0.3 (0.7)	39	0.0 (0.1)	68	0.5 (0.8)	40	0.1 (0.1)	-0.1 [-0.4; 0.2] 0.488
Overall treatment effect			156	-0.1 (0.0)			148	0.1 (0.0)	-0.1 [-0.2; 0.0] 0.014
PRO-CTCAE: Muscle Pain - Frequency									
Baseline	157	0.6 (0.9)			154	0.6 (1.0)			
Week 1	195	1.1 (1.2)	103	0.5 (0.1)	186	1.1 (1.2)	93	0.6 (0.1)	-0.2 [-0.5; 0.2] 0.359
Week 2	205	1.2 (1.2)	111	0.4 (0.1)	206	1.0 (1.2)	120	0.3 (0.1)	0.0 [-0.3; 0.3] 0.773
Week 3	180	1.1 (1.2)	94	0.4 (0.1)	173	0.9 (1.1)	102	0.1 (0.1)	0.3 [0.0; 0.6] 0.030
Week 4	215	0.9 (1.1)	130	0.2 (0.1)	184	0.8 (1.0)	107	0.1 (0.1)	0.2 [-0.1; 0.4] 0.188
Week 5	191	0.9 (1.1)	101	0.3 (0.1)	167	0.9 (1.1)	92	0.1 (0.1)	0.2 [-0.1; 0.5] 0.112
Week 6	176	0.9 (1.0)	99	0.2 (0.1)	167	0.9 (1.0)	94	0.0 (0.1)	0.2 [-0.1; 0.4] 0.124

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 7	180	0.9 (1.1)	95	0.2 (0.1)	156	0.7 (0.9)	87	0.1 (0.1)	0.1 [-0.1; 0.4] 0.277
Week 8	153	0.9 (1.1)	89	0.3 (0.1)	133	0.7 (1.0)	76	0.1 (0.1)	0.2 [0.0; 0.5] 0.075
Week 9	180	0.9 (1.1)	104	0.2 (0.1)	157	0.8 (0.9)	87	0.1 (0.1)	0.1 [-0.1; 0.4] 0.267
Week 10	168	0.9 (1.0)	94	0.2 (0.1)	162	0.8 (0.9)	84	0.1 (0.1)	0.0 [-0.2; 0.3] 0.772
Week 11	178	0.8 (1.0)	98	0.2 (0.1)	156	0.9 (1.1)	89	0.2 (0.1)	0.1 [-0.2; 0.3] 0.661
Week 12	191	0.7 (1.0)	111	0.1 (0.1)	180	0.8 (1.0)	103	0.1 (0.1)	0.1 [-0.2; 0.3] 0.613
Week 13	174	0.8 (1.0)	103	0.2 (0.1)	150	0.7 (0.9)	80	0.0 (0.1)	0.2 [-0.1; 0.4] 0.218
Week 14	162	0.7 (1.0)	90	0.1 (0.1)	140	0.8 (0.9)	77	0.0 (0.1)	0.1 [-0.1; 0.4] 0.364
Week 15	166	0.6 (1.0)	93	0.1 (0.1)	149	0.7 (0.9)	83	0.0 (0.1)	0.1 [-0.1; 0.4] 0.350
Week 16	165	0.7 (1.0)	93	0.1 (0.1)	149	0.8 (1.0)	81	0.1 (0.1)	0.0 [-0.3; 0.2] 0.803
Week 17	163	0.7 (0.9)	90	0.1 (0.1)	145	0.7 (0.9)	80	0.1 (0.1)	0.0 [-0.2; 0.2] 0.900
Week 18	165	0.6 (0.9)	98	0.0 (0.1)	145	0.9 (0.9)	77	0.1 (0.1)	-0.1 [-0.3; 0.2] 0.571
Week 19	162	0.6 (0.9)	90	0.0 (0.1)	141	0.8 (1.0)	73	0.0 (0.1)	0.0 [-0.3; 0.2] 0.672
Week 20	165	0.6 (0.9)	92	0.1 (0.1)	140	0.8 (1.0)	73	0.1 (0.1)	-0.1 [-0.3; 0.2] 0.668
Week 21	164	0.6 (0.9)	90	0.1 (0.1)	147	0.7 (0.9)	80	0.0 (0.1)	0.1 [-0.1; 0.4] 0.291
Week 22	149	0.6 (1.0)	85	0.1 (0.1)	145	0.8 (1.0)	77	0.2 (0.1)	-0.1 [-0.4; 0.2] 0.505

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 23	162	0.6 (1.0)	93	0.1 (0.1)	154	0.9 (1.0)	83	0.2 (0.1)	-0.1 [-0.4; 0.2] 0.487
Week 24	218	0.5 (0.9)	132	0.0 (0.1)	205	0.8 (1.0)	118	0.1 (0.1)	-0.1 [-0.3; 0.1] 0.444
Week 36	189	0.7 (0.9)	107	0.2 (0.1)	160	0.8 (1.0)	95	0.1 (0.1)	0.0 [-0.2; 0.3] 0.737
Week 40	125	0.6 (0.9)	72	0.1 (0.1)	93	0.7 (1.0)	58	0.1 (0.1)	0.0 [-0.3; 0.3] 0.870
Week 44	115	0.7 (0.9)	62	0.1 (0.1)	84	0.9 (1.0)	50	0.2 (0.1)	-0.1 [-0.4; 0.2] 0.537
Week 48	169	0.7 (1.0)	100	0.1 (0.1)	149	0.7 (0.9)	97	0.1 (0.1)	0.0 [-0.3; 0.3] 0.999
Week 52	97	0.6 (0.9)	51	0.1 (0.1)	74	0.9 (1.0)	40	0.2 (0.1)	-0.1 [-0.4; 0.3] 0.727
Week 56	88	0.6 (0.9)	44	0.2 (0.1)	70	0.8 (1.0)	37	0.2 (0.1)	0.0 [-0.4; 0.3] 0.888
Week 60	113	0.6 (0.9)	55	0.1 (0.1)	89	0.6 (0.8)	54	0.0 (0.1)	0.1 [-0.2; 0.4] 0.501
Week 64	75	0.8 (1.0)	35	0.3 (0.1)	53	0.6 (0.8)	32	0.1 (0.2)	0.2 [-0.2; 0.6] 0.409
Week 68	70	0.8 (1.0)	41	0.2 (0.1)	43	0.6 (0.7)	23	0.1 (0.2)	0.2 [-0.2; 0.6] 0.382
Week 72	80	0.9 (1.1)	39	0.2 (0.1)	68	0.6 (0.8)	40	0.1 (0.1)	0.2 [-0.2; 0.5] 0.360
Overall treatment effect			156	0.2 (0.1)			148	0.1 (0.1)	0.1 [-0.1; 0.2] 0.510
PRO-CTCAE: Muscle Pain - Severity									
Baseline	157	0.5 (0.8)			154	0.5 (0.9)			
Week 1	195	1.0 (1.0)	103	0.4 (0.1)	186	1.0 (1.0)	93	0.5 (0.1)	-0.2 [-0.4; 0.1] 0.215

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 2	205	1.0 (1.1)	111	0.3 (0.1)	206	0.8 (1.0)	120	0.3 (0.1)	0.0 [-0.2; 0.3] 0.847
Week 3	180	0.9 (1.0)	94	0.2 (0.1)	173	0.8 (0.9)	102	0.1 (0.1)	0.1 [-0.2; 0.3] 0.524
Week 4	215	0.7 (0.9)	130	0.2 (0.1)	184	0.7 (0.9)	107	0.1 (0.1)	0.1 [-0.1; 0.3] 0.291
Week 5	191	0.7 (0.9)	101	0.2 (0.1)	167	0.8 (0.9)	92	0.1 (0.1)	0.1 [-0.1; 0.3] 0.465
Week 6	176	0.7 (0.9)	99	0.1 (0.1)	167	0.7 (0.9)	94	0.0 (0.1)	0.1 [-0.1; 0.3] 0.308
Week 7	180	0.7 (0.9)	95	0.2 (0.1)	156	0.6 (0.8)	87	0.0 (0.1)	0.1 [-0.1; 0.4] 0.181
Week 8	153	0.8 (1.0)	89	0.2 (0.1)	133	0.7 (1.0)	76	0.1 (0.1)	0.1 [-0.1; 0.4] 0.254
Week 9	180	0.7 (0.9)	104	0.2 (0.1)	157	0.7 (0.8)	87	0.1 (0.1)	0.0 [-0.2; 0.3] 0.788
Week 10	168	0.7 (0.9)	94	0.1 (0.1)	162	0.6 (0.8)	84	0.0 (0.1)	0.1 [-0.1; 0.3] 0.427
Week 11	178	0.7 (0.9)	98	0.2 (0.1)	156	0.7 (0.9)	89	0.2 (0.1)	0.0 [-0.2; 0.3] 0.828
Week 12	191	0.6 (0.9)	111	0.1 (0.1)	180	0.6 (0.9)	103	0.1 (0.1)	0.0 [-0.2; 0.2] 0.797
Week 13	174	0.6 (0.9)	103	0.1 (0.1)	150	0.6 (0.9)	80	0.1 (0.1)	0.1 [-0.1; 0.3] 0.497
Week 14	162	0.6 (0.9)	90	0.2 (0.1)	140	0.7 (0.8)	77	0.1 (0.1)	0.0 [-0.2; 0.3] 0.694
Week 15	166	0.5 (0.9)	93	0.1 (0.1)	149	0.6 (0.8)	83	0.1 (0.1)	0.0 [-0.2; 0.3] 0.746
Week 16	165	0.6 (0.9)	93	0.1 (0.1)	149	0.7 (0.9)	81	0.1 (0.1)	0.0 [-0.2; 0.2] 0.852
Week 17	163	0.6 (0.8)	90	0.0 (0.1)	145	0.6 (0.8)	80	0.1 (0.1)	0.0 [-0.2; 0.2] 0.709

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 18	165	0.5 (0.9)	98	0.0 (0.1)	145	0.8 (0.9)	77	0.1 (0.1)	-0.1 [-0.3; 0.1] 0.440
Week 19	162	0.5 (0.8)	90	0.0 (0.1)	141	0.7 (0.8)	73	0.1 (0.1)	-0.1 [-0.3; 0.1] 0.531
Week 20	165	0.5 (0.9)	92	0.1 (0.1)	140	0.7 (0.8)	73	0.1 (0.1)	0.0 [-0.2; 0.2] 0.757
Week 21	164	0.5 (0.8)	90	0.1 (0.1)	147	0.7 (0.9)	80	0.1 (0.1)	0.0 [-0.2; 0.2] 0.975
Week 22	149	0.6 (0.9)	85	0.1 (0.1)	145	0.7 (0.9)	77	0.2 (0.1)	-0.1 [-0.3; 0.1] 0.322
Week 23	162	0.5 (0.9)	93	0.0 (0.1)	154	0.8 (0.9)	83	0.2 (0.1)	-0.1 [-0.4; 0.1] 0.227
Week 24	218	0.5 (0.9)	132	0.0 (0.1)	205	0.7 (0.9)	118	0.1 (0.1)	-0.1 [-0.3; 0.1] 0.549
Week 36	189	0.5 (0.8)	107	0.2 (0.1)	160	0.7 (0.9)	95	0.2 (0.1)	0.0 [-0.2; 0.2] 0.885
Week 40	125	0.4 (0.7)	72	0.0 (0.1)	93	0.6 (0.8)	58	0.1 (0.1)	-0.1 [-0.3; 0.1] 0.429
Week 44	115	0.6 (0.8)	62	0.1 (0.1)	84	0.7 (0.9)	50	0.2 (0.1)	-0.1 [-0.4; 0.1] 0.342
Week 48	169	0.6 (0.9)	100	0.0 (0.1)	149	0.6 (0.8)	97	0.1 (0.1)	0.0 [-0.2; 0.2] 0.877
Week 52	97	0.5 (0.8)	51	0.1 (0.1)	74	0.7 (0.9)	40	0.1 (0.1)	-0.1 [-0.3; 0.2] 0.574
Week 56	88	0.6 (0.8)	44	0.2 (0.1)	70	0.7 (0.9)	37	0.2 (0.1)	0.0 [-0.3; 0.4] 0.804
Week 60	113	0.5 (0.8)	55	0.1 (0.1)	89	0.6 (0.8)	54	0.0 (0.1)	0.1 [-0.2; 0.3] 0.625
Week 64	75	0.7 (1.0)	35	0.2 (0.1)	53	0.5 (0.7)	32	0.1 (0.1)	0.1 [-0.2; 0.4] 0.566
Week 68	70	0.7 (0.8)	41	0.2 (0.1)	43	0.6 (0.7)	23	0.1 (0.1)	0.1 [-0.3; 0.4] 0.737

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 72	80	0.7 (0.9)	39	0.2 (0.1)	68	0.6 (0.8)	40	0.0 (0.1)	0.2 [-0.1; 0.5] 0.185
Overall treatment effect			156	0.1 (0.1)			148	0.1 (0.1)	0.0 [-0.1; 0.2] 0.845
PRO-CTCAE: Muscle Pain - Interference									
Baseline	157	0.4 (0.7)			154	0.5 (0.8)			
Week 1	195	0.7 (1.0)	103	0.2 (0.1)	186	0.7 (1.0)	93	0.4 (0.1)	-0.2 [-0.5; 0.1] 0.161
Week 2	205	0.6 (1.0)	111	0.2 (0.1)	206	0.6 (0.9)	120	0.2 (0.1)	0.0 [-0.3; 0.2] 0.895
Week 3	180	0.6 (0.9)	94	0.1 (0.1)	173	0.6 (0.9)	102	0.0 (0.1)	0.1 [-0.1; 0.3] 0.515
Week 4	215	0.5 (0.8)	130	0.1 (0.1)	184	0.4 (0.8)	107	0.0 (0.1)	0.1 [-0.1; 0.3] 0.320
Week 5	191	0.5 (0.9)	101	0.1 (0.1)	167	0.6 (1.0)	92	0.1 (0.1)	0.0 [-0.2; 0.2] 0.889
Week 6	176	0.5 (0.8)	99	0.0 (0.1)	167	0.4 (0.7)	94	0.0 (0.1)	0.1 [-0.1; 0.3] 0.361
Week 7	180	0.5 (0.9)	95	0.1 (0.1)	156	0.5 (0.7)	87	0.0 (0.1)	0.1 [-0.1; 0.3] 0.310
Week 8	153	0.6 (1.0)	89	0.2 (0.1)	133	0.5 (0.9)	76	0.1 (0.1)	0.1 [-0.2; 0.3] 0.505
Week 9	180	0.5 (0.9)	104	0.1 (0.1)	157	0.5 (0.7)	87	0.0 (0.1)	0.1 [-0.1; 0.3] 0.194
Week 10	168	0.5 (0.9)	94	0.1 (0.1)	162	0.5 (0.8)	84	0.0 (0.1)	0.0 [-0.2; 0.2] 0.887
Week 11	178	0.5 (0.8)	98	0.1 (0.1)	156	0.5 (0.9)	89	0.1 (0.1)	0.1 [-0.2; 0.3] 0.600
Week 12	191	0.5 (0.9)	111	0.1 (0.1)	180	0.4 (0.7)	103	0.0 (0.1)	0.1 [-0.1; 0.3] 0.213

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 13	174	0.5 (0.8)	103	0.1 (0.1)	150	0.5 (0.8)	80	0.0 (0.1)	0.1 [-0.1; 0.3] 0.551
Week 14	162	0.5 (0.9)	90	0.2 (0.1)	140	0.5 (0.8)	77	0.1 (0.1)	0.1 [-0.2; 0.3] 0.495
Week 15	166	0.4 (0.8)	93	0.2 (0.1)	149	0.5 (0.8)	83	0.0 (0.1)	0.2 [0.0; 0.4] 0.120
Week 16	165	0.5 (0.9)	93	0.1 (0.1)	149	0.5 (0.7)	81	0.0 (0.1)	0.1 [-0.1; 0.3] 0.360
Week 17	163	0.4 (0.7)	90	0.0 (0.1)	145	0.4 (0.7)	80	0.0 (0.1)	0.0 [-0.2; 0.2] 0.919
Week 18	165	0.4 (0.8)	98	0.0 (0.1)	145	0.6 (0.8)	77	0.2 (0.1)	-0.1 [-0.3; 0.1] 0.307
Week 19	162	0.4 (0.7)	90	0.0 (0.1)	141	0.5 (0.7)	73	0.0 (0.1)	0.0 [-0.2; 0.2] 0.926
Week 20	165	0.4 (0.8)	92	0.1 (0.1)	140	0.5 (0.8)	73	0.1 (0.1)	0.0 [-0.2; 0.3] 0.781
Week 21	164	0.4 (0.8)	90	0.1 (0.1)	147	0.5 (0.7)	80	0.0 (0.1)	0.1 [-0.1; 0.3] 0.320
Week 22	149	0.4 (0.9)	85	0.1 (0.1)	145	0.5 (0.8)	77	0.1 (0.1)	0.0 [-0.2; 0.3] 0.869
Week 23	162	0.4 (0.8)	93	0.1 (0.1)	154	0.6 (0.9)	83	0.1 (0.1)	0.0 [-0.2; 0.2] 0.863
Week 24	218	0.4 (0.9)	132	0.0 (0.1)	205	0.5 (0.9)	118	0.0 (0.1)	0.0 [-0.2; 0.2] 0.806
Week 36	189	0.4 (0.7)	107	0.1 (0.1)	160	0.5 (0.7)	95	0.1 (0.1)	0.1 [-0.1; 0.3] 0.398
Week 40	125	0.3 (0.5)	72	0.0 (0.1)	93	0.4 (0.6)	58	0.0 (0.1)	0.0 [-0.1; 0.2] 0.611
Week 44	115	0.3 (0.6)	62	0.0 (0.1)	84	0.5 (0.8)	50	0.1 (0.1)	-0.1 [-0.3; 0.1] 0.461
Week 48	169	0.4 (0.9)	100	0.0 (0.1)	149	0.3 (0.7)	97	-0.1 (0.1)	0.1 [-0.1; 0.3] 0.270

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 52	97	0.4 (0.7)	51	0.1 (0.1)	74	0.5 (0.8)	40	0.1 (0.1)	0.1 [-0.2; 0.3] 0.618
Week 56	88	0.4 (0.6)	44	0.2 (0.1)	70	0.5 (0.8)	37	0.2 (0.1)	0.1 [-0.3; 0.4] 0.692
Week 60	113	0.4 (0.8)	55	0.0 (0.1)	89	0.4 (0.7)	54	-0.1 (0.1)	0.1 [-0.1; 0.3] 0.258
Week 64	75	0.5 (0.9)	35	0.1 (0.1)	53	0.3 (0.6)	32	0.0 (0.1)	0.2 [-0.1; 0.4] 0.160
Week 68	70	0.5 (0.8)	41	0.2 (0.1)	43	0.4 (0.5)	23	0.1 (0.1)	0.1 [-0.2; 0.4] 0.598
Week 72	80	0.5 (0.8)	39	0.2 (0.1)	68	0.5 (0.6)	40	0.1 (0.1)	0.2 [-0.1; 0.4] 0.282
Overall treatment effect			156	0.1 (0.1)			148	0.1 (0.1)	0.1 [-0.1; 0.2] 0.479
PRO-CTCAE: Fatigue - Severity									
Baseline	157	1.1 (1.0)			154	1.2 (1.1)			
Week 1	195	1.3 (1.1)	103	0.1 (0.1)	186	1.5 (1.1)	93	0.0 (0.1)	0.2 [-0.1; 0.4] 0.230
Week 2	205	1.2 (1.0)	111	-0.1 (0.1)	206	1.4 (1.1)	120	0.0 (0.1)	-0.2 [-0.4; 0.1] 0.197
Week 3	180	1.0 (1.0)	94	-0.2 (0.1)	173	1.4 (1.1)	102	0.0 (0.1)	-0.2 [-0.4; 0.1] 0.195
Week 4	215	1.0 (1.0)	130	-0.2 (0.1)	184	1.2 (1.1)	107	-0.1 (0.1)	-0.1 [-0.3; 0.1] 0.486
Week 5	191	1.0 (1.0)	101	-0.2 (0.1)	167	1.3 (1.0)	92	-0.1 (0.1)	-0.1 [-0.4; 0.1] 0.334
Week 6	176	1.0 (1.0)	99	-0.3 (0.1)	167	1.1 (1.0)	94	-0.3 (0.1)	0.0 [-0.2; 0.2] 0.959
Week 7	180	0.9 (1.0)	95	-0.3 (0.1)	156	1.0 (1.0)	87	-0.3 (0.1)	0.0 [-0.2; 0.2] 0.985

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 8	153	1.1 (1.0)	89	-0.2 (0.1)	133	1.2 (1.0)	76	-0.2 (0.1)	0.0 [-0.3; 0.2] 0.815
Week 9	180	1.0 (1.0)	104	-0.3 (0.1)	157	1.0 (0.9)	87	-0.3 (0.1)	0.1 [-0.2; 0.3] 0.647
Week 10	168	1.0 (1.0)	94	-0.4 (0.1)	162	1.0 (0.9)	84	-0.3 (0.1)	-0.1 [-0.3; 0.1] 0.407
Week 11	178	0.9 (0.9)	98	-0.2 (0.1)	156	1.1 (1.0)	89	-0.2 (0.1)	-0.1 [-0.3; 0.2] 0.537
Week 12	191	0.9 (0.9)	111	-0.3 (0.1)	180	1.1 (1.0)	103	-0.1 (0.1)	-0.2 [-0.4; 0.1] 0.138
Week 13	174	0.9 (1.0)	103	-0.3 (0.1)	150	1.1 (0.9)	80	-0.2 (0.1)	-0.1 [-0.3; 0.1] 0.483
Week 14	162	0.9 (0.9)	90	-0.2 (0.1)	140	1.0 (1.0)	77	-0.3 (0.1)	0.1 [-0.1; 0.3] 0.375
Week 15	166	0.8 (0.9)	93	-0.4 (0.1)	149	1.0 (1.0)	83	-0.4 (0.1)	0.0 [-0.2; 0.2] 0.964
Week 16	165	0.8 (1.0)	93	-0.3 (0.1)	149	1.0 (1.0)	81	-0.3 (0.1)	0.0 [-0.2; 0.2] 0.988
Week 17	163	0.9 (0.9)	90	-0.3 (0.1)	145	1.0 (1.0)	80	-0.3 (0.1)	0.0 [-0.2; 0.2] 0.991
Week 18	165	0.9 (1.0)	98	-0.3 (0.1)	145	1.1 (0.9)	77	-0.3 (0.1)	0.0 [-0.2; 0.2] 0.901
Week 19	162	0.8 (0.9)	90	-0.3 (0.1)	141	1.0 (1.0)	73	-0.3 (0.1)	0.0 [-0.2; 0.2] 0.994
Week 20	165	0.9 (1.0)	92	-0.2 (0.1)	140	1.0 (0.9)	73	-0.3 (0.1)	0.1 [-0.2; 0.3] 0.542
Week 21	164	0.8 (0.9)	90	-0.3 (0.1)	147	1.0 (1.0)	80	-0.3 (0.1)	0.0 [-0.2; 0.3] 0.838
Week 22	149	1.0 (1.0)	85	-0.2 (0.1)	145	1.0 (1.0)	77	-0.3 (0.1)	0.1 [-0.2; 0.3] 0.657
Week 23	162	0.8 (0.9)	93	-0.4 (0.1)	154	1.1 (1.0)	83	-0.3 (0.1)	-0.1 [-0.3; 0.1] 0.323

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 24	218	0.8 (0.9)	132	-0.4 (0.1)	205	1.1 (1.0)	118	-0.2 (0.1)	-0.2 [-0.4; 0.0] 0.040
Week 36	189	0.9 (1.0)	107	-0.2 (0.1)	160	1.0 (1.0)	95	-0.2 (0.1)	0.0 [-0.2; 0.2] 0.899
Week 40	125	0.8 (0.9)	72	-0.3 (0.1)	93	1.0 (1.0)	58	-0.3 (0.1)	0.0 [-0.3; 0.3] 0.992
Week 44	115	0.9 (1.0)	62	-0.2 (0.1)	84	1.1 (1.0)	50	-0.1 (0.1)	-0.1 [-0.4; 0.2] 0.559
Week 48	169	1.0 (0.9)	100	-0.2 (0.1)	149	1.1 (1.0)	97	-0.2 (0.1)	0.0 [-0.2; 0.3] 0.865
Week 52	97	1.0 (0.9)	51	-0.2 (0.1)	74	1.1 (0.9)	40	-0.1 (0.1)	0.0 [-0.3; 0.3] 0.802
Week 56	88	1.0 (1.1)	44	0.0 (0.1)	70	1.1 (1.0)	37	0.0 (0.1)	0.0 [-0.3; 0.4] 0.903
Week 60	113	1.0 (1.0)	55	-0.2 (0.1)	89	1.0 (0.9)	54	-0.4 (0.1)	0.2 [-0.1; 0.5] 0.225
Week 64	75	1.0 (1.0)	35	-0.2 (0.1)	53	1.0 (0.8)	32	-0.2 (0.1)	0.0 [-0.3; 0.3] 0.785
Week 68	70	1.0 (1.0)	41	-0.2 (0.1)	43	1.0 (0.9)	23	-0.1 (0.1)	-0.1 [-0.4; 0.3] 0.723
Week 72	80	1.1 (0.9)	39	-0.2 (0.1)	68	1.0 (0.9)	40	-0.2 (0.1)	0.0 [-0.3; 0.3] 0.971
Overall treatment effect			156	-0.2 (0.1)			148	-0.2 (0.1)	0.0 [-0.2; 0.1] 0.757
PRO-CTCAE: Fatigue - Interference									
Baseline	157	0.9 (1.1)			154	1.0 (1.1)			
Week 1	195	1.0 (1.1)	103	-0.1 (0.1)	186	1.3 (1.2)	93	0.0 (0.1)	0.0 [-0.3; 0.2] 0.761
Week 2	205	0.9 (1.1)	111	-0.2 (0.1)	206	1.2 (1.2)	120	-0.1 (0.1)	-0.2 [-0.4; 0.1] 0.234

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 3	180	0.8 (1.0)	94	-0.2 (0.1)	173	1.1 (1.1)	102	-0.1 (0.1)	-0.1 [-0.4; 0.1] 0.384
Week 4	215	0.8 (0.9)	130	-0.2 (0.1)	184	1.0 (1.1)	107	-0.2 (0.1)	-0.1 [-0.3; 0.2] 0.523
Week 5	191	0.8 (0.9)	101	-0.2 (0.1)	167	1.1 (1.0)	92	-0.2 (0.1)	-0.1 [-0.3; 0.2] 0.656
Week 6	176	0.8 (0.9)	99	-0.3 (0.1)	167	0.9 (1.0)	94	-0.3 (0.1)	-0.1 [-0.3; 0.2] 0.545
Week 7	180	0.8 (1.0)	95	-0.3 (0.1)	156	0.9 (1.0)	87	-0.2 (0.1)	0.0 [-0.3; 0.2] 0.743
Week 8	153	0.8 (1.0)	89	-0.3 (0.1)	133	0.9 (1.0)	76	-0.2 (0.1)	-0.1 [-0.4; 0.1] 0.373
Week 9	180	0.9 (1.0)	104	-0.2 (0.1)	157	0.9 (0.9)	87	-0.2 (0.1)	0.0 [-0.2; 0.2] 0.892
Week 10	168	0.8 (1.0)	94	-0.4 (0.1)	162	0.9 (1.0)	84	-0.2 (0.1)	-0.2 [-0.4; 0.1] 0.166
Week 11	178	0.7 (0.9)	98	-0.2 (0.1)	156	0.9 (1.0)	89	-0.2 (0.1)	-0.1 [-0.3; 0.2] 0.622
Week 12	191	0.7 (0.9)	111	-0.3 (0.1)	180	0.9 (1.0)	103	-0.2 (0.1)	-0.1 [-0.3; 0.1] 0.406
Week 13	174	0.7 (0.9)	103	-0.3 (0.1)	150	1.0 (1.0)	80	-0.2 (0.1)	-0.1 [-0.3; 0.1] 0.295
Week 14	162	0.7 (0.9)	90	-0.3 (0.1)	140	0.9 (1.0)	77	-0.3 (0.1)	0.0 [-0.2; 0.3] 0.798
Week 15	166	0.7 (0.9)	93	-0.3 (0.1)	149	0.9 (1.0)	83	-0.3 (0.1)	0.1 [-0.2; 0.3] 0.660
Week 16	165	0.7 (0.9)	93	-0.3 (0.1)	149	0.9 (1.0)	81	-0.3 (0.1)	0.0 [-0.2; 0.3] 0.877
Week 17	163	0.7 (0.8)	90	-0.3 (0.1)	145	0.9 (1.0)	80	-0.2 (0.1)	-0.1 [-0.4; 0.1] 0.306
Week 18	165	0.6 (0.9)	98	-0.3 (0.1)	145	0.9 (1.0)	77	-0.3 (0.1)	0.0 [-0.2; 0.2] 0.866

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 19	162	0.6 (0.8)	90	-0.3 (0.1)	141	0.8 (1.0)	73	-0.3 (0.1)	0.0 [-0.2; 0.2] 0.852
Week 20	165	0.7 (1.0)	92	-0.2 (0.1)	140	1.0 (1.0)	73	-0.2 (0.1)	0.0 [-0.3; 0.2] 0.947
Week 21	164	0.7 (0.9)	90	-0.3 (0.1)	147	0.9 (1.0)	80	-0.3 (0.1)	0.0 [-0.2; 0.2] 0.905
Week 22	149	0.8 (1.0)	85	-0.3 (0.1)	145	0.9 (1.0)	77	-0.2 (0.1)	-0.1 [-0.3; 0.2] 0.534
Week 23	162	0.7 (0.9)	93	-0.3 (0.1)	154	0.9 (1.0)	83	-0.2 (0.1)	-0.1 [-0.3; 0.1] 0.459
Week 24	218	0.6 (0.9)	132	-0.4 (0.1)	205	0.9 (1.1)	118	-0.2 (0.1)	-0.1 [-0.3; 0.1] 0.220
Week 36	189	0.7 (0.9)	107	-0.2 (0.1)	160	0.9 (1.0)	95	-0.2 (0.1)	0.0 [-0.3; 0.2] 0.831
Week 40	125	0.6 (0.8)	72	-0.3 (0.1)	93	0.8 (1.0)	58	-0.2 (0.1)	-0.1 [-0.3; 0.2] 0.525
Week 44	115	0.7 (0.9)	62	-0.3 (0.1)	84	0.9 (1.0)	50	-0.1 (0.1)	-0.1 [-0.4; 0.1] 0.299
Week 48	169	0.8 (1.0)	100	-0.2 (0.1)	149	0.8 (1.0)	97	-0.3 (0.1)	0.1 [-0.2; 0.3] 0.489
Week 52	97	0.8 (0.9)	51	-0.2 (0.1)	74	1.0 (1.0)	40	-0.2 (0.1)	0.0 [-0.3; 0.3] 0.874
Week 56	88	0.8 (1.0)	44	0.0 (0.1)	70	0.9 (1.0)	37	0.0 (0.1)	0.0 [-0.4; 0.4] 0.920
Week 60	113	0.8 (0.9)	55	-0.3 (0.1)	89	0.8 (0.9)	54	-0.4 (0.1)	0.1 [-0.2; 0.4] 0.465
Week 64	75	0.8 (1.0)	35	-0.2 (0.1)	53	0.8 (0.8)	32	-0.1 (0.1)	-0.1 [-0.4; 0.3] 0.715
Week 68	70	0.8 (1.0)	41	-0.2 (0.1)	43	0.8 (0.8)	23	-0.2 (0.1)	0.0 [-0.4; 0.3] 0.775
Week 72	80	1.0 (1.0)	39	-0.1 (0.1)	68	1.0 (1.0)	40	-0.1 (0.1)	0.0 [-0.4; 0.4] 0.994

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Overall treatment effect			156	-0.2 (0.1)			148	-0.2 (0.1)	0.0 [-0.2; 0.1] 0.588
PRO-CTCAE: Increased Sweating - Frequency									
Baseline	157	0.8 (1.2)			154	0.9 (1.2)			
Week 1	195	0.7 (1.0)	103	-0.2 (0.1)	186	0.8 (1.1)	93	-0.3 (0.1)	0.1 [-0.2; 0.4] 0.501
Week 2	205	0.7 (0.9)	111	-0.3 (0.1)	206	0.7 (1.0)	120	-0.2 (0.1)	-0.1 [-0.3; 0.1] 0.410
Week 3	180	0.5 (0.9)	94	-0.4 (0.1)	173	0.6 (0.9)	102	-0.4 (0.1)	0.0 [-0.3; 0.2] 0.661
Week 4	215	0.6 (0.9)	130	-0.3 (0.1)	184	0.6 (0.9)	107	-0.4 (0.1)	0.1 [-0.1; 0.3] 0.420
Week 5	191	0.6 (1.0)	101	-0.4 (0.1)	167	0.6 (0.8)	92	-0.5 (0.1)	0.1 [-0.1; 0.3] 0.432
Week 6	176	0.5 (0.9)	99	-0.4 (0.1)	167	0.5 (0.8)	94	-0.4 (0.1)	0.0 [-0.2; 0.2] 0.748
Week 7	180	0.5 (0.8)	95	-0.5 (0.1)	156	0.4 (0.7)	87	-0.5 (0.1)	0.0 [-0.2; 0.2] 0.966
Week 8	153	0.5 (0.9)	89	-0.4 (0.1)	133	0.6 (0.9)	76	-0.4 (0.1)	-0.1 [-0.3; 0.2] 0.546
Week 9	180	0.5 (0.9)	104	-0.4 (0.1)	157	0.5 (0.8)	87	-0.5 (0.1)	0.1 [-0.1; 0.2] 0.608
Week 10	168	0.5 (0.8)	94	-0.4 (0.1)	162	0.5 (0.8)	84	-0.5 (0.1)	0.1 [-0.1; 0.3] 0.503
Week 11	178	0.5 (0.8)	98	-0.4 (0.1)	156	0.5 (0.7)	89	-0.5 (0.1)	0.0 [-0.1; 0.2] 0.725
Week 12	191	0.5 (0.8)	111	-0.5 (0.1)	180	0.5 (0.8)	103	-0.5 (0.1)	0.1 [-0.1; 0.2] 0.483
Week 13	174	0.5 (0.9)	103	-0.4 (0.1)	150	0.5 (0.8)	80	-0.4 (0.1)	0.0 [-0.2; 0.2] 0.880

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 14	162	0.4 (0.8)	90	-0.5 (0.1)	140	0.5 (0.8)	77	-0.4 (0.1)	-0.1 [-0.3; 0.1] 0.307
Week 15	166	0.4 (0.8)	93	-0.5 (0.1)	149	0.5 (0.8)	83	-0.4 (0.1)	-0.1 [-0.3; 0.1] 0.366
Week 16	165	0.5 (0.9)	93	-0.5 (0.1)	149	0.5 (0.8)	81	-0.5 (0.1)	0.0 [-0.2; 0.2] 0.858
Week 17	163	0.5 (0.8)	90	-0.5 (0.1)	145	0.4 (0.8)	80	-0.4 (0.1)	0.0 [-0.2; 0.2] 0.695
Week 18	165	0.4 (0.8)	98	-0.5 (0.1)	145	0.6 (0.8)	77	-0.4 (0.1)	-0.1 [-0.3; 0.1] 0.354
Week 19	162	0.4 (0.8)	90	-0.5 (0.1)	141	0.5 (0.8)	73	-0.5 (0.1)	0.0 [-0.3; 0.2] 0.668
Week 20	165	0.5 (0.9)	92	-0.5 (0.1)	140	0.6 (0.9)	73	-0.4 (0.1)	-0.1 [-0.3; 0.1] 0.324
Week 21	164	0.4 (0.8)	90	-0.6 (0.1)	147	0.4 (0.7)	80	-0.5 (0.1)	-0.1 [-0.3; 0.1] 0.429
Week 22	149	0.5 (0.9)	85	-0.5 (0.1)	145	0.5 (0.8)	77	-0.5 (0.1)	0.0 [-0.2; 0.2] 0.690
Week 23	162	0.4 (0.8)	93	-0.5 (0.1)	154	0.5 (0.9)	83	-0.4 (0.1)	-0.1 [-0.3; 0.1] 0.365
Week 24	218	0.5 (0.8)	132	-0.4 (0.1)	205	0.6 (0.8)	118	-0.4 (0.1)	0.0 [-0.2; 0.1] 0.634
Week 36	189	0.4 (0.7)	107	-0.5 (0.1)	160	0.5 (0.9)	95	-0.4 (0.1)	-0.1 [-0.3; 0.1] 0.242
Week 40	125	0.4 (0.7)	72	-0.5 (0.1)	93	0.4 (0.7)	58	-0.5 (0.1)	0.0 [-0.2; 0.2] 0.933
Week 44	115	0.4 (0.7)	62	-0.5 (0.1)	84	0.6 (0.9)	50	-0.4 (0.1)	-0.1 [-0.4; 0.1] 0.253
Week 48	169	0.5 (0.8)	100	-0.4 (0.1)	149	0.5 (0.9)	97	-0.4 (0.1)	-0.1 [-0.3; 0.2] 0.571
Week 52	97	0.4 (0.8)	51	-0.5 (0.1)	74	0.5 (0.8)	40	-0.4 (0.1)	-0.1 [-0.4; 0.2] 0.430

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 56	88	0.4 (0.7)	44	-0.5 (0.1)	70	0.5 (0.7)	37	-0.5 (0.1)	0.0 [-0.2; 0.3] 0.772
Week 60	113	0.5 (0.8)	55	-0.5 (0.1)	89	0.4 (0.8)	54	-0.5 (0.1)	0.1 [-0.2; 0.3] 0.528
Week 64	75	0.6 (1.1)	35	-0.2 (0.1)	53	0.5 (0.8)	32	-0.5 (0.1)	0.2 [-0.1; 0.6] 0.246
Week 68	70	0.5 (0.9)	41	-0.4 (0.1)	43	0.5 (0.9)	23	-0.3 (0.2)	-0.1 [-0.5; 0.3] 0.548
Week 72	80	0.7 (1.0)	39	-0.3 (0.1)	68	0.5 (0.8)	40	-0.5 (0.1)	0.2 [-0.1; 0.6] 0.179
Overall treatment effect			156	-0.4 (0.0)			148	-0.4 (0.1)	0.0 [-0.1; 0.1] 0.844
PRO-CTCAE: Increased Sweating - Severity									
Baseline	157	0.7 (1.0)			154	0.7 (1.1)			
Week 1	195	0.6 (0.9)	103	-0.2 (0.1)	186	0.7 (1.0)	93	-0.2 (0.1)	0.0 [-0.3; 0.2] 0.852
Week 2	205	0.5 (0.8)	111	-0.3 (0.1)	206	0.6 (0.9)	120	-0.1 (0.1)	-0.2 [-0.4; 0.0] 0.089
Week 3	180	0.5 (0.8)	94	-0.3 (0.1)	173	0.5 (0.8)	102	-0.3 (0.1)	0.0 [-0.2; 0.1] 0.626
Week 4	215	0.5 (0.8)	130	-0.3 (0.1)	184	0.5 (0.9)	107	-0.3 (0.1)	0.0 [-0.2; 0.2] 0.823
Week 5	191	0.5 (0.8)	101	-0.3 (0.1)	167	0.5 (0.9)	92	-0.3 (0.1)	0.1 [-0.1; 0.3] 0.512
Week 6	176	0.4 (0.7)	99	-0.3 (0.1)	167	0.4 (0.7)	94	-0.3 (0.1)	0.0 [-0.1; 0.2] 0.621
Week 7	180	0.5 (0.9)	95	-0.3 (0.1)	156	0.4 (0.7)	87	-0.4 (0.1)	0.1 [-0.1; 0.2] 0.541
Week 8	153	0.4 (0.8)	89	-0.4 (0.1)	133	0.5 (0.9)	76	-0.3 (0.1)	-0.1 [-0.3; 0.1] 0.359

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 9	180	0.4 (0.7)	104	-0.4 (0.1)	157	0.4 (0.7)	87	-0.4 (0.1)	0.1 [-0.1; 0.2] 0.534
Week 10	168	0.4 (0.7)	94	-0.4 (0.1)	162	0.4 (0.8)	84	-0.4 (0.1)	0.0 [-0.1; 0.2] 0.693
Week 11	178	0.4 (0.7)	98	-0.3 (0.1)	156	0.4 (0.7)	89	-0.4 (0.1)	0.1 [-0.1; 0.2] 0.401
Week 12	191	0.4 (0.7)	111	-0.4 (0.1)	180	0.5 (0.8)	103	-0.4 (0.1)	0.0 [-0.1; 0.2] 0.562
Week 13	174	0.5 (0.8)	103	-0.4 (0.1)	150	0.4 (0.7)	80	-0.4 (0.1)	0.0 [-0.2; 0.2] 0.933
Week 14	162	0.4 (0.7)	90	-0.4 (0.1)	140	0.4 (0.7)	77	-0.4 (0.1)	0.0 [-0.1; 0.2] 0.677
Week 15	166	0.3 (0.7)	93	-0.4 (0.1)	149	0.4 (0.8)	83	-0.3 (0.1)	-0.1 [-0.3; 0.1] 0.176
Week 16	165	0.4 (0.7)	93	-0.4 (0.1)	149	0.4 (0.8)	81	-0.4 (0.1)	0.0 [-0.2; 0.1] 0.616
Week 17	163	0.4 (0.8)	90	-0.4 (0.1)	145	0.4 (0.7)	80	-0.4 (0.1)	-0.1 [-0.2; 0.1] 0.556
Week 18	165	0.4 (0.7)	98	-0.4 (0.1)	145	0.5 (0.8)	77	-0.3 (0.1)	-0.1 [-0.3; 0.0] 0.138
Week 19	162	0.4 (0.8)	90	-0.4 (0.1)	141	0.4 (0.7)	73	-0.4 (0.1)	0.0 [-0.2; 0.2] 0.726
Week 20	165	0.4 (0.8)	92	-0.4 (0.1)	140	0.5 (0.8)	73	-0.4 (0.1)	-0.1 [-0.2; 0.1] 0.490
Week 21	164	0.3 (0.7)	90	-0.5 (0.1)	147	0.3 (0.6)	80	-0.4 (0.1)	-0.1 [-0.3; 0.1] 0.358
Week 22	149	0.4 (0.8)	85	-0.4 (0.1)	145	0.4 (0.7)	77	-0.4 (0.1)	0.0 [-0.2; 0.1] 0.744
Week 23	162	0.4 (0.7)	93	-0.4 (0.1)	154	0.4 (0.7)	83	-0.4 (0.1)	0.0 [-0.2; 0.2] 0.910
Week 24	218	0.4 (0.7)	132	-0.4 (0.1)	205	0.5 (0.8)	118	-0.3 (0.1)	-0.1 [-0.2; 0.1] 0.533

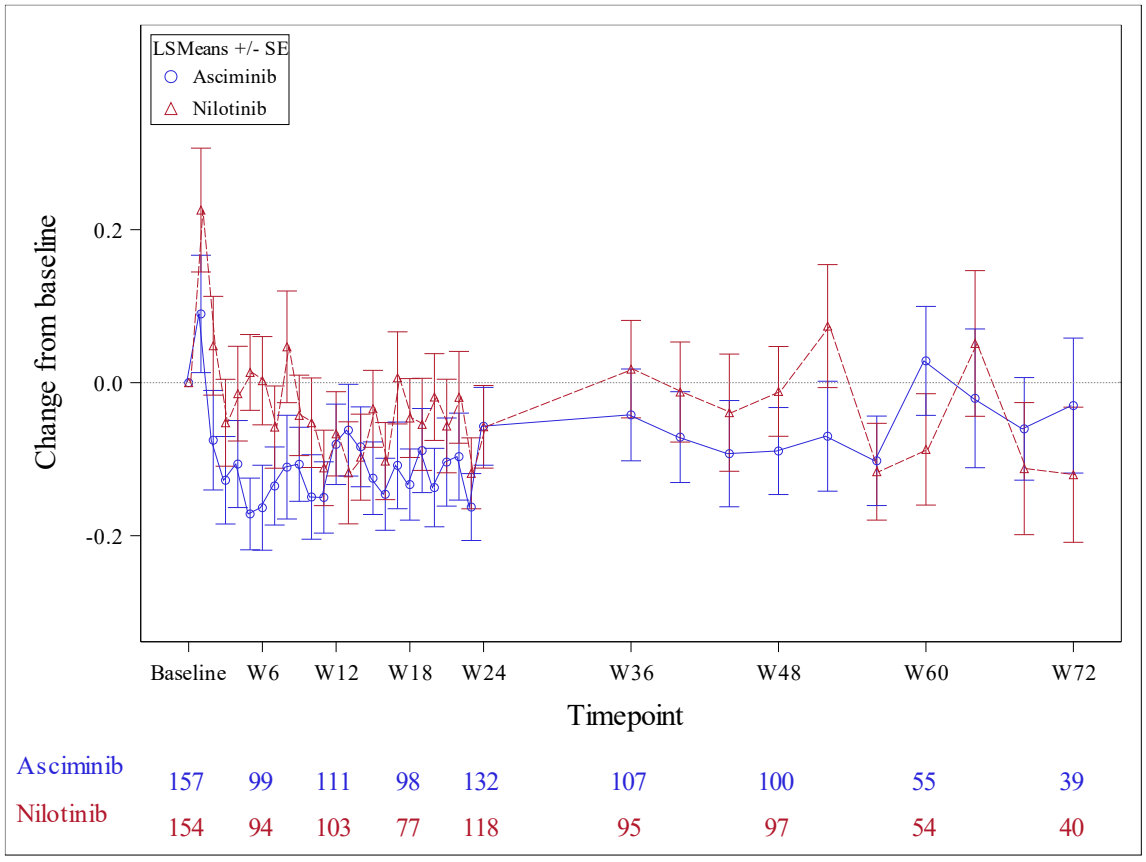
	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value
Week 36	189	0.3 (0.6)	107	-0.4 (0.1)	160	0.4 (0.8)	95	-0.3 (0.1)	0.0 [-0.2; 0.1] 0.662
Week 40	125	0.3 (0.7)	72	-0.5 (0.1)	93	0.4 (0.6)	58	-0.4 (0.1)	-0.1 [-0.2; 0.1] 0.409
Week 44	115	0.3 (0.7)	62	-0.5 (0.1)	84	0.5 (0.8)	50	-0.3 (0.1)	-0.2 [-0.4; 0.0] 0.087
Week 48	169	0.4 (0.7)	100	-0.3 (0.1)	149	0.5 (0.8)	97	-0.3 (0.1)	-0.1 [-0.3; 0.1] 0.429
Week 52	97	0.4 (0.7)	51	-0.3 (0.1)	74	0.5 (0.9)	40	-0.3 (0.1)	0.0 [-0.3; 0.3] 0.924
Week 56	88	0.3 (0.6)	44	-0.4 (0.1)	70	0.4 (0.6)	37	-0.4 (0.1)	0.0 [-0.2; 0.3] 0.705
Week 60	113	0.4 (0.7)	55	-0.4 (0.1)	89	0.4 (0.6)	54	-0.5 (0.1)	0.1 [-0.1; 0.3] 0.537
Week 64	75	0.5 (0.9)	35	-0.2 (0.1)	53	0.3 (0.6)	32	-0.4 (0.1)	0.2 [-0.1; 0.5] 0.256
Week 68	70	0.4 (0.7)	41	-0.4 (0.1)	43	0.4 (0.8)	23	-0.2 (0.1)	-0.2 [-0.5; 0.2] 0.309
Week 72	80	0.5 (0.8)	39	-0.2 (0.1)	68	0.4 (0.7)	40	-0.5 (0.1)	0.2 [-0.1; 0.5] 0.158
Overall treatment effect			156	-0.4 (0.0)			148	-0.4 (0.0)	0.0 [-0.1; 0.1] 0.773

	Treatment groups								Comparison
	Asciminib (N = 284)				Nilotinib (N = 284)				
Timepoint	N[a]	Mean (SD)	N[b]	LS Mean (SE)	N[a]	Mean (SD)	N[b]	LS Mean (SE)	Difference [95% CI] p-value

N[a]: Number of patients with non-missing values at the timepoint
N[b]: Number of patients with non-missing values at baseline and at the timepoint after baseline
CI: Confidence Interval
MMRM: Mixed Model for Repeated Measures
LS Mean: Least Square Mean
SE: Standard Error
SD: Standard Deviation
N.E.: Not Estimable
.....
The column 'Mean (SD)' contains the raw mean and SD of the score at the respective timepoint, the column 'LS mean (SE)' contains the model based LS mean and SE of the change from baseline of the score at the respective timepoint. The difference in the comparison is the difference of the LS mean changes from baseline between Asciminib and Nilotinib.
PRO-CTCAE scores range from 0 to 4 with higher scores indicating that the respective item causes a higher burden for the patient.
The mixed model includes the PRO change from baseline as the dependent variable, treatment arm, study visit, baseline PRO and the stratification factors as recorded in the IRT system as covariates, and treatment arm*study visit interaction as fixed effects with study visit being treated as a repeated effect (repeated by subject).
Models were run using a CSH covariance matrix.
Data Cut/15MAY2025

Figure 3-3.4 MMRM - PRO-CTCAE (Full Analysis Set)

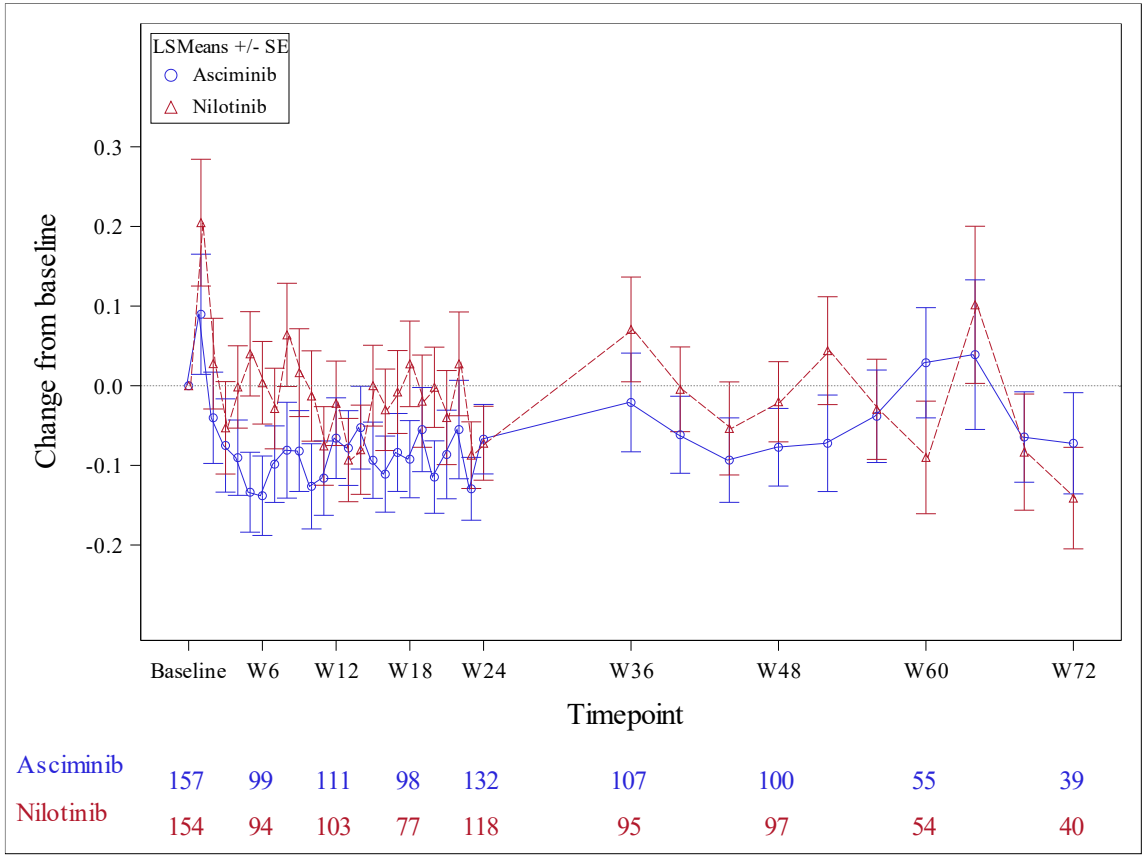
PRO-CTCAE: Nausea - Frequency



Data Cut/15MAY2025

Figure 3-3.4 MMRM - PRO-CTCAE (Full Analysis Set)

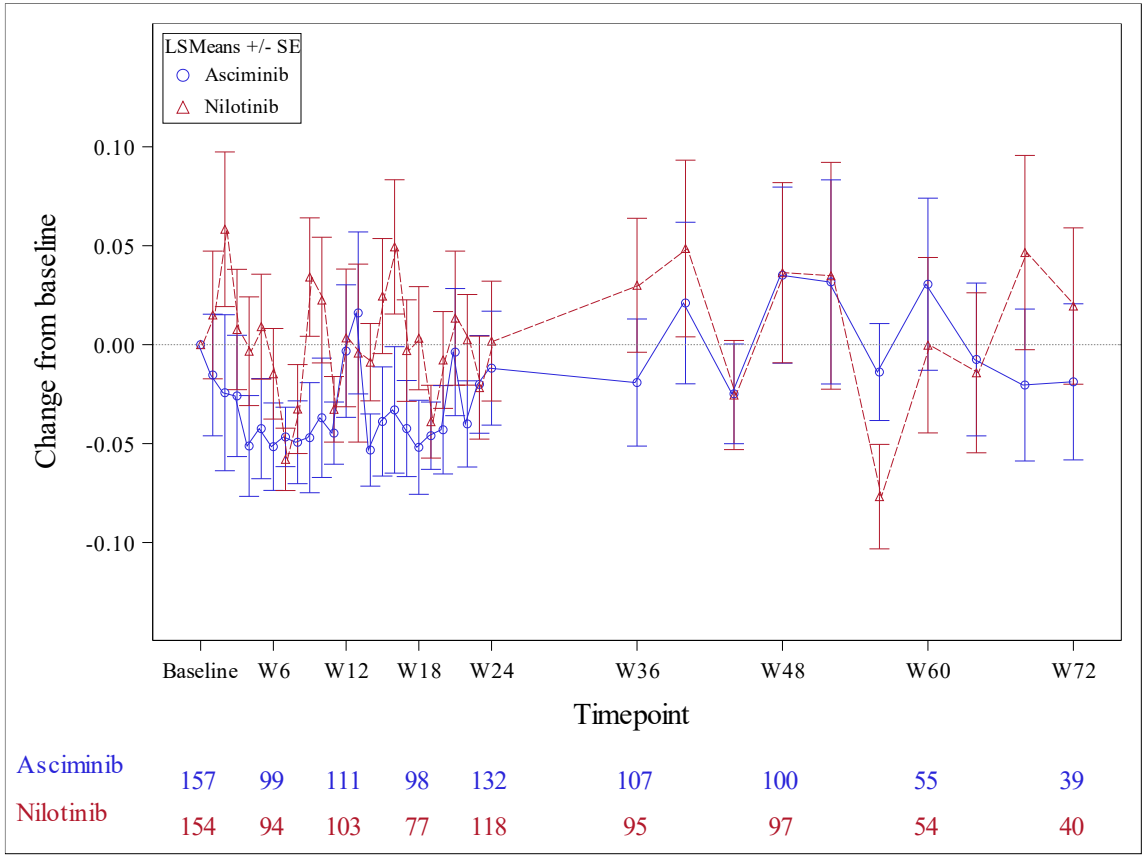
PRO-CTCAE: Nausea - Severity



Data Cut/15MAY2025

Figure 3-3.4 MMRM - PRO-CTCAE (Full Analysis Set)

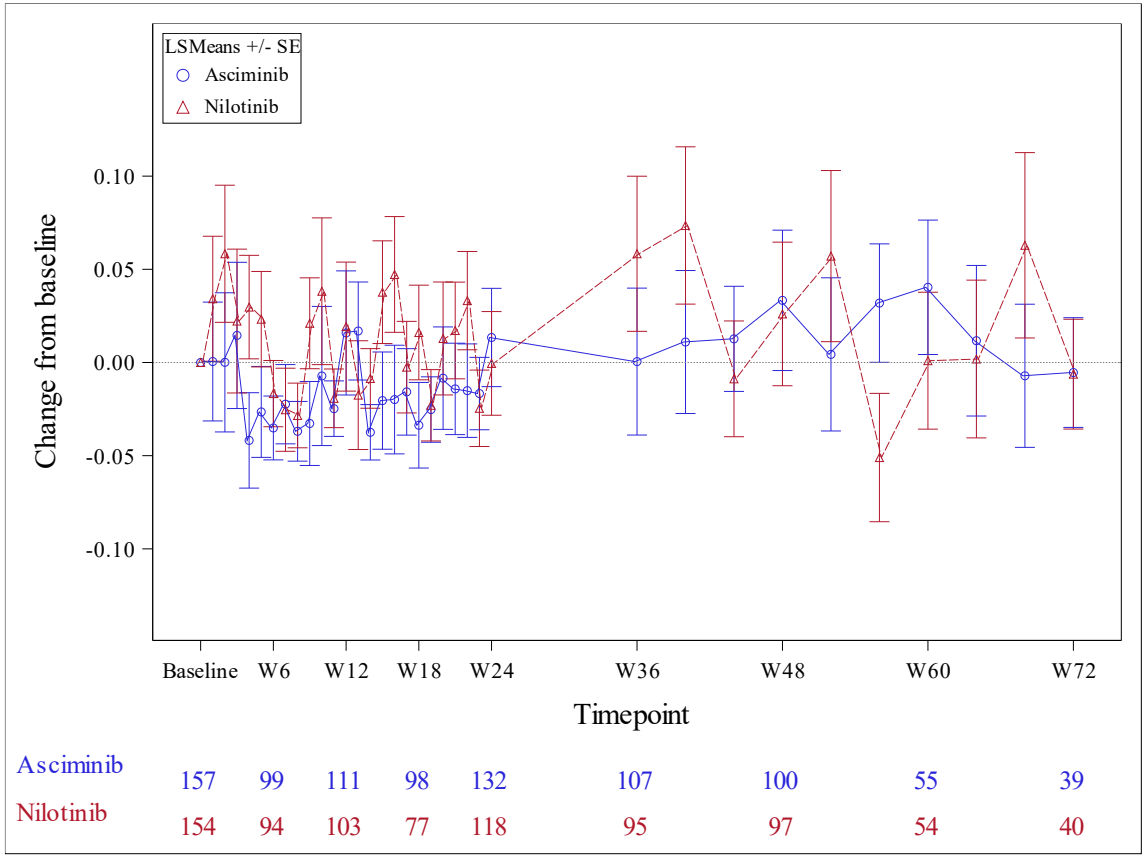
PRO-CTCAE: Vomiting - Frequency



Data Cut/15MAY2025

Figure 3-3.4 MMRM - PRO-CTCAE (Full Analysis Set)

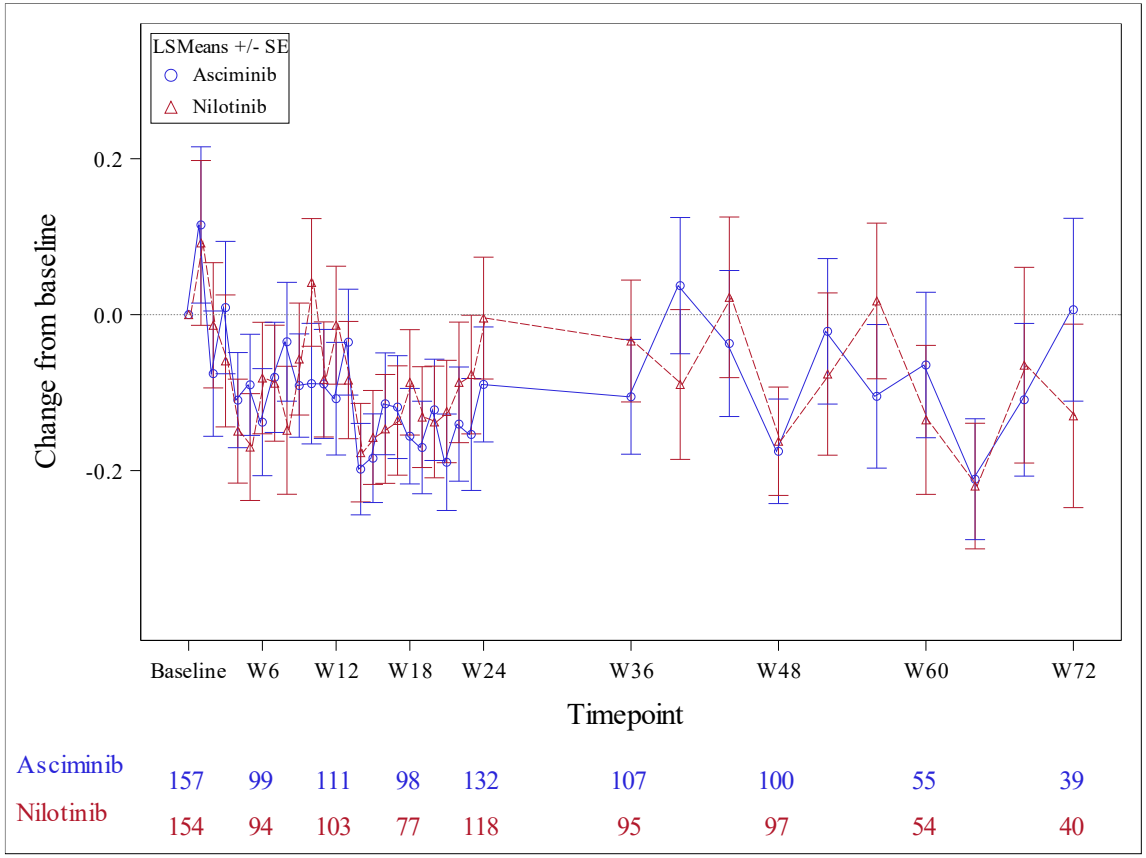
PRO-CTCAE: Vomiting - Severity



Data Cut/15MAY2025

Figure 3-3.4 MMRM - PRO-CTCAE (Full Analysis Set)

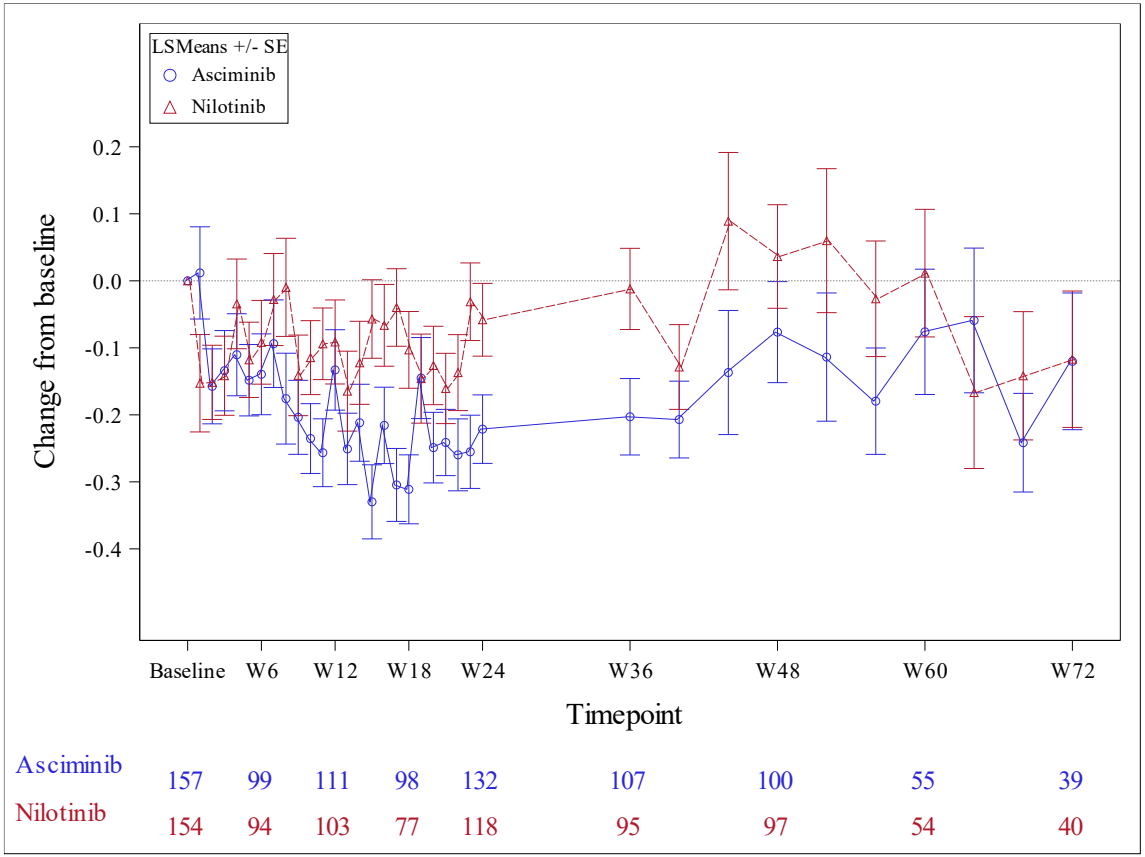
PRO-CTCAE: Diarrhea - Frequency



Data Cut/15MAY2025

Figure 3-3.4 MMRM - PRO-CTCAE (Full Analysis Set)

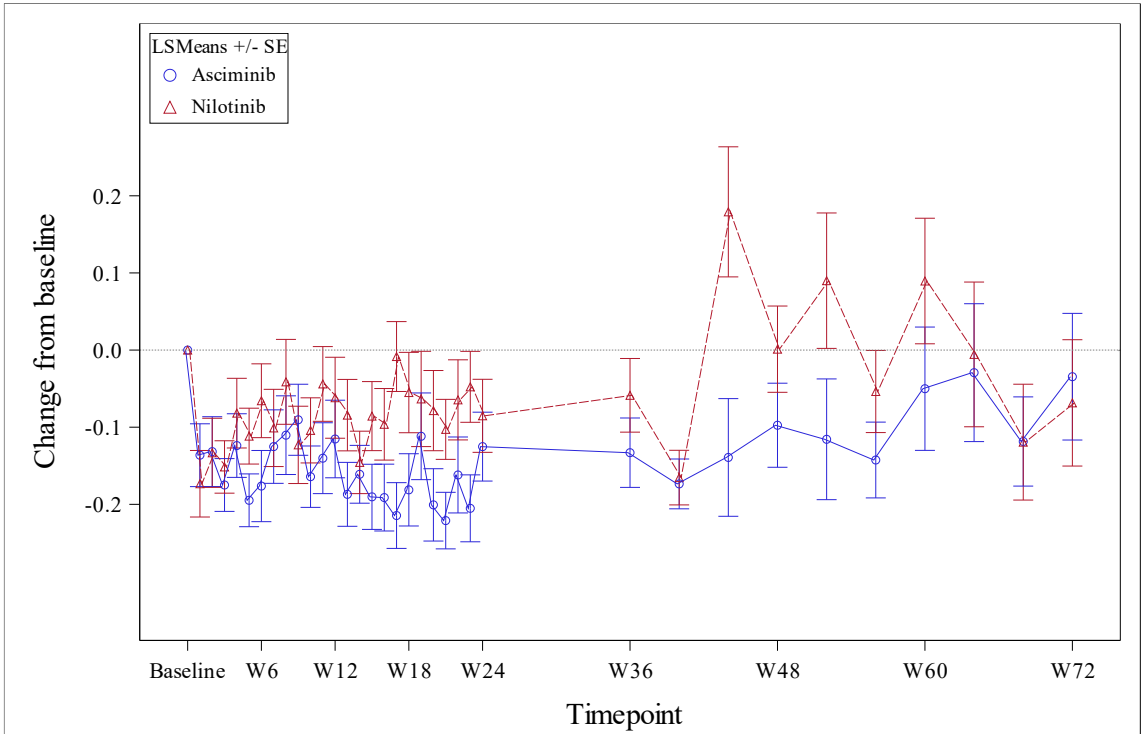
PRO-CTCAE: Cough - Severity



Data Cut/15MAY2025

Figure 3-3.4 MMRM - PRO-CTCAE (Full Analysis Set)

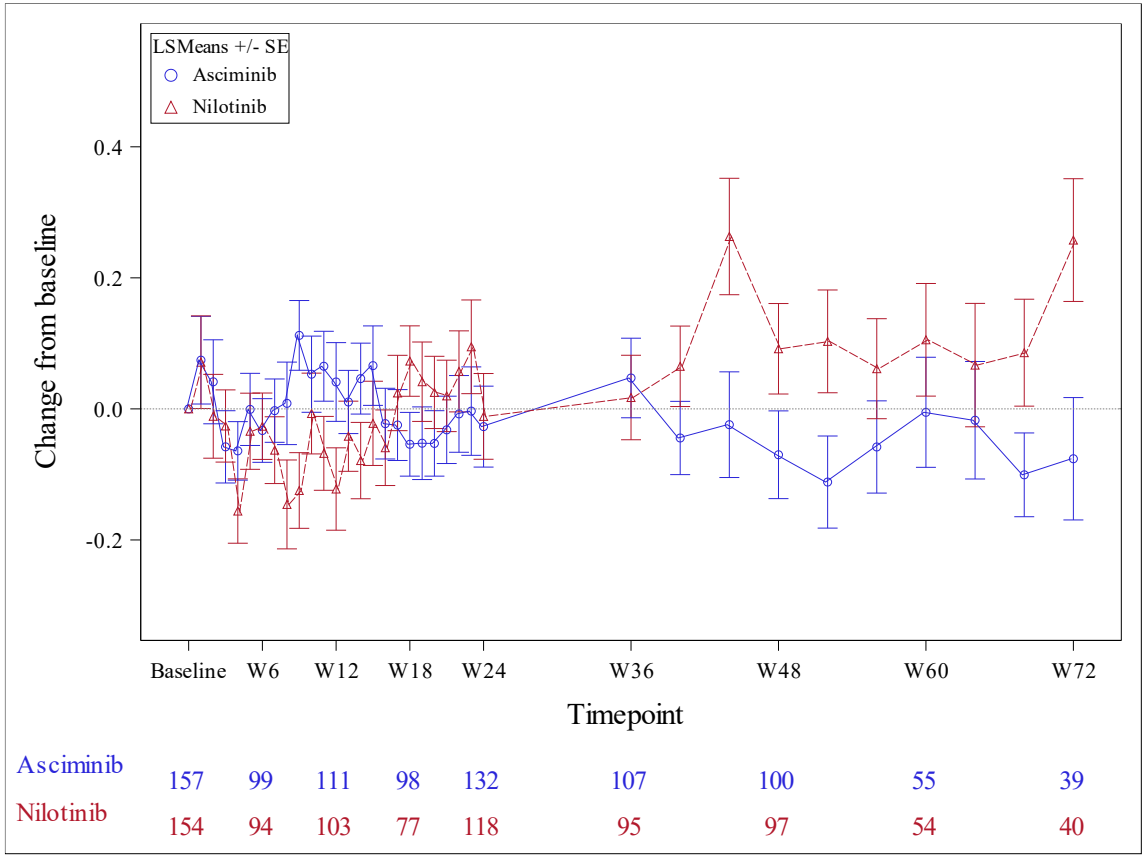
PRO-CTCAE: Cough - Interference



Data Cut/15MAY2025

Figure 3-3.4 MMRM - PRO-CTCAE (Full Analysis Set)

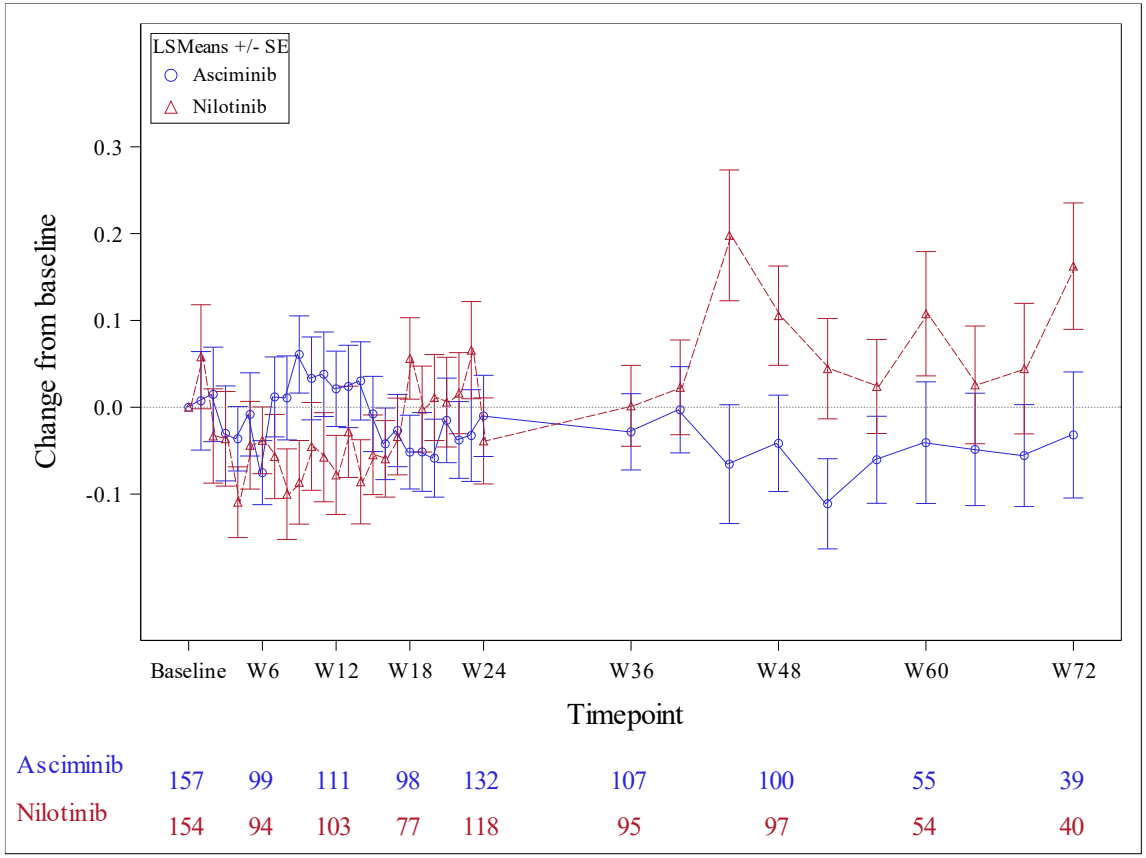
PRO-CTCAE: Swelling - Frequency



Data Cut/15MAY2025

Figure 3-3.4 MMRM - PRO-CTCAE (Full Analysis Set)

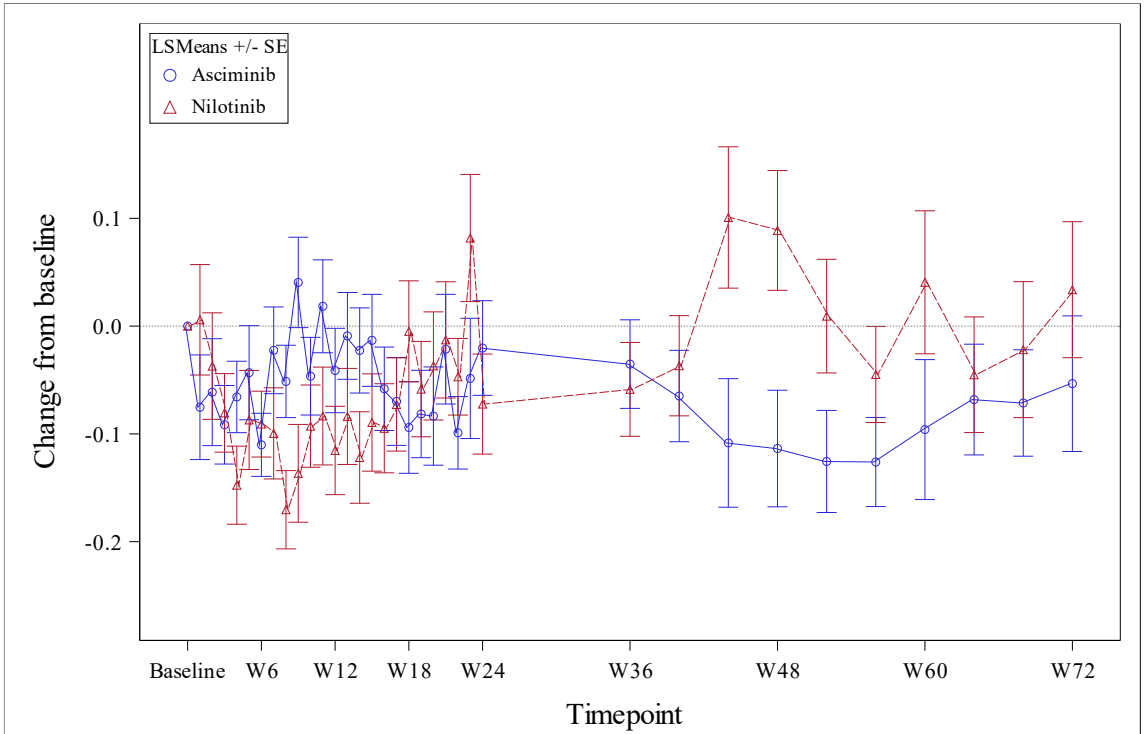
PRO-CTCAE: Swelling - Severity



Data Cut/15MAY2025

Figure 3-3.4 MMRM - PRO-CTCAE (Full Analysis Set)

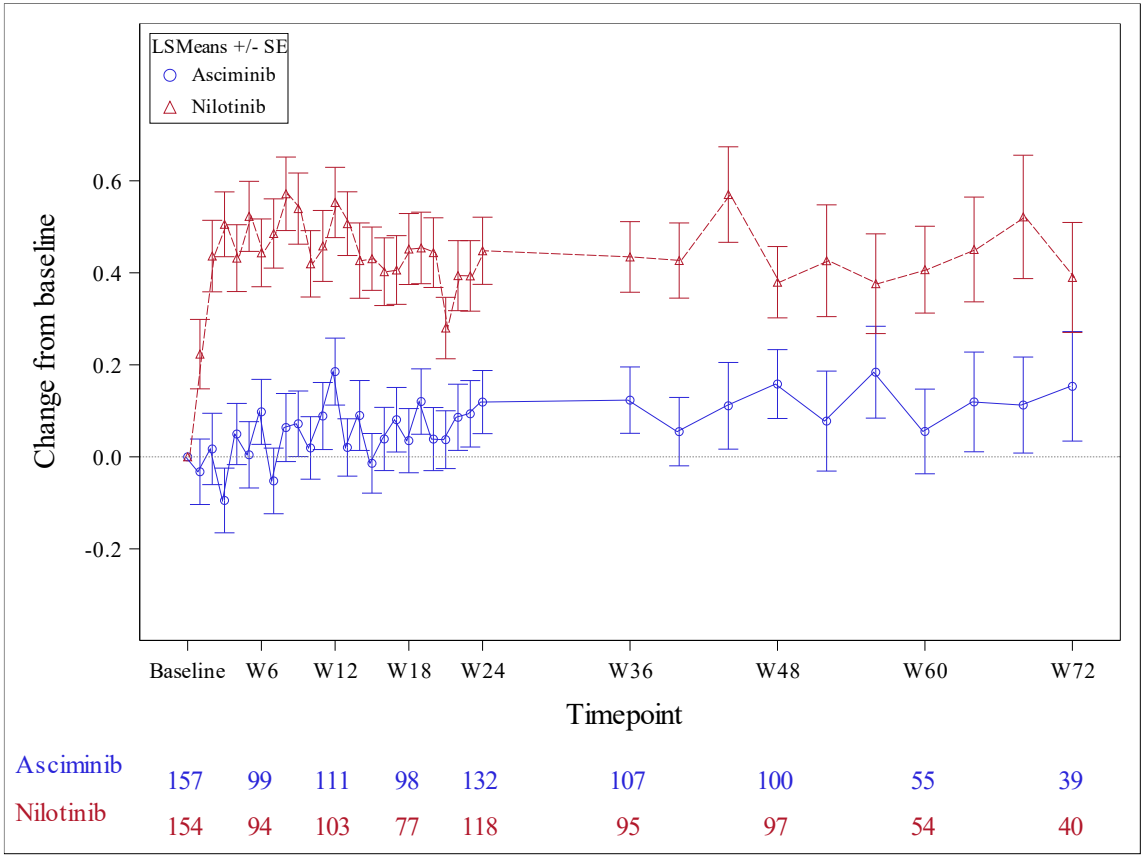
PRO-CTCAE: Swelling - Interference



Data Cut/15MAY2025

Figure 3-3.4 MMRM - PRO-CTCAE (Full Analysis Set)

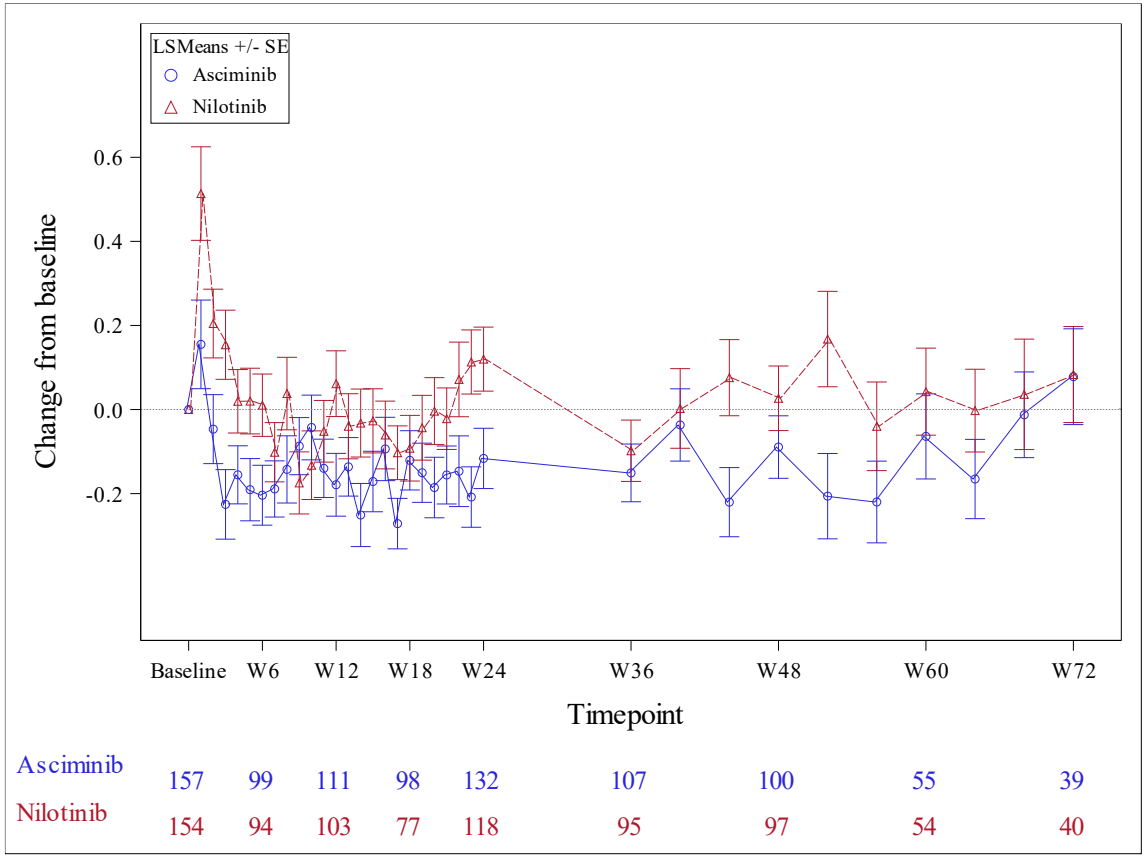
PRO-CTCAE: Itching - Severity



Data Cut/15MAY2025

Figure 3-3.4 MMRM - PRO-CTCAE (Full Analysis Set)

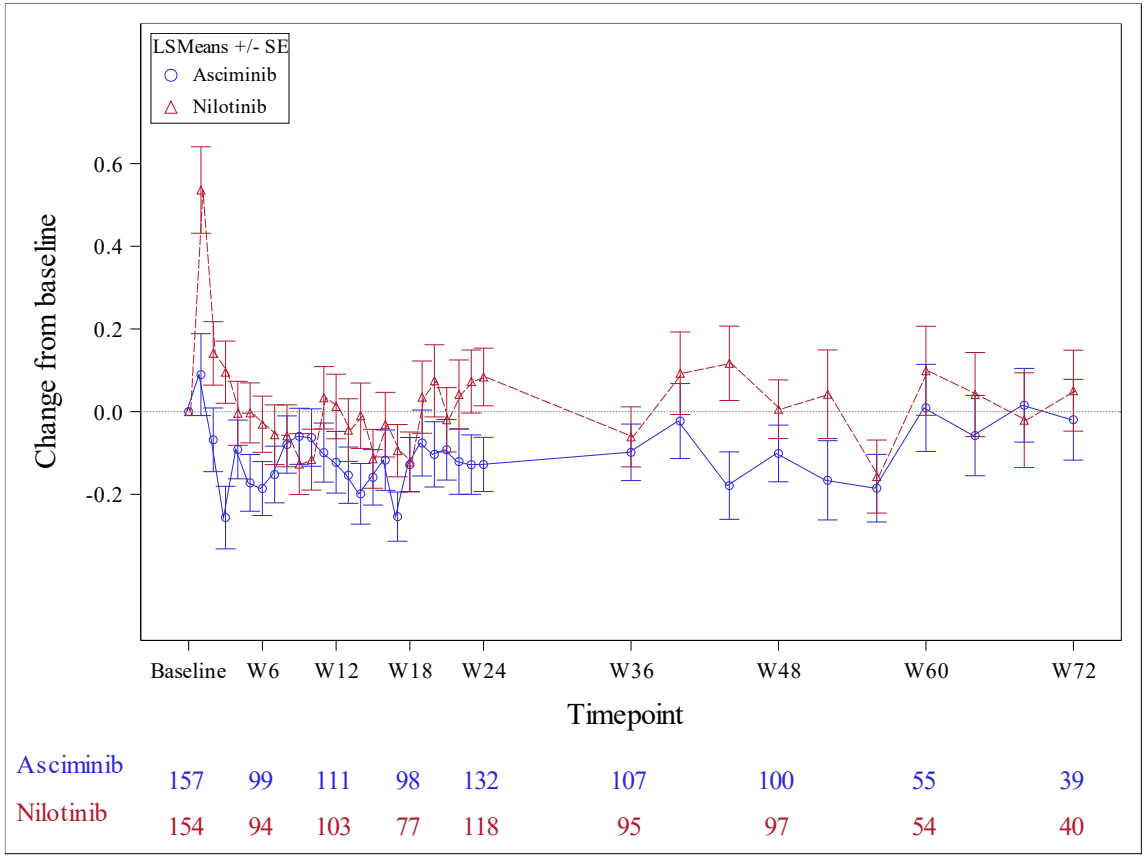
PRO-CTCAE: Headache - Frequency



Data Cut/15MAY2025

Figure 3-3.4 MMRM - PRO-CTCAE (Full Analysis Set)

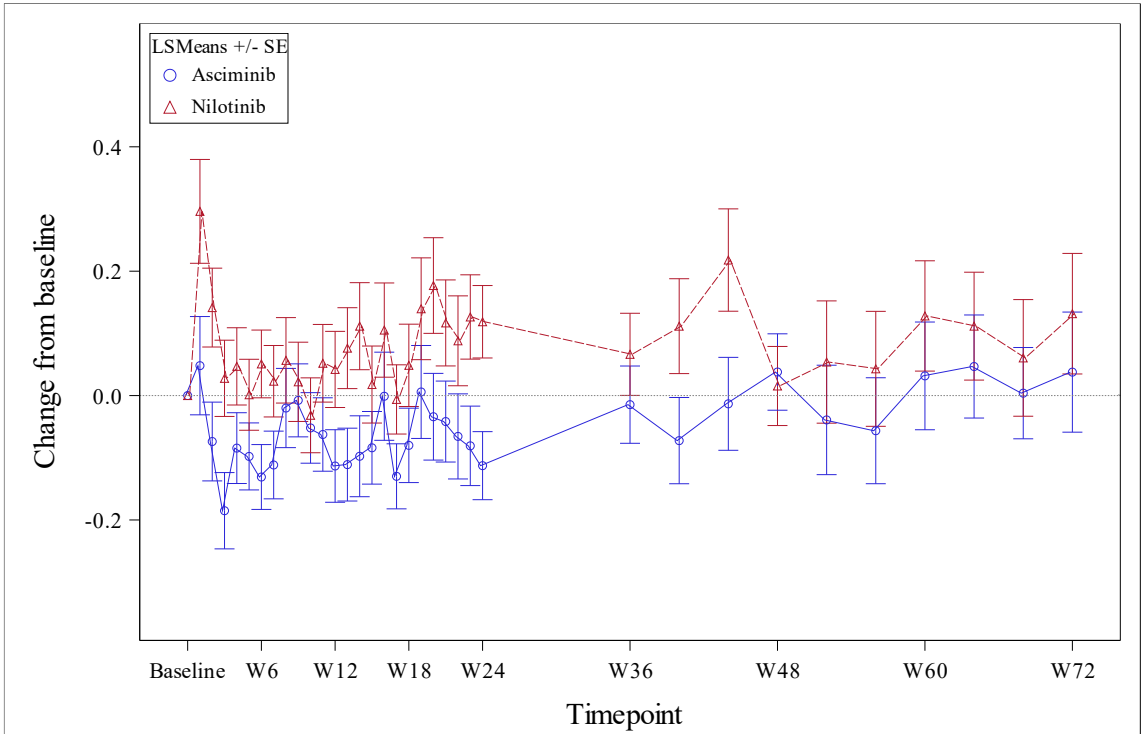
PRO-CTCAE: Headache - Severity



Data Cut/15MAY2025

Figure 3-3.4 MMRM - PRO-CTCAE (Full Analysis Set)

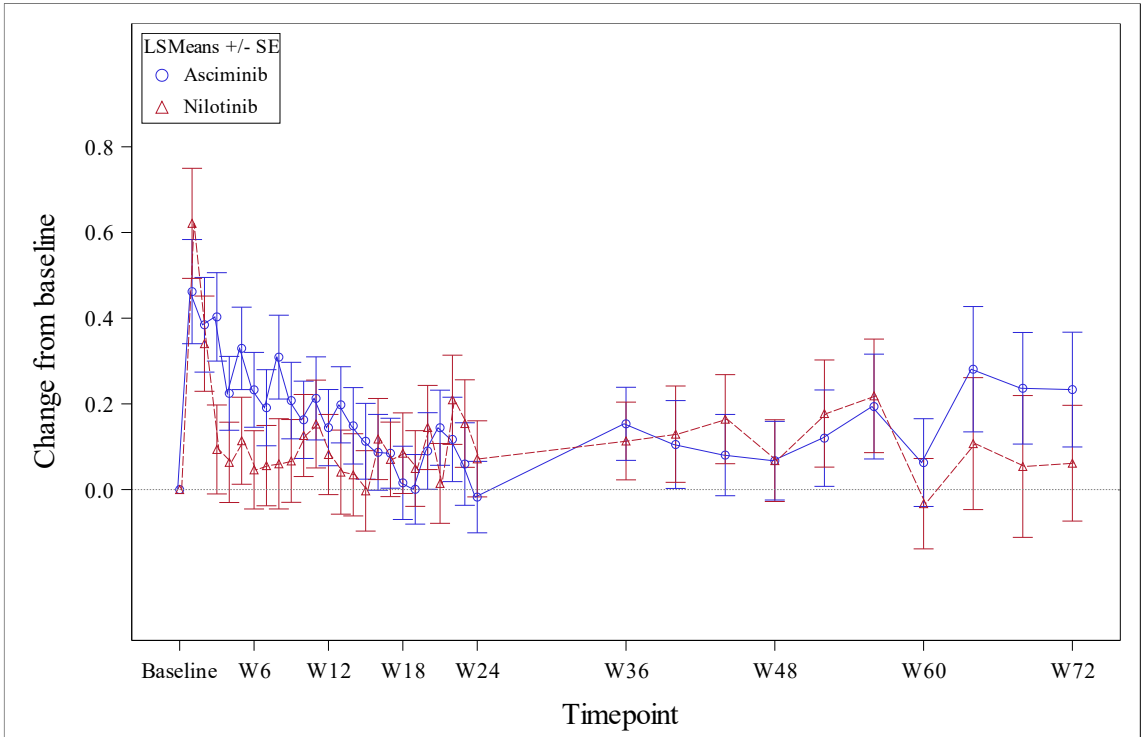
PRO-CTCAE: Headache - Interference



Data Cut/15MAY2025

Figure 3-3.4 MMRM - PRO-CTCAE (Full Analysis Set)

PRO-CTCAE: Muscle Pain - Frequency

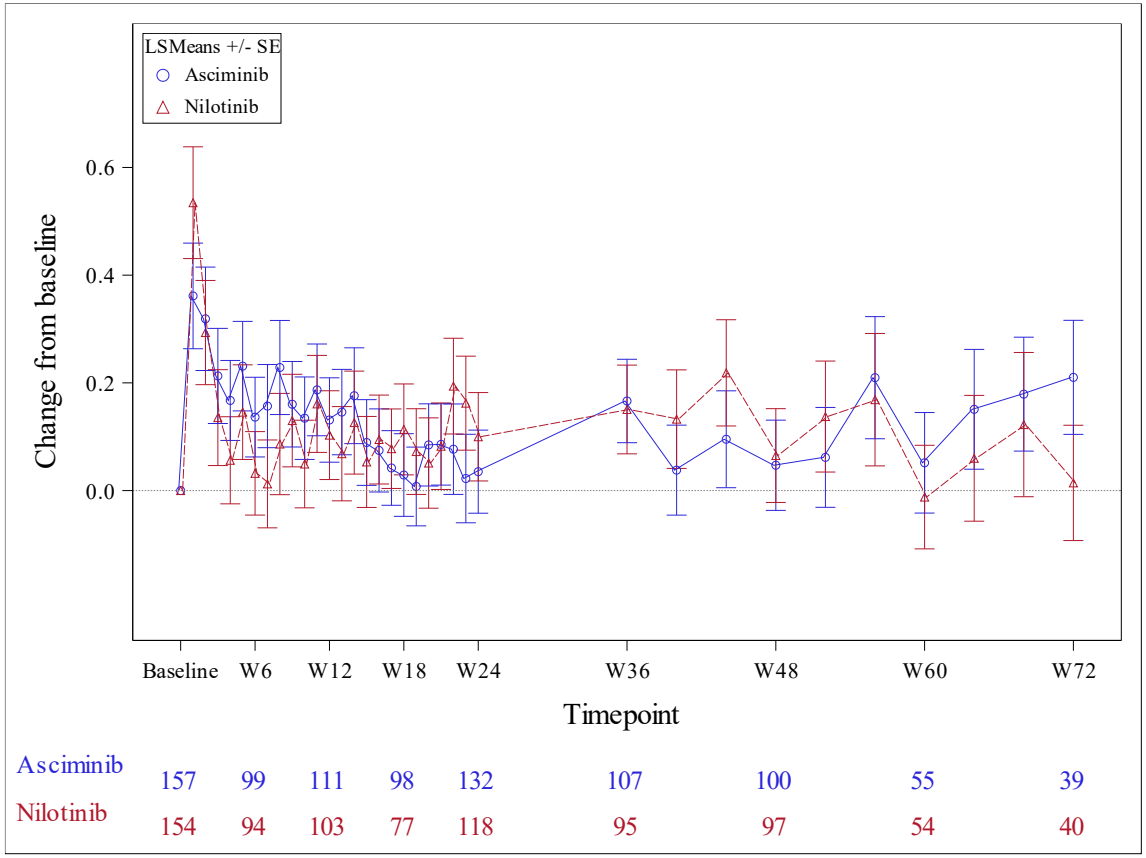


	Baseline	W6	W12	W18	W24	W36	W48	W60	W72
Asciminib	157	99	111	98	132	107	100	55	39
Nilotinib	154	94	103	77	118	95	97	54	40

Data Cut/15MAY2025

Figure 3-3.4 MMRM - PRO-CTCAE (Full Analysis Set)

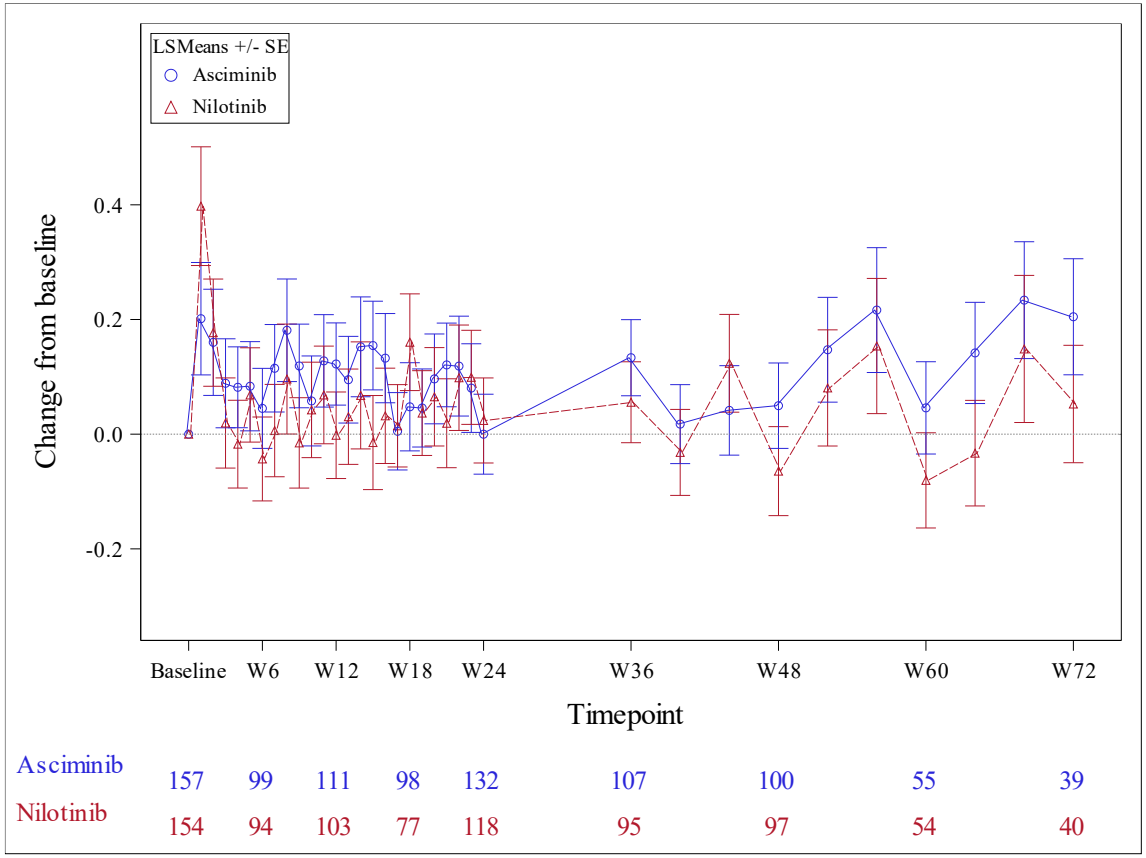
PRO-CTCAE: Muscle Pain - Severity



Data Cut/15MAY2025

Figure 3-3.4 MMRM - PRO-CTCAE (Full Analysis Set)

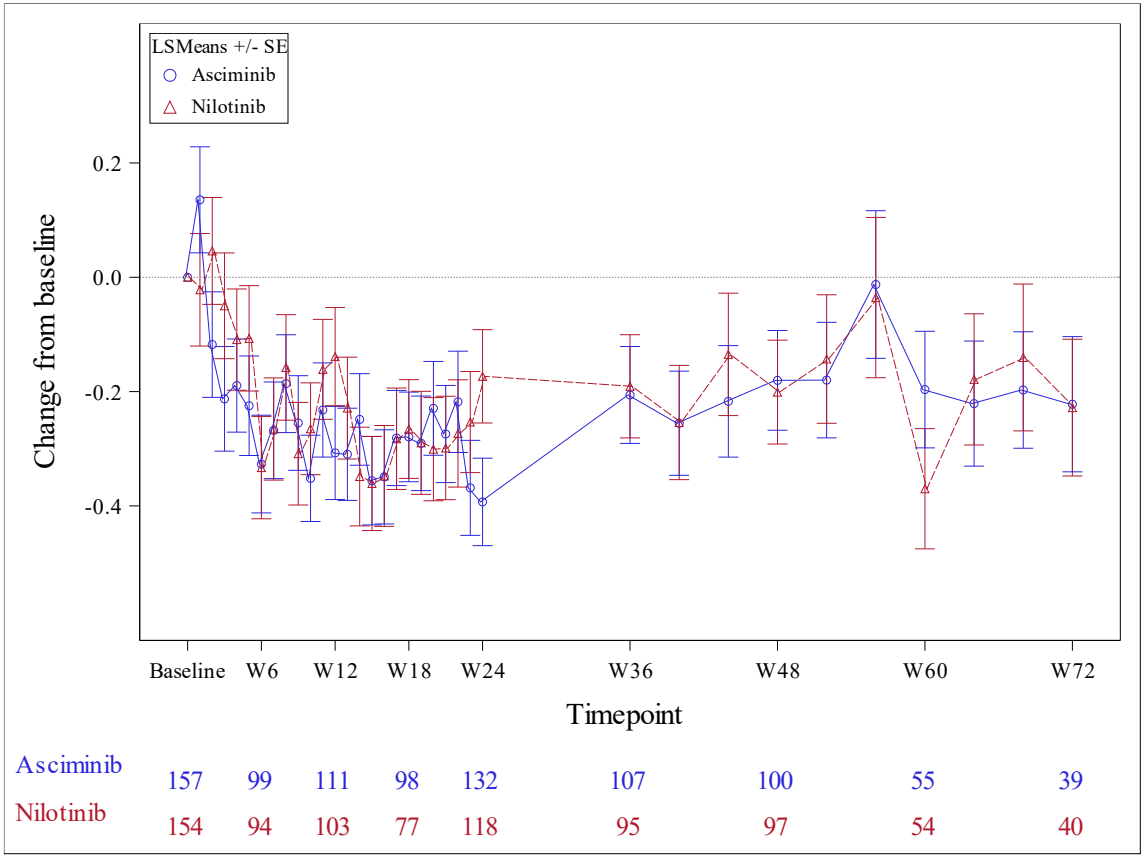
PRO-CTCAE: Muscle Pain - Interference



Data Cut/15MAY2025

Figure 3-3.4 MMRM - PRO-CTCAE (Full Analysis Set)

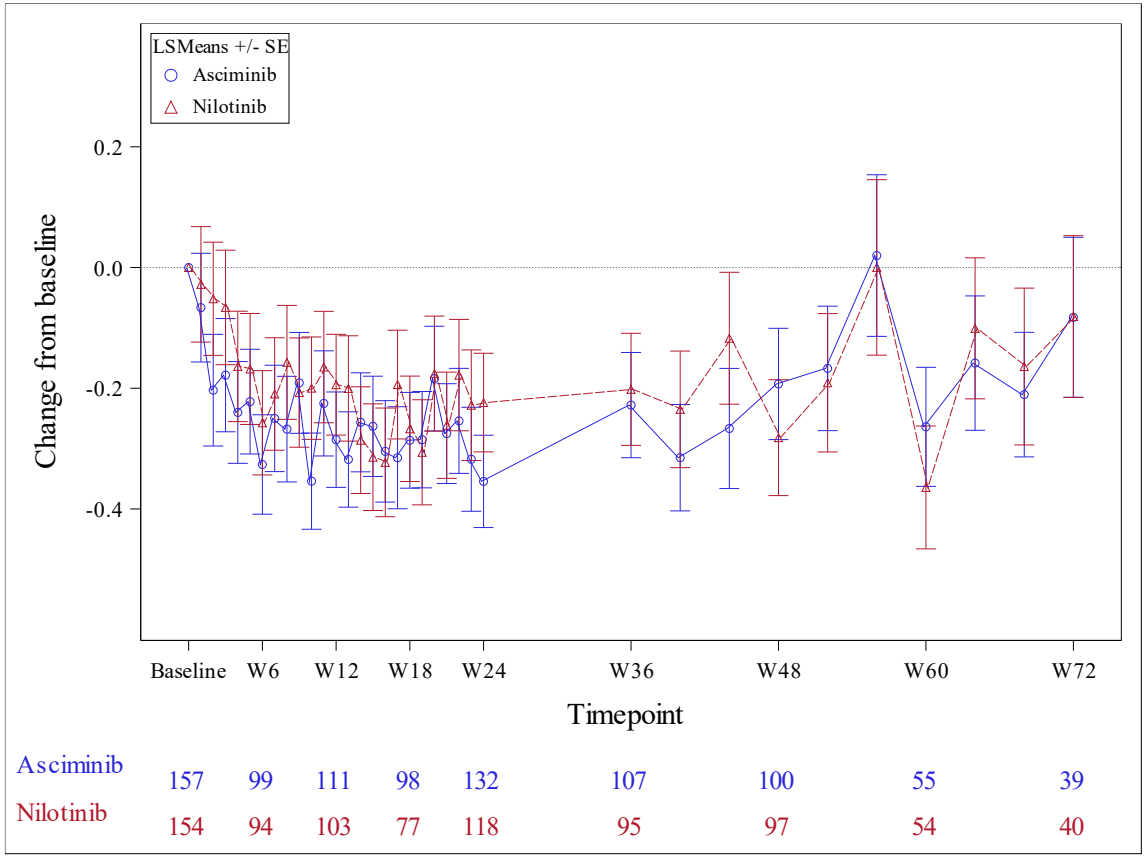
PRO-CTCAE: Fatigue - Severity



Data Cut/15MAY2025

Figure 3-3.4 MMRM - PRO-CTCAE (Full Analysis Set)

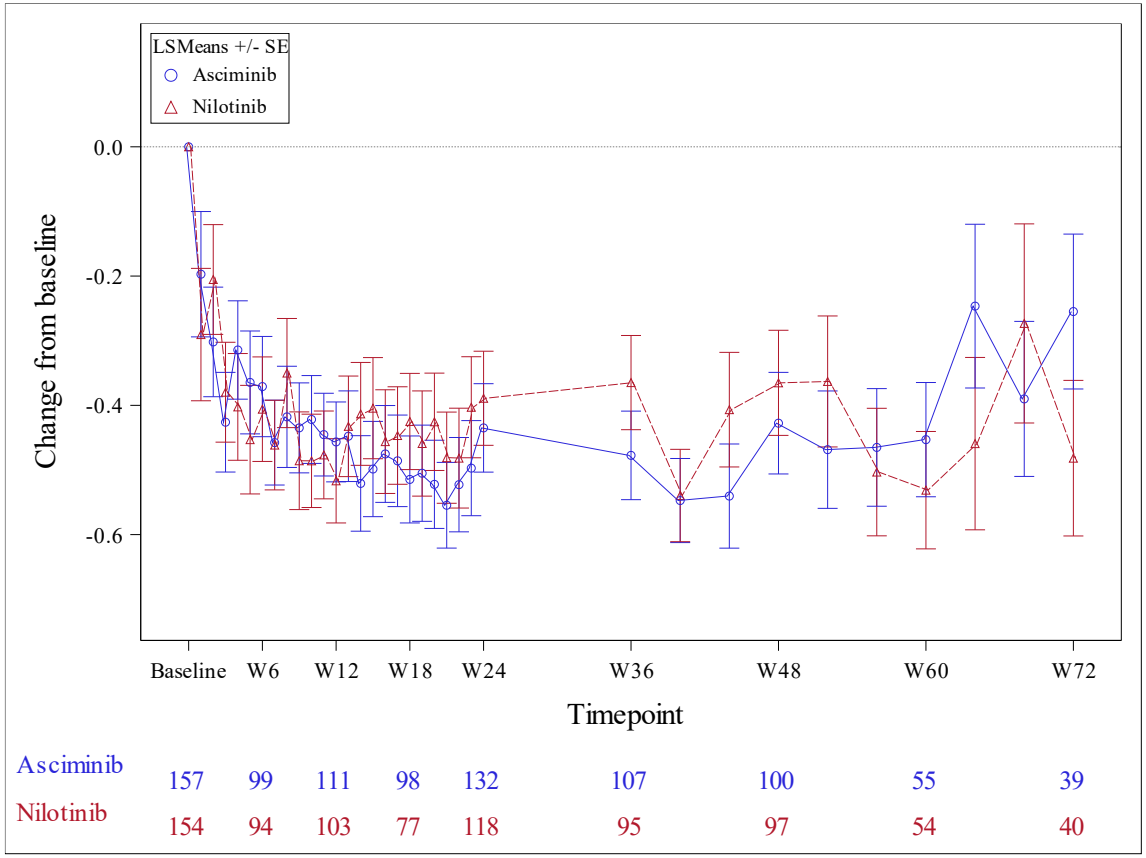
PRO-CTCAE: Fatigue - Interference



Data Cut/15MAY2025

Figure 3-3.4 MMRM - PRO-CTCAE (Full Analysis Set)

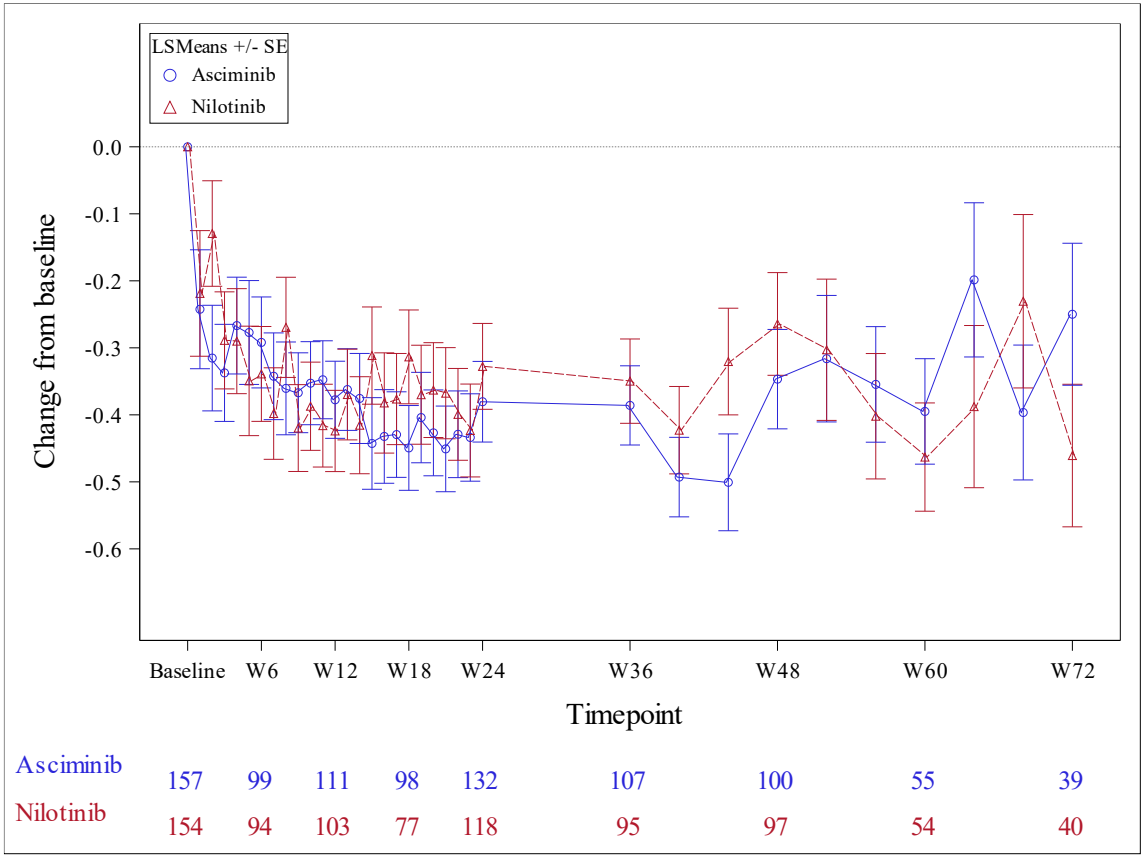
PRO-CTCAE: Increased Sweating - Frequency



Data Cut/15MAY2025

Figure 3-3.4 MMRM - PRO-CTCAE (Full Analysis Set)

PRO-CTCAE: Increased Sweating - Severity



Data Cut/15MAY2025

Table 3-4.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values) (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Global health status/QoL (MID=10)			
N*	284	284	0.84
Number of patients with events, n (%)	108 (38.0)	116 (40.8)	[0.64; 1.12]
			0.537
Percentiles (months) [95% CI]			
25th	1.9 [1.0; 2.9]	1.9 [1.4; 2.3]	
Median	22.1 [15.3; 28.9]	22.0 [9.8; 34.2]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Physical functioning (MID=10)			
N*	284	284	0.84
Number of patients with events, n (%)	82 (28.9)	88 (31.0)	[0.60; 1.16]
			0.613
Percentiles (months) [95% CI]			
25th	4.2 [-0.4; 8.9]	2.0 [-0.3; 4.2]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Role functioning (MID=10)			
N*	284	284	0.85
Number of patients with events, n (%)	110 (38.7)	118 (41.5)	[0.65; 1.13]
			0.809
Percentiles (months) [95% CI]			
25th	1.9 [1.0; 2.9]	1.9 [1.4; 2.4]	
Median	22.2 [7.2; 37.1]	11.3 [5.9; 16.8]	
75th	22.6 [22.5; 22.6]	22.3 [22.3; 22.4]	
Emotional functioning (MID=10)			
N*	284	284	0.72
Number of patients with events, n (%)	93 (32.7)	104 (36.6)	[0.53; 0.98]
			0.461
Percentiles (months) [95% CI]			
25th	2.8 [0.7; 4.9]	2.7 [2.2; 3.3]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	22.3 [22.2; 22.4]	22.1 [4.9; 39.3]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Cognitive functioning (MID=10)			
N*	284	284	0.86
Number of patients with events, n (%)	129 (45.4)	134 (47.2)	[0.66; 1.11]
			0.654
Percentiles (months) [95% CI]			
25th	1.9 [1.5; 2.3]	1.9 [1.4; 2.4]	
Median	11.2 [11.0; 11.3]	5.7 [2.1; 9.2]	
75th	22.2 [22.1; 22.2]	N.E. [N.E.; N.E.]	
Social functioning (MID=10)			
N*	284	284	0.66
Number of patients with events, n (%)	100 (35.2)	124 (43.7)	[0.50; 0.86]
			0.018
Percentiles (months) [95% CI]			
25th	1.9 [1.2; 2.7]	1.1 [0.9; 1.3]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	22.6 [22.1; 23.0]	11.2 [1.9; 20.5]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Fatigue (MID=10)			
N*	284	284	0.79
Number of patients with events, n (%)	94 (33.1)	102 (35.9)	[0.58; 1.08]
			0.574
Percentiles (months) [95% CI]			
25th	2.3 [0.3; 4.3]	1.9 [0.9; 2.9]	
Median	N.E. [N.E.; N.E.]	22.1 [22.0; 22.3]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Nausea and vomiting (MID=10)			
N*	284	284	0.70
Number of patients with events, n (%)	62 (21.8)	81 (28.5)	[0.50; 0.99]
			0.059
Percentiles (months) [95% CI]			
25th	11.2 [6.0; 16.4]	3.0 [-0.8; 6.8]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	22.2 [22.1; 22.3]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Pain (MID=10)			
N*	284	284	0.89
Number of patients with events, n (%)	127 (44.7)	135 (47.5)	[0.69; 1.16]
			0.730
Percentiles (months) [95% CI]			
25th	1.1 [0.8; 1.5]	1.1 [0.8; 1.4]	
Median	11.2 [7.9; 14.5]	5.8 [2.2; 9.4]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Dyspnoea (MID=10)			
N*	284	284	0.91
Number of patients with events, n (%)	89 (31.3)	92 (32.4)	[0.67; 1.23]
			0.799
Percentiles (months) [95% CI]			
25th	2.9 [0.7; 5.0]	2.0 [1.1; 2.9]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	22.2 [22.1; 22.3]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Insomnia (MID=10)			
N*	284	284	0.82
Number of patients with events, n (%)	102 (35.9)	106 (37.3)	[0.61; 1.09]
			0.520
Percentiles (months) [95% CI]			
25th	2.9 [0.9; 4.8]	1.9 [1.0; 2.8]	
Median	22.1 [12.4; 31.9]	22.1 [13.3; 30.9]	
75th	22.6 [22.3; 22.9]	N.E. [N.E.; N.E.]	
Appetite loss (MID=10)			
N*	284	284	0.75
Number of patients with events, n (%)	57 (20.1)	72 (25.4)	[0.52; 1.08]
			0.164
Percentiles (months) [95% CI]			
25th	11.2 [5.5; 16.9]	5.6 [-0.5; 11.7]	

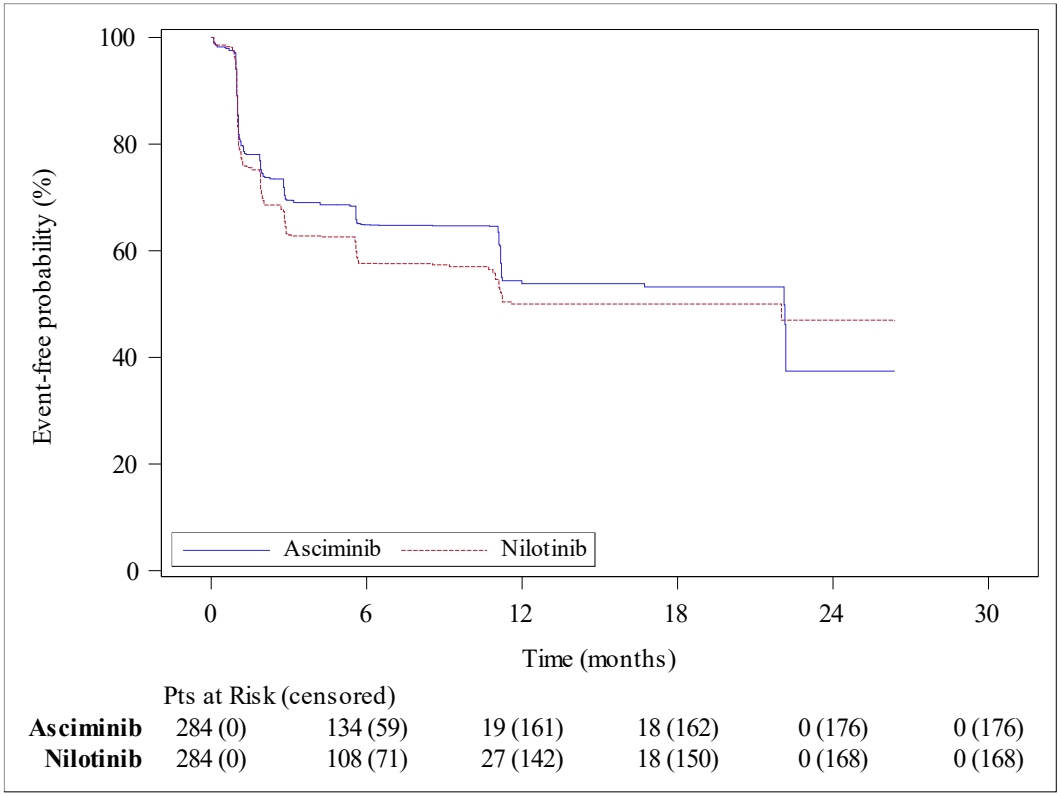
	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Constipation (MID=10)			
N*	284	284	0.56
Number of patients with events, n (%)	70 (24.6)	100 (35.2)	[0.41; 0.77]
			0.003
Percentiles (months) [95% CI]			
25th	11.1 [8.5; 13.7]	2.7 [2.1; 3.3]	
Median	22.3 [22.2; 22.3]	19.4 [6.2; 32.7]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Diarrhoea (MID=10)			
N*	284	284	1.05
Number of patients with events, n (%)	80 (28.2)	80 (28.2)	[0.76; 1.44]
			0.533
Percentiles (months) [95% CI]			
25th	5.6 [1.6; 9.5]	3.0 [1.7; 4.3]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Financial difficulties (MID=10)			
N*	284	284	0.93
Number of patients with events, n (%)	71 (25.0)	77 (27.1)	[0.66; 1.30]
			0.828
Percentiles (months) [95% CI]			
25th	5.6 [0.5; 10.6]	5.6 [1.1; 10.1]	
Median	N.E. [N.E.; N.E.]	22.3 [22.2; 22.4]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

MID: Minimal important difference
HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event. The number of patients is the mean number over all imputations rounded to the nearest integer
.....
Missing baseline values are multiply imputed by simple imputation using 500 repetitions under a MAR assumption.
Two-sided 95% CI for KM percentiles are derived by the approach outlined in Moscovici and Ratitch (2017).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factor ELTS Score (IRT) and covariates treatment arm and baseline score.
P-Values are based on stratified logrank test with stratification factor ELTS Score (IRT).
Test results are combined using the Wilson-Hilferty transformation.
Data Cut/15MAY2025

Figure 3-4.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

Global health status/QoL (MID=10)

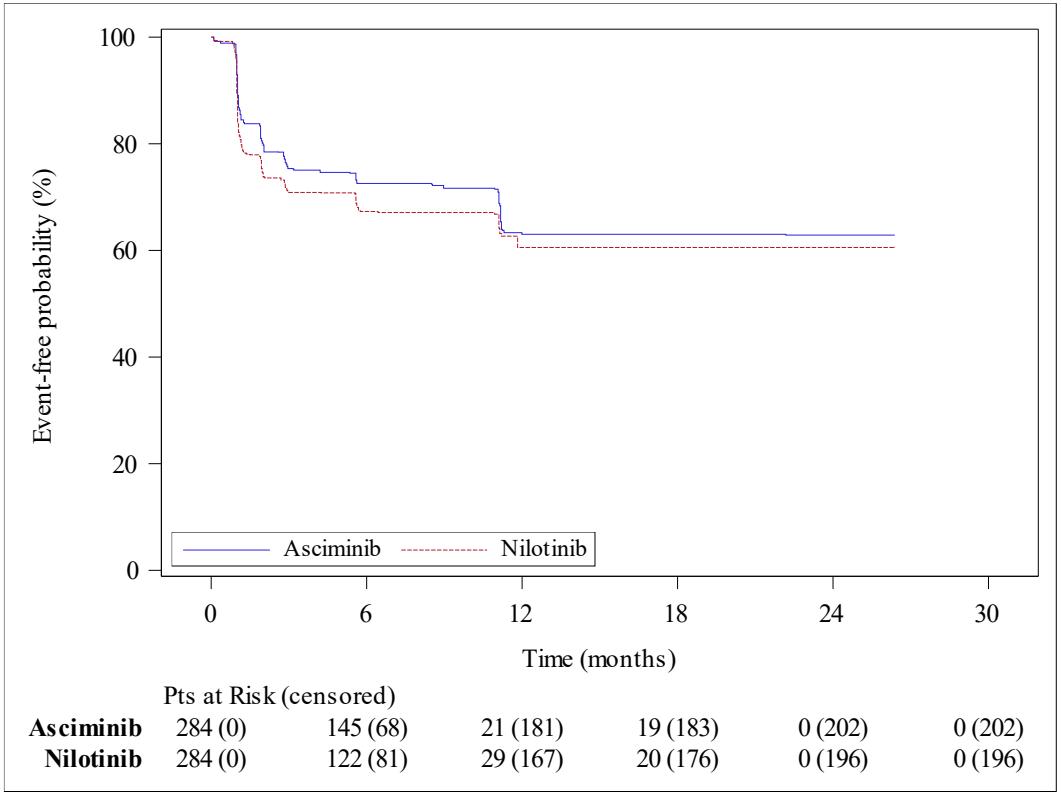


	Pts at Risk (censored)					
Asciminib	284 (0)	134 (59)	19 (161)	18 (162)	0 (176)	0 (176)
Nilotinib	284 (0)	108 (71)	27 (142)	18 (150)	0 (168)	0 (168)

Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

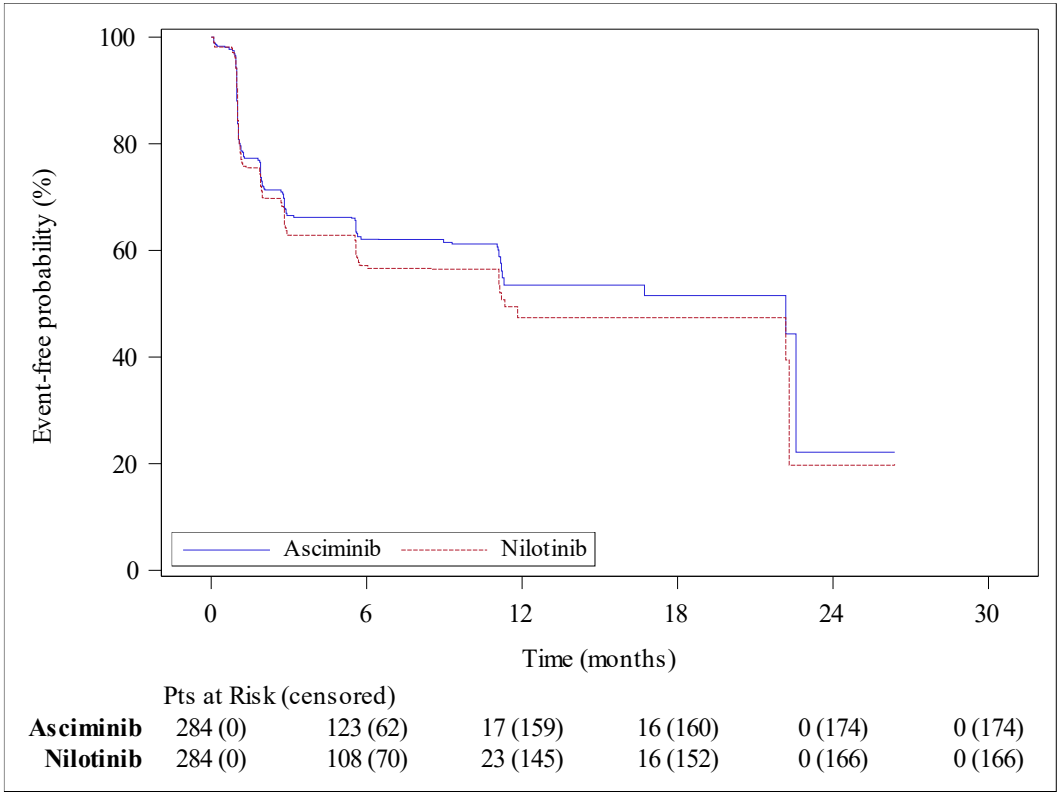
Physical functioning (MID=10)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

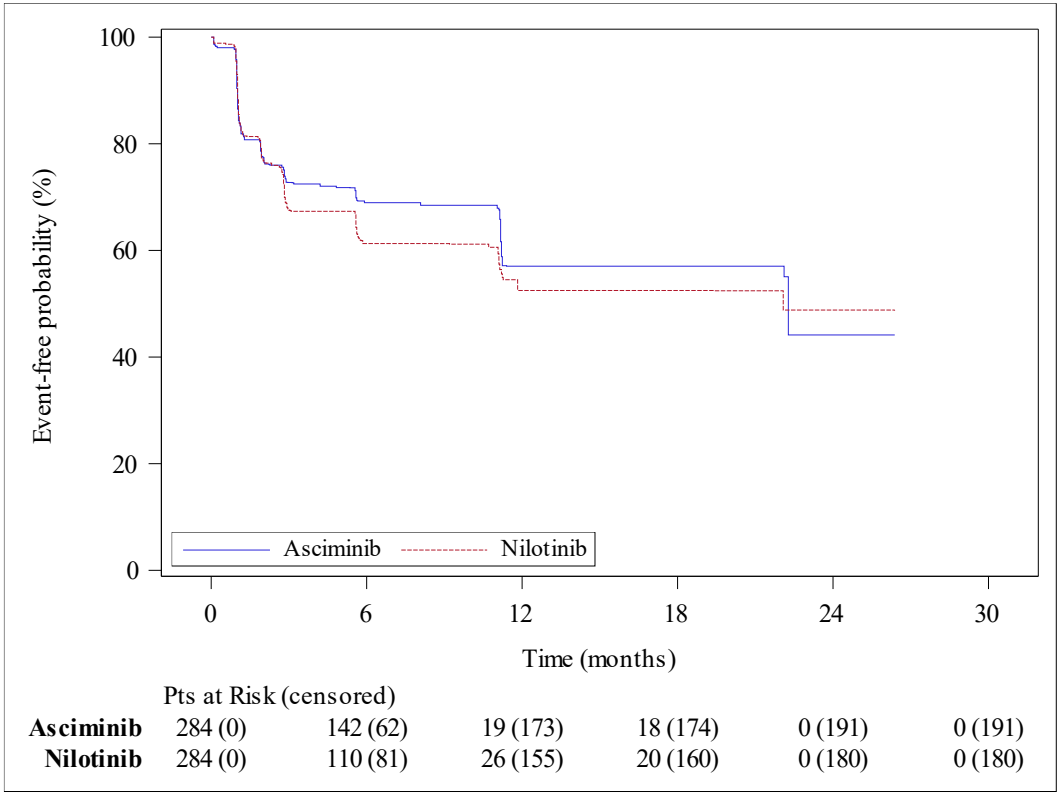
Role functioning (MID=10)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

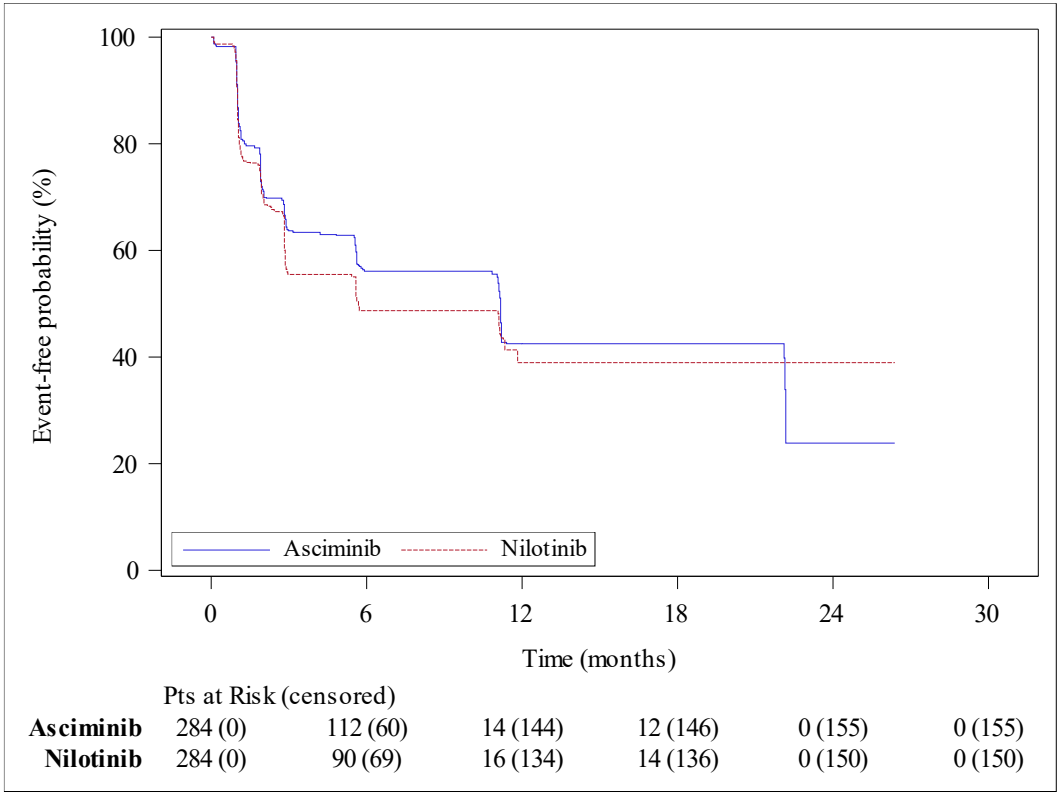
Emotional functioning (MID=10)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

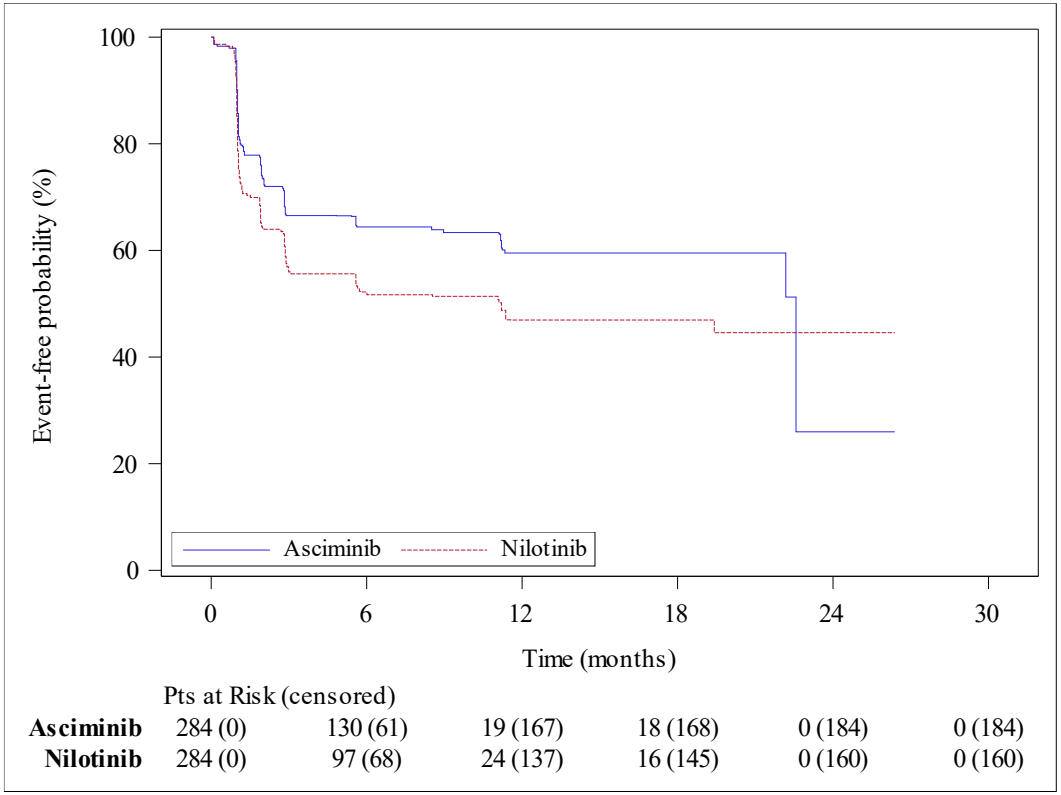
Cognitive functioning (MID=10)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

Social functioning (MID=10)

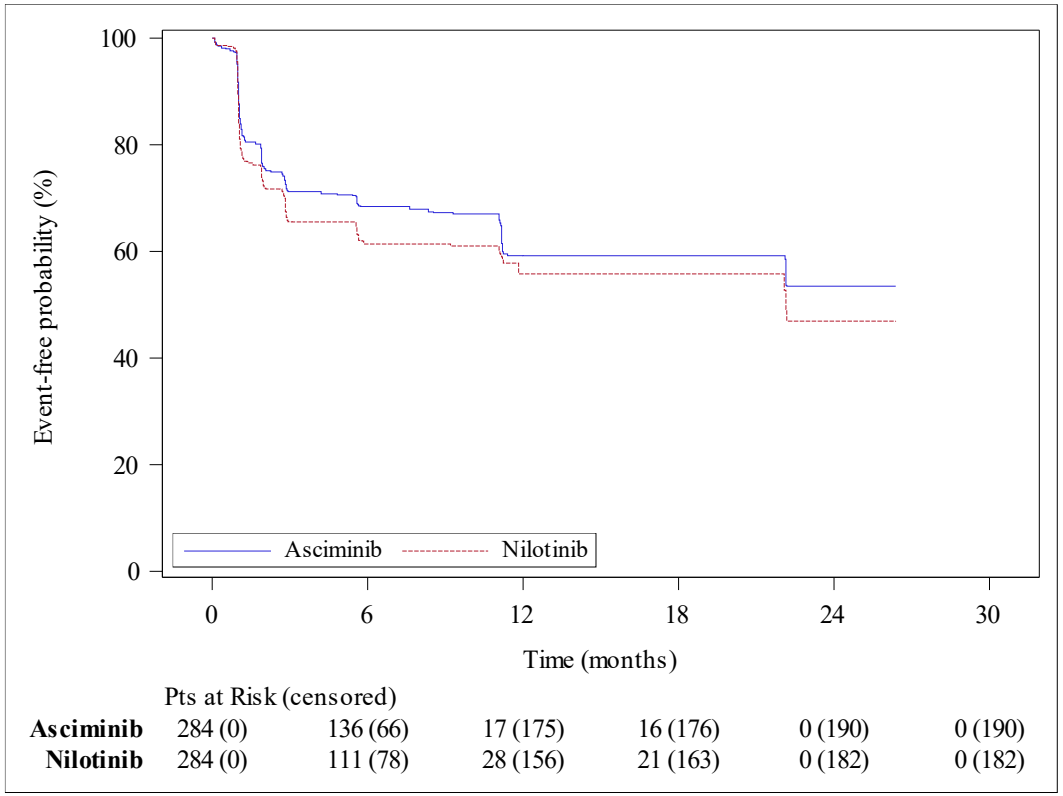


	Pts at Risk (censored)					
Asciminib	284 (0)	130 (61)	19 (167)	18 (168)	0 (184)	0 (184)
Nilotinib	284 (0)	97 (68)	24 (137)	16 (145)	0 (160)	0 (160)

Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

Fatigue (MID=10)

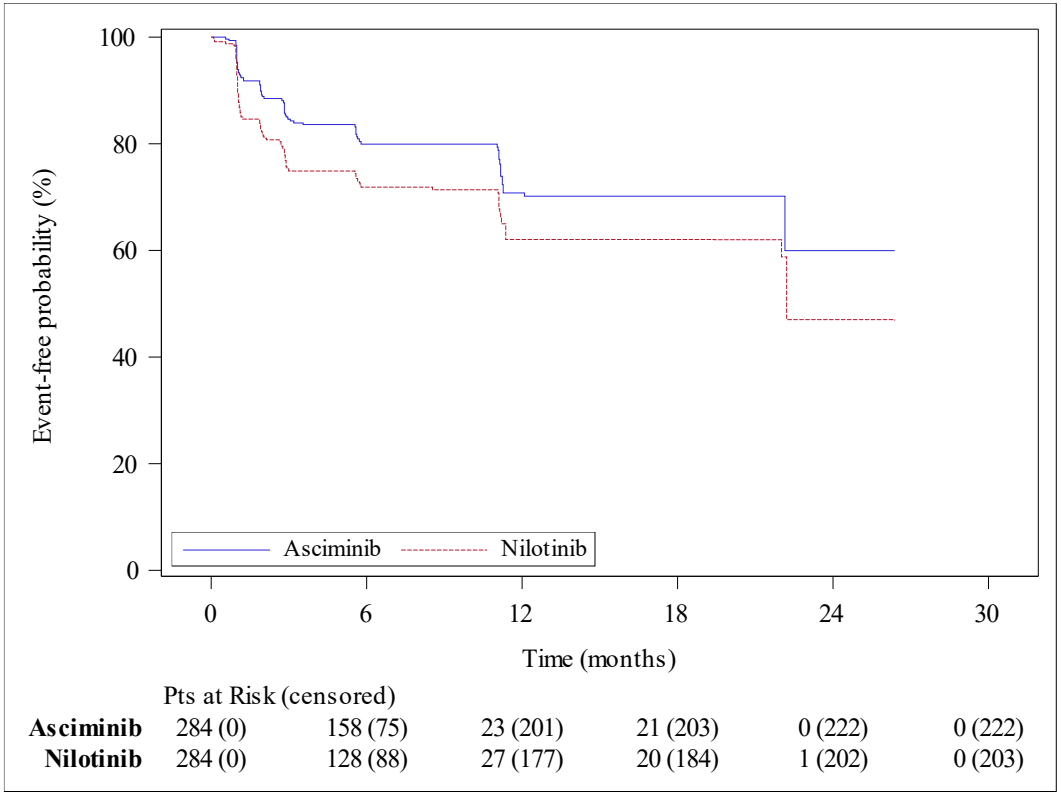


	Pts at Risk (censored)					
Asciminib	284 (0)	136 (66)	17 (175)	16 (176)	0 (190)	0 (190)
Nilotinib	284 (0)	111 (78)	28 (156)	21 (163)	0 (182)	0 (182)

Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

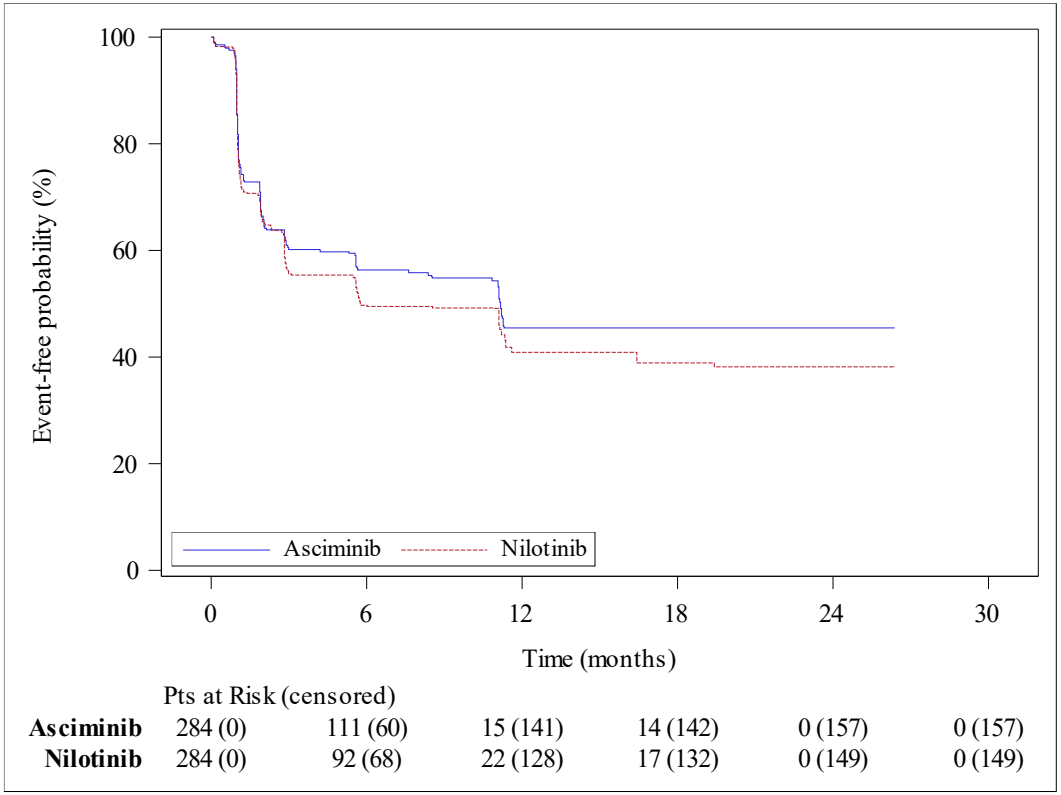
Nausea and vomiting (MID=10)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

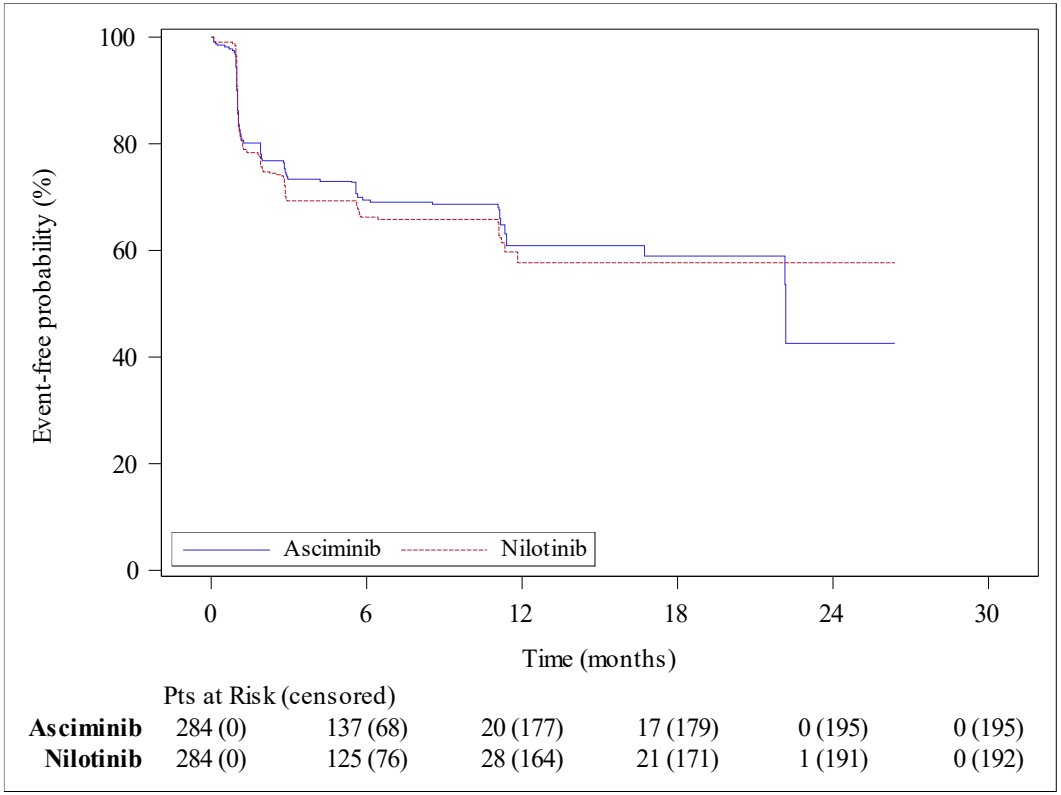
Pain (MID=10)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

Dyspnoea (MID=10)

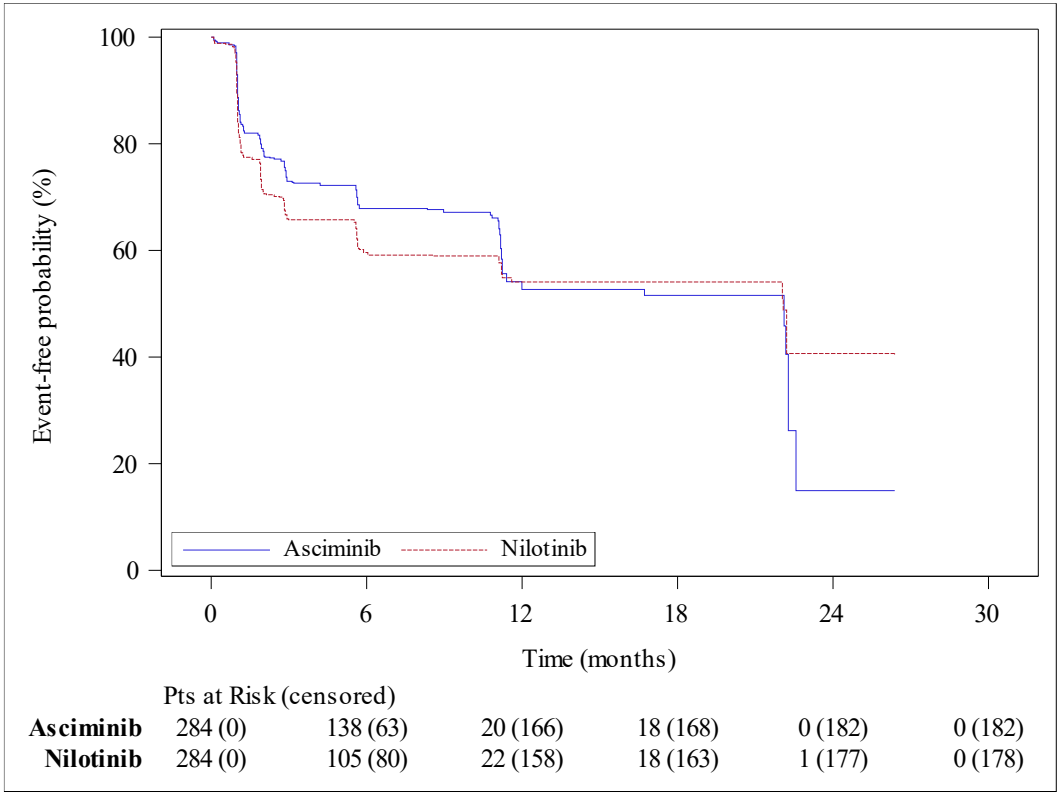


	Pts at Risk (censored)					
Asciminib	284 (0)	137 (68)	20 (177)	17 (179)	0 (195)	0 (195)
Nilotinib	284 (0)	125 (76)	28 (164)	21 (171)	1 (191)	0 (192)

Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

Insomnia (MID=10)

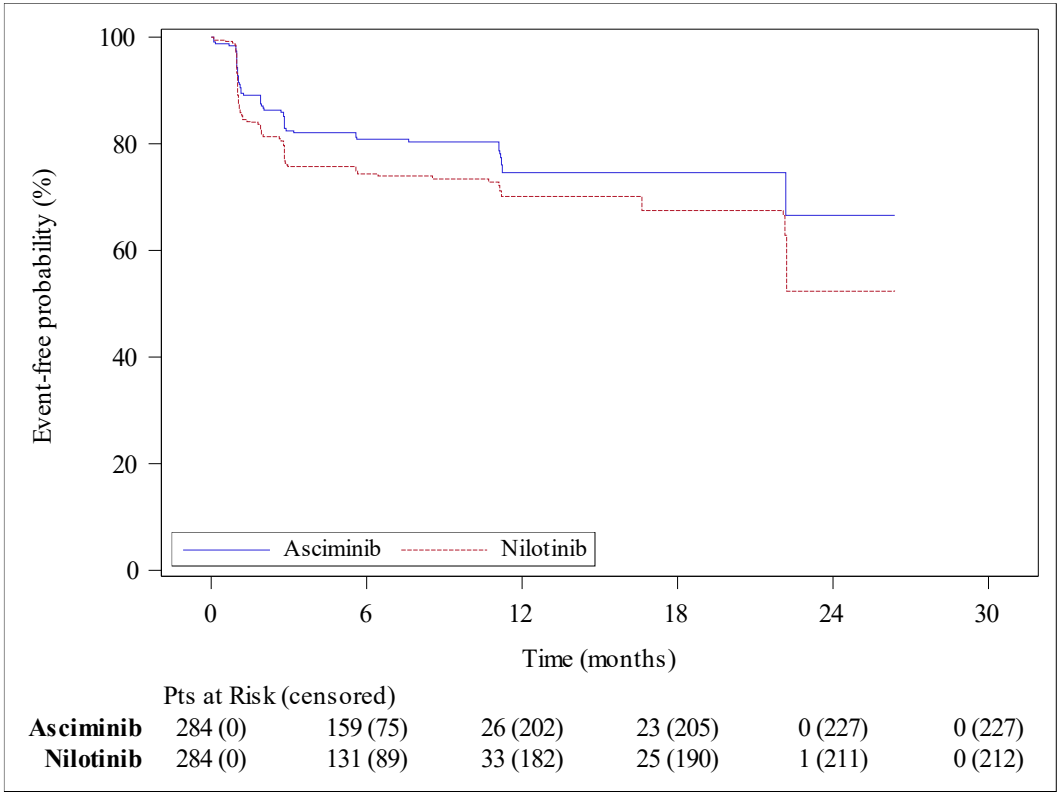


	Pts at Risk (censored)					
Asciminib	284 (0)	138 (63)	20 (166)	18 (168)	0 (182)	0 (182)
Nilotinib	284 (0)	105 (80)	22 (158)	18 (163)	1 (177)	0 (178)

Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

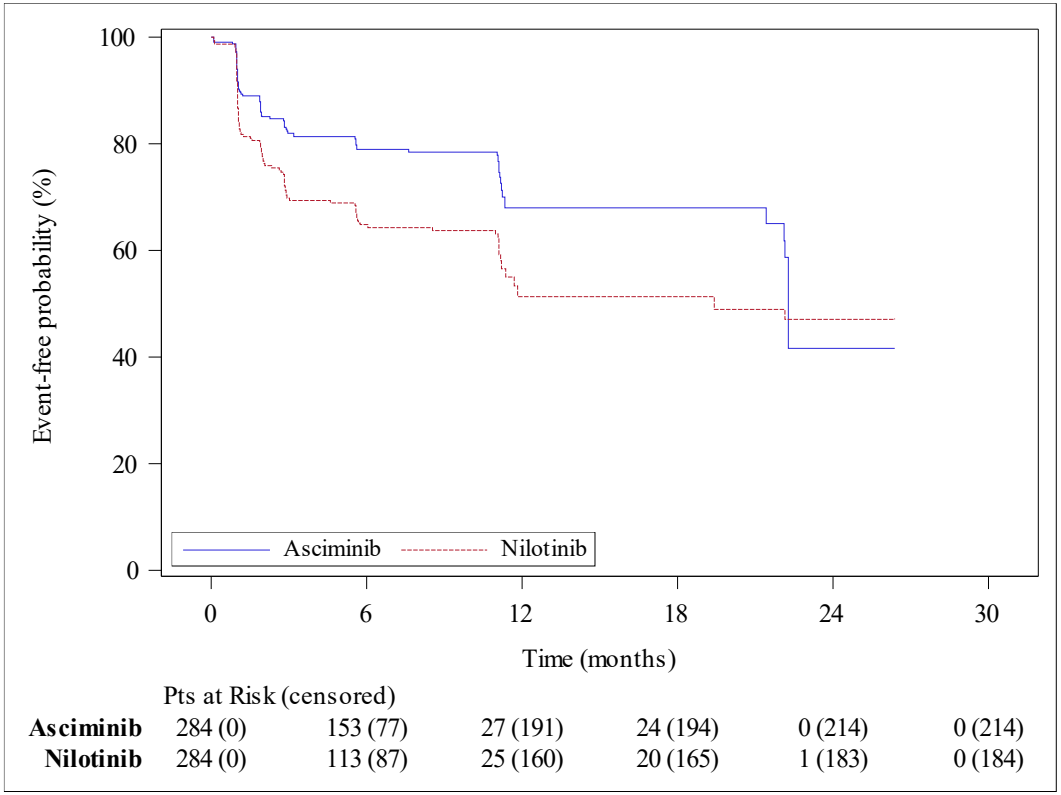
Appetite loss (MID=10)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

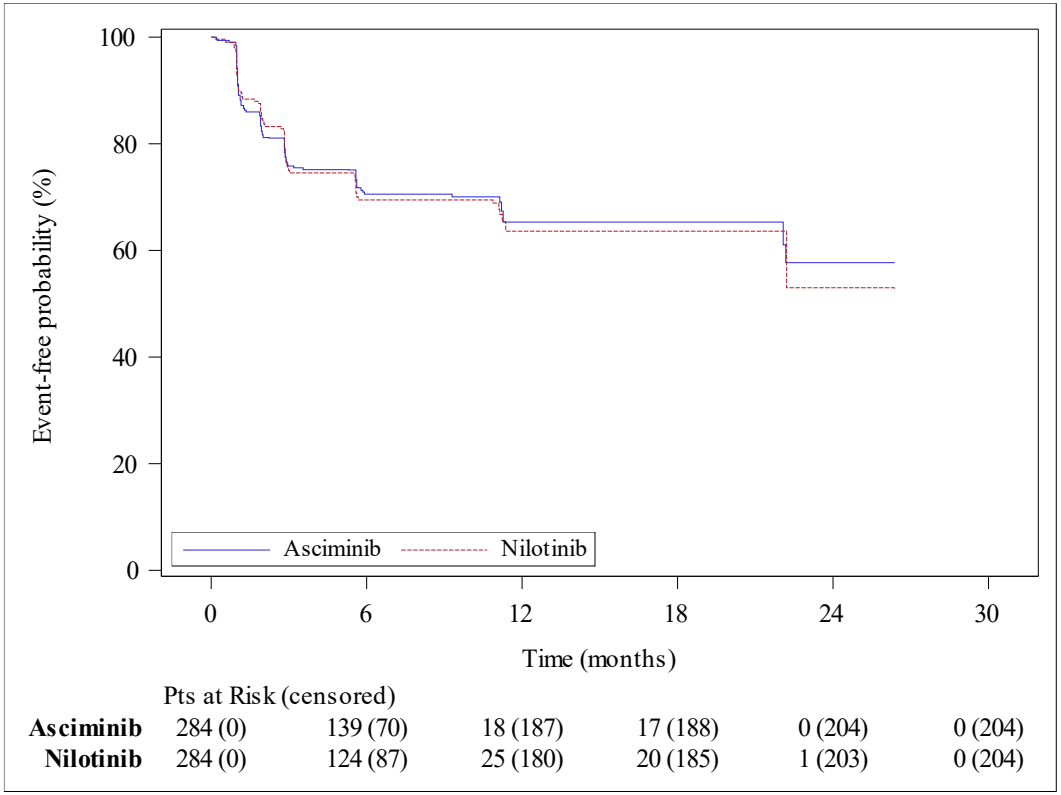
Constipation (MID=10)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

Diarrhoea (MID=10)

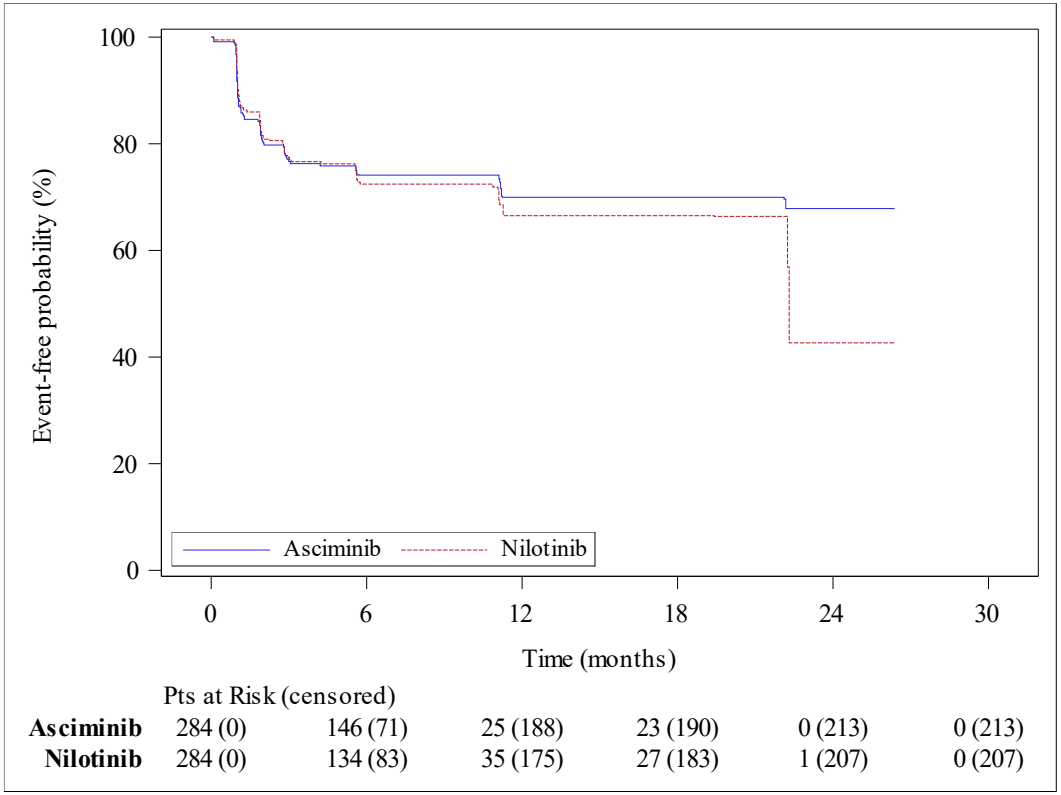


	Pts at Risk (censored)					
Asciminib	284 (0)	139 (70)	18 (187)	17 (188)	0 (204)	0 (204)
Nilotinib	284 (0)	124 (87)	25 (180)	20 (185)	1 (203)	0 (204)

Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

Financial difficulties (MID=10)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Table 3-4.2 EORTC QLQ-CML24: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values) (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Body Image Problems (MID=15)			
N*	284	284	0.92
Number of patients with events, n (%)	112 (39.4)	111 (39.1)	[0.69; 1.21]
			0.762
Percentiles (months) [95% CI]			
25th	2.8 [2.3; 3.3]	1.9 [1.1; 2.7]	
Median	22.2 [-11.8; 56.2]	16.7 [9.7; 23.6]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Impact on Daily Life (MID=15)			
N*	284	284	0.65
Number of patients with events, n (%)	77 (27.1)	97 (34.2)	[0.47; 0.91]
			0.097
Percentiles (months) [95% CI]			
25th	8.5 [4.2; 12.8]	2.7 [1.8; 3.6]	

	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 284)	HR [95% CI] p-value
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Impact on Worry/Mood (MID=15)			
N*	284	284	0.92
Number of patients with events, n (%)	58 (20.4)	53 (18.7)	[0.60; 1.40]
			0.718
Percentiles (months) [95% CI]			
25th	11.2 [0.9; 21.6]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Symptom Burden (MID=15)			
N*	284	284	0.52
Number of patients with events, n (%)	35 (12.3)	56 (19.7)	[0.32; 0.84]
			0.035
Percentiles (months) [95% CI]			
25th	22.6 [22.5; 22.7]	11.3 [-0.4; 23.0]	

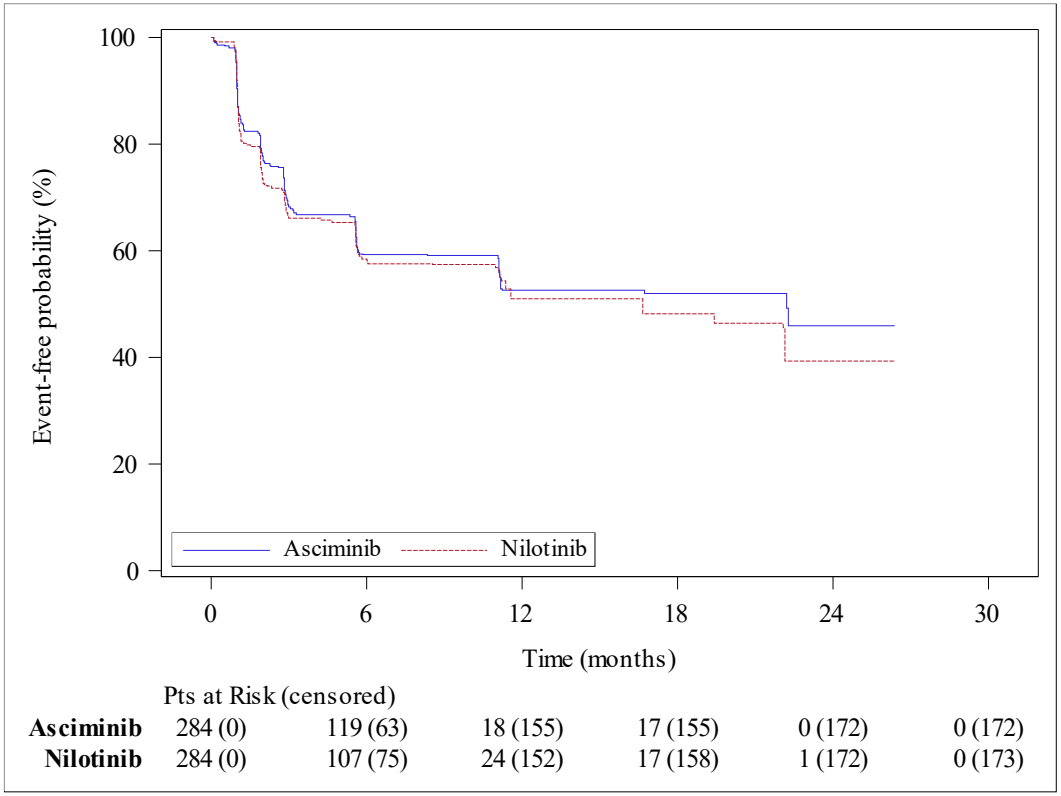
	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 284)	HR [95% CI] p-value
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Satisfaction with Care and Information (MID=15)			
N*	284	284	1.17
Number of patients with events, n (%)	93 (32.7)	73 (25.7)	[0.85; 1.63]
			0.479
Percentiles (months) [95% CI]			
25th	5.6 [4.1; 7.1]	5.6 [0.8; 10.4]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Satisfaction with Social Life (MID=15)			
N*	284	284	1.00
Number of patients with events, n (%)	134 (47.2)	125 (44.0)	[0.77; 1.30]
			0.680
Percentiles (months) [95% CI]			
25th	1.1 [0.7; 1.6]	1.9 [1.4; 2.3]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	11.1 [7.5; 14.7]	11.1 [5.2; 17.0]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

MID: Minimal important difference
HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event. The number of patients is the mean number over all imputations rounded to the nearest integer
.....
Missing baseline values are multiply imputed by simple imputation using 500 repetitions under a MAR assumption.
Two-sided 95% CI for KM percentiles are derived by the approach outlined in Moscovici and Ratitch (2017).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factor ELTS Score (IRT) and covariates treatment arm and baseline score.
P-Values are based on stratified logrank test with stratification factor ELTS Score (IRT).
Test results are combined using the Wilson-Hilferty transformation.
Data Cut/15MAY2025

Figure 3-4.2 EORTC QLQ-CML24: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

Body Image Problems (MID=15)

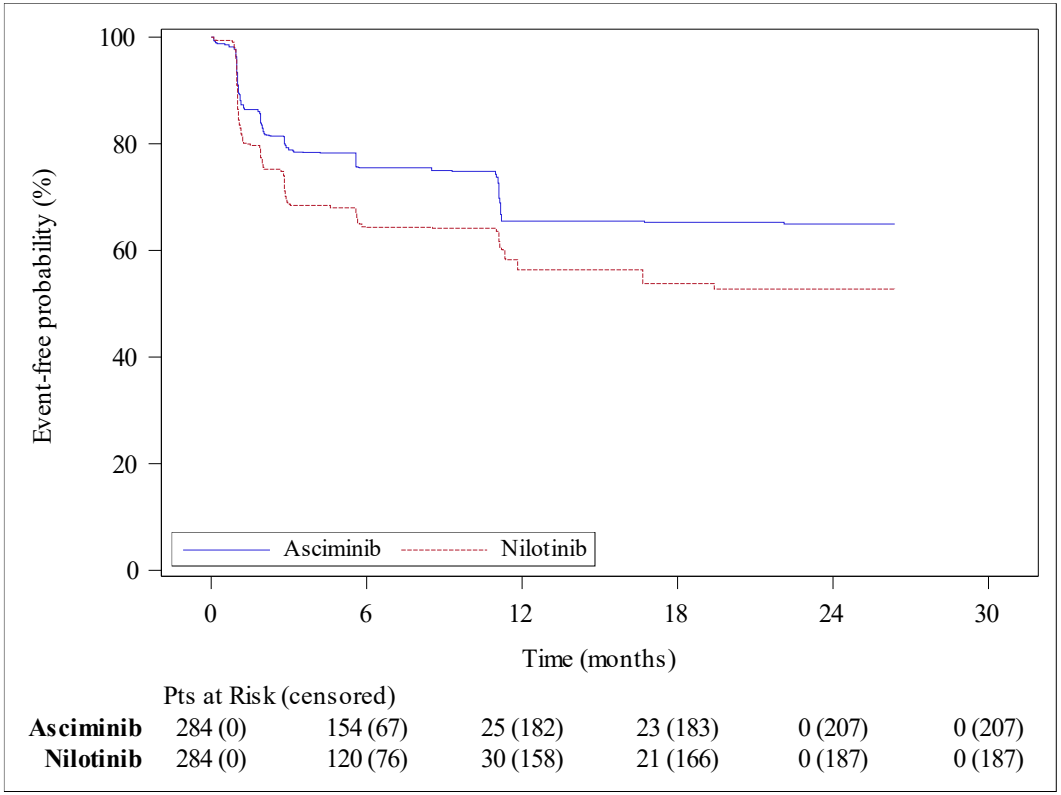


	Pts at Risk (censored)					
Asciminib	284 (0)	119 (63)	18 (155)	17 (155)	0 (172)	0 (172)
Nilotinib	284 (0)	107 (75)	24 (152)	17 (158)	1 (172)	0 (173)

Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.2 EORTC QLQ-CML24: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

Impact on Daily Life (MID=15)

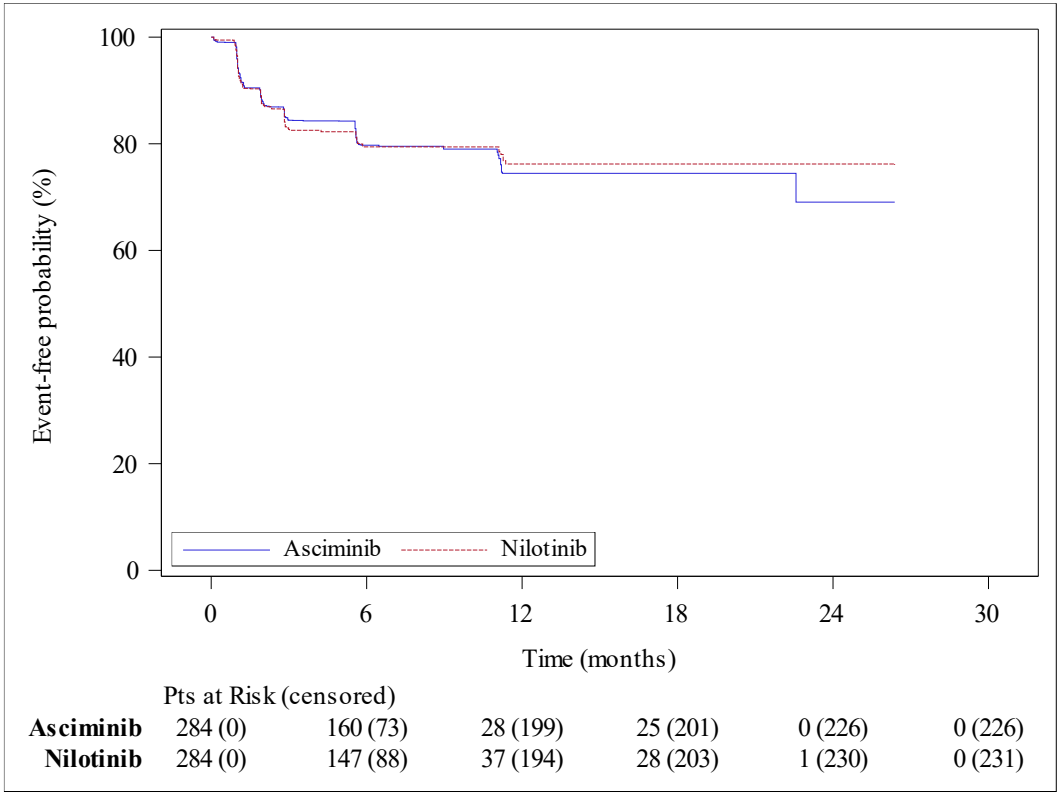


	Pts at Risk (censored)					
Asciminib	284 (0)	154 (67)	25 (182)	23 (183)	0 (207)	0 (207)
Nilotinib	284 (0)	120 (76)	30 (158)	21 (166)	0 (187)	0 (187)

Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.2 EORTC QLQ-CML24: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

Impact on Worry/Mood (MID=15)

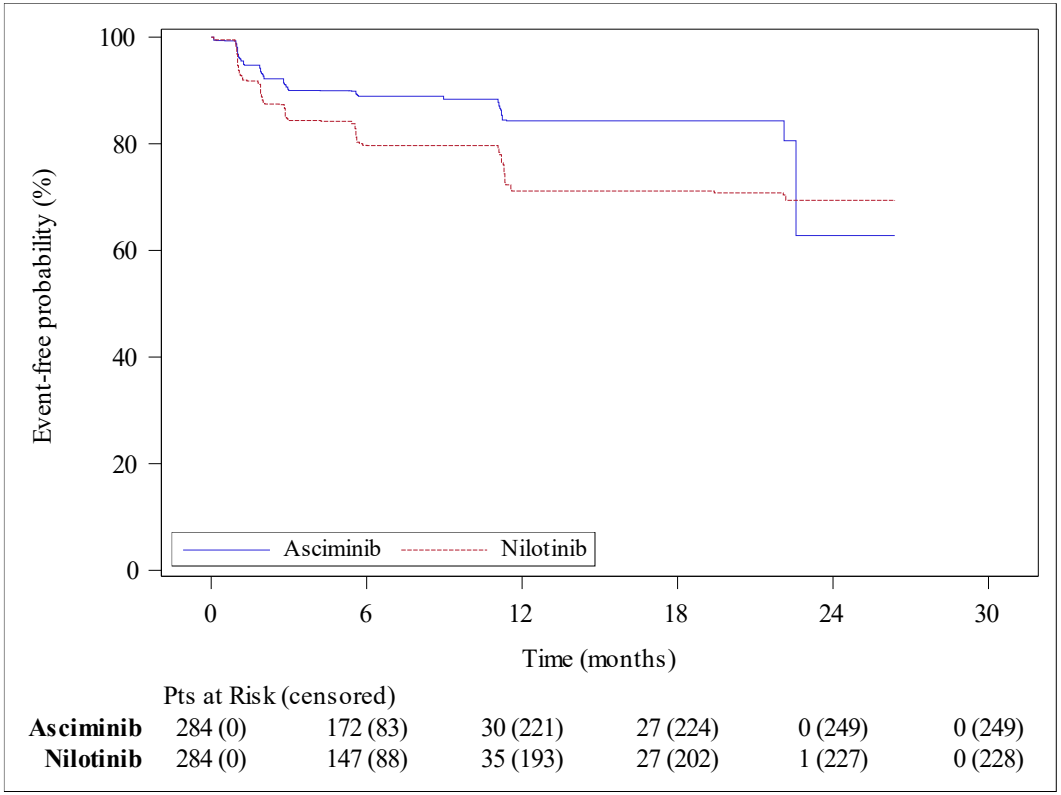


	Pts at Risk (censored)					
Asciminib	284 (0)	160 (73)	28 (199)	25 (201)	0 (226)	0 (226)
Nilotinib	284 (0)	147 (88)	37 (194)	28 (203)	1 (230)	0 (231)

Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.2 EORTC QLQ-CML24: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

Symptom Burden (MID=15)

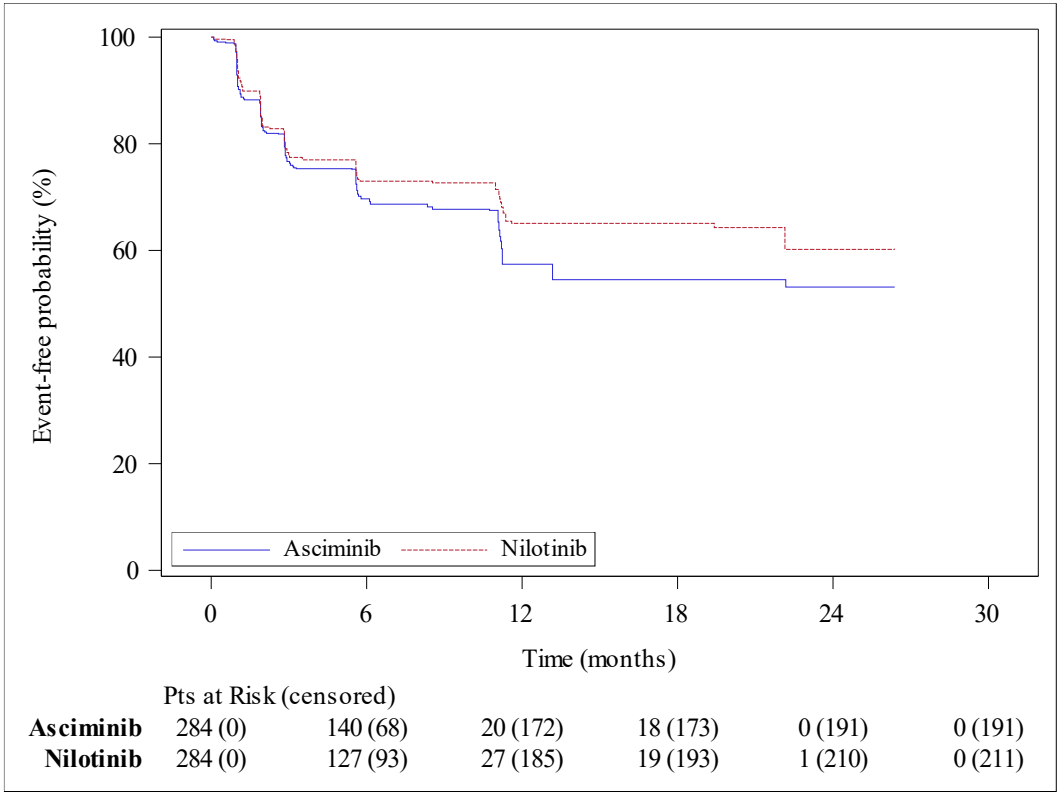


	Pts at Risk (censored)					
Asciminib	284 (0)	172 (83)	30 (221)	27 (224)	0 (249)	0 (249)
Nilotinib	284 (0)	147 (88)	35 (193)	27 (202)	1 (227)	0 (228)

Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.2 EORTC QLQ-CML24: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

Satisfaction with Care and Information (MID=15)

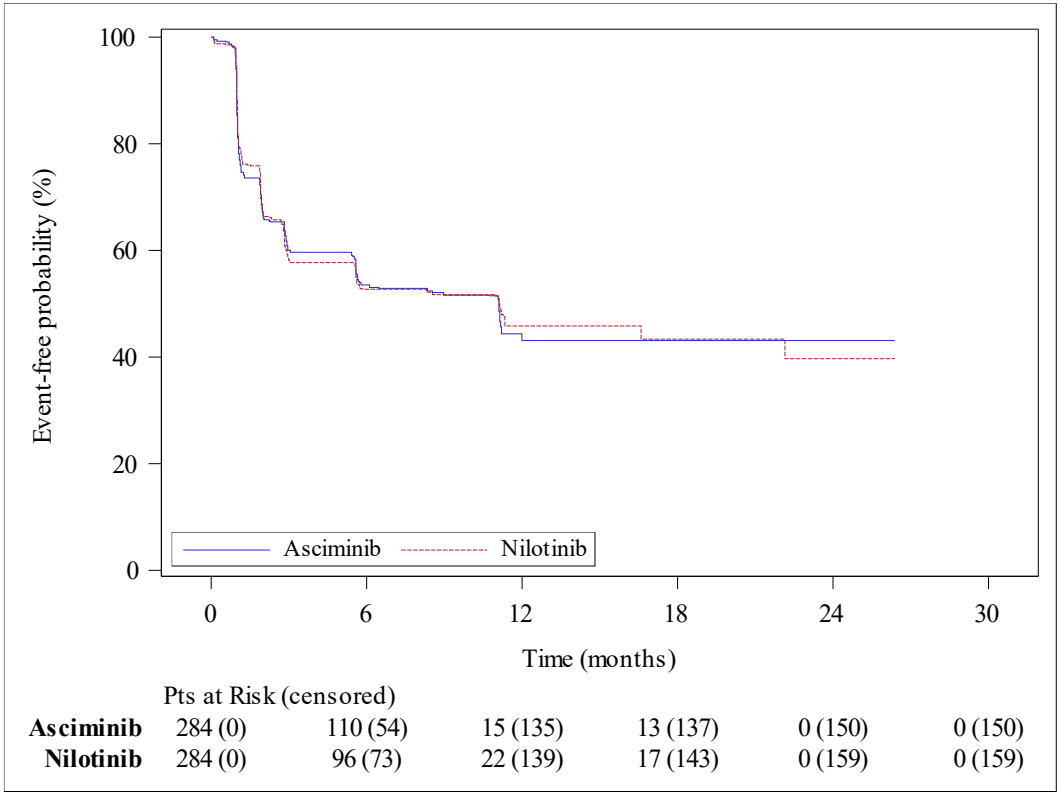


	Pts at Risk (censored)					
Asciminib	284 (0)	140 (68)	20 (172)	18 (173)	0 (191)	0 (191)
Nilotinib	284 (0)	127 (93)	27 (185)	19 (193)	1 (210)	0 (211)

Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.2 EORTC QLQ-CML24: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

Satisfaction with Social Life (MID=15)



	Pts at Risk (censored)					
Asciminib	284 (0)	110 (54)	15 (135)	13 (137)	0 (150)	0 (150)
Nilotinib	284 (0)	96 (73)	22 (139)	17 (143)	0 (159)	0 (159)

Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

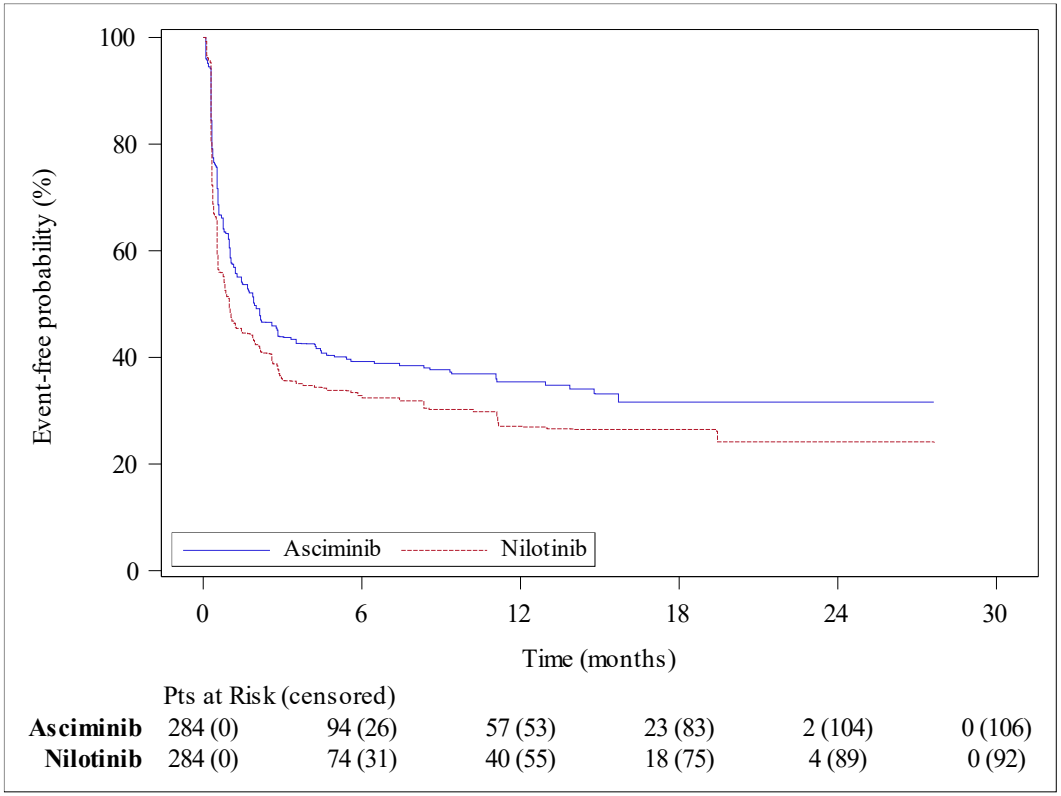
Table 3-4.3 FACT-ITEM GP5: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values) (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
V4 (MID=1)			
N*	284	284	0.74
Number of patients with events, n (%)	178 (62.7)	192 (67.6)	[0.60; 0.92]
			0.157
Percentiles (months) [95% CI]			
25th	0.5 [0.4; 0.6]	0.3 [0.3; 0.4]	
Median	1.9 [1.1; 2.8]	1.0 [0.5; 1.4]	
75th	N.E. [N.E.; N.E.]	19.4 [7.9; 31.0]	

MID: Minimal important difference
HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event. The number of patients is the mean number over all imputations rounded to the nearest integer
.....
Missing baseline values are multiply imputed by simple imputation using 500 repetitions under a MAR assumption.
Two-sided 95% CI for KM percentiles are derived by the approach outlined in Moscovici and Ratitch (2017).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factor ELTS Score (IRT) and covariates treatment arm and baseline score.
P-Values are based on stratified logrank test with stratification factor ELTS Score (IRT).
Test results are combined using the Wilson-Hilferty transformation.
Data Cut/15MAY2025

Figure 3-4.3 FACT-ITEM GP5: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

V4 (MID=1)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Table 3-4.4 PRO-CTCAE - Frequency: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values) (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Headache - Frequency (MID=1)			
N*	284	284	0.72
Number of patients with events, n (%)	177 (62.3)	195 (68.7)	[0.58; 0.90]
			0.075
Percentiles (months) [95% CI]			
25th	0.5 [0.3; 0.7]	0.3 [0.3; 0.4]	
Median	2.8 [1.3; 4.3]	1.2 [0.5; 2.0]	
75th	N.E. [N.E.; N.E.]	16.7 [9.0; 24.4]	
Rash - Presence/Absence (MID=1)			
N*	284	284	0.63
Number of patients with events, n (%)	148 (52.1)	166 (58.5)	[0.50; 0.80]
			0.016
Percentiles (months) [95% CI]			
25th	1.4 [1.1; 1.8]	0.6 [0.5; 0.7]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	8.3 [4.3; 12.4]	2.8 [1.5; 4.1]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Diarrhea - Frequency (MID=1)			
N*	284	284	1.11
Number of patients with events, n (%)	170 (59.9)	159 (56.0)	[0.88; 1.40]
			0.944
Percentiles (months) [95% CI]			
25th	0.6 [0.4; 0.7]	0.6 [0.3; 0.8]	
Median	2.4 [1.2; 3.5]	3.2 [1.2; 5.2]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Vomiting - Frequency (MID=1)			
N*	284	284	0.59
Number of patients with events, n (%)	54 (19.0)	77 (27.1)	[0.42; 0.85]
			0.009
Percentiles (months) [95% CI]			
25th	22.1 [13.5; 30.7]	5.6 [0.5; 10.6]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Nausea - Frequency (MID=1)			
N*	284	284	0.71
Number of patients with events, n (%)	127 (44.7)	150 (52.8)	[0.55; 0.91]
			0.023
Percentiles (months) [95% CI]			
25th	1.4 [0.5; 2.4]	0.6 [0.3; 0.8]	
Median	22.1 [14.3; 30.0]	4.5 [0.9; 8.2]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Edema - Frequency (MID=1)			
N*	284	284	0.90
Number of patients with events, n (%)	113 (39.8)	117 (41.2)	[0.69; 1.18]
			0.964
Percentiles (months) [95% CI]			
25th	2.1 [1.4; 2.9]	2.4 [1.0; 3.8]	

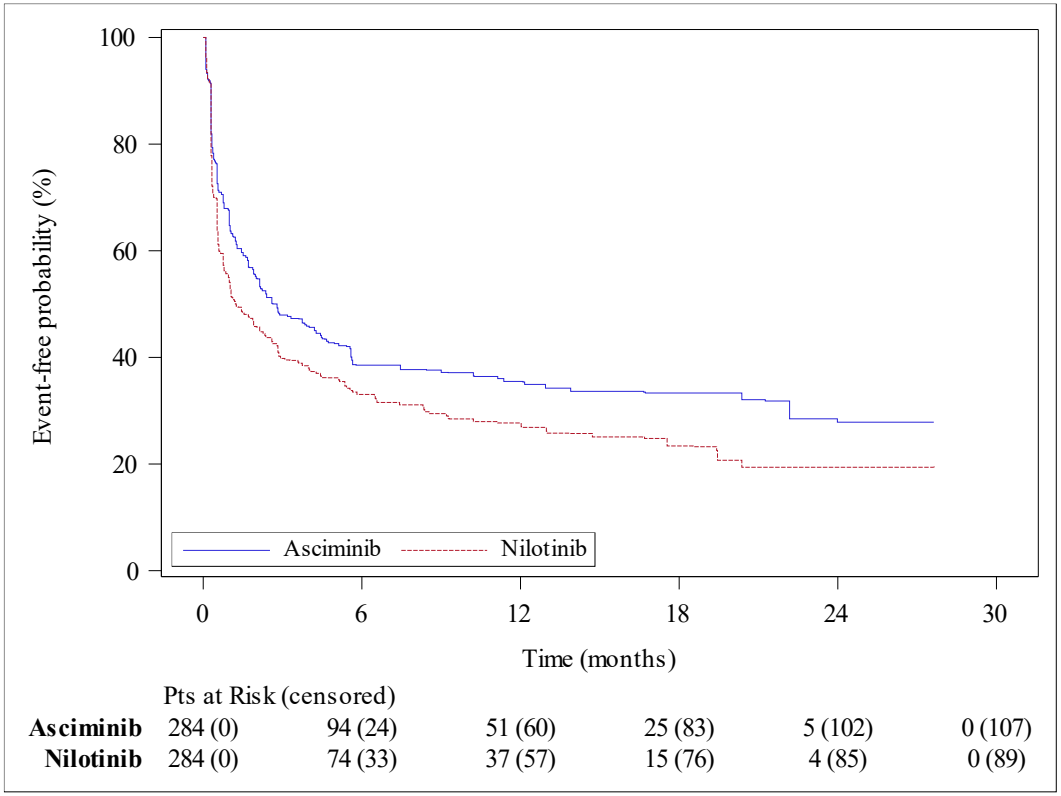
	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	22.1 [22.1; 22.2]	16.6 [10.0; 23.2]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Muscle Pain - Frequency (MID=1)			
N*	284	284	0.93
Number of patients with events, n (%)	186 (65.5)	193 (68.0)	[0.75; 1.16]
			0.967
Percentiles (months) [95% CI]			
25th	0.4 [0.3; 0.4]	0.3 [0.3; 0.4]	
Median	1.0 [0.6; 1.5]	1.2 [0.6; 1.8]	
75th	N.E. [N.E.; N.E.]	19.4 [5.6; 33.2]	
Increased Sweating - Frequency (MID=1)			
N*	284	284	1.06
Number of patients with events, n (%)	147 (51.8)	140 (49.3)	[0.82; 1.36]
			0.905
Percentiles (months) [95% CI]			
25th	0.6 [0.3; 0.9]	0.8 [0.5; 1.0]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	8.4 [1.7; 15.0]	11.1 [6.6; 15.6]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

MID: Minimal important difference
HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event. The number of patients is the mean number over all imputations rounded to the nearest integer
.....
Missing baseline values are multiply imputed by simple imputation using 500 repetitions under a MAR assumption.
Two-sided 95% CI for KM percentiles are derived by the approach outlined in Moscovici and Ratitch (2017).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factor ELTS Score (IRT) and covariates treatment arm and baseline score.
P-Values are based on stratified logrank test with stratification factor ELTS Score (IRT).
Test results are combined using the Wilson-Hilferty transformation.
Data Cut/15MAY2025

Figure 3-4.4 PRO-CTCAE - Frequency: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

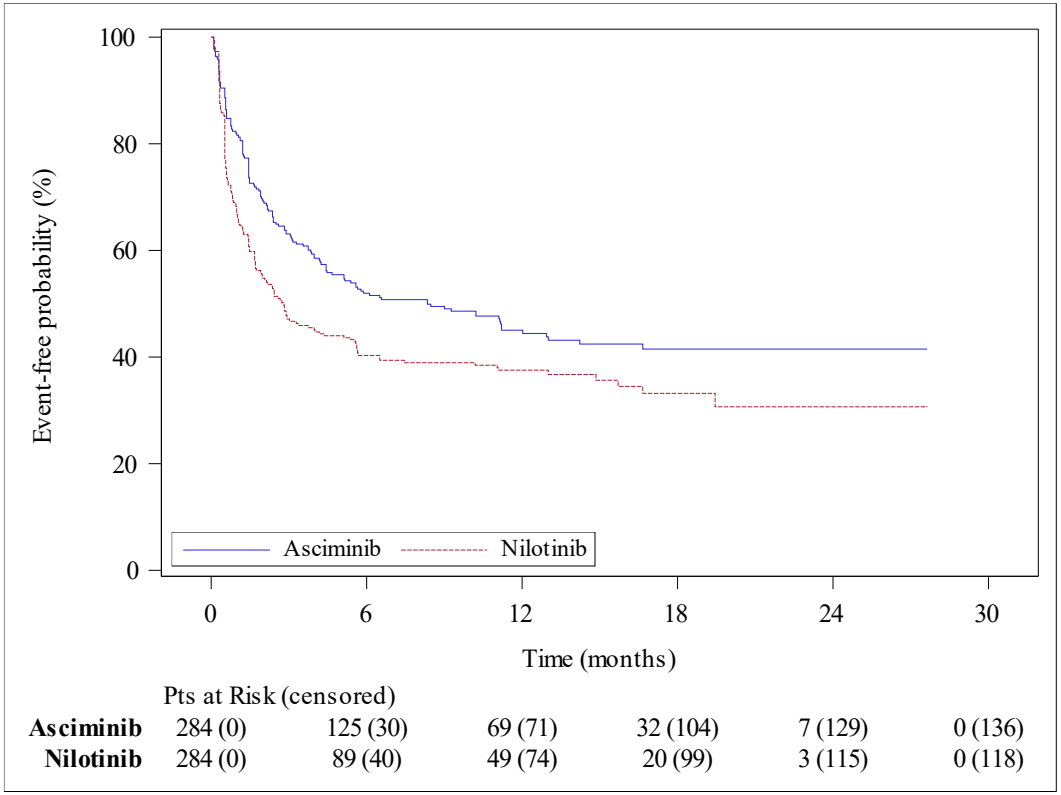
Headache - Frequency (MID=1)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.4 PRO-CTCAE - Frequency: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

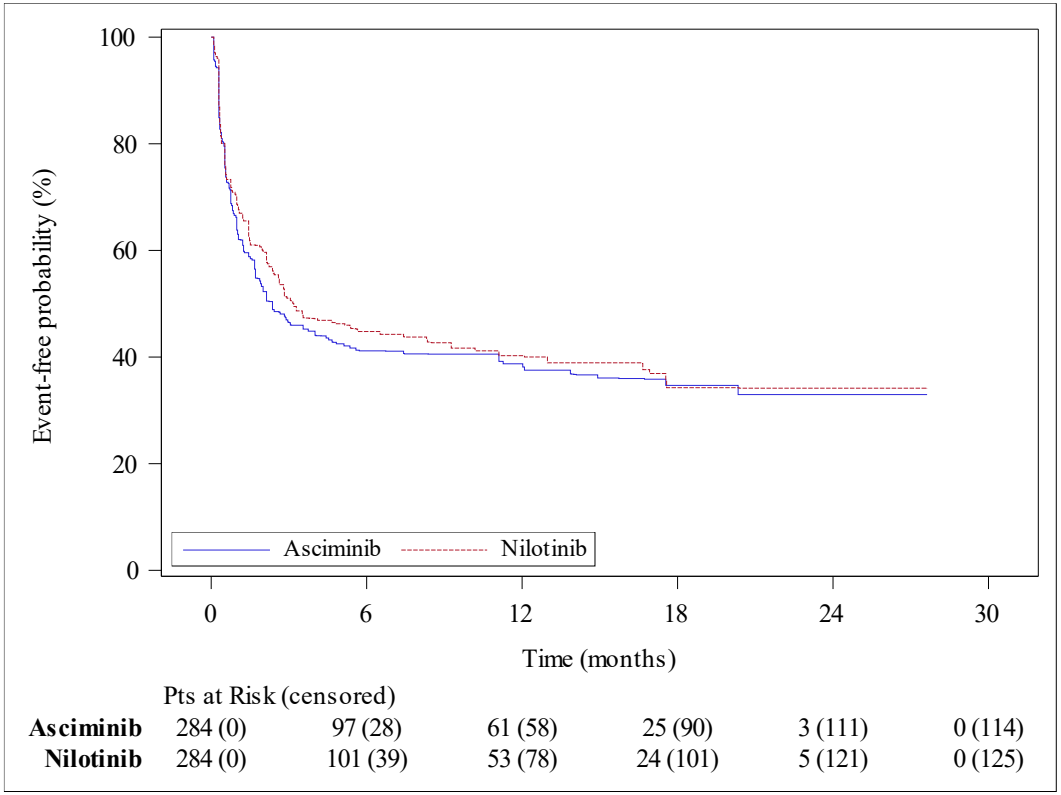
Rash - Presence/Absence (MID=1)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.4 PRO-CTCAE - Frequency: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

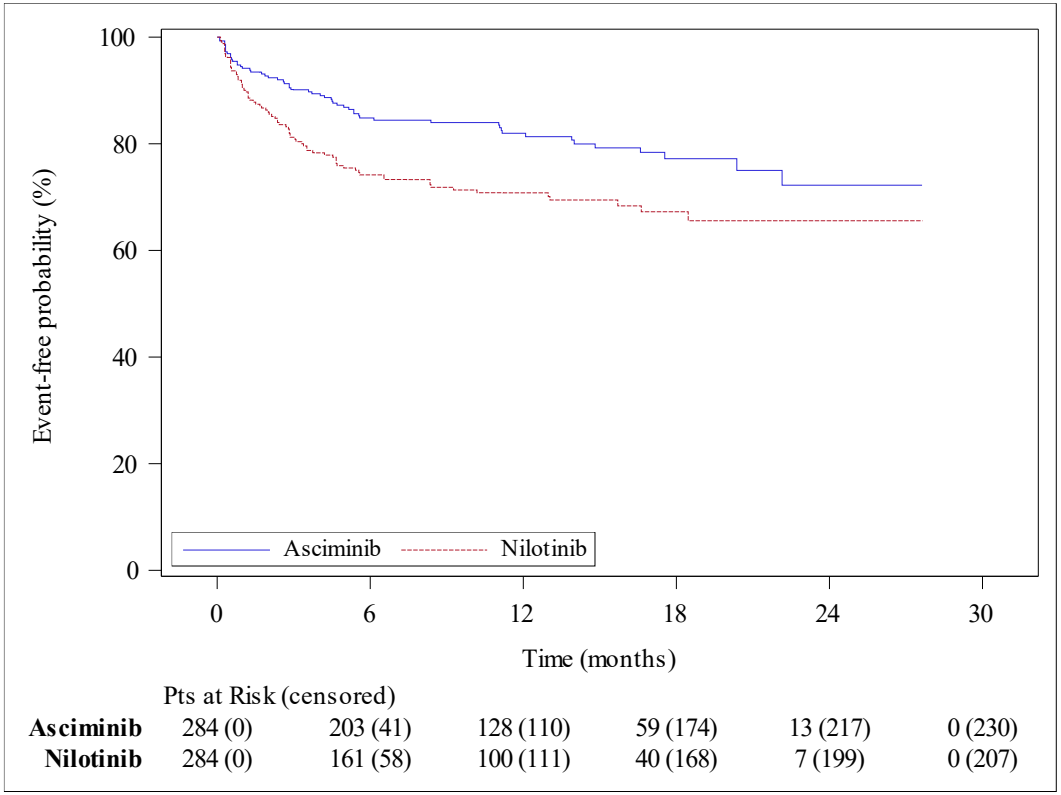
Diarrhea - Frequency (MID=1)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.4 PRO-CTCAE - Frequency: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

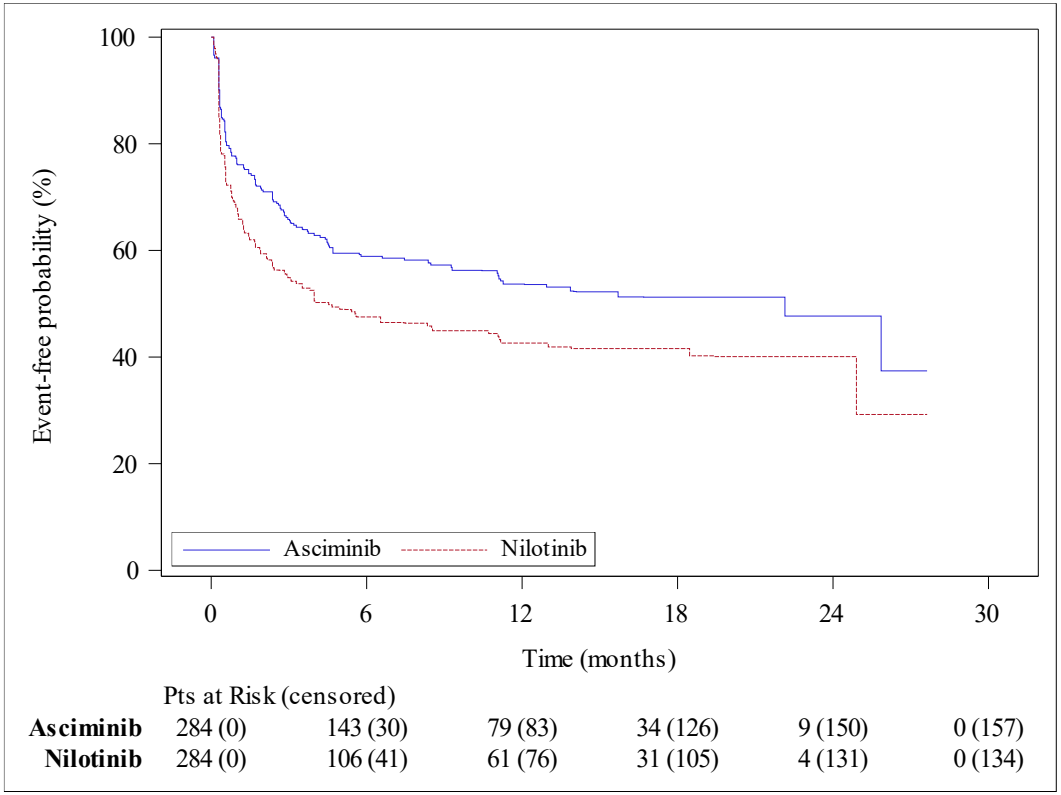
Vomiting - Frequency (MID=1)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.4 PRO-CTCAE - Frequency: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

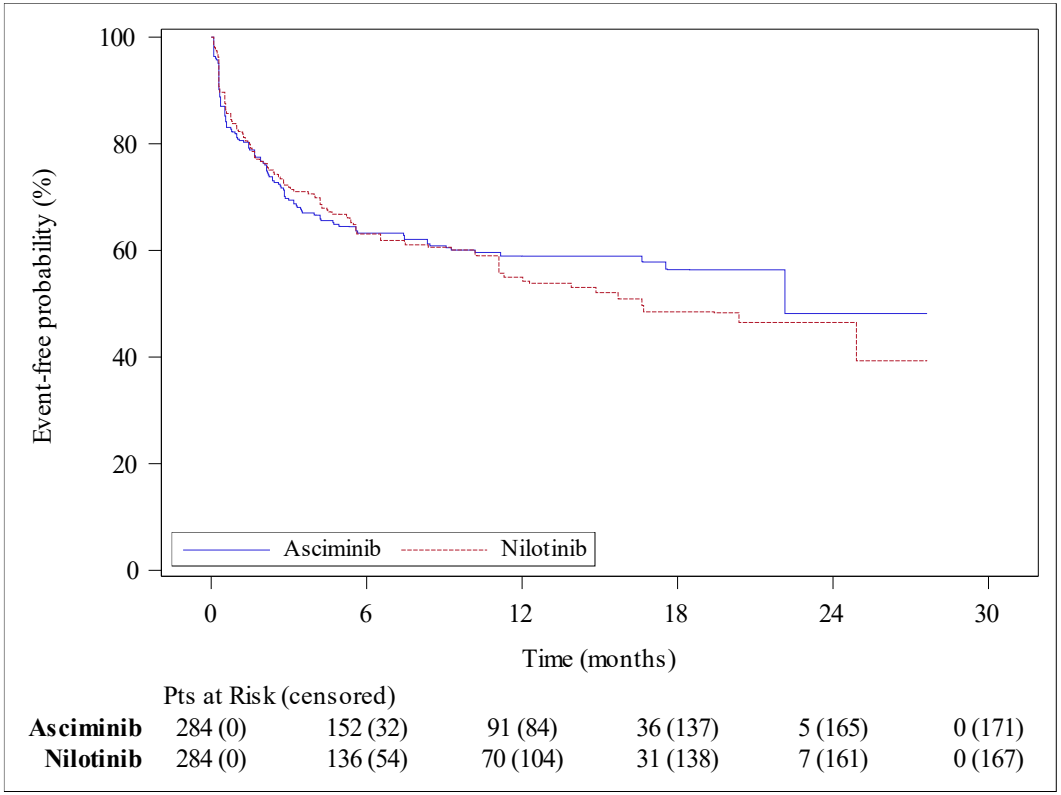
Nausea - Frequency (MID=1)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.4 PRO-CTCAE - Frequency: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

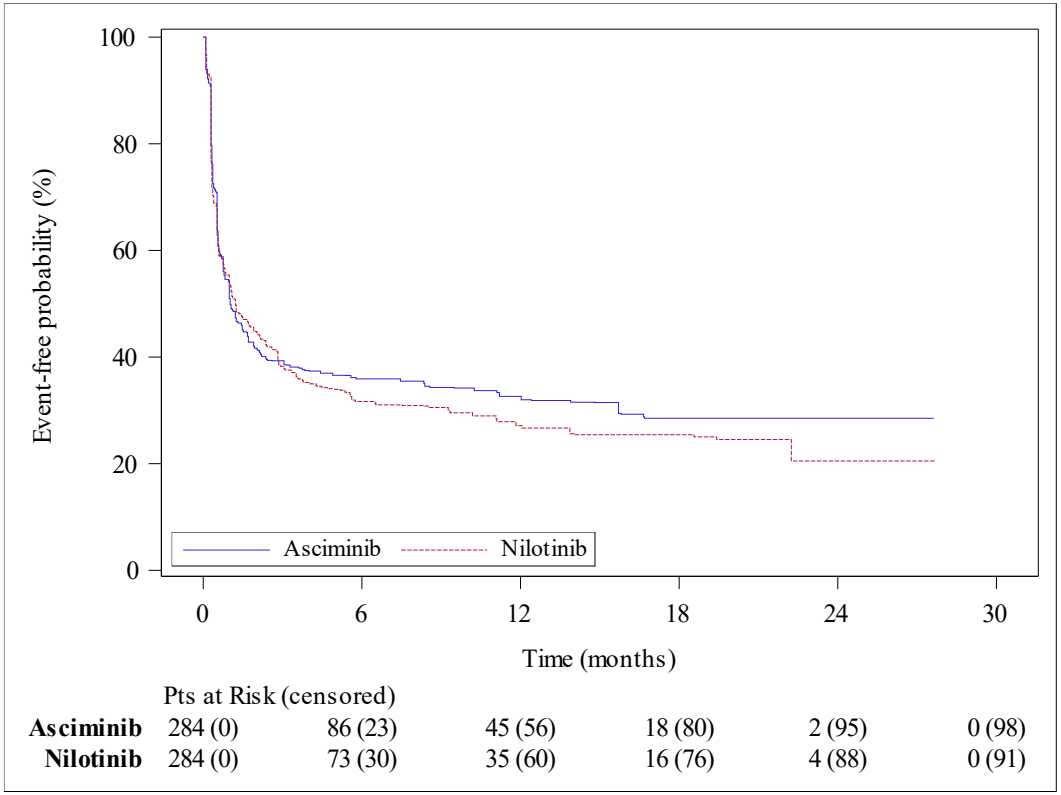
Edema - Frequency (MID=1)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.4 PRO-CTCAE - Frequency: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

Muscle Pain - Frequency (MID=1)

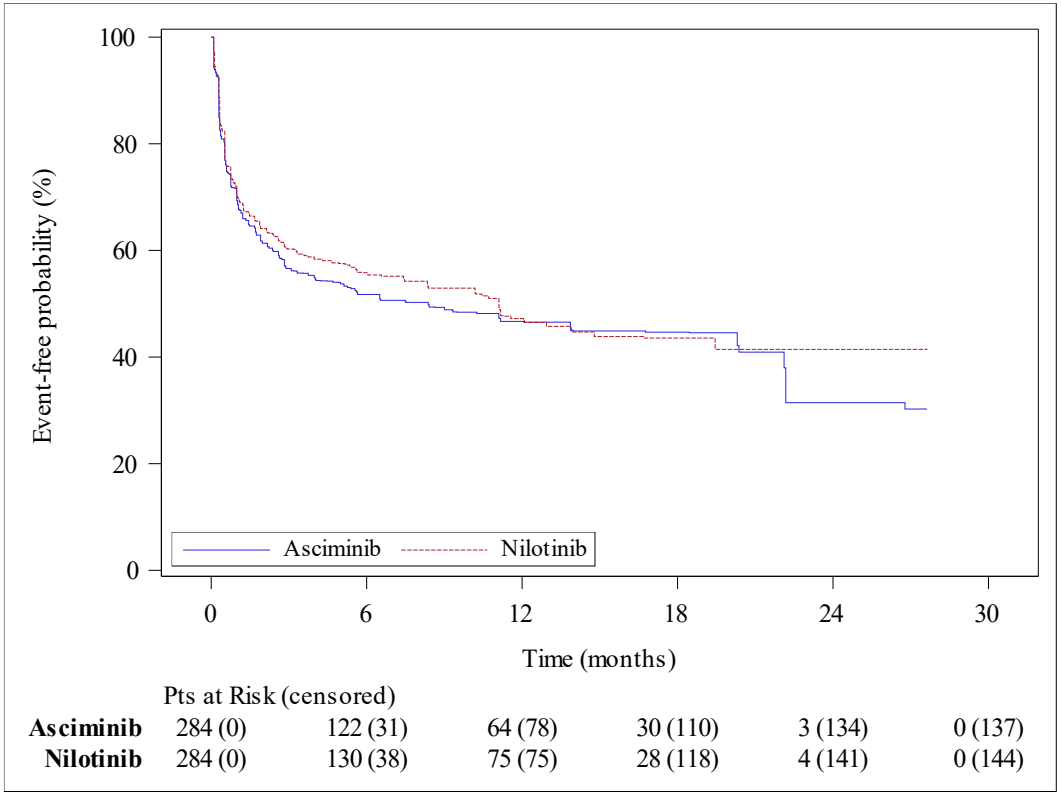


	Pts at Risk (censored)					
Asciminib	284 (0)	86 (23)	45 (56)	18 (80)	2 (95)	0 (98)
Nilotinib	284 (0)	73 (30)	35 (60)	16 (76)	4 (88)	0 (91)

Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.4 PRO-CTCAE - Frequency: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

Increased Sweating - Frequency (MID=1)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Table 3-4.5 PRO-CTCAE - Severity: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values) (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Fatigue - Severity (MID=1)			
N*	284	284	0.84
Number of patients with events, n (%)	172 (60.6)	174 (61.3)	[0.67; 1.07]
			0.934
Percentiles (months) [95% CI]			
25th	0.4 [0.3; 0.5]	0.4 [0.3; 0.4]	
Median	2.6 [-0.2; 5.4]	2.4 [0.7; 4.0]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Headache - Severity (MID=1)			
N*	284	284	0.77
Number of patients with events, n (%)	176 (62.0)	185 (65.1)	[0.62; 0.96]
			0.325
Percentiles (months) [95% CI]			
25th	0.5 [0.3; 0.8]	0.3 [0.3; 0.4]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	2.6 [1.4; 3.8]	1.7 [0.5; 2.9]	
75th	N.E. [N.E.; N.E.]	19.4 [12.2; 26.7]	
Vomiting - Severity (MID=1)			
N*	284	284	0.62
Number of patients with events, n (%)	51 (18.0)	71 (25.0)	[0.43; 0.90]
			0.021
Percentiles (months) [95% CI]			
25th	22.1 [15.1; 29.2]	9.3 [3.5; 15.1]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Nausea - Severity (MID=1)			
N*	284	284	0.70
Number of patients with events, n (%)	120 (42.3)	148 (52.1)	[0.55; 0.90]
			0.014
Percentiles (months) [95% CI]			
25th	1.4 [0.5; 2.4]	0.8 [0.4; 1.1]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	5.6 [0.8; 10.3]	
75th	N.E. [N.E.; N.E.]	24.9 [24.8; 25.0]	
Edema - Severity (MID=1)			
N*	284	284	0.85
Number of patients with events, n (%)	100 (35.2)	108 (38.0)	[0.64; 1.13]
			0.584
Percentiles (months) [95% CI]			
25th	2.8 [1.6; 4.0]	2.6 [1.3; 4.0]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Muscle Pain - Severity (MID=1)			
N*	284	284	0.87
Number of patients with events, n (%)	174 (61.3)	192 (67.6)	[0.70; 1.08]
			0.397
Percentiles (months) [95% CI]			
25th	0.4 [0.3; 0.5]	0.3 [0.3; 0.4]	

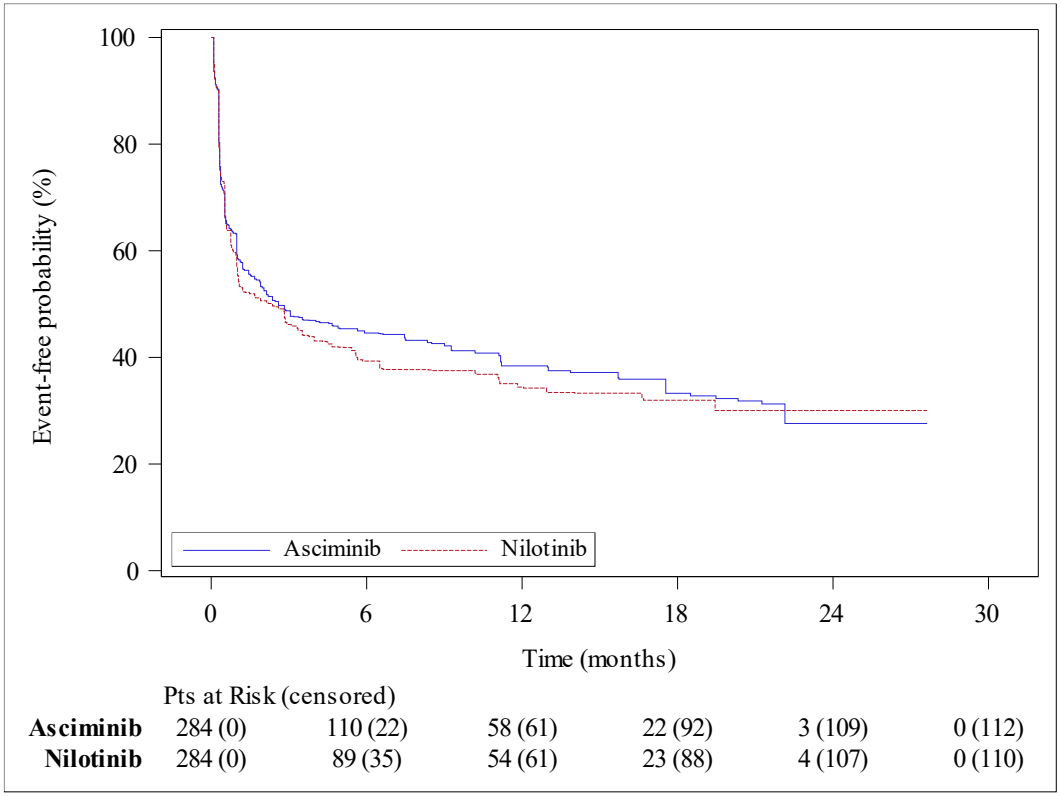
	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	1.5 [0.8; 2.2]	1.5 [0.6; 2.4]	
75th	N.E. [N.E.; N.E.]	16.6 [5.7; 27.6]	
Pruritus - Severity (MID=1)			
N*	284	284	0.62
Number of patients with events, n (%)	173 (60.9)	206 (72.5)	[0.50; 0.77]
			<0.001
Percentiles (months) [95% CI]			
25th	0.8 [0.6; 1.0]	0.5 [0.4; 0.6]	
Median	3.5 [2.1; 5.0]	1.5 [1.0; 2.0]	
75th	24.0 [21.4; 26.6]	10.4 [6.0; 14.9]	
Increased Sweating - Severity (MID=1)			
N*	284	284	1.01
Number of patients with events, n (%)	136 (47.9)	131 (46.1)	[0.78; 1.31]
			0.713
Percentiles (months) [95% CI]			
25th	0.8 [0.4; 1.1]	0.8 [0.5; 1.0]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	13.9 [5.2; 22.5]	13.0 [7.3; 18.7]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Cough - Severity (MID=1)			
N*	284	284	0.88
Number of patients with events, n (%)	170 (59.9)	178 (62.7)	[0.71; 1.11]
			0.255
Percentiles (months) [95% CI]			
25th	0.8 [0.5; 1.1]	0.8 [0.5; 1.0]	
Median	5.1 [1.8; 8.5]	3.0 [1.8; 4.1]	
75th	22.2 [19.6; 24.7]	19.4 [13.8; 25.0]	

MID: Minimal important difference
HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event. The number of patients is the mean number over all imputations rounded to the nearest integer
.....
Missing baseline values are multiply imputed by simple imputation using 500 repetitions under a MAR assumption.
Two-sided 95% CI for KM percentiles are derived by the approach outlined in Moscovici and Ratitch (2017).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factor ELTS Score (IRT) and covariates treatment arm and baseline score.
P-Values are based on stratified logrank test with stratification factor ELTS Score (IRT).
Test results are combined using the Wilson-Hilferty transformation.
Data Cut/15MAY2025

Figure 3-4.5 PRO-CTCAE - Severity: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

Fatigue - Severity (MID=1)

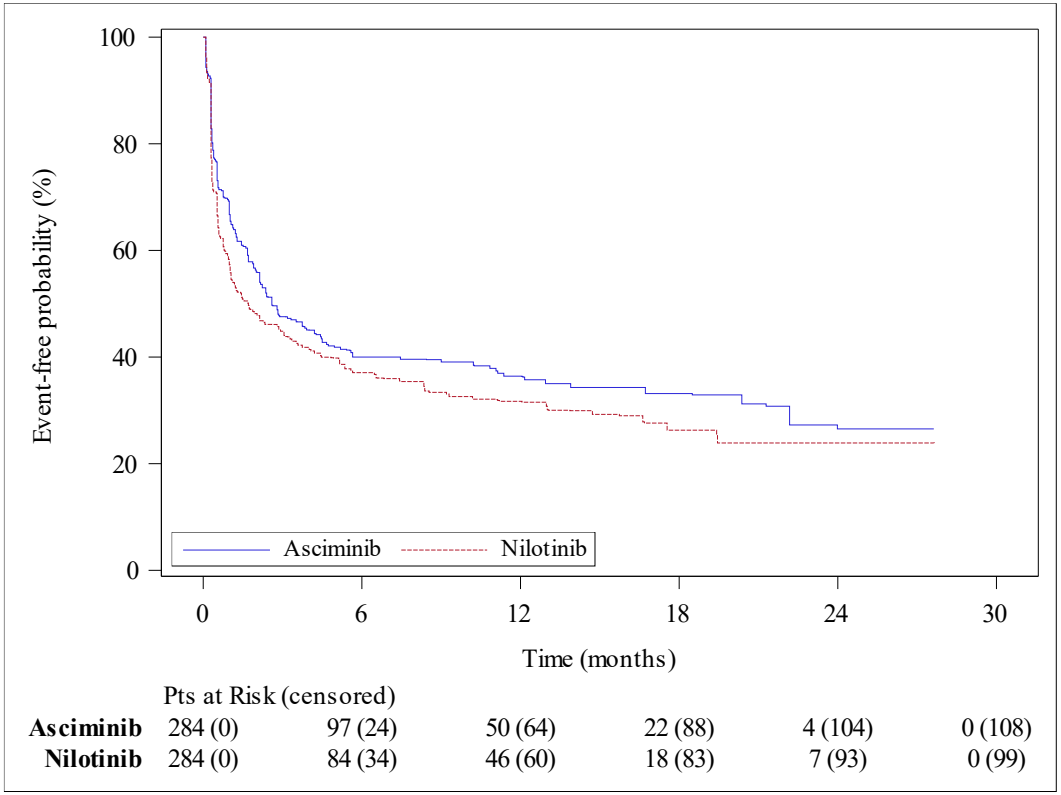


	Pts at Risk (censored)					
Asciminib	284 (0)	110 (22)	58 (61)	22 (92)	3 (109)	0 (112)
Nilotinib	284 (0)	89 (35)	54 (61)	23 (88)	4 (107)	0 (110)

Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.5 PRO-CTCAE - Severity: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

Headache - Severity (MID=1)

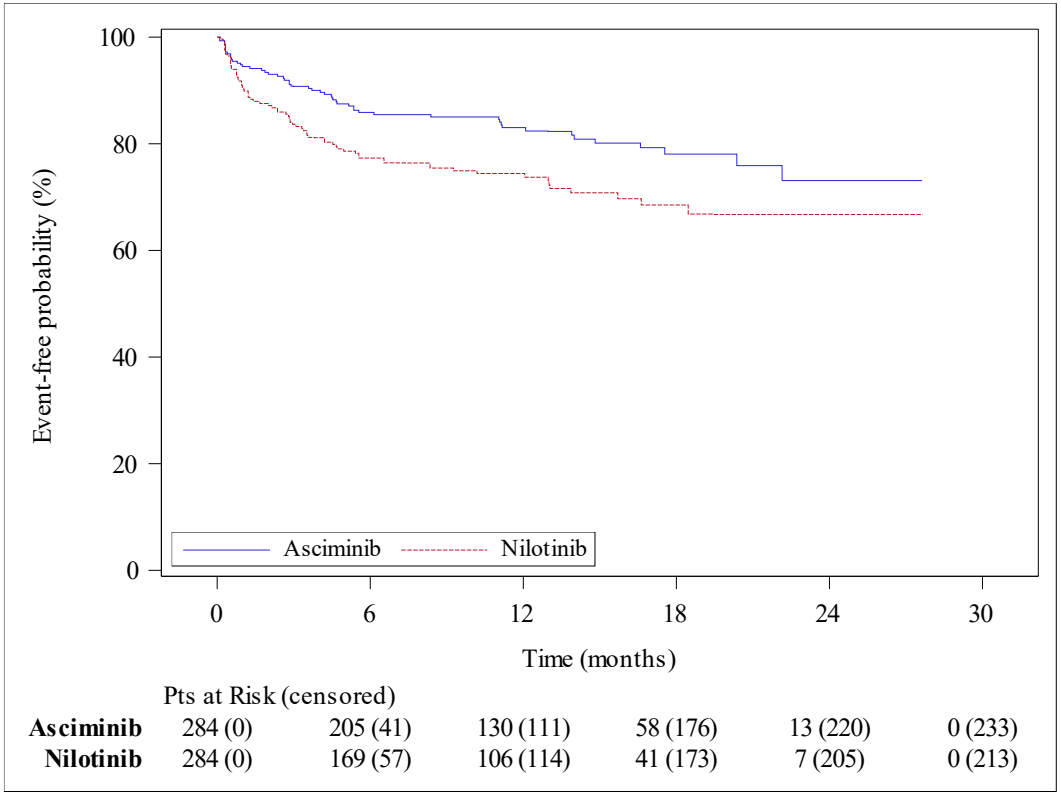


	Pts at Risk (censored)					
Asciminib	284 (0)	97 (24)	50 (64)	22 (88)	4 (104)	0 (108)
Nilotinib	284 (0)	84 (34)	46 (60)	18 (83)	7 (93)	0 (99)

Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.5 PRO-CTCAE - Severity: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

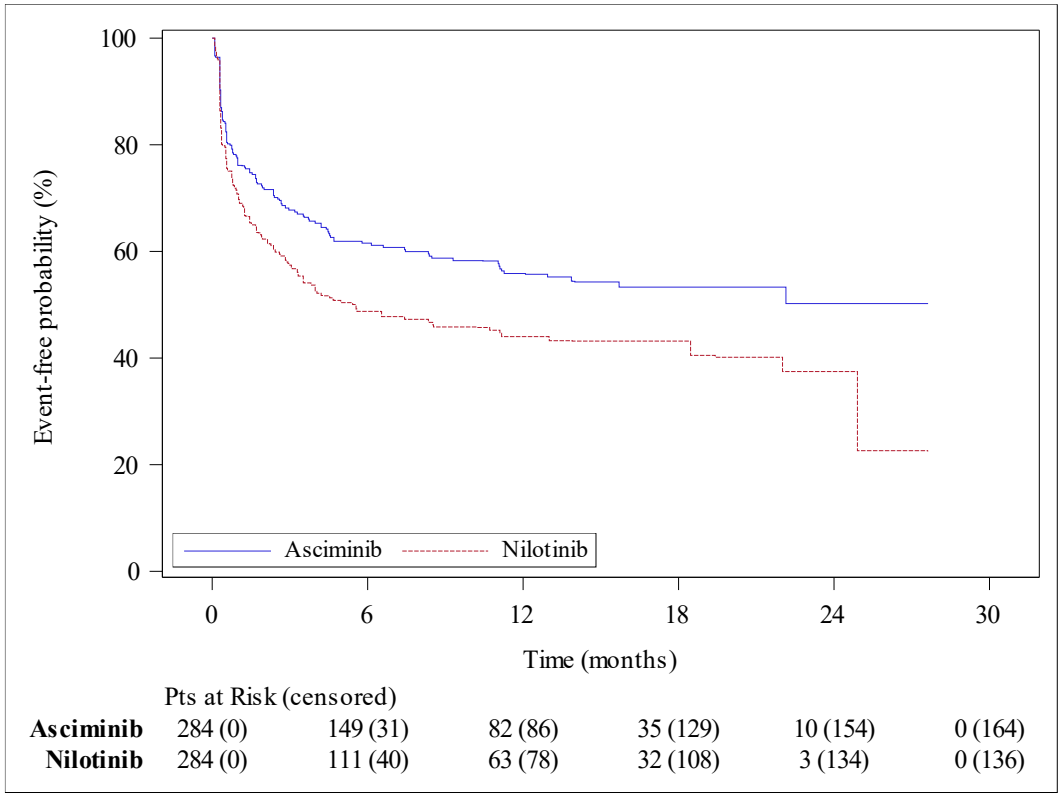
Vomiting - Severity (MID=1)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.5 PRO-CTCAE - Severity: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

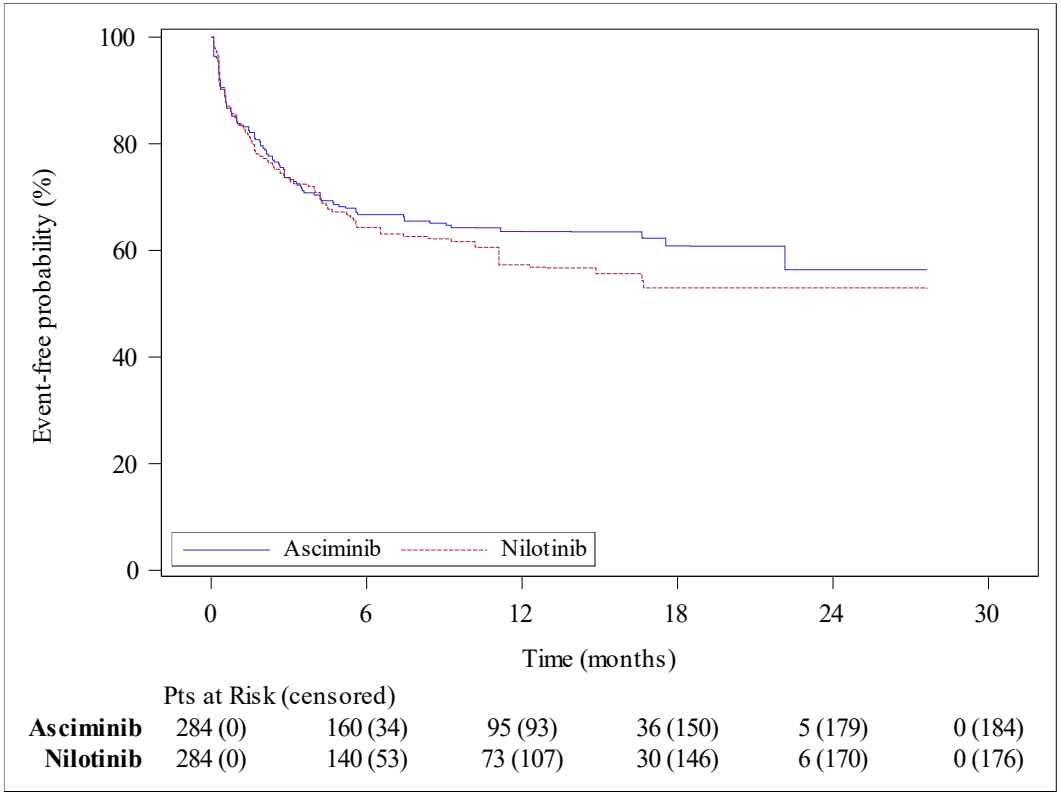
Nausea - Severity (MID=1)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.5 PRO-CTCAE - Severity: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

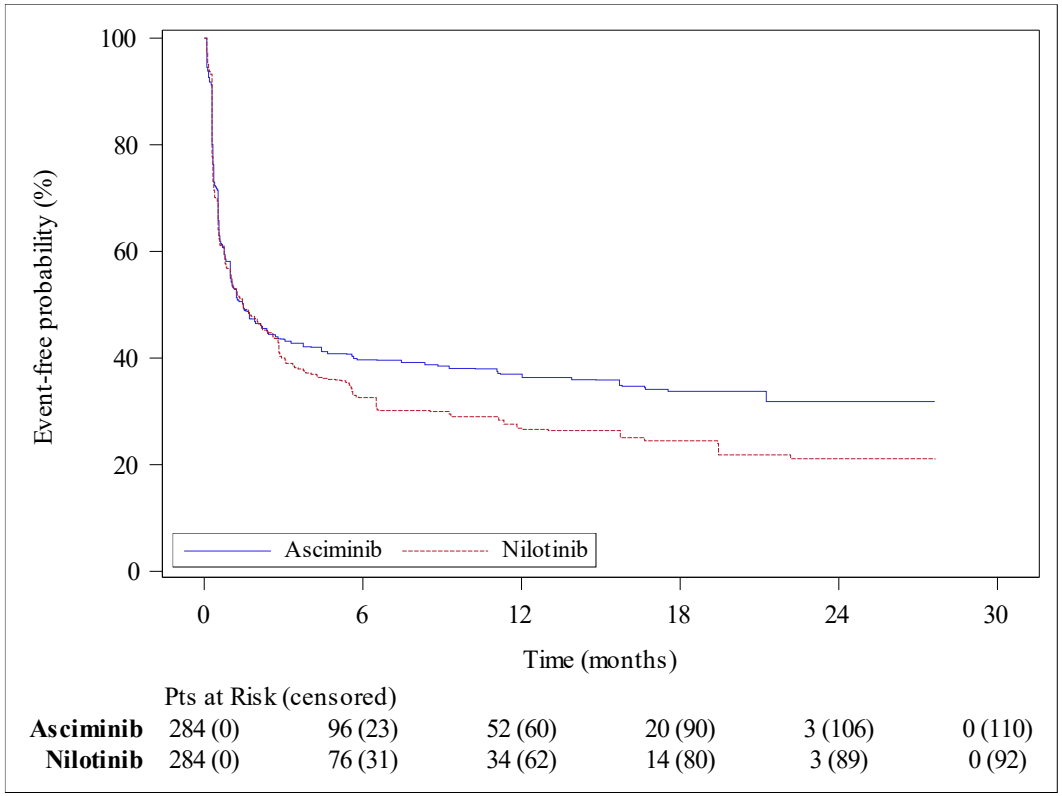
Edema - Severity (MID=1)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.5 PRO-CTCAE - Severity: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

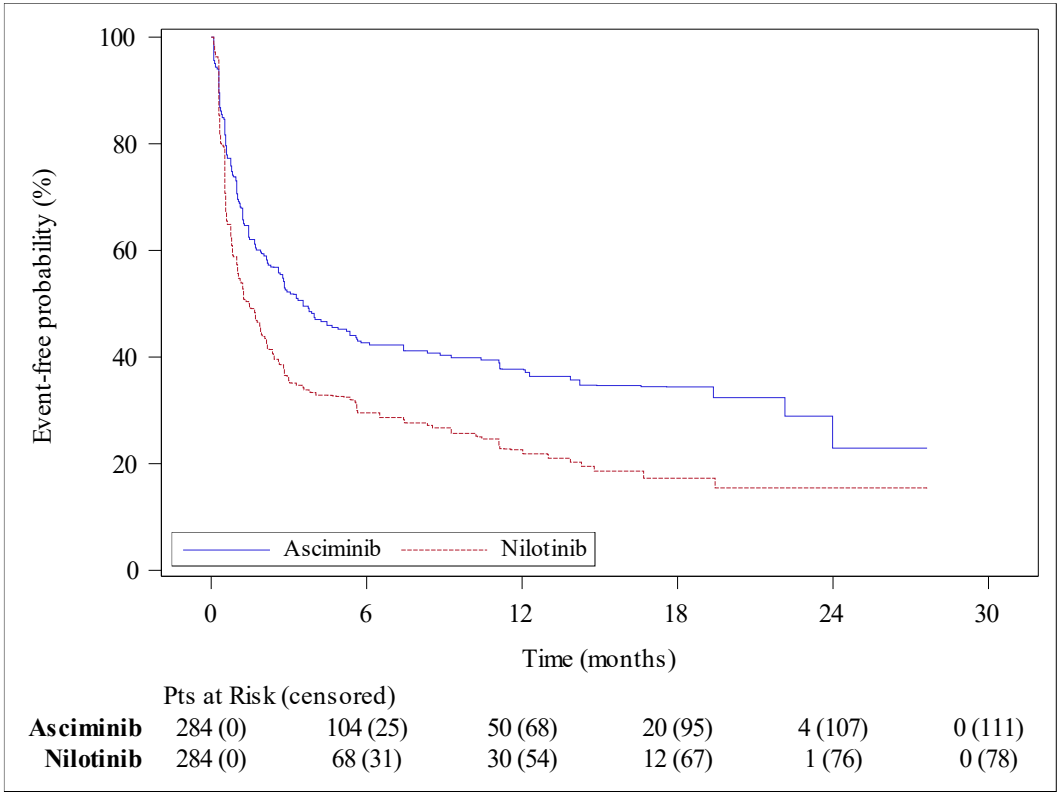
Muscle Pain - Severity (MID=1)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.5 PRO-CTCAE - Severity: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

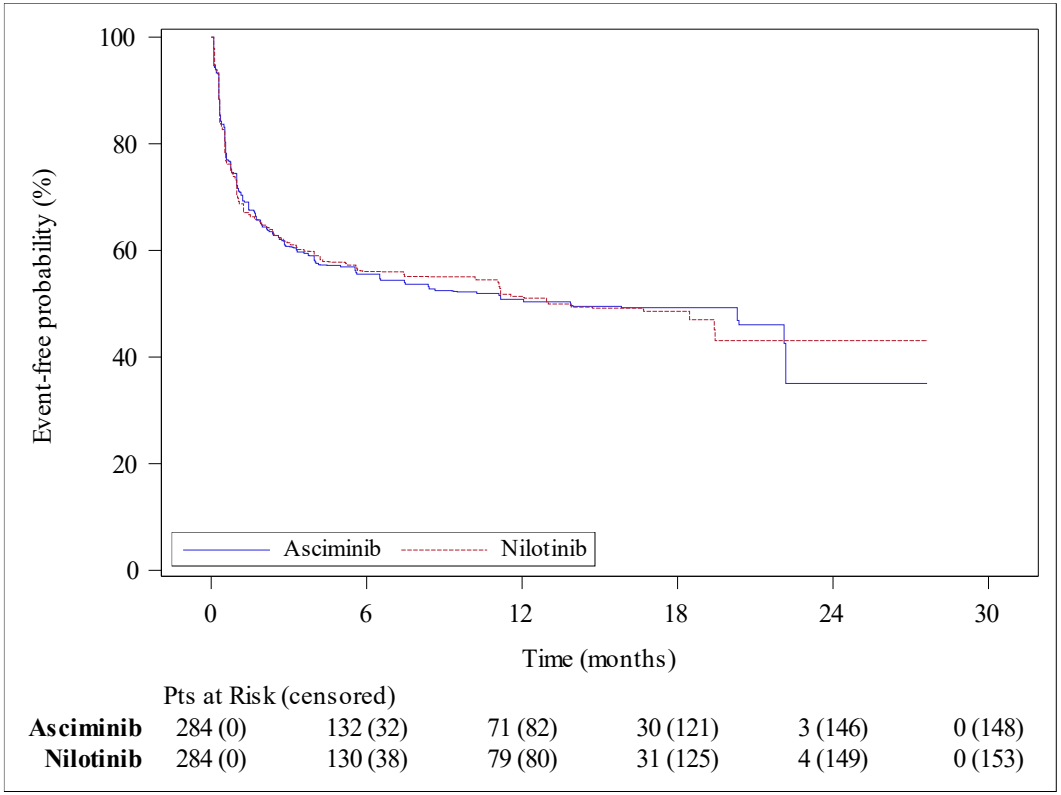
Pruritus - Severity (MID=1)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.5 PRO-CTCAE - Severity: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

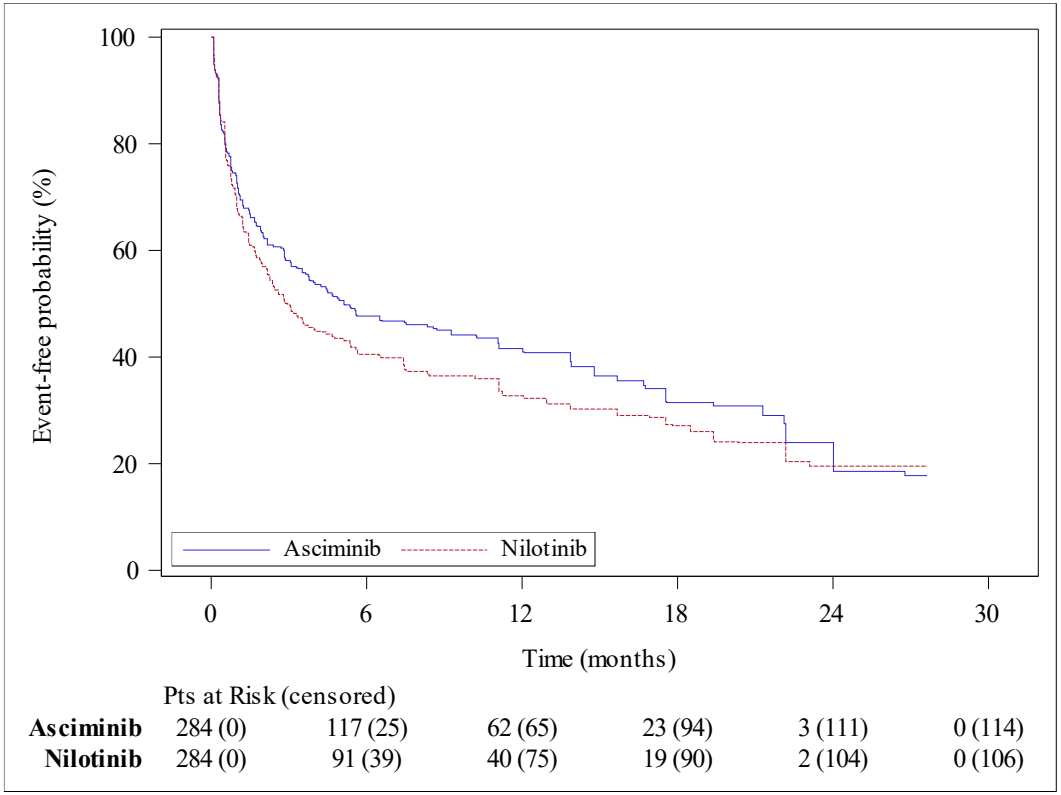
Increased Sweating - Severity (MID=1)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.5 PRO-CTCAE - Severity: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

Cough - Severity (MID=1)



	Pts at Risk (censored)					
Asciminib	284 (0)	117 (25)	62 (65)	23 (94)	3 (111)	0 (114)
Nilotinib	284 (0)	91 (39)	40 (75)	19 (90)	2 (104)	0 (106)

Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Table 3-4.6 PRO-CTCAE - Interference: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values) (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Fatigue - Interference (MID=1)			
N*	284	284	0.93
Number of patients with events, n (%)	174 (61.3)	166 (58.5)	[0.73; 1.17]
			0.821
Percentiles (months) [95% CI]			
25th	0.5 [0.4; 0.7]	0.3 [0.3; 0.4]	
Median	2.9 [1.0; 4.7]	2.8 [1.1; 4.6]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Headache - Interference (MID=1)			
N*	284	284	0.81
Number of patients with events, n (%)	153 (53.9)	159 (56.0)	[0.64; 1.02]
			0.388
Percentiles (months) [95% CI]			
25th	1.4 [0.9; 2.0]	0.5 [0.2; 0.8]	

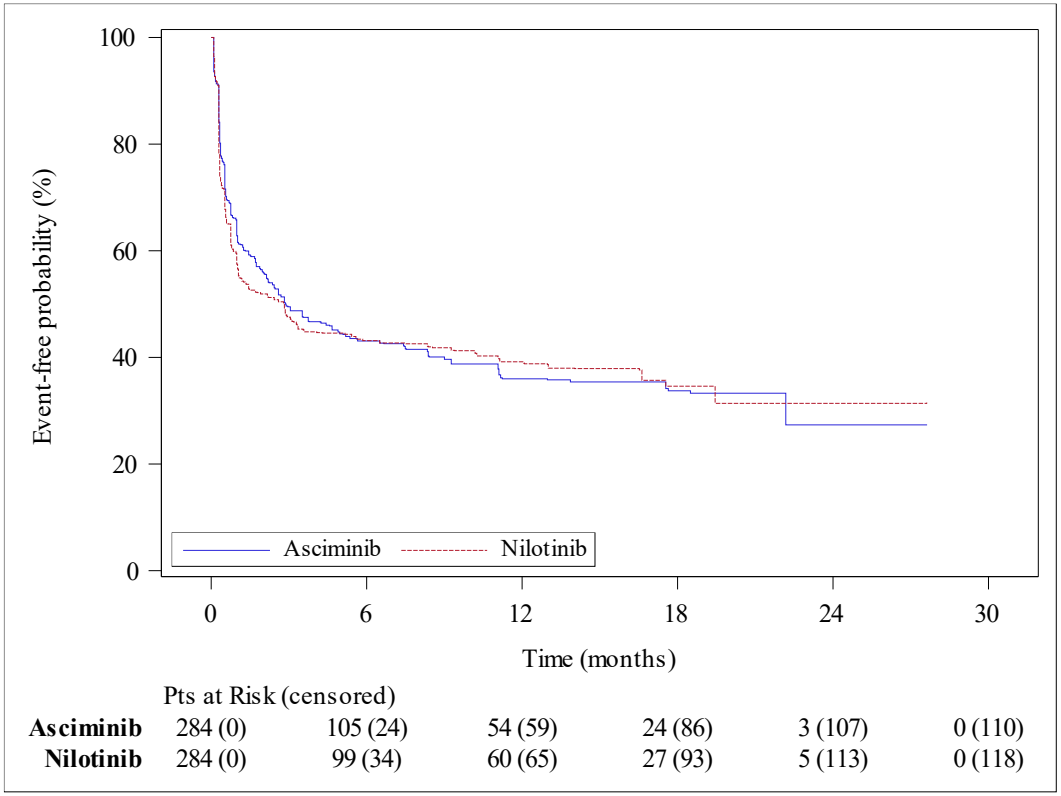
	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	6.5 [2.3; 10.8]	3.8 [1.4; 6.2]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Edema - Interference (MID=1)			
N*	284	284	0.75
Number of patients with events, n (%)	71 (25.0)	85 (29.9)	[0.55; 1.04]
			0.176
Percentiles (months) [95% CI]			
25th	9.3 [2.0; 16.5]	4.3 [1.3; 7.3]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Muscle Pain - Interference (MID=1)			
N*	284	284	0.97
Number of patients with events, n (%)	162 (57.0)	162 (57.0)	[0.77; 1.22]
			0.653
Percentiles (months) [95% CI]			
25th	0.5 [0.4; 0.7]	0.5 [0.4; 0.7]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	3.3 [1.4; 5.1]	2.9 [0.7; 5.0]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Cough - Interference (MID=1)			
N*	284	284	0.97
Number of patients with events, n (%)	131 (46.1)	124 (43.7)	[0.75; 1.25]
			0.578
Percentiles (months) [95% CI]			
25th	2.0 [1.3; 2.7]	2.2 [1.3; 3.0]	
Median	15.7 [11.6; 19.8]	11.3 [9.9; 12.7]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

MID: Minimal important difference
HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event. The number of patients is the mean number over all imputations rounded to the nearest integer
.....
Missing baseline values are multiply imputed by simple imputation using 500 repetitions under a MAR assumption.
Two-sided 95% CI for KM percentiles are derived by the approach outlined in Moscovici and Ratitch (2017).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factor ELTS Score (IRT) and covariates treatment arm and baseline score.
P-Values are based on stratified logrank test with stratification factor ELTS Score (IRT).
Test results are combined using the Wilson-Hilferty transformation.
Data Cut/15MAY2025

Figure 3-4.6 PRO-CTCAE - Interference: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

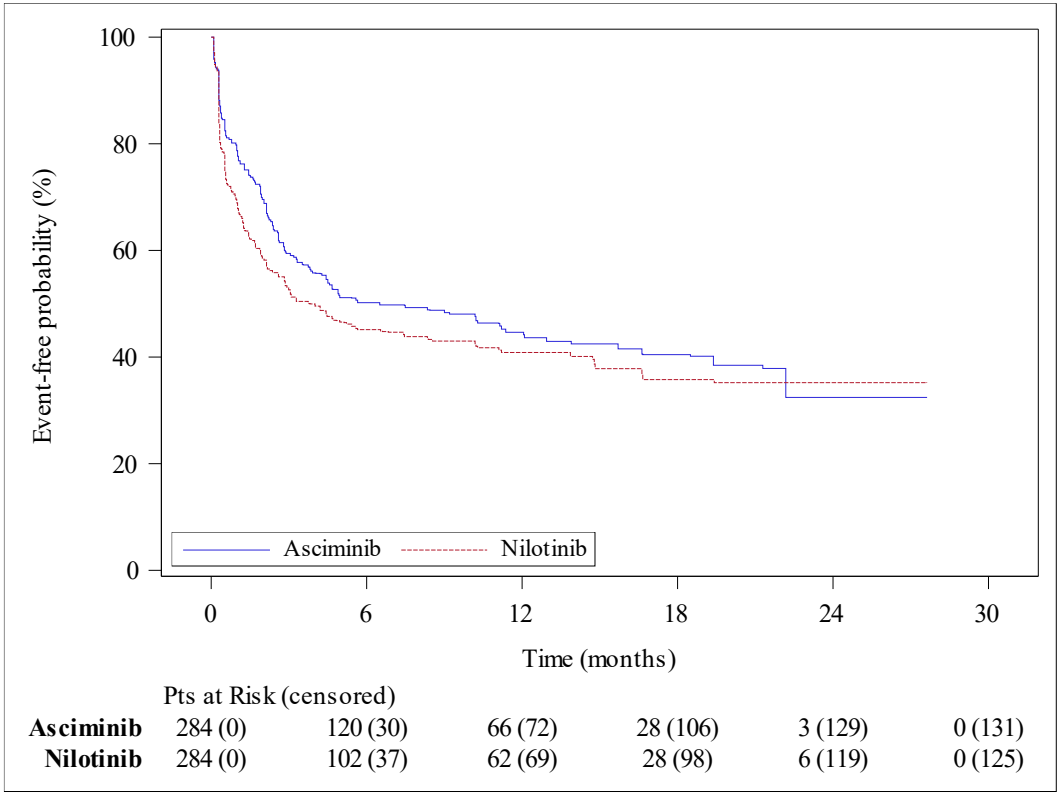
Fatigue - Interference (MID=1)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.6 PRO-CTCAE - Interference: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

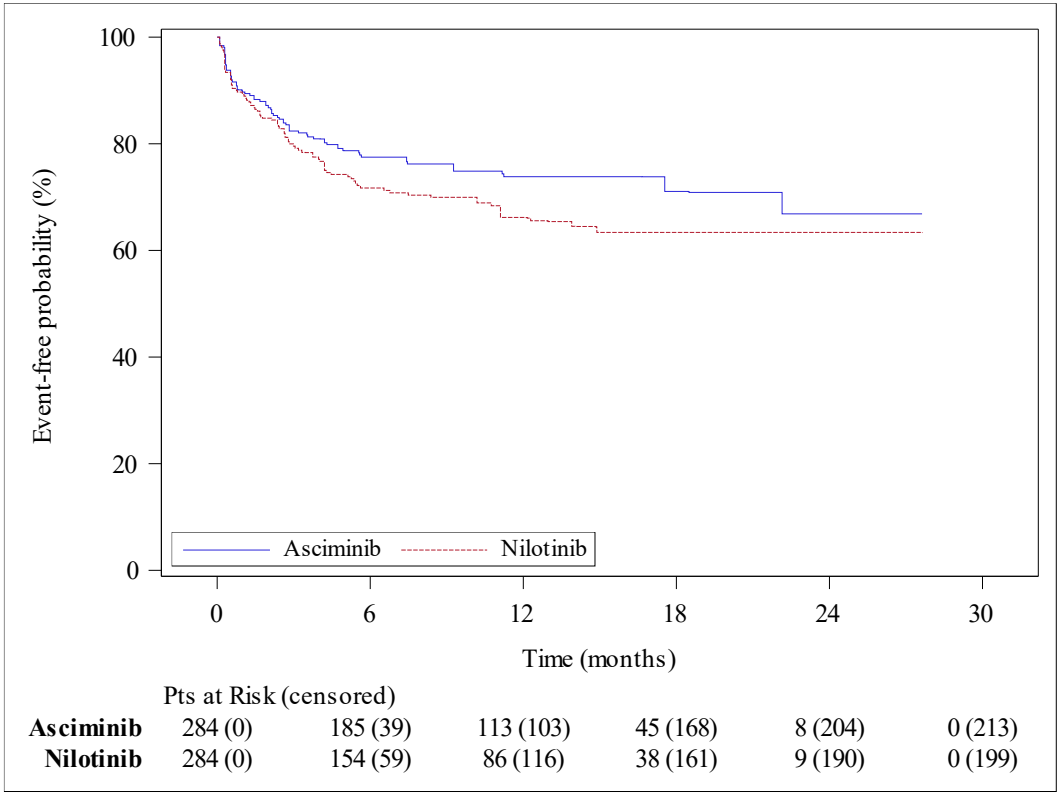
Headache - Interference (MID=1)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.6 PRO-CTCAE - Interference: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

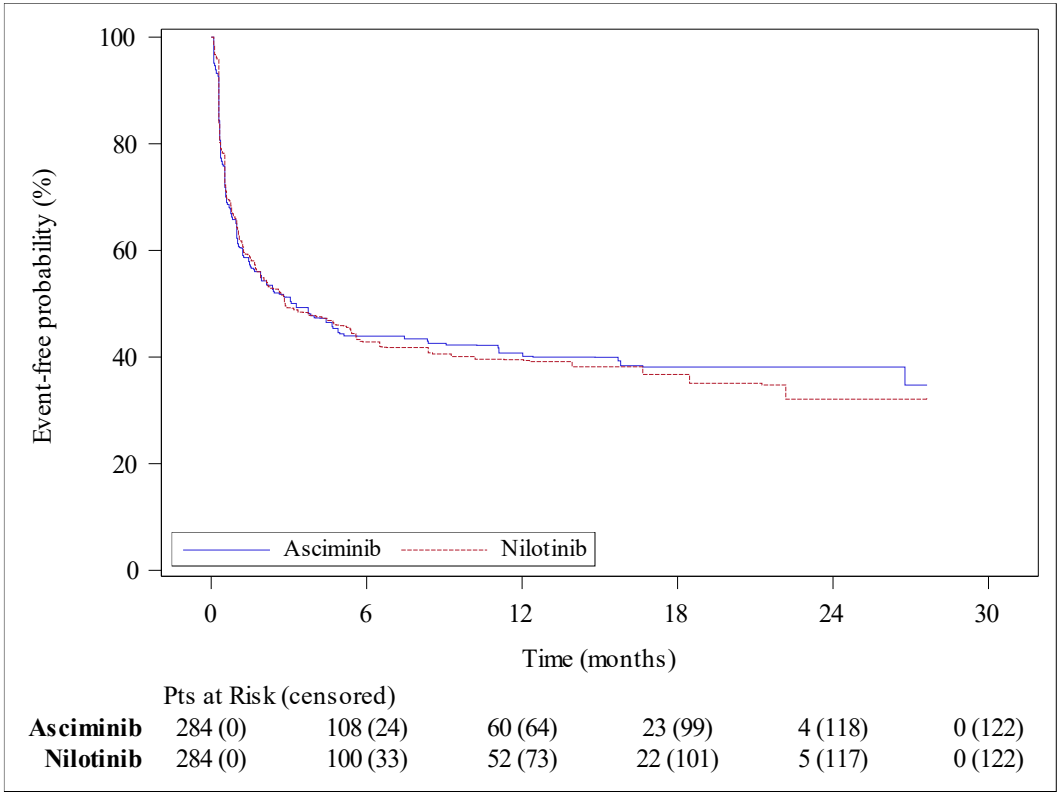
Edema - Interference (MID=1)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.6 PRO-CTCAE - Interference: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

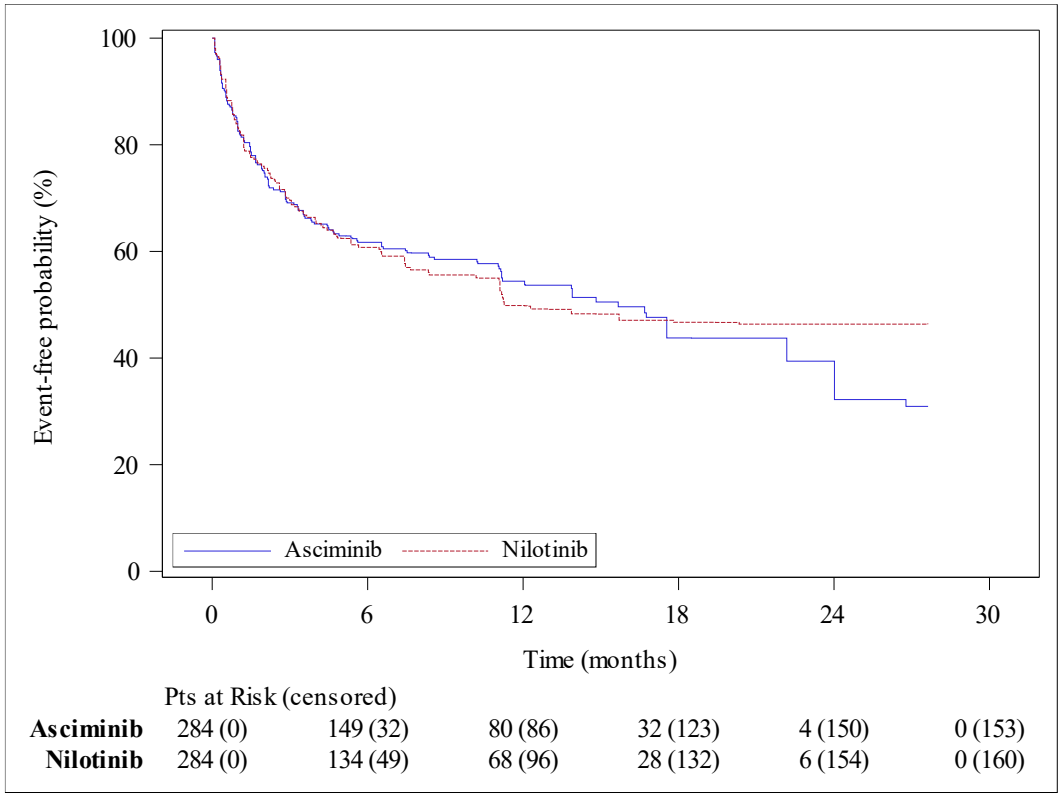
Muscle Pain - Interference (MID=1)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-4.6 PRO-CTCAE - Interference: Time to first deterioration - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

Cough - Interference (MID=1)



Note: The number of patients at risk and then number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Table 3-5.1 EORTC QLQ-C30: Time to first deterioration analysis by subgroups - Sensitivity analysis (multiple imputation of missing baseline values) (Full Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Global health status/QoL (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.952)							
Low	76/171 (44.4)	11.2 [4.1; 18.3]	78/172 (45.3)	11.1 [2.7; 19.5]	0.95	[0.67; 1.33]	0.793
Intermediate	23/75 (30.7)	22.1 [22.1; 22.2]	27/75 (36.0)	N.E. [N.E.; N.E.]	0.66	[0.35; 1.22]	0.466
High	8/38 (21.1)	N.E. [N.E.; N.E.]	11/37 (29.7)	N.E. [N.E.; N.E.]	0.62	[0.23; 1.65]	0.860
Sex							
(Interaction test p = 0.628)							
Female	43/107 (40.2)	11.2 [11.1; 11.3]	51/126 (40.5)	11.2 [-2.5; 24.9]	0.89	[0.57; 1.40]	0.821
Male	65/177	22.1 [22.1; 22.2]	65/158	N.E. [N.E.; N.E.]	0.83	[0.57; 1.20]	0.589

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(36.7)		(41.1)				
Race							
(Interaction test p = 0.914)							
Asian	15/40	11.2 [11.1; 11.3]	22/46	11.0 [-0.3; 22.2]	0.64	[0.32; 1.30]	0.534
	(37.5)		(47.8)				
White	87/227	22.1 [15.4; 28.9]	90/217	11.6 [10.5; 12.7]	0.89	[0.65; 1.23]	0.664
	(38.3)		(41.5)				
Other	6/17	N.E. [N.E.; N.E.]	5/21	N.E. [N.E.; N.E.]	0.94	[0.18; 4.95]	0.998
	(35.3)		(23.8)				
Age groups							
(Interaction test p = 0.362)							
18 - < 65 years	91/237	22.1 [14.6; 29.6]	103/247	11.2 [10.8; 11.6]	0.84	[0.62; 1.15]	0.556
	(38.4)		(41.7)				
65 - < 75 years	14/38	22.1 [22.1; 22.2]	8/24	N.E. [N.E.; N.E.]	0.78	[0.26; 2.32]	0.675
	(36.8)		(33.3)				
>= 75 years	3/9	2.8 [2.8; 2.9]	5/13	N.E. [N.E.; N.E.]	0.91	[0.15; 5.49]	0.617
	(33.3)		(38.5)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test p = 0.618)							
Europe excluding Germany	51/138 (37.0)	22.1 [22.0; 22.2]	58/141 (41.1)	22.0 [7.1; 36.9]	0.88	[0.59; 1.33]	0.905
Germany	32/72 (44.4)	11.2 [4.7; 17.6]	24/53 (45.3)	9.2 [-5.3; 23.7]	0.63	[0.34; 1.18]	0.615
Others	24/74 (32.4)	N.E. [N.E.; N.E.]	35/90 (38.9)	N.E. [N.E.; N.E.]	0.84	[0.48; 1.47]	0.952
Physical functioning (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.048)							
Low	45/171 (26.3)	N.E. [N.E.; N.E.]	66/172 (38.4)	N.E. [N.E.; N.E.]	0.61	[0.40; 0.92]	0.042
Intermediate	27/75 (36.0)	N.E. [N.E.; N.E.]	16/75 (21.3)	N.E. [N.E.; N.E.]	1.60	[0.82; 3.11]	0.519
High	10/38	N.E. [N.E.; N.E.]	6/37	N.E. [N.E.; N.E.]	1.38	[0.44; 4.30]	0.787

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(26.3)		(16.2)				
Sex							
(Interaction test p = 0.643)							
Female	39/107	N.E. [N.E.; N.E.]	47/126	11.8 [10.6; 13.1]	0.92	[0.58; 1.47]	0.814
	(36.4)		(37.3)				
Male	43/177	N.E. [N.E.; N.E.]	42/158	N.E. [N.E.; N.E.]	0.83	[0.53; 1.31]	0.825
	(24.3)		(26.6)				
Race							
(Interaction test p = 0.504)							
Asian	18/40	N.E. [N.E.; N.E.]	18/46	N.E. [N.E.; N.E.]	0.99	[0.50; 1.98]	0.368
	(45.0)		(39.1)				
White	61/227	N.E. [N.E.; N.E.]	65/217	N.E. [N.E.; N.E.]	0.84	[0.57; 1.22]	0.687
	(26.9)		(30.0)				
Other	3/17	N.E. [N.E.; N.E.]	6/21	11.1 [11.1; 11.2]	0.58	[0.11; 3.15]	0.948
	(17.6)		(28.6)				
Age groups							
(Interaction test p = 0.561)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
18 - < 65 years	68/237 (28.7)	N.E. [N.E.; N.E.]	78/247 (31.6)	N.E. [N.E.; N.E.]	0.81	[0.57; 1.16]	0.561
65 - < 75 years	12/38 (31.6)	N.E. [N.E.; N.E.]	8/24 (33.3)	N.E. [N.E.; N.E.]	0.88	[0.31; 2.49]	0.821
>= 75 years	3/9 (33.3)	N.E. [N.E.; N.E.]	2/13 (15.4)	N.E. [N.E.; N.E.]	1.79	[0.14; 23.61]	0.931
Geographic region (Interaction test p = 0.480)							
Europe excluding Germany	34/138 (24.6)	N.E. [N.E.; N.E.]	42/141 (29.8)	N.E. [N.E.; N.E.]	0.76	[0.47; 1.24]	0.499
Germany	23/72 (31.9)	N.E. [N.E.; N.E.]	21/53 (39.6)	N.E. [N.E.; N.E.]	0.56	[0.29; 1.11]	0.485
Others	24/74 (32.4)	N.E. [N.E.; N.E.]	25/90 (27.8)	N.E. [N.E.; N.E.]	1.19	[0.66; 2.16]	0.868
Role functioning (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test p = 0.889)							
Low	73/171 (42.7)	16.7 [7.5; 25.9]	77/172 (44.8)	11.1 [7.1; 15.1]	0.84	[0.60; 1.18]	0.929
Intermediate	30/75 (40.0)	N.E. [N.E.; N.E.]	30/75 (40.0)	11.3 [5.1; 17.5]	1.02	[0.59; 1.77]	0.573
High	7/38 (18.4)	N.E. [N.E.; N.E.]	11/37 (29.7)	N.E. [N.E.; N.E.]	0.59	[0.20; 1.68]	0.774
Sex							
(Interaction test p = 0.619)							
Female	46/107 (43.0)	11.2 [11.1; 11.3]	58/126 (46.0)	6.0 [0.9; 11.2]	0.93	[0.61; 1.42]	0.851
Male	65/177 (36.7)	22.2 [13.0; 31.4]	60/158 (38.0)	22.2 [22.1; 22.3]	0.86	[0.59; 1.26]	0.748
Race							
(Interaction test p = 0.627)							
Asian	14/40 (35.0)	11.2 [11.2; 11.3]	20/46 (43.5)	11.1 [11.0; 11.2]	0.72	[0.35; 1.48]	0.910

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
White	90/227 (39.6)	22.2 [7.8; 36.6]	89/217 (41.0)	11.8 [6.7; 16.9]	0.90	[0.66; 1.24]	0.847
Other	7/17 (41.2)	N.E. [N.E.; N.E.]	9/21 (42.9)	5.7 [5.6; 5.8]	0.47	[0.14; 1.53]	0.687
Age groups (Interaction test p = 0.531)							
18 - < 65 years	96/237 (40.5)	16.7 [7.6; 25.8]	102/247 (41.3)	11.3 [8.3; 14.3]	0.89	[0.66; 1.20]	0.778
65 - < 75 years	12/38 (31.6)	N.E. [N.E.; N.E.]	10/24 (41.7)	8.5 [-1.0; 18.1]	0.75	[0.29; 1.99]	0.740
>= 75 years	3/9 (33.3)	N.E. [N.E.; N.E.]	6/13 (46.2)	5.6 [-3.6; 14.7]	1.37	[0.19; 10.09]	0.697
Geographic region (Interaction test p = 0.996)							
Europe excluding Germany	52/138 (37.7)	22.6 [22.5; 22.6]	58/141 (41.1)	11.8 [6.6; 17.1]	0.85	[0.57; 1.28]	0.972
Germany	34/72	11.1 [4.7; 17.5]	28/53	2.7 [1.2; 4.3]	0.60	[0.33; 1.07]	0.520

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(47.2)		(52.8)				
Others	24/74	N.E. [N.E.; N.E.]	32/90	N.E. [N.E.; N.E.]	0.88	[0.51; 1.53]	0.589
	(32.4)		(35.6)				
Emotional functioning (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.856)							
Low	59/171	22.3 [21.8; 22.7]	73/172	11.3 [0.1; 22.4]	0.65	[0.45; 0.95]	0.268
	(34.5)		(42.4)				
Intermediate	28/75	N.E. [N.E.; N.E.]	22/75	N.E. [N.E.; N.E.]	1.06	[0.58; 1.95]	0.950
	(37.3)		(29.3)				
High	6/38	N.E. [N.E.; N.E.]	10/37	N.E. [N.E.; N.E.]	0.52	[0.17; 1.60]	0.660
	(15.8)		(27.0)				
Sex							
(Interaction test p = 0.553)							
Female	36/107	N.E. [N.E.; N.E.]	47/126	11.8 [10.7; 12.9]	0.73	[0.45; 1.17]	0.714
	(33.6)		(37.3)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Male	56/177 (31.6)	N.E. [N.E.; N.E.]	57/158 (36.1)	N.E. [N.E.; N.E.]	0.73	[0.49; 1.09]	0.832
Race (Interaction test p = 0.714)							
Asian	10/40 (25.0)	N.E. [N.E.; N.E.]	19/46 (41.3)	N.E. [N.E.; N.E.]	0.47	[0.21; 1.05]	0.221
White	75/227 (33.0)	22.3 [21.8; 22.8]	80/217 (36.9)	22.1 [4.9; 39.3]	0.77	[0.55; 1.09]	0.726
Other	8/17 (47.1)	11.2 [2.8; 19.6]	6/21 (28.6)	N.E. [N.E.; N.E.]	0.99	[0.24; 4.12]	0.908
Age groups (Interaction test p = 0.639)							
18 - < 65 years	80/237 (33.8)	22.3 [21.8; 22.8]	95/247 (38.5)	11.8 [10.6; 13.0]	0.72	[0.52; 0.99]	0.484
65 - < 75 years	11/38 (28.9)	N.E. [N.E.; N.E.]	7/24 (29.2)	22.1 [22.0; 22.1]	1.10	[0.33; 3.68]	0.661
>= 75 years	2/9	N.E. [N.E.; N.E.]	3/13	N.E. [N.E.; N.E.]	1.72	[0.14; 21.49]	0.492

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(22.2)		(23.1)				
Geographic region							
(Interaction test p = 0.790)							
Europe excluding Germany	48/138	22.3 [21.8; 22.8]	51/141	11.8 [10.4; 13.2]	0.79	[0.51; 1.20]	0.943
	(34.8)		(36.2)				
Germany	25/72	N.E. [N.E.; N.E.]	20/53	22.1 [22.0; 22.2]	0.74	[0.37; 1.47]	0.911
	(34.7)		(37.7)				
Others	20/74	N.E. [N.E.; N.E.]	34/90	N.E. [N.E.; N.E.]	0.60	[0.33; 1.09]	0.422
	(27.0)		(37.8)				
Cognitive functioning (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.786)							
Low	76/171	11.2 [11.0; 11.3]	88/172	5.6 [0.4; 10.8]	0.77	[0.55; 1.06]	0.297
	(44.4)		(51.2)				
Intermediate	40/75	5.6 [-1.1; 12.3]	33/75	5.7 [0.1; 11.3]	1.09	[0.67; 1.78]	0.787
	(53.3)		(44.0)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
High	13/38 (34.2)	N.E. [N.E.; N.E.]	13/37 (35.1)	N.E. [N.E.; N.E.]	0.88	[0.38; 2.03]	0.672
Sex							
(Interaction test p = 0.636)							
Female	57/107 (53.3)	5.6 [-2.0; 13.1]	61/126 (48.4)	5.6 [-0.9; 12.1]	1.02	[0.70; 1.49]	0.600
Male	71/177 (40.1)	11.2 [1.0; 21.4]	73/158 (46.2)	5.7 [5.5; 6.0]	0.78	[0.55; 1.11]	0.421
Race							
(Interaction test p = 0.663)							
Asian	19/40 (47.5)	11.2 [11.0; 11.4]	20/46 (43.5)	11.1 [-1.4; 23.6]	0.94	[0.48; 1.82]	0.422
White	103/227 (45.4)	11.2 [10.9; 11.4]	104/217 (47.9)	5.6 [-0.5; 11.7]	0.87	[0.65; 1.16]	0.706
Other	7/17 (41.2)	N.E. [N.E.; N.E.]	10/21 (47.6)	5.6 [-0.3; 11.5]	0.81	[0.25; 2.64]	0.835
Age groups							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test p = 0.797)							
18 - < 65 years	110/237 (46.4)	11.2 [11.1; 11.3]	121/247 (49.0)	5.6 [0.1; 11.1]	0.84	[0.64; 1.11]	0.602
65 - < 75 years	15/38 (39.5)	N.E. [N.E.; N.E.]	8/24 (33.3)	N.E. [N.E.; N.E.]	1.07	[0.42; 2.72]	0.595
>= 75 years	5/9 (55.6)	2.8 [2.8; 2.9]	5/13 (38.5)	2.8 [2.7; 2.9]	0.87	[0.14; 5.33]	0.846
Geographic region							
(Interaction test p = 0.428)							
Europe excluding Germany	62/138 (44.9)	11.2 [11.1; 11.3]	66/141 (46.8)	5.7 [0.5; 10.8]	0.89	[0.61; 1.28]	0.998
Germany	36/72 (50.0)	5.9 [-1.0; 12.8]	27/53 (50.9)	2.9 [2.7; 3.0]	0.67	[0.38; 1.18]	0.703
Others	31/74 (41.9)	11.2 [11.0; 11.4]	41/90 (45.6)	11.1 [-1.4; 23.6]	0.86	[0.53; 1.42]	0.852
Social functioning (MID=10)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.598)							
Low	63/171 (36.8)	22.2 [22.1; 22.2]	83/172 (48.3)	5.7 [-0.6; 11.9]	0.61	[0.43; 0.86]	0.023
Intermediate	28/75 (37.3)	N.E. [N.E.; N.E.]	29/75 (38.7)	11.4 [5.3; 17.4]	0.78	[0.45; 1.35]	0.894
High	9/38 (23.7)	N.E. [N.E.; N.E.]	12/37 (32.4)	N.E. [N.E.; N.E.]	0.73	[0.29; 1.80]	1.000
Sex							
(Interaction test p = 0.532)							
Female	38/107 (35.5)	N.E. [N.E.; N.E.]	59/126 (46.8)	3.0 [-3.7; 9.7]	0.64	[0.42; 0.99]	0.077
Male	62/177 (35.0)	22.2 [21.9; 22.4]	66/158 (41.8)	N.E. [N.E.; N.E.]	0.70	[0.49; 1.01]	0.259
Race							
(Interaction test p = 0.980)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Asian	17/40 (42.5)	N.E. [N.E.; N.E.]	19/46 (41.3)	N.E. [N.E.; N.E.]	0.80	[0.41; 1.55]	0.989
White	76/227 (33.5)	22.6 [22.1; 23.0]	98/217 (45.2)	11.1 [1.2; 20.9]	0.62	[0.45; 0.84]	0.014
Other	7/17 (41.2)	N.E. [N.E.; N.E.]	7/21 (33.3)	N.E. [N.E.; N.E.]	0.95	[0.28; 3.16]	0.678
Age groups (Interaction test p = 0.785)							
18 - < 65 years	85/237 (35.9)	22.6 [22.1; 23.0]	109/247 (44.1)	11.2 [1.7; 20.7]	0.67	[0.50; 0.90]	0.039
65 - < 75 years	14/38 (36.8)	N.E. [N.E.; N.E.]	10/24 (41.7)	N.E. [N.E.; N.E.]	0.66	[0.27; 1.63]	0.935
>= 75 years	1/9 (11.1)	N.E. [N.E.; N.E.]	5/13 (38.5)	2.0 [1.8; 2.1]	0.45	[0.05; 4.09]	0.485
Geographic region (Interaction test p = 0.895)							
Europe excluding Germany	46/138	22.6 [22.5; 22.6]	66/141	5.7 [-1.6; 12.9]	0.58	[0.39; 0.86]	0.023

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(33.3)		(46.8)				
Germany	28/72	22.2 [22.1; 22.2]	24/53	2.9 [1.1; 4.6]	0.58	[0.32; 1.06]	0.304
	(38.9)		(45.3)				
Others	26/74	N.E. [N.E.; N.E.]	34/90	19.4 [19.3; 19.5]	0.87	[0.51; 1.46]	0.729
	(35.1)		(37.8)				
Fatigue (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.457)							
Low	61/171	N.E. [N.E.; N.E.]	74/172	11.8 [0.4; 23.3]	0.71	[0.49; 1.03]	0.310
	(35.7)		(43.0)				
Intermediate	26/75	22.1 [22.1; 22.2]	18/75	N.E. [N.E.; N.E.]	1.25	[0.64; 2.48]	0.704
	(34.7)		(24.0)				
High	7/38	N.E. [N.E.; N.E.]	11/37	N.E. [N.E.; N.E.]	0.67	[0.22; 2.07]	0.585
	(18.4)		(29.7)				
Sex							
(Interaction test p = 0.595)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Female	37/107 (34.6)	22.1 [22.1; 22.2]	47/126 (37.3)	11.8 [10.5; 13.2]	0.85	[0.52; 1.38]	0.888
Male	57/177 (32.2)	N.E. [N.E.; N.E.]	55/158 (34.8)	22.2 [22.0; 22.3]	0.78	[0.52; 1.18]	0.906
Race (Interaction test p = 0.683)							
Asian	10/40 (25.0)	N.E. [N.E.; N.E.]	19/46 (41.3)	N.E. [N.E.; N.E.]	0.48	[0.21; 1.07]	0.190
White	76/227 (33.5)	N.E. [N.E.; N.E.]	79/217 (36.4)	22.1 [22.0; 22.3]	0.84	[0.59; 1.19]	0.786
Other	7/17 (41.2)	11.4 [1.3; 21.5]	5/21 (23.8)	N.E. [N.E.; N.E.]	0.75	[0.16; 3.53]	0.909
Age groups (Interaction test p = 0.673)							
18 - < 65 years	78/237 (32.9)	N.E. [N.E.; N.E.]	91/247 (36.8)	22.1 [3.9; 40.4]	0.78	[0.56; 1.09]	0.501
65 - < 75 years	13/38	N.E. [N.E.; N.E.]	9/24	N.E. [N.E.; N.E.]	0.74	[0.25; 2.18]	0.764

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(34.2)		(37.5)				
>= 75 years	2/9	N.E. [N.E.; N.E.]	2/13	N.E. [N.E.; N.E.]	2.81	[0.13; 59.19]	0.960
	(22.2)		(15.4)				
Geographic region							
(Interaction test p = 0.376)							
Europe excluding Germany	47/138	N.E. [N.E.; N.E.]	55/141	11.8 [1.1; 22.6]	0.76	[0.50; 1.16]	0.445
	(34.1)		(39.0)				
Germany	26/72	N.E. [N.E.; N.E.]	20/53	22.1 [22.0; 22.2]	0.70	[0.35; 1.41]	0.985
	(36.1)		(37.7)				
Others	21/74	N.E. [N.E.; N.E.]	28/90	N.E. [N.E.; N.E.]	0.77	[0.41; 1.43]	0.802
	(28.4)		(31.1)				
Nausea and vomiting (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.566)							
Low	37/171	N.E. [N.E.; N.E.]	51/172	22.2 [22.2; 22.3]	0.67	[0.43; 1.03]	0.131
	(21.6)		(29.7)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Intermediate	16/75 (21.3)	N.E. [N.E.; N.E.]	21/75 (28.0)	N.E. [N.E.; N.E.]	0.71	[0.36; 1.41]	0.421
High	9/38 (23.7)	22.1 [22.1; 22.2]	9/37 (24.3)	N.E. [N.E.; N.E.]	0.85	[0.32; 2.23]	0.464
Sex (Interaction test p = 0.959)							
Female	28/107 (26.2)	22.1 [22.1; 22.2]	44/126 (34.9)	22.0 [4.7; 39.3]	0.63	[0.38; 1.04]	0.124
Male	34/177 (19.2)	N.E. [N.E.; N.E.]	38/158 (24.1)	N.E. [N.E.; N.E.]	0.77	[0.48; 1.25]	0.456
Race (Interaction test p = 0.601)							
Asian	14/40 (35.0)	N.E. [N.E.; N.E.]	18/46 (39.1)	N.E. [N.E.; N.E.]	0.83	[0.40; 1.70]	0.793
White	43/227 (18.9)	N.E. [N.E.; N.E.]	60/217 (27.6)	22.2 [22.2; 22.3]	0.64	[0.42; 0.97]	0.041
Other	5/17	N.E. [N.E.; N.E.]	3/21	N.E. [N.E.; N.E.]	1.72	[0.36; 8.30]	0.859

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(29.4)		(14.3)				
Age groups							
(Interaction test p = 0.590)							
18 - < 65 years	53/237	N.E. [N.E.; N.E.]	73/247	N.E. [N.E.; N.E.]	0.68	[0.47; 0.98]	0.050
	(22.4)		(29.6)				
65 - < 75 years	7/38	22.1 [22.1; 22.2]	4/24	22.2 [22.2; 22.3]	1.11	[0.26; 4.69]	0.553
	(18.4)		(16.7)				
>= 75 years	2/9	N.E. [N.E.; N.E.]	3/13	N.E. [N.E.; N.E.]	0.57	[0.06; 5.71]	0.688
	(22.2)		(23.1)				
Geographic region							
(Interaction test p = 0.623)							
Europe excluding Germany	30/138	N.E. [N.E.; N.E.]	38/141	22.2 [22.2; 22.3]	0.70	[0.42; 1.16]	0.251
	(21.7)		(27.0)				
Germany	13/72	N.E. [N.E.; N.E.]	15/53	N.E. [N.E.; N.E.]	0.57	[0.25; 1.29]	0.309
	(18.1)		(28.3)				
Others	20/74	N.E. [N.E.; N.E.]	28/90	N.E. [N.E.; N.E.]	0.85	[0.47; 1.54]	0.927
	(27.0)		(31.1)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Pain (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.233)							
Low	75/171 (43.9)	11.2 [10.9; 11.5]	89/172 (51.7)	5.6 [0.7; 10.5]	0.73	[0.53; 1.02]	0.199
Intermediate	37/75 (49.3)	11.1 [5.8; 16.4]	29/75 (38.7)	16.4 [4.2; 28.7]	1.36	[0.81; 2.28]	0.758
High	15/38 (39.5)	N.E. [N.E.; N.E.]	17/37 (45.9)	5.7 [5.4; 5.9]	1.08	[0.51; 2.26]	0.566
Sex							
(Interaction test p = 0.324)							
Female	57/107 (53.3)	2.9 [-1.0; 6.8]	63/126 (50.0)	5.5 [0.2; 10.8]	1.14	[0.77; 1.69]	0.753
Male	70/177 (39.5)	N.E. [N.E.; N.E.]	73/158 (46.2)	11.1 [6.8; 15.4]	0.80	[0.56; 1.13]	0.383
Race							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test p = 0.550)							
Asian	21/40 (52.5)	11.1 [-1.6; 23.8]	24/46 (52.2)	5.6 [2.1; 9.1]	0.84	[0.46; 1.54]	0.913
White	99/227 (43.6)	11.2 [11.0; 11.4]	103/217 (47.5)	11.1 [6.8; 15.4]	0.89	[0.66; 1.19]	0.754
Other	7/17 (41.2)	7.6 [7.5; 7.7]	8/21 (38.1)	N.E. [N.E.; N.E.]	0.82	[0.24; 2.84]	0.828
Age groups							
(Interaction test p = 0.840)							
18 - < 65 years	108/237 (45.6)	11.2 [8.9; 13.4]	119/247 (48.2)	11.1 [5.4; 16.8]	0.90	[0.68; 1.19]	0.763
65 - < 75 years	16/38 (42.1)	N.E. [N.E.; N.E.]	12/24 (50.0)	5.7 [5.6; 5.8]	0.85	[0.36; 2.01]	0.786
>= 75 years	4/9 (44.4)	1.1 [1.0; 1.2]	4/13 (30.8)	5.8 [5.7; 5.9]	1.61	[0.25; 10.47]	0.844
Geographic region							
(Interaction test p = 0.700)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Europe excluding Germany	56/138 (40.6)	11.3 [11.0; 11.5]	67/141 (47.5)	5.7 [-1.4; 12.8]	0.78	[0.54; 1.14]	0.393
Germany	34/72 (47.2)	8.5 [0.9; 16.2]	25/53 (47.2)	5.7 [-3.9; 15.3]	0.87	[0.48; 1.59]	0.811
Others	38/74 (51.4)	5.7 [-1.3; 12.6]	43/90 (47.8)	11.1 [5.4; 16.8]	1.12	[0.71; 1.77]	0.645
Dyspnoea (MID=10)							
Stratification factor: ELTS based on randomization data from IRT (Interaction test p = 0.891)							
Low	60/171 (35.1)	22.1 [13.2; 31.0]	66/172 (38.4)	N.E. [N.E.; N.E.]	0.87	[0.60; 1.26]	0.894
Intermediate	22/75 (29.3)	N.E. [N.E.; N.E.]	22/75 (29.3)	N.E. [N.E.; N.E.]	0.86	[0.46; 1.64]	0.755
High	7/38 (18.4)	N.E. [N.E.; N.E.]	4/37 (10.8)	N.E. [N.E.; N.E.]	1.77	[0.43; 7.22]	0.869
Sex							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test p = 0.914)							
Female	36/107 (33.6)	22.1 [22.1; 22.2]	47/126 (37.3)	11.3 [10.6; 12.1]	0.82	[0.52; 1.30]	0.948
Male	53/177 (29.9)	22.2 [22.1; 22.2]	45/158 (28.5)	N.E. [N.E.; N.E.]	1.01	[0.67; 1.54]	0.549
Race							
(Interaction test p = 0.354)							
Asian	12/40 (30.0)	N.E. [N.E.; N.E.]	13/46 (28.3)	N.E. [N.E.; N.E.]	1.00	[0.44; 2.29]	0.312
White	71/227 (31.3)	22.2 [22.1; 22.3]	69/217 (31.8)	N.E. [N.E.; N.E.]	0.92	[0.64; 1.30]	0.744
Other	7/17 (41.2)	N.E. [N.E.; N.E.]	9/21 (42.9)	5.7 [4.6; 6.9]	0.67	[0.22; 2.03]	0.878
Age groups							
(Interaction test p = 0.628)							
18 - < 65 years	75/237 (31.6)	22.2 [22.1; 22.3]	84/247 (34.0)	N.E. [N.E.; N.E.]	0.87	[0.63; 1.22]	0.973

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
65 - < 75 years	12/38 (31.6)	N.E. [N.E.; N.E.]	6/24 (25.0)	N.E. [N.E.; N.E.]	1.14	[0.38; 3.38]	0.729
>= 75 years	2/9 (22.2)	N.E. [N.E.; N.E.]	2/13 (15.4)	N.E. [N.E.; N.E.]	0.42	[0.02; 9.08]	0.665
Geographic region (Interaction test p = 0.696)							
Europe excluding Germany	44/138 (31.9)	N.E. [N.E.; N.E.]	51/141 (36.2)	N.E. [N.E.; N.E.]	0.81	[0.53; 1.25]	0.800
Germany	27/72 (37.5)	22.2 [14.8; 29.5]	16/53 (30.2)	N.E. [N.E.; N.E.]	1.05	[0.52; 2.12]	0.701
Others	19/74 (25.7)	22.1 [22.1; 22.2]	25/90 (27.8)	N.E. [N.E.; N.E.]	0.84	[0.45; 1.57]	0.724
Insomnia (MID=10)							
Stratification factor: ELTS based on randomization data from IRT (Interaction test p = 0.920)							
Low	62/171	22.2 [6.1; 38.2]	68/172	22.0 [7.5; 36.6]	0.75	[0.52; 1.09]	0.546

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(36.3)		(39.5)				
Intermediate	26/75	22.1 [8.3; 35.9]	27/75	N.E. [N.E.; N.E.]	0.85	[0.48; 1.51]	0.729
	(34.7)		(36.0)				
High	14/38	11.2 [11.1; 11.3]	11/37	N.E. [N.E.; N.E.]	1.11	[0.46; 2.71]	0.943
	(36.8)		(29.7)				
Sex							
(Interaction test p = 0.985)							
Female	44/107	11.2 [10.3; 12.1]	49/126	11.2 [4.2; 18.2]	0.94	[0.61; 1.47]	0.701
	(41.1)		(38.9)				
Male	58/177	22.1 [22.0; 22.2]	57/158	N.E. [N.E.; N.E.]	0.76	[0.51; 1.14]	0.545
	(32.8)		(36.1)				
Race							
(Interaction test p = 0.351)							
Asian	13/40	N.E. [N.E.; N.E.]	15/46	N.E. [N.E.; N.E.]	0.89	[0.41; 1.92]	0.455
	(32.5)		(32.6)				
White	83/227	22.1 [10.5; 33.7]	84/217	22.0 [15.6; 28.5]	0.79	[0.57; 1.10]	0.531
	(36.6)		(38.7)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Other	7/17 (41.2)	N.E. [N.E.; N.E.]	7/21 (33.3)	N.E. [N.E.; N.E.]	0.80	[0.24; 2.73]	0.752
Age groups (Interaction test p = 0.782)							
18 - < 65 years	84/237 (35.4)	22.1 [12.0; 32.2]	95/247 (38.5)	22.0 [6.7; 37.4]	0.78	[0.57; 1.07]	0.326
65 - < 75 years	16/38 (42.1)	N.E. [N.E.; N.E.]	7/24 (29.2)	22.2 [22.2; 22.3]	1.61	[0.56; 4.63]	0.526
>= 75 years	2/9 (22.2)	N.E. [N.E.; N.E.]	4/13 (30.8)	N.E. [N.E.; N.E.]	0.69	[0.06; 7.92]	0.712
Geographic region (Interaction test p = 0.959)							
Europe excluding Germany	56/138 (40.6)	11.2 [2.4; 20.1]	57/141 (40.4)	11.6 [0.2; 23.0]	0.86	[0.57; 1.28]	0.703
Germany	23/72 (31.9)	N.E. [N.E.; N.E.]	20/53 (37.7)	N.E. [N.E.; N.E.]	0.49	[0.24; 1.02]	0.263

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Others	24/74 (32.4)	N.E. [N.E.; N.E.]	29/90 (32.2)	22.1 [22.0; 22.2]	0.95	[0.53; 1.69]	0.480
Appetite loss (MID=10)							
Stratification factor: ELTS based on randomization data from IRT (Interaction test p = 0.323)							
Low	38/171 (22.2)	N.E. [N.E.; N.E.]	44/172 (25.6)	N.E. [N.E.; N.E.]	0.79	[0.50; 1.24]	0.717
Intermediate	13/75 (17.3)	N.E. [N.E.; N.E.]	19/75 (25.3)	N.E. [N.E.; N.E.]	0.63	[0.30; 1.33]	0.313
High	6/38 (15.8)	N.E. [N.E.; N.E.]	9/37 (24.3)	N.E. [N.E.; N.E.]	0.83	[0.26; 2.66]	0.801
Sex (Interaction test p = 0.817)							
Female	28/107 (26.2)	N.E. [N.E.; N.E.]	43/126 (34.1)	22.2 [22.1; 22.3]	0.74	[0.45; 1.22]	0.229
Male	29/177	N.E. [N.E.; N.E.]	29/158	N.E. [N.E.; N.E.]	0.87	[0.51; 1.49]	0.858

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(16.4)		(18.4)				
Race							
(Interaction test p = 0.496)							
Asian	7/40	N.E. [N.E.; N.E.]	15/46	N.E. [N.E.; N.E.]	0.40	[0.16; 1.01]	0.076
	(17.5)		(32.6)				
White	45/227	N.E. [N.E.; N.E.]	51/217	22.2 [22.1; 22.3]	0.82	[0.54; 1.24]	0.475
	(19.8)		(23.5)				
Other	6/17	N.E. [N.E.; N.E.]	6/21	N.E. [N.E.; N.E.]	1.12	[0.25; 4.97]	0.832
	(35.3)		(28.6)				
Age groups							
(Interaction test p = 0.668)							
18 - < 65 years	45/237	N.E. [N.E.; N.E.]	57/247	N.E. [N.E.; N.E.]	0.76	[0.51; 1.15]	0.322
	(19.0)		(23.1)				
65 - < 75 years	9/38	N.E. [N.E.; N.E.]	10/24	22.2 [22.2; 22.3]	0.66	[0.23; 1.88]	0.742
	(23.7)		(41.7)				
>= 75 years	3/9	2.8 [2.8; 2.9]	5/13	22.1 [-24.1; 68.4]	1.15	[0.21; 6.27]	0.623
	(33.3)		(38.5)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test p = 0.532)							
Europe excluding Germany	25/138 (18.1)	N.E. [N.E.; N.E.]	30/141 (21.3)	22.2 [22.2; 22.3]	0.87	[0.50; 1.50]	0.911
Germany	14/72 (19.4)	22.2 [22.1; 22.2]	13/53 (24.5)	N.E. [N.E.; N.E.]	0.76	[0.33; 1.77]	0.808
Others	18/74 (24.3)	N.E. [N.E.; N.E.]	29/90 (32.2)	N.E. [N.E.; N.E.]	0.66	[0.36; 1.21]	0.466
Constipation (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.695)							
Low	41/171 (24.0)	N.E. [N.E.; N.E.]	67/172 (39.0)	11.7 [3.9; 19.5]	0.48	[0.32; 0.72]	0.003
Intermediate	21/75 (28.0)	22.1 [22.0; 22.2]	25/75 (33.3)	22.1 [-8.5; 52.8]	0.67	[0.36; 1.23]	0.484
High	8/38	N.E. [N.E.; N.E.]	8/37	N.E. [N.E.; N.E.]	1.01	[0.36; 2.85]	0.390

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(21.1)		(21.6)				
Sex							
(Interaction test p = 0.360)							
Female	31/107	22.1 [21.1; 23.2]	50/126	11.2 [10.4; 12.0]	0.56	[0.35; 0.90]	0.041
	(29.0)		(39.7)				
Male	39/177	N.E. [N.E.; N.E.]	50/158	N.E. [N.E.; N.E.]	0.55	[0.36; 0.86]	0.047
	(22.0)		(31.6)				
Race							
(Interaction test p = 0.562)							
Asian	9/40	N.E. [N.E.; N.E.]	20/46	11.1 [11.0; 11.2]	0.42	[0.19; 0.93]	0.059
	(22.5)		(43.5)				
White	56/227	22.3 [22.2; 22.3]	74/217	22.1 [4.2; 40.1]	0.61	[0.42; 0.87]	0.029
	(24.7)		(34.1)				
Other	4/17	N.E. [N.E.; N.E.]	6/21	N.E. [N.E.; N.E.]	0.45	[0.10; 2.02]	0.992
	(23.5)		(28.6)				
Age groups							
(Interaction test p = 0.337)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
18 - < 65 years	54/237 (22.8)	22.3 [22.2; 22.3]	90/247 (36.4)	19.4 [6.4; 32.5]	0.51	[0.36; 0.72]	0.001
65 - < 75 years	13/38 (34.2)	21.4 [21.4; 21.5]	6/24 (25.0)	N.E. [N.E.; N.E.]	1.31	[0.47; 3.59]	0.952
>= 75 years	2/9 (22.2)	N.E. [N.E.; N.E.]	5/13 (38.5)	3.0 [2.9; 3.1]	0.63	[0.09; 4.44]	0.986
Geographic region (Interaction test p = 0.802)							
Europe excluding Germany	36/138 (26.1)	22.3 [22.2; 22.3]	47/141 (33.3)	N.E. [N.E.; N.E.]	0.64	[0.41; 1.01]	0.157
Germany	14/72 (19.4)	N.E. [N.E.; N.E.]	17/53 (32.1)	N.E. [N.E.; N.E.]	0.43	[0.20; 0.93]	0.124
Others	20/74 (27.0)	N.E. [N.E.; N.E.]	36/90 (40.0)	11.7 [4.8; 18.6]	0.60	[0.34; 1.05]	0.192
Diarrhoea (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test p = 0.157)							
Low	51/171 (29.8)	N.E. [N.E.; N.E.]	53/172 (30.8)	22.2 [22.2; 22.3]	1.07	[0.72; 1.60]	0.615
Intermediate	21/75 (28.0)	N.E. [N.E.; N.E.]	19/75 (25.3)	N.E. [N.E.; N.E.]	1.01	[0.53; 1.94]	0.452
High	8/38 (21.1)	22.1 [22.0; 22.1]	7/37 (18.9)	N.E. [N.E.; N.E.]	1.08	[0.38; 3.04]	0.448
Sex							
(Interaction test p = 0.999)							
Female	31/107 (29.0)	N.E. [N.E.; N.E.]	31/126 (24.6)	22.2 [22.2; 22.3]	1.19	[0.70; 2.01]	0.600
Male	50/177 (28.2)	N.E. [N.E.; N.E.]	48/158 (30.4)	N.E. [N.E.; N.E.]	0.97	[0.64; 1.47]	0.825
Race							
(Interaction test p = 0.472)							
Asian	9/40 (22.5)	N.E. [N.E.; N.E.]	15/46 (32.6)	N.E. [N.E.; N.E.]	0.72	[0.30; 1.70]	0.442

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
White	66/227 (29.1)	N.E. [N.E.; N.E.]	62/217 (28.6)	22.2 [22.2; 22.3]	1.06	[0.74; 1.53]	0.451
Other	6/17 (35.3)	N.E. [N.E.; N.E.]	3/21 (14.3)	N.E. [N.E.; N.E.]	2.32	[0.52; 10.29]	0.644
Age groups (Interaction test p = 0.547)							
18 - < 65 years	70/237 (29.5)	N.E. [N.E.; N.E.]	73/247 (29.6)	N.E. [N.E.; N.E.]	1.04	[0.74; 1.46]	0.633
65 - < 75 years	11/38 (28.9)	N.E. [N.E.; N.E.]	2/24 (8.3)	22.2 [22.2; 22.3]	4.64	[0.77; 27.92]	0.071
>= 75 years	0/9		4/13 (30.8)	5.6 [5.6; 5.7]	0.10	[0.00; 3.15]	0.093
Geographic region (Interaction test p = 0.340)							
Europe excluding Germany	44/138 (31.9)	N.E. [N.E.; N.E.]	42/141 (29.8)	22.2 [22.2; 22.3]	1.11	[0.72; 1.73]	0.516
Germany	18/72	N.E. [N.E.; N.E.]	14/53	N.E. [N.E.; N.E.]	0.92	[0.43; 1.98]	0.804

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(25.0)		(26.4)				
Others	18/74	N.E. [N.E.; N.E.]	24/90	N.E. [N.E.; N.E.]	0.98	[0.52; 1.83]	0.717
	(24.3)		(26.7)				
Financial difficulties (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.939)							
Low	45/171	N.E. [N.E.; N.E.]	53/172	N.E. [N.E.; N.E.]	0.85	[0.56; 1.28]	0.829
	(26.3)		(30.8)				
Intermediate	21/75	N.E. [N.E.; N.E.]	18/75	22.3 [22.3; 22.4]	1.30	[0.65; 2.61]	0.946
	(28.0)		(24.0)				
High	5/38	N.E. [N.E.; N.E.]	7/37	N.E. [N.E.; N.E.]	0.69	[0.21; 2.34]	0.892
	(13.2)		(18.9)				
Sex							
(Interaction test p = 0.479)							
Female	26/107	N.E. [N.E.; N.E.]	32/126	22.2 [22.2; 22.3]	0.98	[0.57; 1.68]	0.564
	(24.3)		(25.4)				

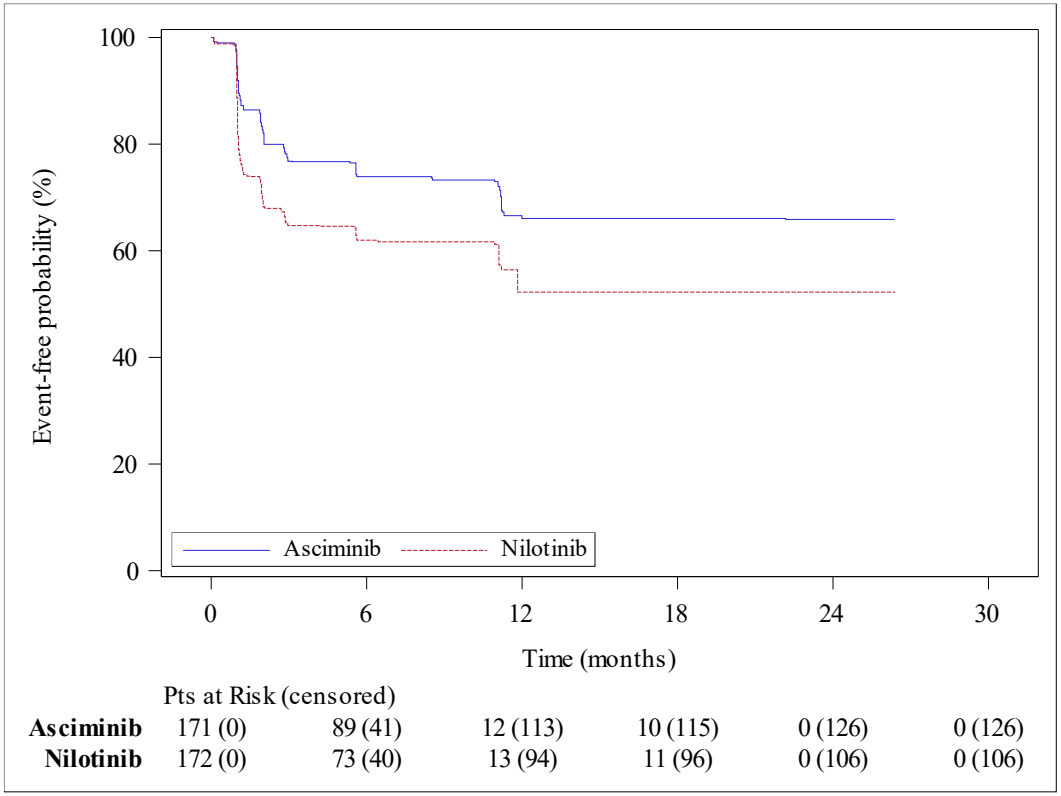
	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Male	45/177 (25.4)	N.E. [N.E.; N.E.]	45/158 (28.5)	22.3 [22.3; 22.4]	0.90	[0.58; 1.39]	0.808
Race (Interaction test p = 0.468)							
Asian	15/40 (37.5)	N.E. [N.E.; N.E.]	14/46 (30.4)	22.3 [22.3; 22.4]	1.11	[0.51; 2.44]	0.930
White	47/227 (20.7)	N.E. [N.E.; N.E.]	58/217 (26.7)	N.E. [N.E.; N.E.]	0.80	[0.53; 1.20]	0.405
Other	9/17 (52.9)	1.8 [-6.7; 10.3]	5/21 (23.8)	N.E. [N.E.; N.E.]	2.44	[0.66; 9.11]	0.292
Age groups (Interaction test p = 0.628)							
18 - < 65 years	61/237 (25.7)	N.E. [N.E.; N.E.]	67/247 (27.1)	22.3 [22.2; 22.4]	0.96	[0.67; 1.38]	0.589
65 - < 75 years	8/38 (21.1)	N.E. [N.E.; N.E.]	8/24 (33.3)	N.E. [N.E.; N.E.]	0.90	[0.26; 3.16]	0.934
>= 75 years	2/9	N.E. [N.E.; N.E.]	2/13	N.E. [N.E.; N.E.]	1.77	[0.13; 23.38]	0.901

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(22.2)		(15.4)				
Geographic region							
(Interaction test p = 0.580)							
Europe excluding Germany	30/138	N.E. [N.E.; N.E.]	36/141	22.2 [22.2; 22.3]	0.82	[0.49; 1.36]	0.789
	(21.7)		(25.5)				
Germany	19/72	N.E. [N.E.; N.E.]	16/53	N.E. [N.E.; N.E.]	0.85	[0.41; 1.76]	0.804
	(26.4)		(30.2)				
Others	22/74	N.E. [N.E.; N.E.]	26/90	N.E. [N.E.; N.E.]	1.11	[0.61; 2.02]	0.725
	(29.7)		(28.9)				

MID: Minimal important difference
N*: Number of patients included in the analysis
n: Number of patients with event. The number of patients is the mean number over all imputations rounded to the nearest integer
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
Missing baseline values are multiply imputed by simple imputation using 500 repetitions under a MAR assumption.
Two-sided 95% CI for KM percentiles are derived by the approach outlined in Moscovici and Ratitch (2017).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factor ELTS Score (IRT) and covariates baseline score and treatment arm.
P-Values are based on stratified logrank test with stratification factor ELTS Score (IRT).
Test results are combined using the Wilson-Hilferty transformation.
For the attribute ELTS Score (IRT) at randomization an unstratified Cox proportional hazard model and an unstratified log-rank teat are applied.
Data Cut/15MAY2025

Figure 3-5.1 EORTC QLQ-C30: Time to first deterioration analysis by subgroups - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

Physical functioning (MID=10): Stratification factor: ELTS based on randomization data from IRT: Low

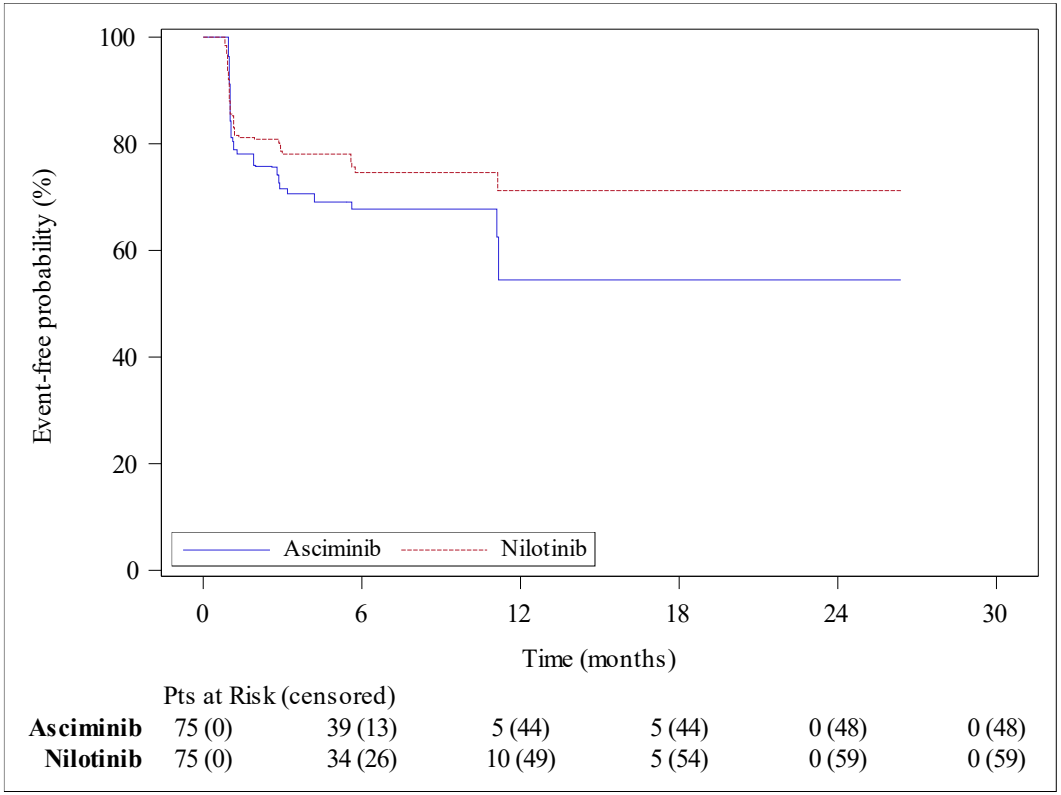


	Pts at Risk (censored)					
Asciminib	171 (0)	89 (41)	12 (113)	10 (115)	0 (126)	0 (126)
Nilotinib	172 (0)	73 (40)	13 (94)	11 (96)	0 (106)	0 (106)

Note: The number of patients at risk and the number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
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Figure 3-5.1 EORTC QLQ-C30: Time to first deterioration analysis by subgroups - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

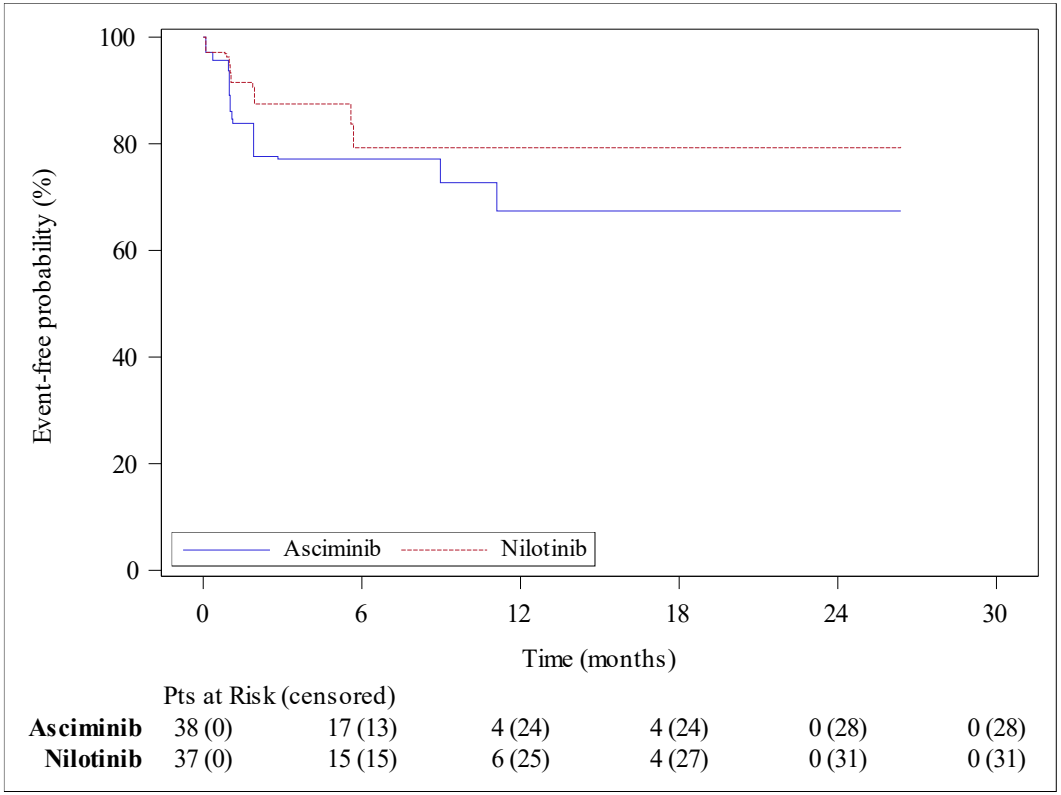
Physical functioning (MID=10): Stratification factor: ELTS based on randomization data from IRT: Intermediate



Note: The number of patients at risk and the number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Figure 3-5.1 EORTC QLQ-C30: Time to first deterioration analysis by subgroups - Sensitivity analysis (multiple imputation of missing baseline values): Kaplan-Meier plot (Full Analysis Set)

Physical functioning (MID=10): Stratification factor: ELTS based on randomization data from IRT: High



	Pts at Risk (censored)					
Asciminib	38 (0)	17 (13)	4 (24)	4 (24)	0 (28)	0 (28)
Nilotinib	37 (0)	15 (15)	6 (25)	4 (27)	0 (31)	0 (31)

Note: The number of patients at risk and the number censored at a timepoint are the mean numbers over all imputations rounded to the nearest integer
Data Cut/15MAY2025

Table 3-5.2 EORTC QLQ-CML24: Time to first deterioration analysis by subgroups - Sensitivity analysis (multiple imputation of missing baseline values) (Full Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Body Image Problems (MID=15)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.400)							
Low	66/171 (38.6)	22.3 [21.8; 22.7]	68/172 (39.5)	19.4 [9.8; 29.0]	0.88	[0.61; 1.25]	0.711
Intermediate	34/75 (45.3)	11.1 [4.7; 17.5]	31/75 (41.3)	11.0 [2.9; 19.0]	0.99	[0.59; 1.66]	0.643
High	12/38 (31.6)	N.E. [N.E.; N.E.]	12/37 (32.4)	N.E. [N.E.; N.E.]	0.98	[0.40; 2.35]	0.630
Sex							
(Interaction test p = 0.672)							
Female	50/107 (46.7)	5.7 [5.5; 6.0]	53/126 (42.1)	11.1 [4.9; 17.3]	0.99	[0.66; 1.50]	0.618
Male	62/177	22.3 [21.8; 22.7]	58/158	22.1 [22.0; 22.3]	0.90	[0.61; 1.32]	0.847

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(35.0)		(36.7)				
Race							
(Interaction test p = 0.384)							
Asian	18/40	11.1 [11.0; 11.2]	18/46	N.E. [N.E.; N.E.]	0.93	[0.47; 1.86]	0.495
	(45.0)		(39.1)				
White	91/227	22.2 [-1.8; 46.3]	87/217	11.6 [3.7; 19.4]	0.92	[0.67; 1.26]	0.775
	(40.1)		(40.1)				
Other	4/17	N.E. [N.E.; N.E.]	7/21	11.1 [11.1; 11.2]	0.89	[0.16; 4.95]	0.822
	(23.5)		(33.3)				
Age groups							
(Interaction test p = 0.826)							
18 - < 65 years	95/237	22.2 [-5.9; 50.4]	101/247	11.6 [6.3; 16.8]	0.87	[0.65; 1.17]	0.899
	(40.1)		(40.9)				
65 - < 75 years	14/38	N.E. [N.E.; N.E.]	7/24	N.E. [N.E.; N.E.]	1.73	[0.59; 5.05]	0.838
	(36.8)		(29.2)				
>= 75 years	3/9	N.E. [N.E.; N.E.]	3/13	N.E. [N.E.; N.E.]	2.26	[0.18; 28.17]	0.728
	(33.3)		(23.1)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test p = 0.441)							
Europe excluding Germany	52/138 (37.7)	N.E. [N.E.; N.E.]	57/141 (40.4)	11.6 [6.6; 16.5]	0.89	[0.60; 1.33]	0.802
Germany	35/72 (48.6)	11.1 [4.7; 17.5]	23/53 (43.4)	5.6 [-0.1; 11.3]	0.70	[0.39; 1.26]	0.838
Others	26/74 (35.1)	N.E. [N.E.; N.E.]	31/90 (34.4)	N.E. [N.E.; N.E.]	1.00	[0.58; 1.73]	0.523
Impact on Daily Life (MID=15)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.356)							
Low	52/171 (30.4)	N.E. [N.E.; N.E.]	66/172 (38.4)	19.4 [6.7; 32.2]	0.65	[0.44; 0.98]	0.292
Intermediate	19/75 (25.3)	N.E. [N.E.; N.E.]	23/75 (30.7)	N.E. [N.E.; N.E.]	0.67	[0.34; 1.32]	0.481
High	6/38	N.E. [N.E.; N.E.]	9/37	N.E. [N.E.; N.E.]	0.57	[0.18; 1.83]	0.900

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(15.8)		(24.3)				
Sex							
(Interaction test p = 0.641)							
Female	32/107	N.E. [N.E.; N.E.]	50/126	11.3 [6.8; 15.8]	0.66	[0.40; 1.07]	0.211
	(29.9)		(39.7)				
Male	45/177	N.E. [N.E.; N.E.]	47/158	N.E. [N.E.; N.E.]	0.70	[0.45; 1.10]	0.653
	(25.4)		(29.7)				
Race							
(Interaction test p = 0.416)							
Asian	15/40	N.E. [N.E.; N.E.]	13/46	N.E. [N.E.; N.E.]	1.19	[0.55; 2.59]	0.936
	(37.5)		(28.3)				
White	58/227	N.E. [N.E.; N.E.]	78/217	N.E. [N.E.; N.E.]	0.59	[0.41; 0.86]	0.038
	(25.6)		(35.9)				
Other	4/17	N.E. [N.E.; N.E.]	7/21	11.1 [11.1; 11.2]	0.64	[0.12; 3.42]	0.976
	(23.5)		(33.3)				
Age groups							
(Interaction test p = 0.352)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
18 - < 65 years	68/237 (28.7)	N.E. [N.E.; N.E.]	88/247 (35.6)	N.E. [N.E.; N.E.]	0.67	[0.47; 0.94]	0.159
65 - < 75 years	9/38 (23.7)	N.E. [N.E.; N.E.]	7/24 (29.2)	N.E. [N.E.; N.E.]	0.57	[0.17; 1.93]	0.799
>= 75 years	1/9 (11.1)	N.E. [N.E.; N.E.]	3/13 (23.1)	N.E. [N.E.; N.E.]	0.75	[0.02; 23.46]	0.764
Geographic region (Interaction test p = 0.377)							
Europe excluding Germany	36/138 (26.1)	N.E. [N.E.; N.E.]	56/141 (39.7)	11.8 [5.7; 17.9]	0.56	[0.36; 0.89]	0.036
Germany	17/72 (23.6)	N.E. [N.E.; N.E.]	15/53 (28.3)	N.E. [N.E.; N.E.]	0.58	[0.25; 1.34]	0.844
Others	24/74 (32.4)	N.E. [N.E.; N.E.]	27/90 (30.0)	N.E. [N.E.; N.E.]	1.07	[0.59; 1.95]	0.695
Impact on Worry/Mood (MID=15)							
Stratification factor: ELTS based on randomization data from IRT							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test p = 0.721)							
Low	36/171 (21.1)	N.E. [N.E.; N.E.]	36/172 (20.9)	N.E. [N.E.; N.E.]	0.85	[0.50; 1.43]	0.658
Intermediate	18/75 (24.0)	N.E. [N.E.; N.E.]	11/75 (14.7)	N.E. [N.E.; N.E.]	1.37	[0.60; 3.15]	0.661
High	4/38 (10.5)	N.E. [N.E.; N.E.]	6/37 (16.2)	N.E. [N.E.; N.E.]	0.55	[0.13; 2.27]	0.963
Sex							
(Interaction test p = 0.542)							
Female	25/107 (23.4)	N.E. [N.E.; N.E.]	21/126 (16.7)	N.E. [N.E.; N.E.]	1.23	[0.64; 2.36]	0.840
Male	33/177 (18.6)	N.E. [N.E.; N.E.]	31/158 (19.6)	N.E. [N.E.; N.E.]	0.79	[0.45; 1.36]	0.773
Race							
(Interaction test p = 0.869)							
Asian	12/40 (30.0)	N.E. [N.E.; N.E.]	8/46 (17.4)	N.E. [N.E.; N.E.]	1.48	[0.57; 3.86]	0.521

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
White	41/227 (18.1)	N.E. [N.E.; N.E.]	41/217 (18.9)	N.E. [N.E.; N.E.]	0.82	[0.50; 1.33]	0.811
Other	5/17 (29.4)	N.E. [N.E.; N.E.]	4/21 (19.0)	N.E. [N.E.; N.E.]	1.46	[0.21; 10.34]	0.947
Age groups (Interaction test p = 0.280)							
18 - < 65 years	54/237 (22.8)	N.E. [N.E.; N.E.]	48/247 (19.4)	N.E. [N.E.; N.E.]	0.97	[0.63; 1.50]	0.952
65 - < 75 years	4/38 (10.5)	N.E. [N.E.; N.E.]	3/24 (12.5)	N.E. [N.E.; N.E.]	0.76	[0.09; 6.50]	0.874
>= 75 years	0/9		2/13 (15.4)	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.
Geographic region (Interaction test p = 0.480)							
Europe excluding Germany	26/138 (18.8)	N.E. [N.E.; N.E.]	24/141 (17.0)	N.E. [N.E.; N.E.]	0.93	[0.50; 1.73]	0.646
Germany	15/72	N.E. [N.E.; N.E.]	14/53	N.E. [N.E.; N.E.]	0.49	[0.20; 1.18]	0.536

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(20.8)		(26.4)				
Others	18/74	N.E. [N.E.; N.E.]	15/90	N.E. [N.E.; N.E.]	1.40	[0.65; 2.99]	0.505
	(24.3)		(16.7)				
Symptom Burden (MID=15)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.367)							
Low	19/171	N.E. [N.E.; N.E.]	40/172	N.E. [N.E.; N.E.]	0.38	[0.21; 0.72]	0.011
	(11.1)		(23.3)				
Intermediate	12/75	N.E. [N.E.; N.E.]	12/75	N.E. [N.E.; N.E.]	0.83	[0.33; 2.04]	0.810
	(16.0)		(16.0)				
High	4/38	N.E. [N.E.; N.E.]	4/37	N.E. [N.E.; N.E.]	1.05	[0.20; 5.40]	0.620
	(10.5)		(10.8)				
Sex							
(Interaction test p = 0.676)							
Female	16/107	N.E. [N.E.; N.E.]	32/126	N.E. [N.E.; N.E.]	0.51	[0.26; 1.00]	0.121
	(15.0)		(25.4)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Male	19/177 (10.7)	N.E. [N.E.; N.E.]	24/158 (15.2)	N.E. [N.E.; N.E.]	0.56	[0.28; 1.12]	0.361
Race (Interaction test p = 0.518)							
Asian	6/40 (15.0)	N.E. [N.E.; N.E.]	13/46 (28.3)	N.E. [N.E.; N.E.]	0.49	[0.17; 1.39]	0.380
White	26/227 (11.5)	N.E. [N.E.; N.E.]	41/217 (18.9)	N.E. [N.E.; N.E.]	0.54	[0.31; 0.94]	0.094
Other	3/17 (17.6)	N.E. [N.E.; N.E.]	3/21 (14.3)	N.E. [N.E.; N.E.]	0.49	[0.05; 4.49]	0.824
Age groups (Interaction test p = 0.307)							
18 - < 65 years	30/237 (12.7)	N.E. [N.E.; N.E.]	49/247 (19.8)	N.E. [N.E.; N.E.]	0.52	[0.31; 0.87]	0.062
65 - < 75 years	4/38 (10.5)	N.E. [N.E.; N.E.]	5/24 (20.8)	N.E. [N.E.; N.E.]	0.55	[0.11; 2.61]	0.709
>= 75 years	1/9	N.E. [N.E.; N.E.]	2/13	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(11.1)		(15.4)				
Geographic region							
(Interaction test p = 0.557)							
Europe excluding Germany	14/138	N.E. [N.E.; N.E.]	27/141	N.E. [N.E.; N.E.]	0.46	[0.22; 0.94]	0.062
	(10.1)		(19.1)				
Germany	12/72	N.E. [N.E.; N.E.]	12/53	N.E. [N.E.; N.E.]	0.52	[0.19; 1.38]	0.767
	(16.7)		(22.6)				
Others	9/74	N.E. [N.E.; N.E.]	17/90	N.E. [N.E.; N.E.]	0.54	[0.22; 1.33]	0.476
	(12.2)		(18.9)				
Satisfaction with Care and Information (MID=15)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.583)							
Low	52/171	N.E. [N.E.; N.E.]	45/172	N.E. [N.E.; N.E.]	1.09	[0.71; 1.67]	0.954
	(30.4)		(26.2)				
Intermediate	29/75	11.2 [9.3; 13.2]	20/75	N.E. [N.E.; N.E.]	1.24	[0.67; 2.28]	0.973
	(38.7)		(26.7)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
High	12/38 (31.6)	N.E. [N.E.; N.E.]	8/37 (21.6)	N.E. [N.E.; N.E.]	1.52	[0.59; 3.88]	0.852
Sex							
(Interaction test p = 0.592)							
Female	40/107 (37.4)	13.2 [10.2; 16.2]	34/126 (27.0)	N.E. [N.E.; N.E.]	1.11	[0.68; 1.82]	0.752
Male	53/177 (29.9)	N.E. [N.E.; N.E.]	40/158 (25.3)	N.E. [N.E.; N.E.]	1.22	[0.79; 1.91]	0.754
Race							
(Interaction test p = 0.786)							
Asian	23/40 (57.5)	5.7 [1.3; 10.0]	13/46 (28.3)	N.E. [N.E.; N.E.]	1.56	[0.74; 3.30]	0.096
White	64/227 (28.2)	N.E. [N.E.; N.E.]	53/217 (24.4)	N.E. [N.E.; N.E.]	1.11	[0.75; 1.64]	0.790
Other	6/17 (35.3)	N.E. [N.E.; N.E.]	7/21 (33.3)	11.1 [11.0; 11.3]	0.93	[0.21; 4.16]	0.650
Age groups							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test p = 0.459)							
18 - < 65 years	82/237 (34.6)	N.E. [N.E.; N.E.]	66/247 (26.7)	N.E. [N.E.; N.E.]	1.19	[0.84; 1.69]	0.399
65 - < 75 years	10/38 (26.3)	N.E. [N.E.; N.E.]	6/24 (25.0)	N.E. [N.E.; N.E.]	0.89	[0.29; 2.71]	0.549
>= 75 years	1/9 (11.1)	N.E. [N.E.; N.E.]	1/13 (7.7)	N.E. [N.E.; N.E.]	1.52	[0.06; 37.02]	N.E.
Geographic region							
(Interaction test p = 0.305)							
Europe excluding Germany	38/138 (27.5)	N.E. [N.E.; N.E.]	38/141 (27.0)	N.E. [N.E.; N.E.]	0.88	[0.54; 1.42]	0.990
Germany	22/72 (30.6)	N.E. [N.E.; N.E.]	12/53 (22.6)	N.E. [N.E.; N.E.]	1.22	[0.55; 2.71]	0.977
Others	33/74 (44.6)	11.1 [6.3; 15.9]	23/90 (25.6)	N.E. [N.E.; N.E.]	1.80	[1.02; 3.17]	0.032
Satisfaction with Social Life (MID=15)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.476)							
Low	77/171 (45.0)	11.2 [11.0; 11.3]	79/172 (45.9)	11.1 [6.3; 15.9]	0.84	[0.60; 1.18]	0.890
Intermediate	43/75 (57.3)	5.6 [5.3; 5.9]	35/75 (46.7)	5.7 [-1.5; 13.0]	1.33	[0.82; 2.16]	0.991
High	14/38 (36.8)	N.E. [N.E.; N.E.]	11/37 (29.7)	N.E. [N.E.; N.E.]	1.23	[0.52; 2.88]	0.862
Sex							
(Interaction test p = 0.505)							
Female	52/107 (48.6)	11.1 [6.7; 15.5]	53/126 (42.1)	11.1 [5.6; 16.6]	1.01	[0.66; 1.53]	0.887
Male	82/177 (46.3)	11.1 [3.2; 19.0]	73/158 (46.2)	11.1 [2.4; 19.9]	1.02	[0.73; 1.43]	0.635
Race							
(Interaction test p = 0.660)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Asian	25/40 (62.5)	5.6 [5.5; 5.6]	19/46 (41.3)	11.3 [11.2; 11.5]	1.34	[0.70; 2.56]	0.296
White	101/227 (44.5)	11.1 [7.6; 14.6]	97/217 (44.7)	11.1 [3.7; 18.4]	0.96	[0.71; 1.29]	0.887
Other	8/17 (47.1)	11.1 [7.6; 14.6]	9/21 (42.9)	5.6 [5.4; 5.9]	0.78	[0.22; 2.71]	0.827
Age groups (Interaction test p = 0.961)							
18 - < 65 years	116/237 (48.9)	11.1 [7.8; 14.4]	111/247 (44.9)	11.1 [7.1; 15.1]	0.98	[0.74; 1.30]	0.792
65 - < 75 years	16/38 (42.1)	N.E. [N.E.; N.E.]	9/24 (37.5)	N.E. [N.E.; N.E.]	1.76	[0.66; 4.68]	0.607
>= 75 years	2/9 (22.2)	N.E. [N.E.; N.E.]	5/13 (38.5)	11.1 [-22.9; 45.2]	0.84	[0.11; 6.34]	0.931
Geographic region (Interaction test p = 0.528)							
Europe excluding Germany	64/138	11.2 [10.5; 11.9]	66/141	8.3 [0.7; 15.9]	1.00	[0.69; 1.45]	0.893

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Germany	(46.4) 32/72	11.1 [7.0; 15.3]	(46.8) 21/53	11.3 [6.1; 16.6]	0.90	[0.46; 1.76]	0.868
Others	(44.4) 38/74	5.6 [2.5; 8.7]	(39.6) 38/90	11.2 [-1.1; 23.5]	1.15	[0.72; 1.86]	0.706
	(51.4)		(42.2)				

MID: Minimal important difference
N*: Number of patients included in the analysis
n: Number of patients with event. The number of patients is the mean number over all imputations rounded to the nearest integer
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
Missing baseline values are multiply imputed by simple imputation using 500 repetitions under a MAR assumption.
Two-sided 95% CI for KM percentiles are derived by the approach outlined in Moscovici and Ratitch (2017).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factor ELTS Score (IRT) and covariates baseline score and treatment arm.
P-Values are based on stratified logrank test with stratification factor ELTS Score (IRT).
Test results are combined using the Wilson-Hilferty transformation.
For the attribute ELTS Score (IRT) at randomization an unstratified Cox proportional hazard model and an unstratified log-rank teat are applied.
Data Cut/15MAY2025

Table 3-5.3 FACT-ITEM GP5: Time to first deterioration analysis by subgroups - Sensitivity analysis (multiple imputation of missing baseline values) (Full Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
V4 (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.442)							
Low	113/171 (66.1)	1.7 [0.8; 2.6]	122/172 (70.9)	0.8 [0.5; 1.2]	0.77	[0.58; 1.00]	0.367
Intermediate	44/75 (58.7)	2.9 [-4.0; 9.8]	44/75 (58.7)	2.6 [1.3; 3.9]	0.75	[0.48; 1.16]	0.760
High	22/38 (57.9)	1.9 [1.0; 2.8]	26/37 (70.3)	1.4 [-0.2; 3.1]	0.61	[0.33; 1.11]	0.778
Sex							
(Interaction test p = 0.609)							
Female	69/107 (64.5)	1.1 [0.1; 2.1]	85/126 (67.5)	0.8 [0.4; 1.3]	0.73	[0.52; 1.02]	0.489
Male	109/177	2.2 [0.9; 3.4]	106/158	1.0 [0.3; 1.8]	0.77	[0.59; 1.02]	0.428

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(61.6)		(67.1)				
Race							
(Interaction test p = 0.583)							
Asian	24/40	2.8 [-5.4; 11.0]	27/46	2.9 [-2.1; 7.9]	1.00	[0.56; 1.80]	0.532
	(60.0)		(58.7)				
White	144/227	1.9 [0.8; 3.0]	152/217	0.8 [0.5; 1.1]	0.69	[0.54; 0.88]	0.090
	(63.4)		(70.0)				
Other	10/17	1.9 [1.3; 2.5]	12/21	1.0 [-1.0; 2.9]	0.49	[0.16; 1.45]	0.776
	(58.8)		(57.1)				
Age groups							
(Interaction test p = 0.867)							
18 - < 65 years	151/237	1.9 [1.0; 2.9]	165/247	1.0 [0.5; 1.5]	0.77	[0.61; 0.97]	0.368
	(63.7)		(66.8)				
65 - < 75 years	24/38	2.1 [1.2; 3.1]	17/24	1.9 [-0.2; 4.0]	0.61	[0.30; 1.21]	0.575
	(63.2)		(70.8)				
>= 75 years	3/9	N.E. [N.E.; N.E.]	9/13	0.8 [0.7; 0.9]	0.61	[0.10; 3.87]	0.753
	(33.3)		(69.2)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test p = 0.094)							
Europe excluding Germany	86/138 (62.3)	2.0 [0.6; 3.4]	102/141 (72.3)	0.8 [0.4; 1.2]	0.66	[0.49; 0.90]	0.073
Germany	46/72 (63.9)	1.7 [0.9; 2.4]	38/53 (71.7)	0.6 [0.4; 0.7]	0.53	[0.32; 0.86]	0.190
Others	46/74 (62.2)	2.8 [1.4; 4.2]	51/90 (56.7)	4.7 [-0.8; 10.1]	1.08	[0.71; 1.64]	0.904

MID: Minimal important difference
N*: Number of patients included in the analysis
n: Number of patients with event. The number of patients is the mean number over all imputations rounded to the nearest integer
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
Missing baseline values are multiply imputed by simple imputation using 500 repetitions under a MAR assumption.
Two-sided 95% CI for KM percentiles are derived by the approach outlined in Moscovici and Ratitch (2017).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factor ELTS Score (IRT) and covariates baseline score and treatment arm.
P-Values are based on stratified logrank test with stratification factor ELTS Score (IRT).
Test results are combined using the Wilson-Hilferty transformation.
For the attribute ELTS Score (IRT) at randomization an unstratified Cox proportional hazard model and an unstratified log-rank teat are applied.
Data Cut/15MAY2025

Table 3-5.4 PRO-CTCAE - Frequency: Time to first deterioration analysis by subgroups - Sensitivity analysis (multiple imputation of missing baseline values) (Full Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Headache - Frequency (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.392)							
Low	106/171 (62.0)	2.6 [0.6; 4.6]	128/172 (74.4)	1.0 [0.6; 1.4]	0.64	[0.49; 0.85]	0.034
Intermediate	49/75 (65.3)	2.4 [0.2; 4.6]	43/75 (57.3)	2.9 [-1.4; 7.1]	1.00	[0.65; 1.54]	0.580
High	23/38 (60.5)	4.4 [1.7; 7.2]	24/37 (64.9)	2.3 [0.1; 4.5]	0.70	[0.38; 1.31]	0.900
Sex							
(Interaction test p = 0.935)							
Female	70/107 (65.4)	1.9 [-0.0; 3.9]	85/126 (67.5)	1.2 [0.2; 2.3]	0.82	[0.58; 1.16]	0.736
Male	108/177	2.9 [1.1; 4.6]	110/158	1.4 [0.5; 2.4]	0.70	[0.52; 0.92]	0.116

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(61.0)		(69.6)				
Race							
(Interaction test p = 0.179)							
Asian	22/40	5.6 [3.3; 7.9]	34/46	2.1 [1.1; 3.2]	0.53	[0.30; 0.94]	0.086
	(55.0)		(73.9)				
White	148/227	2.1 [1.0; 3.3]	147/217	1.2 [0.4; 2.1]	0.81	[0.63; 1.03]	0.597
	(65.2)		(67.7)				
Other	7/17	N.E. [N.E.; N.E.]	14/21	0.5 [0.2; 0.8]	0.36	[0.12; 1.14]	0.295
	(41.2)		(66.7)				
Age groups							
(Interaction test p = 0.917)							
18 - < 65 years	150/237	2.8 [1.3; 4.3]	173/247	1.2 [0.4; 2.1]	0.73	[0.58; 0.92]	0.083
	(63.3)		(70.0)				
65 - < 75 years	22/38	3.8 [-0.1; 7.8]	15/24	2.9 [-4.3; 10.0]	0.73	[0.35; 1.53]	0.992
	(57.9)		(62.5)				
>= 75 years	5/9	0.8 [0.4; 1.2]	7/13	1.7 [-2.8; 6.3]	1.98	[0.34; 11.45]	0.918
	(55.6)		(53.8)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test p = 0.960)							
Europe excluding Germany	91/138 (65.9)	2.1 [0.9; 3.4]	97/141 (68.8)	1.1 [-0.2; 2.4]	0.82	[0.60; 1.11]	0.848
Germany	43/72 (59.7)	4.4 [2.6; 6.3]	34/53 (64.2)	1.1 [-0.0; 2.1]	0.58	[0.34; 0.98]	0.345
Others	43/74 (58.1)	2.8 [-0.3; 6.0]	63/90 (70.0)	1.9 [0.6; 3.3]	0.69	[0.46; 1.04]	0.165
Rash - Presence/Absence (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.401)							
Low	93/171 (54.4)	5.8 [1.1; 10.4]	99/172 (57.6)	2.7 [-0.0; 5.4]	0.68	[0.51; 0.91]	0.333
Intermediate	39/75 (52.0)	8.3 [-2.4; 19.1]	46/75 (61.3)	2.7 [1.9; 3.5]	0.58	[0.38; 0.90]	0.045
High	16/38	11.2 [8.9; 13.5]	20/37	2.9 [0.7; 5.2]	0.53	[0.27; 1.07]	0.357

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(42.1)		(54.1)				
Sex							
(Interaction test p = 0.358)							
Female	64/107	4.4 [-1.3; 10.1]	74/126	2.4 [1.3; 3.6]	0.65	[0.46; 0.93]	0.417
	(59.8)		(58.7)				
Male	84/177	11.1 [3.9; 18.3]	92/158	3.3 [0.7; 5.9]	0.63	[0.47; 0.86]	0.038
	(47.5)		(58.2)				
Race							
(Interaction test p = 0.970)							
Asian	17/40	N.E. [N.E.; N.E.]	26/46	2.9 [0.6; 5.2]	0.43	[0.22; 0.83]	0.087
	(42.5)		(56.5)				
White	125/227	5.7 [2.3; 9.0]	128/217	2.7 [1.2; 4.2]	0.68	[0.52; 0.87]	0.114
	(55.1)		(59.0)				
Other	5/17	N.E. [N.E.; N.E.]	12/21	3.4 [-0.7; 7.4]	0.54	[0.16; 1.78]	0.545
	(29.4)		(57.1)				
Age groups							
(Interaction test p = 0.995)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
18 - < 65 years	130/237 (54.9)	5.7 [1.7; 9.6]	146/247 (59.1)	2.7 [1.7; 3.6]	0.67	[0.53; 0.86]	0.089
65 - < 75 years	16/38 (42.1)	N.E. [N.E.; N.E.]	13/24 (54.2)	6.5 [1.3; 11.7]	0.53	[0.24; 1.18]	0.291
>= 75 years	2/9 (22.2)	N.E. [N.E.; N.E.]	7/13 (53.8)	1.7 [1.0; 2.4]	0.33	[0.05; 2.10]	0.213
Geographic region (Interaction test p = 0.927)							
Europe excluding Germany	78/138 (56.5)	5.2 [1.7; 8.6]	81/141 (57.4)	2.9 [0.2; 5.6]	0.71	[0.52; 0.98]	0.481
Germany	36/72 (50.0)	11.1 [-3.2; 25.5]	32/53 (60.4)	2.4 [-0.2; 5.0]	0.63	[0.38; 1.05]	0.302
Others	34/74 (45.9)	12.0 [8.8; 15.2]	52/90 (57.8)	2.7 [0.4; 5.0]	0.52	[0.33; 0.82]	0.045
Diarrhea - Frequency (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test p = 0.313)							
Low	107/171 (62.6)	1.8 [1.1; 2.5]	107/172 (62.2)	2.6 [1.7; 3.5]	1.08	[0.81; 1.44]	0.724
Intermediate	42/75 (56.0)	4.8 [-5.0; 14.6]	34/75 (45.3)	9.3 [-4.8; 23.3]	1.11	[0.69; 1.79]	0.870
High	21/38 (55.3)	2.9 [-0.4; 6.2]	18/37 (48.6)	5.4 [0.3; 10.5]	1.25	[0.64; 2.43]	0.998
Sex							
(Interaction test p = 0.747)							
Female	60/107 (56.1)	2.9 [-5.9; 11.7]	69/126 (54.8)	2.8 [-0.4; 6.1]	0.96	[0.66; 1.40]	0.697
Male	110/177 (62.1)	2.0 [1.1; 2.9]	90/158 (57.0)	3.3 [0.9; 5.7]	1.21	[0.90; 1.63]	0.610
Race							
(Interaction test p = 0.681)							
Asian	26/40 (65.0)	4.0 [0.6; 7.4]	25/46 (54.3)	4.8 [-5.8; 15.4]	1.19	[0.66; 2.15]	0.785

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
White	134/227 (59.0)	2.4 [1.1; 3.6]	124/217 (57.1)	2.9 [0.9; 4.9]	1.06	[0.82; 1.37]	0.804
Other	10/17 (58.8)	1.9 [1.2; 2.7]	10/21 (47.6)	3.2 [2.7; 3.6]	1.58	[0.53; 4.75]	0.783
Age groups (Interaction test p = 0.490)							
18 - < 65 years	142/237 (59.9)	2.1 [0.9; 3.4]	140/247 (56.7)	3.1 [1.1; 5.0]	1.10	[0.86; 1.41]	0.934
65 - < 75 years	24/38 (63.2)	3.1 [-7.7; 13.9]	12/24 (50.0)	7.4 [-7.2; 22.0]	1.28	[0.59; 2.78]	0.946
>= 75 years	4/9 (44.4)	2.8 [2.7; 2.9]	7/13 (53.8)	2.6 [1.0; 4.3]	0.84	[0.20; 3.45]	0.651
Geographic region (Interaction test p = 0.939)							
Europe excluding Germany	90/138 (65.2)	1.7 [1.1; 2.3]	84/141 (59.6)	2.8 [1.8; 3.9]	1.21	[0.88; 1.66]	0.570
Germany	34/72	12.0 [-3.5; 27.6]	25/53	6.5 [-9.9; 23.0]	0.88	[0.50; 1.56]	0.951

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Others	(47.2) 46/74 (62.2)	2.4 [0.2; 4.6]	(47.2) 49/90 (54.4)	3.6 [-2.7; 10.0]	1.26	[0.82; 1.94]	0.712
Vomiting - Frequency (MID=1)							
Stratification factor: ELTS based on randomization data from IRT (Interaction test p = 0.746)							
Low	32/171 (18.7)	N.E. [N.E.; N.E.]	53/172 (30.8)	N.E. [N.E.; N.E.]	0.51	[0.32; 0.80]	0.007
Intermediate	17/75 (22.7)	N.E. [N.E.; N.E.]	15/75 (20.0)	N.E. [N.E.; N.E.]	0.89	[0.44; 1.82]	0.536
High	5/38 (13.2)	N.E. [N.E.; N.E.]	9/37 (24.3)	N.E. [N.E.; N.E.]	0.53	[0.16; 1.72]	0.531
Sex (Interaction test p = 0.157)							
Female	22/107 (20.6)	N.E. [N.E.; N.E.]	44/126 (34.9)	N.E. [N.E.; N.E.]	0.44	[0.26; 0.75]	0.004

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Male	32/177 (18.1)	N.E. [N.E.; N.E.]	33/158 (20.9)	N.E. [N.E.; N.E.]	0.81	[0.49; 1.33]	0.834
Race (Interaction test p = 0.692)							
Asian	10/40 (25.0)	20.4 [20.3; 20.4]	16/46 (34.8)	N.E. [N.E.; N.E.]	0.53	[0.23; 1.21]	0.249
White	41/227 (18.1)	N.E. [N.E.; N.E.]	51/217 (23.5)	N.E. [N.E.; N.E.]	0.66	[0.43; 1.00]	0.101
Other	3/17 (17.6)	N.E. [N.E.; N.E.]	9/21 (42.9)	15.7 [13.2; 18.2]	0.44	[0.10; 2.02]	0.470
Age groups (Interaction test p = 0.584)							
18 - < 65 years	45/237 (19.0)	N.E. [N.E.; N.E.]	71/247 (28.7)	N.E. [N.E.; N.E.]	0.57	[0.39; 0.84]	0.008
65 - < 75 years	8/38 (21.1)	N.E. [N.E.; N.E.]	4/24 (16.7)	N.E. [N.E.; N.E.]	0.99	[0.28; 3.49]	0.336
>= 75 years	1/9		2/13	N.E. [N.E.; N.E.]	1.14	[0.05; 25.49]	0.149

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(11.1)		(15.4)				
Geographic region							
(Interaction test p = 0.732)							
Europe excluding Germany	29/138	N.E. [N.E.; N.E.]	31/141	N.E. [N.E.; N.E.]	0.82	[0.49; 1.37]	0.920
	(21.0)		(22.0)				
Germany	8/72	N.E. [N.E.; N.E.]	10/53	N.E. [N.E.; N.E.]	0.45	[0.17; 1.20]	0.195
	(11.1)		(18.9)				
Others	17/74	N.E. [N.E.; N.E.]	36/90	N.E. [N.E.; N.E.]	0.45	[0.25; 0.83]	0.014
	(23.0)		(40.0)				
Nausea - Frequency (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.466)							
Low	82/171	13.9 [6.5; 21.2]	94/172	3.5 [-3.2; 10.3]	0.76	[0.55; 1.03]	0.209
	(48.0)		(54.7)				
Intermediate	30/75	22.1 [22.1; 22.2]	38/75	5.6 [0.1; 11.1]	0.60	[0.36; 0.99]	0.074
	(40.0)		(50.7)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
High	15/38 (39.5)	N.E. [N.E.; N.E.]	19/37 (51.4)	5.6 [-3.0; 14.2]	0.71	[0.35; 1.43]	0.985
Sex							
(Interaction test p = 0.492)							
Female	55/107 (51.4)	11.2 [1.6; 20.8]	75/126 (59.5)	1.9 [0.5; 3.4]	0.61	[0.42; 0.89]	0.055
Male	72/177 (40.7)	25.9 [25.8; 25.9]	75/158 (47.5)	11.2 [4.0; 18.4]	0.81	[0.58; 1.13]	0.375
Race							
(Interaction test p = 0.187)							
Asian	17/40 (42.5)	N.E. [N.E.; N.E.]	23/46 (50.0)	5.6 [1.6; 9.6]	0.72	[0.37; 1.39]	0.752
White	102/227 (44.9)	22.1 [13.8; 30.5]	117/217 (53.9)	4.0 [-0.1; 8.1]	0.71	[0.54; 0.95]	0.046
Other	8/17 (47.1)	2.8 [1.8; 3.9]	11/21 (52.4)	18.5 [-4.4; 41.3]	0.50	[0.16; 1.50]	0.835
Age groups							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test p = 0.993)							
18 - < 65 years	107/237 (45.1)	25.9 [4.9; 46.8]	130/247 (52.6)	5.0 [-0.5; 10.4]	0.74	[0.57; 0.97]	0.073
65 - < 75 years	18/38 (47.4)	15.7 [9.8; 21.6]	14/24 (58.3)	2.1 [-2.5; 6.7]	0.51	[0.23; 1.12]	0.311
>= 75 years	2/9 (22.2)	N.E. [N.E.; N.E.]	6/13 (46.2)	1.2 [-12.0; 14.3]	0.35	[0.04; 2.77]	0.318
Geographic region							
(Interaction test p = 0.386)							
Europe excluding Germany	66/138 (47.8)	15.7 [6.0; 25.4]	79/141 (56.0)	3.1 [-0.4; 6.6]	0.70	[0.50; 0.99]	0.082
Germany	32/72 (44.4)	25.9 [-7.7; 59.4]	29/53 (54.7)	4.0 [-0.0; 8.1]	0.62	[0.36; 1.08]	0.189
Others	29/74 (39.2)	N.E. [N.E.; N.E.]	41/90 (45.6)	11.1 [1.5; 20.6]	0.79	[0.48; 1.29]	0.776
Edema - Frequency (MID=1)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.990)							
Low	64/171 (37.4)	N.E. [N.E.; N.E.]	76/172 (44.2)	14.9 [9.9; 19.8]	0.79	[0.56; 1.12]	0.437
Intermediate	32/75 (42.7)	22.1 [22.1; 22.2]	25/75 (33.3)	N.E. [N.E.; N.E.]	1.17	[0.67; 2.04]	0.883
High	17/38 (44.7)	16.6 [-2.6; 35.9]	16/37 (43.2)	16.7 [12.2; 21.1]	0.98	[0.48; 1.98]	0.505
Sex							
(Interaction test p = 0.617)							
Female	54/107 (50.5)	9.3 [0.5; 18.0]	57/126 (45.2)	11.1 [3.6; 18.6]	0.97	[0.66; 1.44]	0.501
Male	59/177 (33.3)	N.E. [N.E.; N.E.]	60/158 (38.0)	20.4 [12.1; 28.7]	0.87	[0.60; 1.25]	0.961
Race							
(Interaction test p = 0.977)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Asian	19/40 (47.5)	10.2 [6.5; 13.9]	25/46 (54.3)	5.4 [-1.2; 12.0]	0.78	[0.42; 1.43]	0.917
White	89/227 (39.2)	22.1 [22.1; 22.2]	83/217 (38.2)	24.9 [14.3; 35.5]	0.99	[0.72; 1.35]	0.502
Other	5/17 (29.4)	N.E. [N.E.; N.E.]	9/21 (42.9)	13.9 [11.7; 16.1]	0.52	[0.16; 1.70]	0.813
Age groups (Interaction test p = 0.826)							
18 - < 65 years	94/237 (39.7)	22.1 [22.1; 22.2]	104/247 (42.1)	15.7 [10.6; 20.8]	0.88	[0.66; 1.18]	0.971
65 - < 75 years	17/38 (44.7)	N.E. [N.E.; N.E.]	9/24 (37.5)	20.4 [20.3; 20.5]	1.13	[0.47; 2.72]	0.866
>= 75 years	2/9 (22.2)	N.E. [N.E.; N.E.]	5/13 (38.5)	N.E. [N.E.; N.E.]	0.46	[0.05; 3.89]	0.787
Geographic region (Interaction test p = 0.261)							
Europe excluding Germany	49/138	N.E. [N.E.; N.E.]	53/141	24.9 [14.5; 35.3]	0.89	[0.60; 1.33]	0.931

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(35.5)		(37.6)				
Germany	30/72	22.1 [22.1; 22.2]	21/53	15.7 [2.6; 28.9]	0.98	[0.54; 1.80]	0.604
	(41.7)		(39.6)				
Others	35/74	11.2 [2.5; 19.9]	43/90	11.1 [3.9; 18.3]	0.95	[0.60; 1.52]	0.433
	(47.3)		(47.8)				
Muscle Pain - Frequency (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.776)							
Low	111/171	1.2 [0.4; 2.1]	120/172	1.0 [0.6; 1.5]	0.87	[0.66; 1.15]	0.809
	(64.9)		(69.8)				
Intermediate	55/75	1.0 [0.7; 1.3]	48/75	2.6 [0.6; 4.6]	1.16	[0.77; 1.75]	0.981
	(73.3)		(64.0)				
High	20/38	1.1 [0.7; 1.5]	25/37	1.7 [0.8; 2.6]	0.79	[0.42; 1.48]	0.961
	(52.6)		(67.6)				
Sex							
(Interaction test p = 0.600)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Female	76/107 (71.0)	0.8 [0.4; 1.2]	88/126 (69.8)	1.0 [0.3; 1.6]	0.98	[0.70; 1.37]	0.811
Male	110/177 (62.1)	1.2 [0.7; 1.8]	105/158 (66.5)	1.5 [0.2; 2.8]	0.92	[0.69; 1.23]	0.821
Race (Interaction test p = 0.787)							
Asian	23/40 (57.5)	3.1 [-7.4; 13.5]	36/46 (78.3)	1.0 [0.7; 1.4]	0.65	[0.38; 1.13]	0.104
White	152/227 (67.0)	1.0 [0.6; 1.3]	144/217 (66.4)	1.2 [0.4; 2.1]	0.99	[0.77; 1.27]	0.774
Other	11/17 (64.7)	1.0 [0.2; 1.8]	12/21 (57.1)	0.6 [-1.8; 3.0]	0.71	[0.26; 1.93]	0.788
Age groups (Interaction test p = 0.444)							
18 - < 65 years	154/237 (65.0)	1.1 [0.5; 1.6]	166/247 (67.2)	1.2 [0.5; 1.9]	0.93	[0.73; 1.17]	0.922
65 - < 75 years	27/38	0.8 [0.2; 1.3]	19/24	1.7 [0.1; 3.3]	0.74	[0.37; 1.47]	0.798

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(71.1)		(79.2)				
>= 75 years	6/9	1.5 [0.7; 2.4]	7/13	2.4 [-3.4; 8.3]	0.67	[0.14; 3.29]	0.781
	(66.7)		(53.8)				
Geographic region							
(Interaction test p = 0.690)							
Europe excluding Germany	94/138	1.0 [0.5; 1.5]	92/141	1.2 [0.4; 2.0]	1.02	[0.75; 1.39]	0.682
	(68.1)		(65.2)				
Germany	45/72	0.8 [-0.0; 1.7]	34/53	1.1 [-0.4; 2.5]	0.88	[0.52; 1.48]	0.819
	(62.5)		(64.2)				
Others	47/74	1.4 [-0.7; 3.6]	66/90	1.2 [0.1; 2.4]	0.82	[0.55; 1.22]	0.422
	(63.5)		(73.3)				
Increased Sweating - Frequency (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.549)							
Low	94/171	5.0 [-0.9; 10.9]	95/172	8.3 [1.9; 14.8]	1.01	[0.75; 1.36]	0.698
	(55.0)		(55.2)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Intermediate	37/75 (49.3)	11.2 [-0.2; 22.6]	31/75 (41.3)	19.4 [5.1; 33.8]	1.15	[0.67; 1.95]	0.862
High	16/38 (42.1)	13.9 [5.0; 22.7]	14/37 (37.8)	N.E. [N.E.; N.E.]	1.22	[0.54; 2.74]	0.882
Sex							
(Interaction test p = 0.567)							
Female	60/107 (56.1)	5.1 [1.0; 9.3]	65/126 (51.6)	7.4 [0.3; 14.6]	1.05	[0.72; 1.54]	0.855
Male	87/177 (49.2)	11.1 [1.4; 20.8]	75/158 (47.5)	13.9 [6.4; 21.4]	1.10	[0.79; 1.54]	0.829
Race							
(Interaction test p = 0.741)							
Asian	15/40 (37.5)	N.E. [N.E.; N.E.]	23/46 (50.0)	11.1 [8.0; 14.2]	0.65	[0.33; 1.30]	0.482
White	124/227 (54.6)	5.7 [-0.2; 11.5]	105/217 (48.4)	11.2 [3.1; 19.2]	1.14	[0.86; 1.51]	0.631
Other	8/17	1.9 [-2.1; 6.0]	12/21	3.3 [-1.3; 7.8]	1.22	[0.41; 3.61]	0.751

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(47.1)		(57.1)				
Age groups							
(Interaction test p = 0.873)							
18 - < 65 years	123/237	8.4 [-0.9; 17.7]	123/247	11.1 [6.8; 15.4]	1.05	[0.81; 1.38]	0.899
	(51.9)		(49.8)				
65 - < 75 years	21/38	6.5 [-2.4; 15.4]	10/24	19.4 [19.4; 19.5]	0.97	[0.41; 2.30]	0.761
	(55.3)		(41.7)				
>= 75 years	3/9	N.E. [N.E.; N.E.]	6/13	4.7 [3.3; 6.0]	0.33	[0.04; 2.52]	0.642
	(33.3)		(46.2)				
Geographic region							
(Interaction test p = 0.934)							
Europe excluding Germany	74/138	5.6 [-2.9; 14.2]	74/141	10.4 [5.6; 15.3]	1.08	[0.76; 1.52]	0.912
	(53.6)		(52.5)				
Germany	42/72	5.1 [-4.0; 14.3]	29/53	1.2 [-1.5; 4.0]	0.72	[0.42; 1.24]	0.881
	(58.3)		(54.7)				
Others	31/74	N.E. [N.E.; N.E.]	37/90	N.E. [N.E.; N.E.]	1.00	[0.60; 1.65]	0.514
	(41.9)		(41.1)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			

MID: Minimal important difference
N*: Number of patients included in the analysis
n: Number of patients with event. The number of patients is the mean number over all imputations rounded to the nearest integer
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
Missing baseline values are multiply imputed by simple imputation using 500 repetitions under a MAR assumption.
Two-sided 95% CI for KM percentiles are derived by the approach outlined in Moscovici and Ratitch (2017).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factor ELTS Score (IRT) and covariates baseline score and treatment arm.
P-Values are based on stratified logrank test with stratification factor ELTS Score (IRT).
Test results are combined using the Wilson-Hilferty transformation.
For the attribute ELTS Score (IRT) at randomization an unstratified Cox proportional hazard model and an unstratified log-rank teat are applied.
Data Cut/15MAY2025

Table 3-5.5 PRO-CTCAE - Severity: Time to first deterioration analysis by subgroups - Sensitivity analysis (multiple imputation of missing baseline values) (Full Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Fatigue - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.665)							
Low	110/171 (64.3)	1.4 [0.6; 2.3]	111/172 (64.5)	1.1 [-0.4; 2.7]	0.90	[0.67; 1.21]	0.805
Intermediate	45/75 (60.0)	4.9 [-2.8; 12.6]	44/75 (58.7)	2.9 [1.2; 4.6]	0.79	[0.50; 1.25]	0.861
High	17/38 (44.7)	11.2 [6.4; 16.0]	18/37 (48.6)	12.9 [9.1; 16.8]	0.64	[0.31; 1.33]	0.958
Sex							
(Interaction test p = 0.590)							
Female	67/107 (62.6)	1.9 [-2.4; 6.2]	76/126 (60.3)	2.8 [0.5; 5.1]	0.85	[0.59; 1.23]	0.885
Male	105/177	2.8 [-1.1; 6.7]	97/158	1.7 [-0.4; 3.7]	0.87	[0.64; 1.17]	0.965

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(59.3)		(61.4)				
Race							
(Interaction test p = 0.386)							
Asian	25/40	2.0 [-1.2; 5.3]	28/46	5.6 [2.1; 9.1]	0.77	[0.42; 1.40]	0.654
	(62.5)		(60.9)				
White	138/227	2.9 [-1.1; 6.8]	137/217	1.2 [-0.1; 2.5]	0.85	[0.65; 1.11]	0.842
	(60.8)		(63.1)				
Other	9/17	2.1 [0.9; 3.3]	9/21	12.9 [12.9; 13.0]	0.57	[0.11; 2.81]	0.980
	(52.9)		(42.9)				
Age groups							
(Interaction test p = 0.678)							
18 - < 65 years	147/237	2.1 [0.6; 3.7]	153/247	2.4 [0.8; 4.0]	0.87	[0.68; 1.12]	0.848
	(62.0)		(61.9)				
65 - < 75 years	21/38	13.9 [-1.7; 29.5]	16/24	0.8 [-0.1; 1.6]	0.70	[0.32; 1.53]	0.502
	(55.3)		(66.7)				
>= 75 years	4/9	11.2 [5.6; 16.8]	5/13	N.E. [N.E.; N.E.]	0.64	[0.07; 5.40]	0.740
	(44.4)		(38.5)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test p = 0.752)							
Europe excluding Germany	84/138 (60.9)	3.1 [-0.6; 6.7]	89/141 (63.1)	1.7 [0.2; 3.2]	0.81	[0.58; 1.13]	0.886
Germany	45/72 (62.5)	1.2 [-3.3; 5.8]	33/53 (62.3)	0.8 [0.2; 1.4]	0.65	[0.38; 1.14]	0.913
Others	43/74 (58.1)	2.8 [-3.6; 9.2]	52/90 (57.8)	5.7 [-0.9; 12.3]	0.94	[0.60; 1.46]	0.618
Headache - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.715)							
Low	108/171 (63.2)	2.6 [1.4; 3.8]	119/172 (69.2)	1.2 [0.5; 1.9]	0.73	[0.55; 0.96]	0.365
Intermediate	45/75 (60.0)	2.9 [1.0; 4.7]	43/75 (57.3)	3.5 [0.1; 6.9]	0.91	[0.58; 1.41]	0.677
High	22/38	3.7 [1.0; 6.5]	23/37	2.1 [-1.4; 5.7]	0.75	[0.40; 1.40]	0.974

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(57.9)		(62.2)				
Sex							
(Interaction test p = 0.966)							
Female	72/107	1.7 [0.7; 2.7]	83/126	1.5 [-0.1; 3.1]	0.87	[0.62; 1.24]	0.883
	(67.3)		(65.9)				
Male	104/177	3.5 [1.6; 5.4]	102/158	1.7 [-0.3; 3.7]	0.74	[0.56; 0.99]	0.332
	(58.8)		(64.6)				
Race							
(Interaction test p = 0.254)							
Asian	23/40	5.6 [1.6; 9.6]	33/46	2.0 [-0.3; 4.4]	0.65	[0.37; 1.15]	0.316
	(57.5)		(71.7)				
White	146/227	2.4 [1.2; 3.5]	139/217	1.5 [0.1; 2.9]	0.84	[0.66; 1.08]	0.964
	(64.3)		(64.1)				
Other	7/17	N.E. [N.E.; N.E.]	14/21	2.1 [0.6; 3.6]	0.31	[0.09; 1.05]	0.286
	(41.2)		(66.7)				
Age groups							
(Interaction test p = 0.767)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
18 - < 65 years	149/237 (62.9)	2.6 [1.4; 3.8]	164/247 (66.4)	1.5 [0.3; 2.6]	0.79	[0.62; 1.00]	0.378
65 - < 75 years	22/38 (57.9)	3.8 [-0.5; 8.2]	14/24 (58.3)	3.1 [-0.8; 6.9]	0.79	[0.37; 1.71]	0.647
>= 75 years	5/9 (55.6)	1.0 [0.9; 1.1]	7/13 (53.8)	1.7 [0.4; 3.0]	1.90	[0.25; 14.18]	0.917
Geographic region (Interaction test p = 0.799)							
Europe excluding Germany	87/138 (63.0)	2.6 [1.0; 4.2]	90/141 (63.8)	1.7 [0.0; 3.4]	0.82	[0.60; 1.12]	0.947
Germany	46/72 (63.9)	3.7 [1.3; 6.1]	34/53 (64.2)	1.1 [0.1; 2.0]	0.60	[0.36; 1.01]	0.495
Others	43/74 (58.1)	2.6 [1.2; 4.0]	61/90 (67.8)	2.8 [1.0; 4.6]	0.78	[0.52; 1.18]	0.572
Vomiting - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test p = 0.928)							
Low	31/171 (18.1)	N.E. [N.E.; N.E.]	51/172 (29.7)	N.E. [N.E.; N.E.]	0.53	[0.34; 0.84]	0.013
Intermediate	15/75 (20.0)	N.E. [N.E.; N.E.]	14/75 (18.7)	N.E. [N.E.; N.E.]	0.89	[0.42; 1.89]	0.462
High	5/38 (13.2)	N.E. [N.E.; N.E.]	7/37 (18.9)	N.E. [N.E.; N.E.]	0.68	[0.20; 2.29]	0.936
Sex							
(Interaction test p = 0.360)							
Female	20/107 (18.7)	N.E. [N.E.; N.E.]	38/126 (30.2)	N.E. [N.E.; N.E.]	0.48	[0.28; 0.84]	0.017
Male	31/177 (17.5)	N.E. [N.E.; N.E.]	33/158 (20.9)	N.E. [N.E.; N.E.]	0.78	[0.47; 1.29]	0.671
Race							
(Interaction test p = 0.378)							
Asian	9/40 (22.5)	20.4 [20.3; 20.4]	13/46 (28.3)	N.E. [N.E.; N.E.]	0.74	[0.30; 1.83]	0.987

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
White	39/227 (17.2)	N.E. [N.E.; N.E.]	51/217 (23.5)	N.E. [N.E.; N.E.]	0.63	[0.42; 0.97]	0.063
Other	3/17 (17.6)	N.E. [N.E.; N.E.]	7/21 (33.3)	18.5 [18.4; 18.6]	0.49	[0.10; 2.31]	0.596
Age groups (Interaction test p = 0.999)							
18 - < 65 years	42/237 (17.7)	N.E. [N.E.; N.E.]	67/247 (27.1)	N.E. [N.E.; N.E.]	0.59	[0.40; 0.87]	0.014
65 - < 75 years	8/38 (21.1)	N.E. [N.E.; N.E.]	3/24 (12.5)	N.E. [N.E.; N.E.]	1.41	[0.36; 5.55]	0.958
>= 75 years	1/9 (11.1)		2/13 (15.4)	N.E. [N.E.; N.E.]	1.10	[0.05; 22.35]	N.E.
Geographic region (Interaction test p = 0.794)							
Europe excluding Germany	27/138 (19.6)	N.E. [N.E.; N.E.]	31/141 (22.0)	N.E. [N.E.; N.E.]	0.78	[0.46; 1.33]	0.728
Germany	8/72	N.E. [N.E.; N.E.]	10/53	N.E. [N.E.; N.E.]	0.47	[0.18; 1.25]	0.230

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Others	(11.1) 16/74 (21.6)	N.E. [N.E.; N.E.]	(18.9) 31/90 (34.4)	N.E. [N.E.; N.E.]	0.51	[0.27; 0.96]	0.054
Nausea - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT (Interaction test p = 0.324)							
Low	77/171 (45.0)	N.E. [N.E.; N.E.]	93/172 (54.1)	4.0 [-2.3; 10.2]	0.74	[0.54; 1.02]	0.135
Intermediate	29/75 (38.7)	22.1 [22.1; 22.2]	37/75 (49.3)	8.3 [4.1; 12.6]	0.61	[0.37; 1.02]	0.099
High	14/38 (36.8)	N.E. [N.E.; N.E.]	19/37 (51.4)	4.5 [-4.7; 13.7]	0.70	[0.34; 1.45]	0.721
Sex (Interaction test p = 0.900)							
Female	52/107 (48.6)	15.7 [3.9; 27.5]	73/126 (57.9)	2.9 [0.9; 5.0]	0.64	[0.44; 0.95]	0.073

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Male	69/177 (39.0)	N.E. [N.E.; N.E.]	76/158 (48.1)	11.2 [5.8; 16.5]	0.77	[0.55; 1.08]	0.193
Race (Interaction test p = 0.246)							
Asian	15/40 (37.5)	N.E. [N.E.; N.E.]	22/46 (47.8)	5.6 [2.5; 8.7]	0.69	[0.35; 1.38]	0.593
White	97/227 (42.7)	N.E. [N.E.; N.E.]	116/217 (53.5)	5.0 [1.2; 8.7]	0.70	[0.53; 0.93]	0.027
Other	8/17 (47.1)	8.3 [-1.3; 18.0]	11/21 (52.4)	3.3 [-14.4; 21.0]	0.61	[0.20; 1.83]	0.943
Age groups (Interaction test p = 0.196)							
18 - < 65 years	100/237 (42.2)	N.E. [N.E.; N.E.]	131/247 (53.0)	5.0 [0.1; 9.8]	0.70	[0.54; 0.92]	0.020
65 - < 75 years	17/38 (44.7)	N.E. [N.E.; N.E.]	12/24 (50.0)	8.5 [-1.0; 18.1]	0.65	[0.29; 1.48]	0.814
>= 75 years	3/9	N.E. [N.E.; N.E.]	5/13	8.4 [-33.2; 50.0]	0.39	[0.05; 3.28]	0.575

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(33.3)		(38.5)				
Geographic region							
(Interaction test p = 0.666)							
Europe excluding Germany	62/138	22.1 [6.1; 38.2]	78/141	4.0 [-1.2; 9.1]	0.68	[0.48; 0.97]	0.056
	(44.9)		(55.3)				
Germany	30/72	N.E. [N.E.; N.E.]	30/53	4.5 [-0.0; 9.1]	0.58	[0.34; 1.01]	0.102
	(41.7)		(56.6)				
Others	28/74	N.E. [N.E.; N.E.]	40/90	19.4 [-8.2; 47.0]	0.81	[0.49; 1.33]	0.865
	(37.8)		(44.4)				
Edema - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.349)							
Low	57/171	N.E. [N.E.; N.E.]	66/172	N.E. [N.E.; N.E.]	0.82	[0.57; 1.17]	0.562
	(33.3)		(38.4)				
Intermediate	29/75	22.1 [22.1; 22.2]	27/75	N.E. [N.E.; N.E.]	0.97	[0.56; 1.67]	0.536
	(38.7)		(36.0)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
High	14/38 (36.8)	N.E. [N.E.; N.E.]	15/37 (40.5)	16.7 [16.6; 16.8]	0.82	[0.38; 1.75]	0.660
Sex							
(Interaction test p = 0.839)							
Female	50/107 (46.7)	N.E. [N.E.; N.E.]	54/126 (42.9)	11.1 [5.4; 16.8]	0.94	[0.63; 1.40]	0.485
Male	50/177 (28.2)	N.E. [N.E.; N.E.]	54/158 (34.2)	N.E. [N.E.; N.E.]	0.81	[0.54; 1.20]	0.539
Race							
(Interaction test p = 0.953)							
Asian	16/40 (40.0)	N.E. [N.E.; N.E.]	22/46 (47.8)	10.2 [0.5; 19.9]	0.66	[0.34; 1.28]	0.511
White	80/227 (35.2)	N.E. [N.E.; N.E.]	78/217 (35.9)	N.E. [N.E.; N.E.]	0.94	[0.68; 1.30]	0.700
Other	4/17 (23.5)	N.E. [N.E.; N.E.]	8/21 (38.1)	N.E. [N.E.; N.E.]	0.45	[0.13; 1.60]	0.444
Age groups							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test p = 0.965)							
18 - < 65 years	83/237 (35.0)	N.E. [N.E.; N.E.]	93/247 (37.7)	N.E. [N.E.; N.E.]	0.88	[0.65; 1.20]	0.936
65 - < 75 years	15/38 (39.5)	N.E. [N.E.; N.E.]	9/24 (37.5)	N.E. [N.E.; N.E.]	0.91	[0.38; 2.17]	0.419
>= 75 years	1/9 (11.1)	N.E. [N.E.; N.E.]	6/13 (46.2)	1.7 [-1.2; 4.6]	0.21	[0.02; 2.65]	0.177
Geographic region							
(Interaction test p = 0.259)							
Europe excluding Germany	42/138 (30.4)	N.E. [N.E.; N.E.]	50/141 (35.5)	N.E. [N.E.; N.E.]	0.81	[0.53; 1.24]	0.567
Germany	28/72 (38.9)	22.1 [22.1; 22.2]	21/53 (39.6)	16.7 [2.2; 31.2]	0.93	[0.51; 1.71]	0.543
Others	30/74 (40.5)	N.E. [N.E.; N.E.]	37/90 (41.1)	N.E. [N.E.; N.E.]	0.86	[0.52; 1.42]	0.751
Muscle Pain - Severity (MID=1)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.624)							
Low	106/171 (62.0)	1.7 [0.3; 3.2]	121/172 (70.3)	1.1 [0.5; 1.7]	0.81	[0.61; 1.07]	0.281
Intermediate	50/75 (66.7)	1.1 [0.6; 1.5]	46/75 (61.3)	2.8 [1.6; 4.1]	1.12	[0.73; 1.71]	0.769
High	18/38 (47.4)	3.7 [-2.7; 10.2]	24/37 (64.9)	2.1 [0.5; 3.7]	0.70	[0.37; 1.33]	0.665
Sex							
(Interaction test p = 0.461)							
Female	70/107 (65.4)	1.0 [0.3; 1.8]	88/126 (69.8)	1.2 [0.5; 2.0]	0.85	[0.60; 1.20]	0.600
Male	104/177 (58.8)	1.9 [0.1; 3.7]	104/158 (65.8)	2.0 [0.3; 3.8]	0.89	[0.67; 1.18]	0.756
Race							
(Interaction test p = 0.983)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Asian	21/40 (52.5)	9.3 [-3.7; 22.3]	35/46 (76.1)	1.1 [-0.1; 2.2]	0.62	[0.35; 1.09]	0.058
White	142/227 (62.6)	1.2 [0.5; 2.0]	142/217 (65.4)	1.5 [0.3; 2.7]	0.91	[0.71; 1.17]	1.000
Other	11/17 (64.7)	1.0 [0.2; 1.8]	14/21 (66.7)	2.1 [-0.6; 4.8]	0.66	[0.24; 1.77]	0.989
Age groups (Interaction test p = 0.364)							
18 - < 65 years	144/237 (60.8)	1.6 [0.7; 2.6]	166/247 (67.2)	1.4 [0.7; 2.2]	0.86	[0.68; 1.09]	0.419
65 - < 75 years	25/38 (65.8)	1.5 [0.7; 2.2]	18/24 (75.0)	2.1 [0.6; 3.6]	0.72	[0.35; 1.47]	0.699
>= 75 years	6/9 (66.7)	1.1 [0.2; 1.9]	8/13 (61.5)	4.3 [-0.6; 9.1]	0.92	[0.21; 3.93]	0.807
Geographic region (Interaction test p = 0.451)							
Europe excluding Germany	86/138	1.5 [0.6; 2.5]	91/141	1.5 [0.0; 2.9]	0.91	[0.67; 1.25]	0.847

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(62.3)		(64.5)				
Germany	44/72	0.8 [-0.3; 1.9]	36/53	1.1 [0.5; 1.6]	0.86	[0.51; 1.42]	0.939
	(61.1)		(67.9)				
Others	44/74	2.4 [0.1; 4.7]	65/90	2.0 [0.7; 3.4]	0.80	[0.53; 1.20]	0.284
	(59.5)		(72.2)				
Pruritus - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.849)							
Low	107/171	3.5 [2.1; 5.0]	128/172	1.2 [0.7; 1.8]	0.64	[0.49; 0.83]	0.011
	(62.6)		(74.4)				
Intermediate	47/75	3.1 [1.3; 4.8]	49/75	2.2 [1.3; 3.0]	0.68	[0.44; 1.03]	0.292
	(62.7)		(65.3)				
High	18/38	11.1 [-2.6; 24.8]	29/37	1.5 [0.3; 2.6]	0.45	[0.24; 0.82]	0.035
	(47.4)		(78.4)				
Sex							
(Interaction test p = 0.785)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Female	66/107 (61.7)	3.4 [1.7; 5.0]	89/126 (70.6)	1.1 [0.2; 2.0]	0.57	[0.40; 0.79]	0.007
Male	107/177 (60.5)	3.5 [1.6; 5.5]	117/158 (74.1)	1.7 [1.1; 2.3]	0.67	[0.51; 0.88]	0.039
Race (Interaction test p = 0.527)							
Asian	17/40 (42.5)	N.E. [N.E.; N.E.]	32/46 (69.6)	1.7 [0.8; 2.6]	0.40	[0.21; 0.75]	0.022
White	145/227 (63.9)	3.1 [1.8; 4.3]	160/217 (73.7)	1.5 [0.9; 2.1]	0.66	[0.52; 0.84]	0.007
Other	10/17 (58.8)	3.4 [0.3; 6.4]	14/21 (66.7)	1.3 [-0.7; 3.4]	0.61	[0.21; 1.74]	0.907
Age groups (Interaction test p = 0.700)							
18 - < 65 years	145/237 (61.2)	3.4 [1.7; 5.0]	175/247 (70.9)	1.5 [1.0; 2.0]	0.66	[0.52; 0.83]	0.006
65 - < 75 years	23/38	4.0 [2.4; 5.5]	20/24	1.1 [-1.9; 4.2]	0.51	[0.26; 0.98]	0.106

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(60.5)		(83.3)				
>= 75 years	4/9	2.1 [2.0; 2.2]	10/13	0.6 [0.5; 0.6]	0.31	[0.07; 1.33]	0.187
	(44.4)		(76.9)				
Geographic region							
(Interaction test p = 0.344)							
Europe excluding Germany	86/138	3.8 [2.2; 5.3]	104/141	1.5 [0.7; 2.2]	0.64	[0.47; 0.87]	0.019
	(62.3)		(73.8)				
Germany	44/72	2.8 [-0.7; 6.2]	39/53	1.2 [0.6; 1.9]	0.60	[0.37; 0.97]	0.173
	(61.1)		(73.6)				
Others	42/74	3.4 [-0.6; 7.3]	63/90	1.2 [-0.3; 2.8]	0.65	[0.43; 0.98]	0.098
	(56.8)		(70.0)				
Increased Sweating - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.367)							
Low	88/171	8.6 [-2.8; 20.1]	88/172	11.2 [0.7; 21.6]	1.01	[0.74; 1.38]	0.658
	(51.5)		(51.2)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Intermediate	35/75 (46.7)	N.E. [N.E.; N.E.]	29/75 (38.7)	19.4 [13.1; 25.8]	1.05	[0.62; 1.80]	0.714
High	13/38 (34.2)	N.E. [N.E.; N.E.]	14/37 (37.8)	N.E. [N.E.; N.E.]	0.92	[0.40; 2.10]	0.675
Sex							
(Interaction test p = 0.712)							
Female	55/107 (51.4)	10.3 [-1.3; 21.8]	64/126 (50.8)	7.5 [-0.1; 15.0]	0.90	[0.61; 1.33]	0.760
Male	81/177 (45.8)	22.1 [12.4; 31.8]	67/158 (42.4)	19.4 [17.4; 21.5]	1.13	[0.80; 1.60]	0.898
Race							
(Interaction test p = 0.464)							
Asian	11/40 (27.5)	N.E. [N.E.; N.E.]	21/46 (45.7)	12.9 [9.6; 16.3]	0.54	[0.25; 1.17]	0.293
White	116/227 (51.1)	8.4 [-2.1; 19.0]	99/217 (45.6)	18.5 [9.1; 27.9]	1.10	[0.82; 1.47]	0.870
Other	8/17	1.9 [0.5; 3.3]	11/21	2.9 [-3.8; 9.5]	1.00	[0.35; 2.86]	0.858

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(47.1)		(52.4)				
Age groups							
(Interaction test p = 0.742)							
18 - < 65 years	115/237	11.2 [2.4; 20.0]	115/247	13.0 [6.5; 19.5]	1.03	[0.78; 1.36]	0.748
	(48.5)		(46.6)				
65 - < 75 years	18/38	13.9 [8.5; 19.2]	11/24	19.4 [7.3; 31.6]	0.73	[0.30; 1.76]	0.859
	(47.4)		(45.8)				
>= 75 years	3/9	N.E. [N.E.; N.E.]	5/13	12.1 [-18.0; 42.2]	0.47	[0.07; 3.35]	0.968
	(33.3)		(38.5)				
Geographic region							
(Interaction test p = 0.745)							
Europe excluding Germany	70/138	8.4 [-3.0; 19.8]	69/141	11.6 [0.5; 22.7]	1.04	[0.73; 1.48]	0.718
	(50.7)		(48.9)				
Germany	40/72	6.5 [-6.0; 19.0]	28/53	1.2 [-5.5; 8.0]	0.78	[0.45; 1.34]	0.922
	(55.6)		(52.8)				
Others	26/74	N.E. [N.E.; N.E.]	34/90	N.E. [N.E.; N.E.]	0.89	[0.52; 1.53]	0.781
	(35.1)		(37.8)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Cough - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.536)							
Low	103/171 (60.2)	5.6 [1.7; 9.4]	119/172 (69.2)	2.4 [1.6; 3.2]	0.81	[0.61; 1.08]	0.062
Intermediate	47/75 (62.7)	4.2 [1.0; 7.4]	35/75 (46.7)	12.1 [0.6; 23.5]	1.20	[0.75; 1.92]	0.747
High	20/38 (52.6)	5.6 [-4.9; 16.0]	23/37 (62.2)	4.7 [1.8; 7.5]	0.78	[0.41; 1.50]	0.842
Sex							
(Interaction test p = 0.959)							
Female	69/107 (64.5)	3.1 [0.4; 5.8]	75/126 (59.5)	2.8 [0.4; 5.3]	0.97	[0.68; 1.38]	0.772
Male	101/177 (57.1)	6.6 [1.5; 11.7]	103/158 (65.2)	3.1 [1.9; 4.2]	0.84	[0.63; 1.13]	0.205
Race							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test p = 0.306)							
Asian	23/40 (57.5)	11.1 [2.5; 19.6]	30/46 (65.2)	4.4 [1.6; 7.2]	0.89	[0.49; 1.62]	0.783
White	138/227 (60.8)	4.9 [1.9; 7.8]	137/217 (63.1)	2.6 [1.4; 3.8]	0.87	[0.68; 1.12]	0.376
Other	9/17 (52.9)	2.9 [2.7; 3.0]	10/21 (47.6)	4.8 [-1.0; 10.5]	0.74	[0.23; 2.38]	0.841
Age groups							
(Interaction test p = 0.198)							
18 - < 65 years	144/237 (60.8)	4.7 [1.9; 7.5]	156/247 (63.2)	2.8 [1.8; 3.9]	0.93	[0.73; 1.18]	0.356
65 - < 75 years	21/38 (55.3)	11.1 [3.4; 18.8]	16/24 (66.7)	2.4 [1.2; 3.5]	0.47	[0.22; 0.99]	0.168
>= 75 years	5/9 (55.6)	2.8 [1.4; 4.3]	5/13 (38.5)	N.E. [N.E.; N.E.]	1.29	[0.13; 13.04]	0.407
Geographic region							
(Interaction test p = 0.669)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Europe excluding Germany	81/138 (58.7)	5.1 [1.1; 9.2]	84/141 (59.6)	4.7 [1.1; 8.2]	0.92	[0.66; 1.27]	0.934
Germany	47/72 (65.3)	2.4 [-0.2; 5.0]	40/53 (75.5)	0.6 [0.2; 1.0]	0.67	[0.41; 1.09]	0.097
Others	42/74 (56.8)	9.3 [3.9; 14.6]	54/90 (60.0)	3.4 [0.7; 6.0]	0.91	[0.59; 1.40]	0.753

MID: Minimal important difference
N*: Number of patients included in the analysis
n: Number of patients with event. The number of patients is the mean number over all imputations rounded to the nearest integer
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
Missing baseline values are multiply imputed by simple imputation using 500 repetitions under a MAR assumption.
Two-sided 95% CI for KM percentiles are derived by the approach outlined in Moscovici and Ratitch (2017).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factor ELTS Score (IRT) and covariates baseline score and treatment arm.
P-Values are based on stratified logrank test with stratification factor ELTS Score (IRT).
Test results are combined using the Wilson-Hilferty transformation.
For the attribute ELTS Score (IRT) at randomization an unstratified Cox proportional hazard model and an unstratified log-rank teat are applied.
Data Cut/15MAY2025

Table 3-5.6 PRO-CTCAE - Interference: Time to first deterioration analysis by subgroups - Sensitivity analysis (multiple imputation of missing baseline values) (Full Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Fatigue - Interference (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.636)							
Low	112/171 (65.5)	2.4 [1.1; 3.8]	105/172 (61.0)	1.4 [-0.1; 3.0]	0.98	[0.73; 1.31]	0.852
Intermediate	46/75 (61.3)	2.6 [-0.8; 6.0]	44/75 (58.7)	3.2 [-3.5; 9.9]	0.90	[0.58; 1.41]	0.765
High	17/38 (44.7)	N.E. [N.E.; N.E.]	17/37 (45.9)	11.1 [-0.7; 22.9]	0.72	[0.34; 1.50]	0.979
Sex							
(Interaction test p = 0.569)							
Female	68/107 (63.6)	2.8 [-0.4; 6.1]	72/126 (57.1)	2.9 [1.2; 4.5]	0.97	[0.67; 1.41]	0.796
Male	106/177	3.5 [0.2; 6.8]	94/158	1.9 [-0.3; 4.1]	0.92	[0.68; 1.24]	0.774

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(59.9)		(59.5)				
Race							
(Interaction test p = 0.734)							
Asian	25/40	4.4 [-0.7; 9.6]	29/46	2.9 [-4.9; 10.7]	0.87	[0.49; 1.55]	0.555
	(62.5)		(63.0)				
White	141/227	2.9 [0.7; 5.0]	127/217	2.6 [0.9; 4.3]	0.97	[0.74; 1.27]	0.836
	(62.1)		(58.5)				
Other	8/17	2.8 [1.3; 4.3]	10/21	1.4 [-25.6; 28.5]	0.50	[0.15; 1.67]	0.835
	(47.1)		(47.6)				
Age groups							
(Interaction test p = 0.856)							
18 - < 65 years	152/237	2.8 [1.5; 4.2]	145/247	2.8 [1.2; 4.5]	0.97	[0.75; 1.25]	0.885
	(64.1)		(58.7)				
65 - < 75 years	21/38	5.0 [-11.5; 21.4]	15/24	1.0 [-0.3; 2.3]	0.71	[0.32; 1.58]	0.745
	(55.3)		(62.5)				
>= 75 years	2/9	N.E. [N.E.; N.E.]	6/13	16.6 [16.5; 16.7]	0.57	[0.09; 3.73]	0.511
	(22.2)		(46.2)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test p = 0.781)							
Europe excluding Germany	87/138 (63.0)	2.4 [0.7; 4.0]	82/141 (58.2)	2.6 [0.7; 4.5]	1.03	[0.75; 1.43]	0.906
Germany	46/72 (63.9)	2.2 [-0.4; 4.8]	31/53 (58.5)	0.8 [-1.8; 3.4]	0.65	[0.37; 1.14]	0.964
Others	41/74 (55.4)	6.5 [-0.6; 13.6]	53/90 (58.9)	5.6 [-1.6; 12.8]	0.85	[0.55; 1.32]	0.916
Headache - Interference (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.651)							
Low	97/171 (56.7)	4.9 [-0.2; 10.0]	110/172 (64.0)	2.4 [1.4; 3.3]	0.73	[0.55; 0.97]	0.177
Intermediate	38/75 (50.7)	10.3 [-1.1; 21.7]	31/75 (41.3)	14.8 [0.1; 29.5]	1.08	[0.66; 1.75]	0.595
High	18/38	11.1 [1.3; 21.0]	18/37	11.1 [-2.9; 25.1]	0.86	[0.43; 1.73]	0.527

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(47.4)		(48.6)				
Sex							
(Interaction test p = 0.488)							
Female	67/107	3.3 [0.8; 5.7]	76/126	2.8 [2.0; 3.7]	0.85	[0.60; 1.20]	0.946
	(62.6)		(60.3)				
Male	85/177	11.4 [5.6; 17.1]	83/158	7.4 [-1.1; 16.0]	0.82	[0.60; 1.12]	0.650
	(48.0)		(52.5)				
Race							
(Interaction test p = 0.664)							
Asian	21/40	8.3 [3.1; 13.6]	29/46	3.3 [0.4; 6.1]	0.73	[0.40; 1.33]	0.619
	(52.5)		(63.0)				
White	126/227	5.0 [-0.1; 10.0]	119/217	4.0 [0.7; 7.3]	0.87	[0.67; 1.13]	0.953
	(55.5)		(54.8)				
Other	5/17	N.E. [N.E.; N.E.]	11/21	3.7 [1.5; 6.0]	0.39	[0.12; 1.24]	0.309
	(29.4)		(52.4)				
Age groups							
(Interaction test p = 0.879)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
18 - < 65 years	129/237 (54.4)	5.6 [0.8; 10.4]	145/247 (58.7)	3.1 [1.4; 4.8]	0.79	[0.62; 1.02]	0.245
65 - < 75 years	21/38 (55.3)	10.2 [-4.9; 25.2]	8/24 (33.3)	N.E. [N.E.; N.E.]	1.25	[0.48; 3.22]	0.761
>= 75 years	3/9 (33.3)	19.4 [19.3; 19.4]	6/13 (46.2)	10.3 [3.2; 17.3]	0.37	[0.06; 2.17]	0.556
Geographic region (Interaction test p = 0.814)							
Europe excluding Germany	75/138 (54.3)	7.5 [1.1; 13.8]	76/141 (53.9)	4.2 [-2.4; 10.8]	0.86	[0.62; 1.20]	0.887
Germany	41/72 (56.9)	4.9 [-0.9; 10.7]	31/53 (58.5)	1.5 [-1.3; 4.4]	0.63	[0.37; 1.06]	0.361
Others	37/74 (50.0)	8.3 [-0.6; 17.3]	51/90 (56.7)	4.2 [-1.6; 10.0]	0.80	[0.51; 1.24]	0.682
Edema - Interference (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test p = 0.905)							
Low	40/171 (23.4)	N.E. [N.E.; N.E.]	53/172 (30.8)	N.E. [N.E.; N.E.]	0.73	[0.48; 1.11]	0.264
Intermediate	22/75 (29.3)	22.1 [22.1; 22.2]	20/75 (26.7)	N.E. [N.E.; N.E.]	0.94	[0.50; 1.77]	0.543
High	9/38 (23.7)	N.E. [N.E.; N.E.]	13/37 (35.1)	N.E. [N.E.; N.E.]	0.53	[0.21; 1.31]	0.507
Sex							
(Interaction test p = 0.444)							
Female	34/107 (31.8)	N.E. [N.E.; N.E.]	42/126 (33.3)	N.E. [N.E.; N.E.]	0.79	[0.49; 1.26]	0.639
Male	38/177 (21.5)	N.E. [N.E.; N.E.]	43/158 (27.2)	N.E. [N.E.; N.E.]	0.74	[0.47; 1.16]	0.385
Race							
(Interaction test p = 0.253)							
Asian	14/40 (35.0)	17.5 [17.5; 17.6]	20/46 (43.5)	N.E. [N.E.; N.E.]	0.65	[0.32; 1.31]	0.466

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
White	53/227 (23.3)	N.E. [N.E.; N.E.]	60/217 (27.6)	N.E. [N.E.; N.E.]	0.77	[0.52; 1.13]	0.353
Other	4/17 (23.5)	N.E. [N.E.; N.E.]	5/21 (23.8)	N.E. [N.E.; N.E.]	0.79	[0.19; 3.25]	0.507
Age groups (Interaction test p = 0.800)							
18 - < 65 years	59/237 (24.9)	N.E. [N.E.; N.E.]	72/247 (29.1)	N.E. [N.E.; N.E.]	0.79	[0.55; 1.12]	0.355
65 - < 75 years	10/38 (26.3)	N.E. [N.E.; N.E.]	7/24 (29.2)	N.E. [N.E.; N.E.]	0.78	[0.28; 2.16]	0.662
>= 75 years	2/9 (22.2)	N.E. [N.E.; N.E.]	6/13 (46.2)	2.5 [-31.3; 36.3]	0.24	[0.02; 2.96]	0.261
Geographic region (Interaction test p = 0.369)							
Europe excluding Germany	29/138 (21.0)	N.E. [N.E.; N.E.]	38/141 (27.0)	N.E. [N.E.; N.E.]	0.72	[0.44; 1.18]	0.309
Germany	19/72	N.E. [N.E.; N.E.]	14/53	N.E. [N.E.; N.E.]	0.83	[0.40; 1.75]	0.632

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Others	(26.4) 23/74 (31.1)	N.E. [N.E.; N.E.]	(26.4) 33/90 (36.7)	N.E. [N.E.; N.E.]	0.74	[0.43; 1.29]	0.627
Muscle Pain - Interference (MID=1)							
Stratification factor: ELTS based on randomization data from IRT (Interaction test p = 0.326)							
Low	95/171 (55.6)	4.4 [-1.8; 10.7]	103/172 (59.9)	2.2 [-0.1; 4.5]	0.87	[0.65; 1.18]	0.900
Intermediate	49/75 (65.3)	1.5 [0.7; 2.3]	38/75 (50.7)	5.6 [-0.0; 11.2]	1.38	[0.89; 2.15]	0.305
High	18/38 (47.4)	4.7 [2.0; 7.3]	22/37 (59.5)	2.8 [-0.5; 6.1]	0.74	[0.38; 1.44]	0.956
Sex (Interaction test p = 0.886)							
Female	69/107 (64.5)	1.4 [0.5; 2.4]	74/126 (58.7)	1.9 [0.8; 3.0]	1.10	[0.77; 1.57]	0.918

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Male	93/177 (52.5)	4.7 [-1.2; 10.5]	89/158 (56.3)	5.4 [1.2; 9.6]	0.92	[0.68; 1.25]	0.693
Race (Interaction test p = 0.490)							
Asian	26/40 (65.0)	2.8 [-0.0; 5.6]	30/46 (65.2)	2.0 [0.8; 3.3]	0.96	[0.55; 1.68]	0.507
White	127/227 (55.9)	3.7 [-0.8; 8.3]	124/217 (57.1)	3.2 [0.7; 5.7]	0.95	[0.73; 1.23]	0.700
Other	9/17 (52.9)	3.3 [-4.8; 11.4]	9/21 (42.9)	N.E. [N.E.; N.E.]	0.91	[0.30; 2.74]	0.559
Age groups (Interaction test p = 0.777)							
18 - < 65 years	134/237 (56.5)	3.7 [1.8; 5.7]	137/247 (55.5)	2.9 [0.5; 5.4]	0.99	[0.77; 1.27]	0.594
65 - < 75 years	23/38 (60.5)	2.8 [-2.5; 8.1]	18/24 (75.0)	2.8 [1.6; 4.0]	0.62	[0.31; 1.25]	0.554
>= 75 years	6/9	1.5 [0.9; 2.1]	7/13	2.6 [-3.0; 8.2]	0.39	[0.06; 2.53]	0.891

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(66.7)		(53.8)				
Geographic region							
(Interaction test p = 0.394)							
Europe excluding Germany	76/138	3.7 [-4.1; 11.6]	80/141	3.8 [0.8; 6.7]	0.94	[0.67; 1.31]	0.614
	(55.1)		(56.7)				
Germany	42/72	3.1 [-0.9; 7.1]	31/53	1.7 [0.1; 3.3]	0.90	[0.54; 1.51]	0.664
	(58.3)		(58.5)				
Others	44/74	3.1 [0.4; 5.7]	52/90	3.4 [0.3; 6.4]	1.05	[0.69; 1.60]	0.493
	(59.5)		(57.8)				
Cough - Interference (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test p = 0.383)							
Low	76/171	17.5 [9.3; 25.8]	79/172	11.2 [9.5; 12.9]	0.93	[0.67; 1.29]	0.883
	(44.4)		(45.9)				
Intermediate	42/75	11.2 [4.5; 17.8]	27/75	N.E. [N.E.; N.E.]	1.33	[0.80; 2.20]	0.377
	(56.0)		(36.0)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
High	13/38 (34.2)	N.E. [N.E.; N.E.]	17/37 (45.9)	11.1 [-11.1; 33.2]	0.58	[0.27; 1.26]	0.522
Sex							
(Interaction test p = 0.907)							
Female	56/107 (52.3)	12.1 [5.4; 18.8]	52/126 (41.3)	11.2 [4.0; 18.4]	1.05	[0.70; 1.56]	0.950
Male	75/177 (42.4)	17.5 [13.2; 21.9]	71/158 (44.9)	12.1 [4.1; 20.0]	0.91	[0.65; 1.28]	0.966
Race							
(Interaction test p = 0.323)							
Asian	18/40 (45.0)	17.5 [15.5; 19.5]	18/46 (39.1)	N.E. [N.E.; N.E.]	0.95	[0.47; 1.90]	0.437
White	107/227 (47.1)	13.9 [8.0; 19.8]	97/217 (44.7)	11.2 [7.4; 15.1]	0.94	[0.71; 1.26]	0.770
Other	6/17 (35.3)	N.E. [N.E.; N.E.]	9/21 (42.9)	15.7 [15.6; 15.8]	0.89	[0.28; 2.86]	0.549
Age groups							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test p = 0.491)							
18 - < 65 years	112/237 (47.3)	14.8 [10.6; 19.0]	106/247 (42.9)	13.9 [10.4; 17.3]	1.06	[0.81; 1.40]	0.739
65 - < 75 years	14/38 (36.8)	N.E. [N.E.; N.E.]	12/24 (50.0)	6.4 [-2.9; 15.7]	0.55	[0.24; 1.26]	0.338
>= 75 years	5/9 (55.6)	6.5 [6.5; 6.6]	6/13 (46.2)	6.6 [4.9; 8.3]	0.46	[0.08; 2.69]	0.959
Geographic region							
(Interaction test p = 0.801)							
Europe excluding Germany	54/138 (39.1)	24.0 [23.9; 24.1]	59/141 (41.8)	13.9 [10.1; 17.6]	0.85	[0.58; 1.25]	0.866
Germany	45/72 (62.5)	3.9 [0.5; 7.4]	30/53 (56.6)	2.2 [-0.4; 4.7]	0.77	[0.47; 1.28]	0.767
Others	32/74 (43.2)	16.8 [15.0; 18.5]	34/90 (37.8)	N.E. [N.E.; N.E.]	1.06	[0.63; 1.77]	0.662

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			

MID: Minimal important difference
N*: Number of patients included in the analysis
n: Number of patients with event. The number of patients is the mean number over all imputations rounded to the nearest integer
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
Missing baseline values are multiply imputed by simple imputation using 500 repetitions under a MAR assumption.
Two-sided 95% CI for KM percentiles are derived by the approach outlined in Moscovici and Ratitch (2017).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factor ELTS Score (IRT) and covariates baseline score and treatment arm.
P-Values are based on stratified logrank test with stratification factor ELTS Score (IRT).
Test results are combined using the Wilson-Hilferty transformation.
For the attribute ELTS Score (IRT) at randomization an unstratified Cox proportional hazard model and an unstratified log-rank teat are applied.
Data Cut/15MAY2025

Table 3-6.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis with alternative definition of baseline (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Global health status/QoL (MID=10)			
N*	284	284	0.91
Number of patients with events, n (%)	61 (21.5)	66 (23.2)	[0.64; 1.29]
			0.571
Percentiles (months) [95% CI]			
25th	5.6 [1.9; 11.1]	2.8 [1.9; 5.5]	
Median	22.1 [11.1; N.E.]	N.E. [11.1; N.E.]	
75th	22.1 [22.1; N.E.]	N.E. [N.E.; N.E.]	
Physical functioning (MID=10)			
N*	284	284	0.90
Number of patients with events, n (%)	49 (17.3)	53 (18.7)	[0.61; 1.32]
			0.538
Percentiles (months) [95% CI]			
25th	5.6 [2.0; 11.1]	4.2 [1.2; 11.1]	
Median	N.E. [11.2; N.E.]	N.E. [11.8; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Role functioning (MID=10)			
N*	284	284	1.11
Number of patients with events, n (%)	66 (23.2)	62 (21.8)	[0.78; 1.57]
			0.530
Percentiles (months) [95% CI]			
25th	2.0 [1.8; 5.6]	2.8 [1.9; 5.6]	
Median	22.1 [11.1; N.E.]	22.1 [11.2; N.E.]	
75th	22.5 [22.1; N.E.]	22.3 [22.1; N.E.]	
Emotional functioning (MID=10)			
N*	284	284	0.69
Number of patients with events, n (%)	48 (16.9)	61 (21.5)	[0.47; 1.02]
			0.156
Percentiles (months) [95% CI]			
25th	8.0 [2.7; 11.1]	2.8 [2.3; 5.6]	
Median	N.E. [11.2; N.E.]	22.0 [11.2; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Cognitive functioning (MID=10)			

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
N*	284	284	0.93
Number of patients with events, n (%)	77 (27.1)	80 (28.2)	[0.68; 1.27]
			0.633
Percentiles (months) [95% CI]			
25th	1.9 [1.9; 2.8]	2.7 [1.9; 2.8]	
Median	11.1 [11.0; 22.1]	11.1 [5.6; N.E.]	
75th	22.1 [22.1; N.E.]	N.E. [N.E.; N.E.]	
Social functioning (MID=10)			
N*	284	284	0.76
Number of patients with events, n (%)	58 (20.4)	67 (23.6)	[0.53; 1.09]
			0.167
Percentiles (months) [95% CI]			
25th	2.8 [1.9; 5.6]	1.9 [1.0; 2.8]	
Median	22.1 [22.1; N.E.]	N.E. [11.1; N.E.]	
75th	22.5 [22.1; N.E.]	N.E. [N.E.; N.E.]	
Fatigue (MID=10)			
N*	284	284	0.74

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Number of patients with events, n (%)	51 (18.0)	61 (21.5)	[0.51; 1.07]
			0.181
Percentiles (months) [95% CI]			
25th	5.6 [1.9; 11.1]	2.8 [1.5; 5.5]	
Median	N.E. [11.2; N.E.]	22.1 [11.8; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Nausea and vomiting (MID=10)			
N*	284	284	0.73
Number of patients with events, n (%)	39 (13.7)	50 (17.6)	[0.48; 1.11]
			0.126
Percentiles (months) [95% CI]			
25th	11.1 [5.7; 22.1]	5.6 [2.7; 11.3]	
Median	22.1 [22.1; N.E.]	22.2 [22.0; N.E.]	
75th	N.E. [22.1; N.E.]	N.E. [22.2; N.E.]	
Pain (MID=10)			
N*	284	284	0.93
Number of patients with events, n (%)	76 (26.8)	80 (28.2)	[0.68; 1.28]

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
			0.544
Percentiles (months) [95% CI]			
25th	1.8 [1.0; 2.0]	1.2 [1.0; 2.3]	
Median	11.2 [8.3; N.E.]	11.1 [5.5; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Dyspnoea (MID=10)			
N*	284	284	0.85
Number of patients with events, n (%)	45 (15.8)	52 (18.3)	[0.57; 1.27]
			0.460
Percentiles (months) [95% CI]			
25th	11.0 [2.9; 22.1]	2.9 [1.9; 11.1]	
Median	22.1 [22.1; N.E.]	N.E. [11.8; N.E.]	
75th	N.E. [22.1; N.E.]	N.E. [N.E.; N.E.]	
Insomnia (MID=10)			
N*	284	284	0.81
Number of patients with events, n (%)	58 (20.4)	65 (22.9)	[0.56; 1.15]
			0.254

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Percentiles (months) [95% CI]			
25th	5.6 [2.8; 11.1]	1.9 [1.2; 5.6]	
Median	12.0 [11.2; N.E.]	22.0 [11.2; N.E.]	
75th	22.5 [22.1; N.E.]	N.E. [22.2; N.E.]	
Appetite loss (MID=10)			
N*	284	284	0.79
Number of patients with events, n (%)	32 (11.3)	41 (14.4)	[0.50; 1.26]
			0.239
Percentiles (months) [95% CI]			
25th	22.1 [11.1; N.E.]	11.1 [2.8; 22.2]	
Median	22.1 [22.1; N.E.]	N.E. [22.1; N.E.]	
75th	N.E. [22.1; N.E.]	N.E. [N.E.; N.E.]	
Constipation (MID=10)			
N*	284	284	0.61
Number of patients with events, n (%)	44 (15.5)	63 (22.2)	[0.41; 0.90]
			0.018
Percentiles (months) [95% CI]			

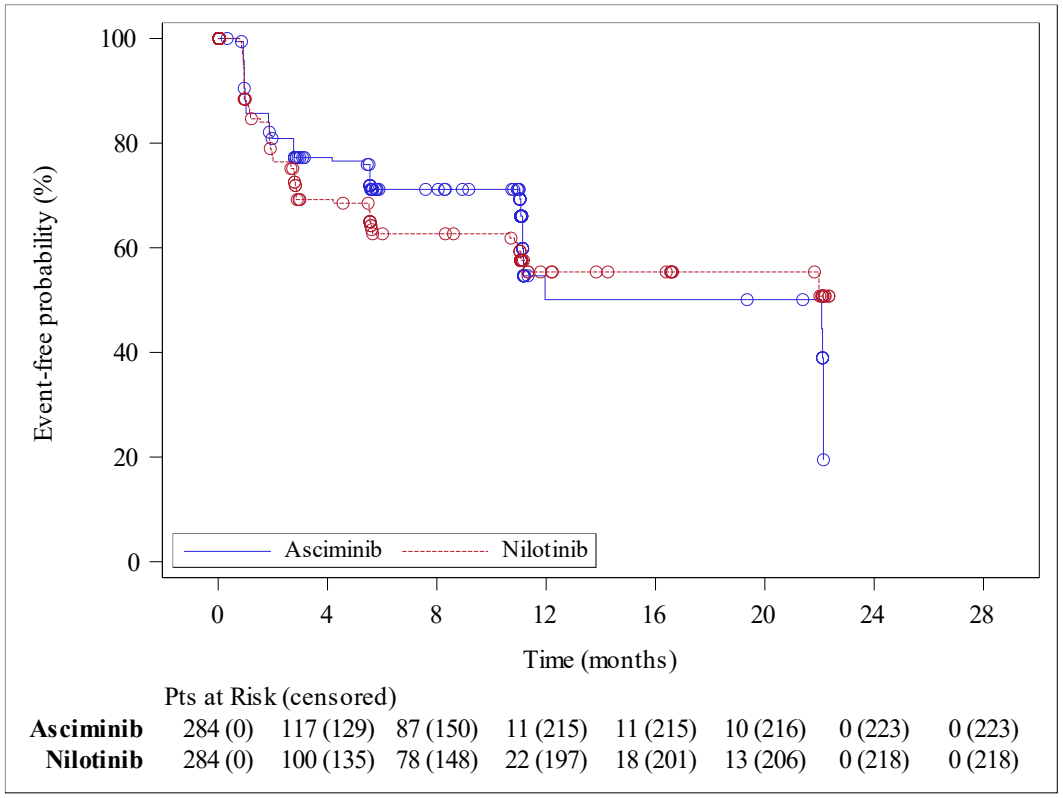
	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
25th	11.1 [5.6; 11.3]	2.8 [1.9; 5.6]	
Median	N.E. [11.3; N.E.]	N.E. [11.1; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Diarrhoea (MID=10)			
N*	284	284	0.72
Number of patients with events, n (%)	40 (14.1)	56 (19.7)	[0.48; 1.09]
			0.052
Percentiles (months) [95% CI]			
25th	11.1 [2.9; N.E.]	2.9 [2.8; 5.6]	
Median	N.E. [22.0; N.E.]	N.E. [22.2; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Financial difficulties (MID=10)			
N*	284	284	1.15
Number of patients with events, n (%)	40 (14.1)	39 (13.7)	[0.73; 1.80]
			0.556
Percentiles (months) [95% CI]			
25th	11.1 [2.8; N.E.]	22.2 [5.5; 22.3]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	22.3 [22.2; N.E.]	
75th	N.E. [N.E.; N.E.]	26.4 [22.3; N.E.]	

MID: Minimal important difference
HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
In this sensitivity analysis a missing assessment before randomization is substituted by the last assessment before or on the day of treatment start, if such an assessment is available.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariates baseline score and treatment arm.
P-Values are from a stratified logrank test with stratification factor ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 3-6.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

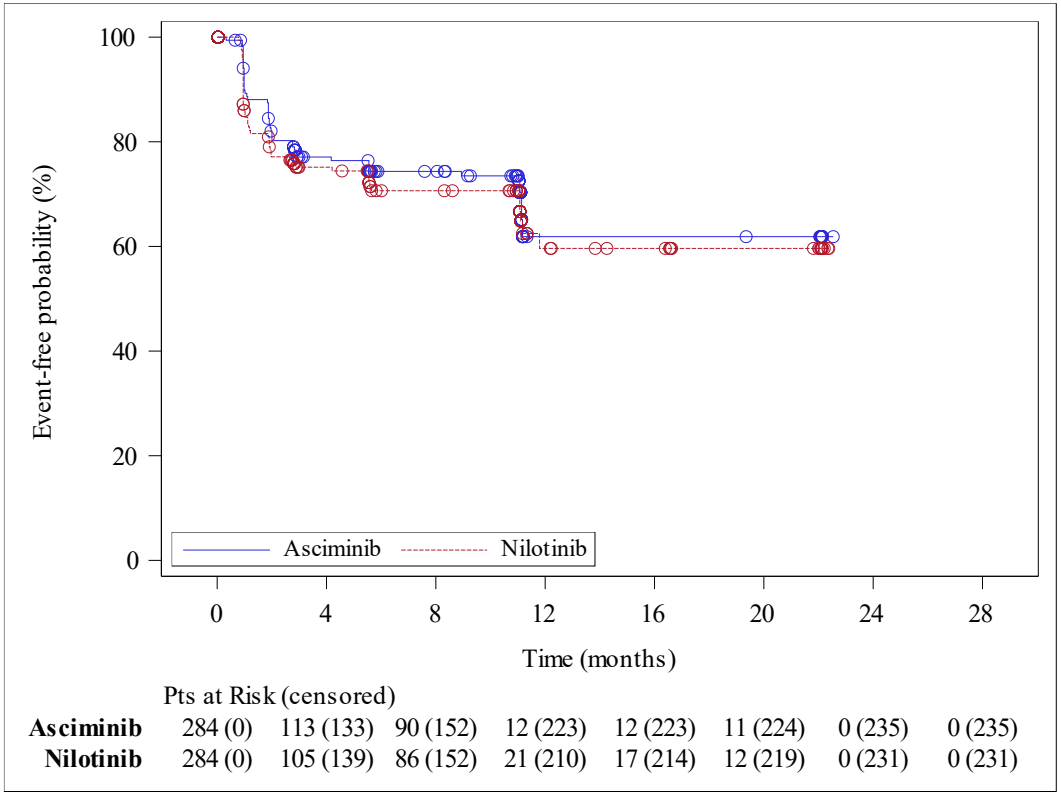
Global health status/QoL (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

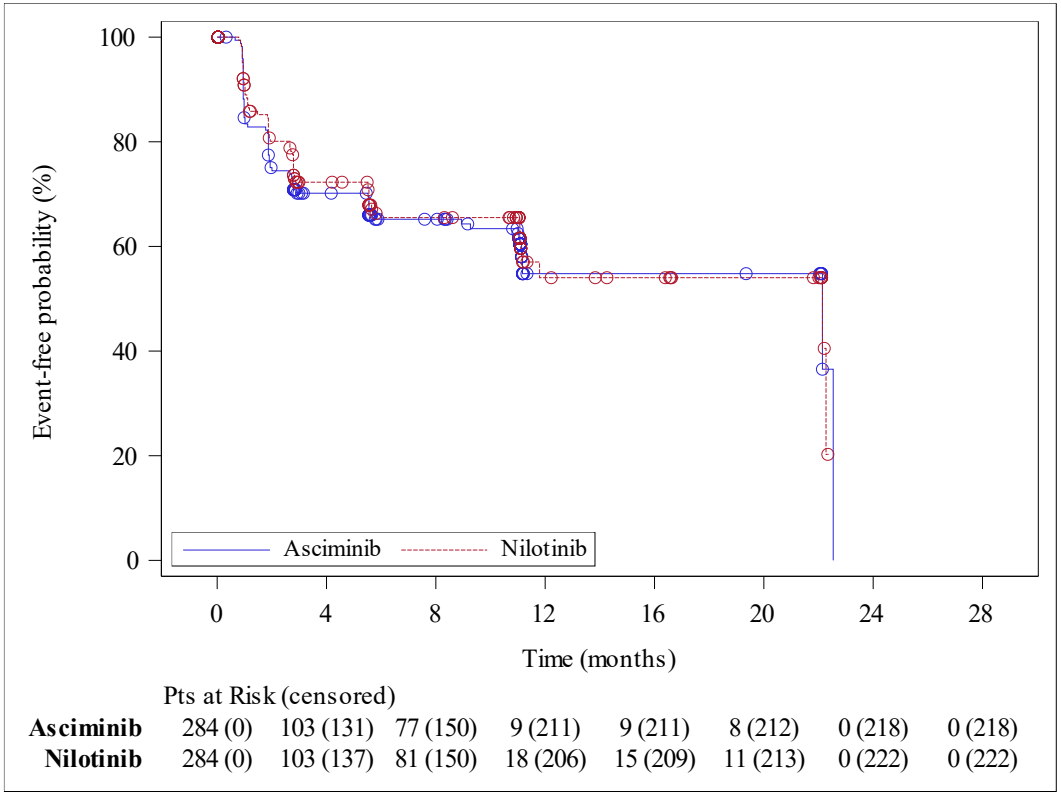
Physical functioning (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

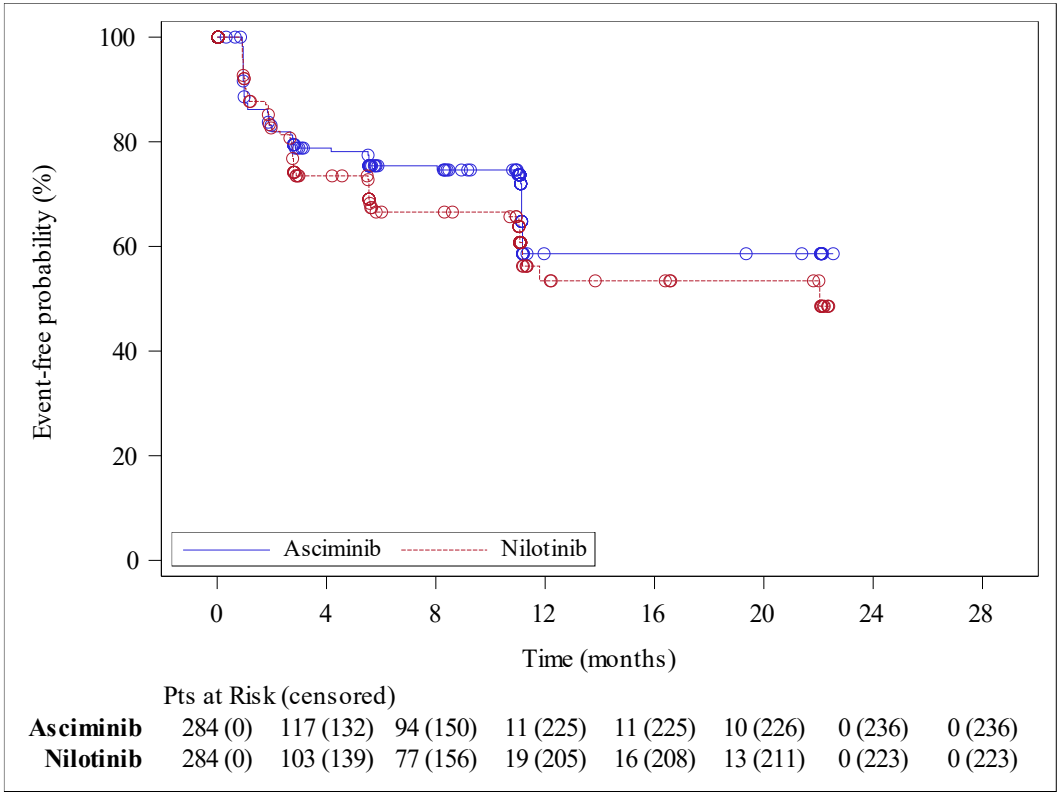
Role functioning (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

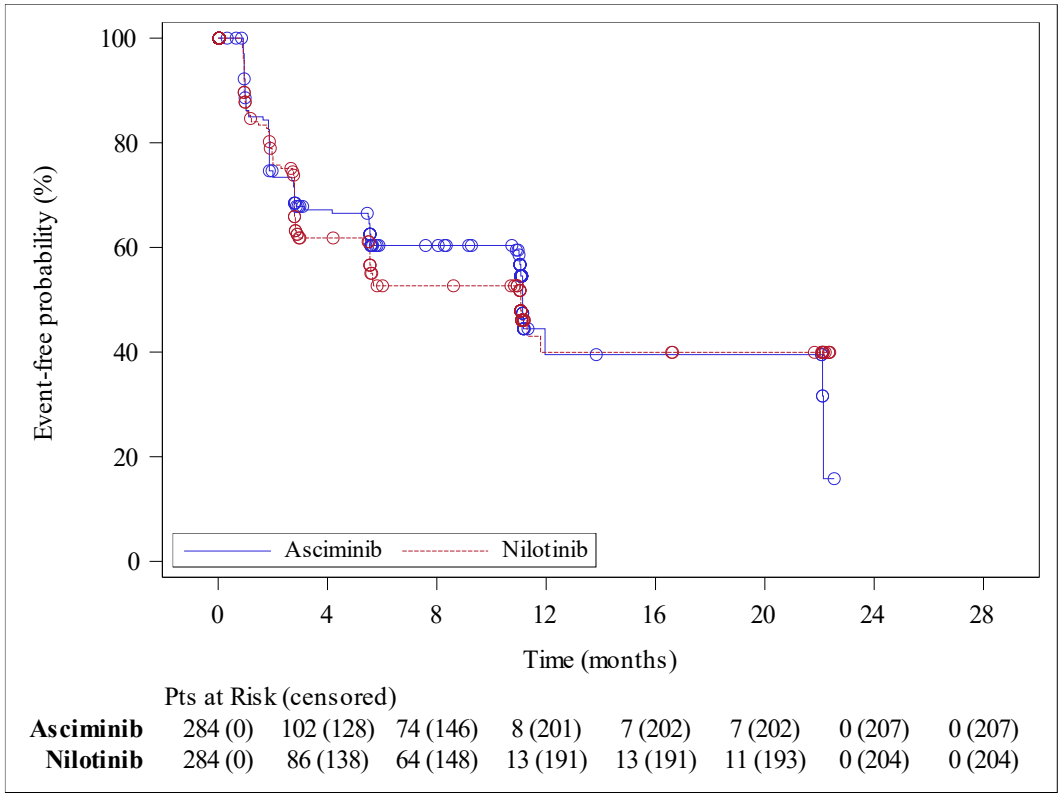
Emotional functioning (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

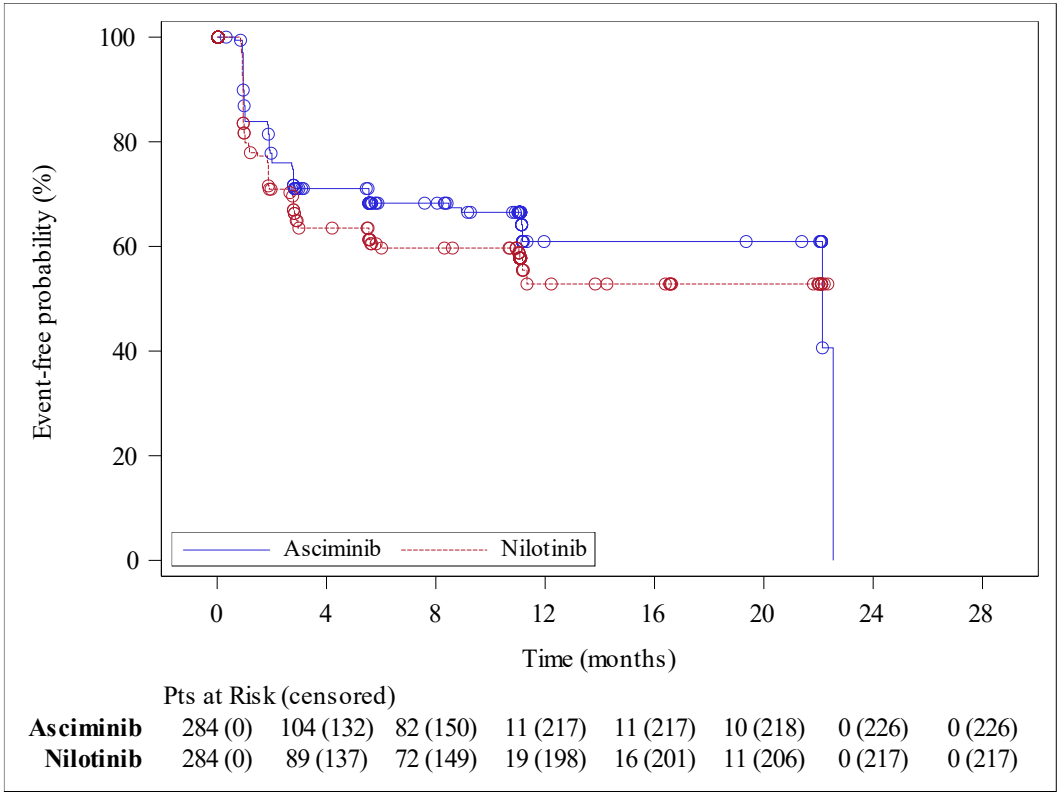
Cognitive functioning (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

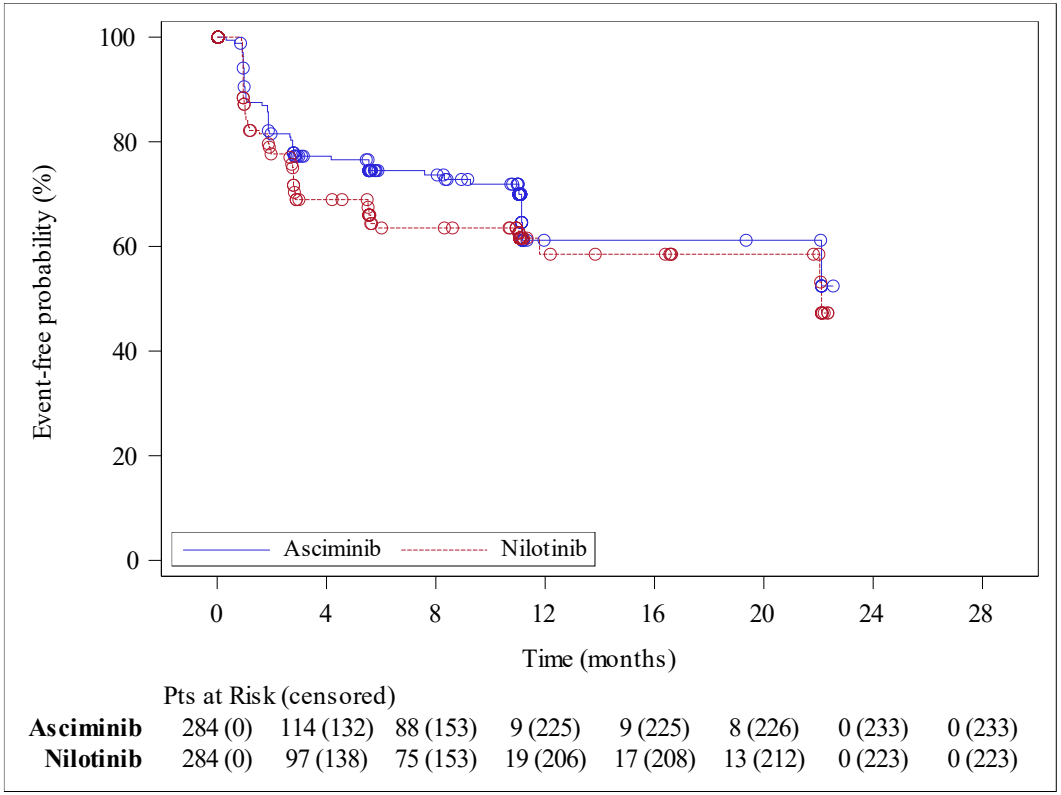
Social functioning (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

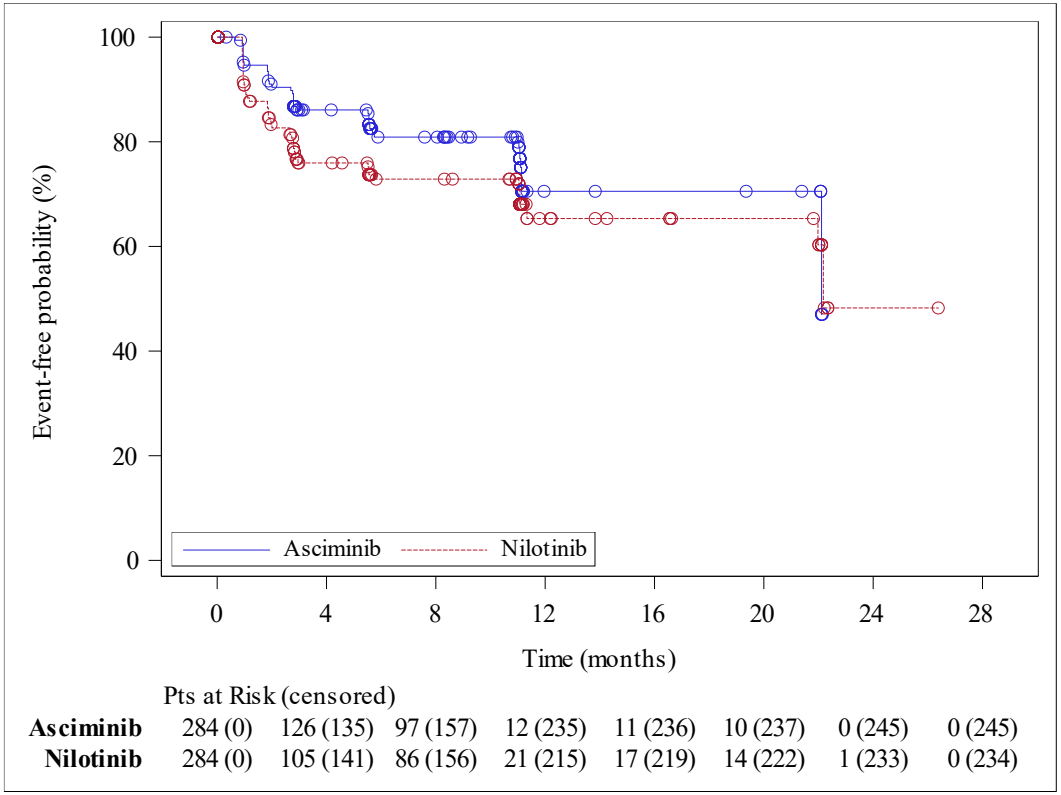
Fatigue (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

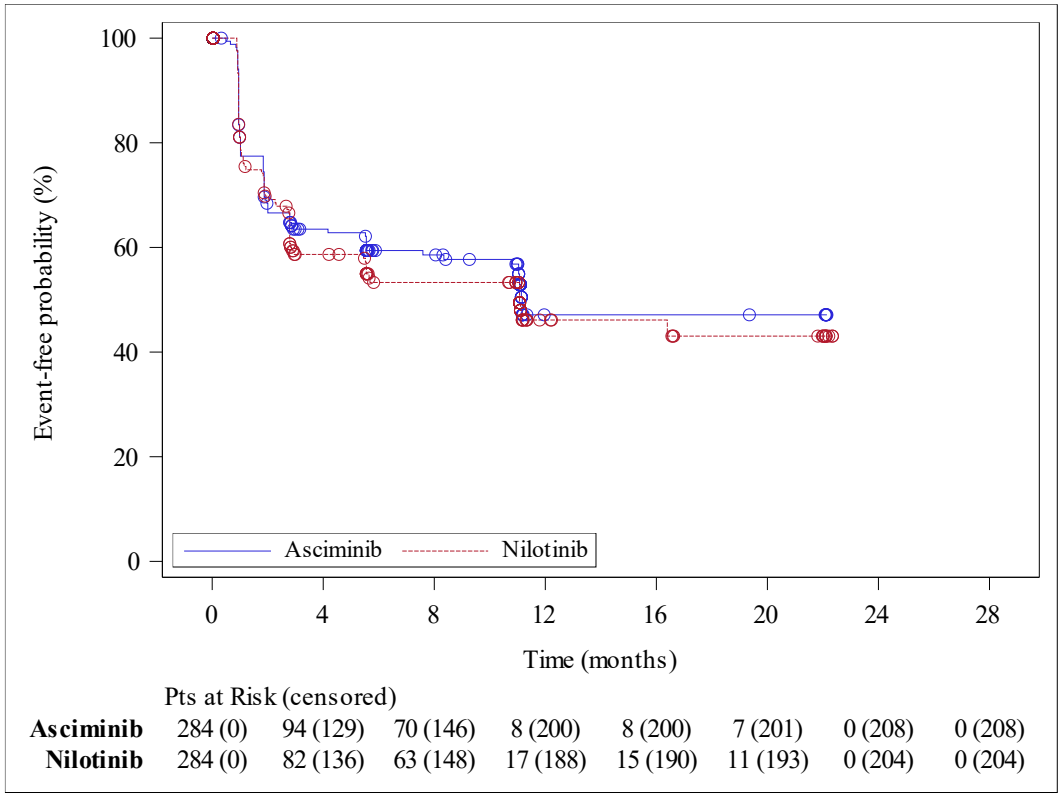
Nausea and vomiting (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

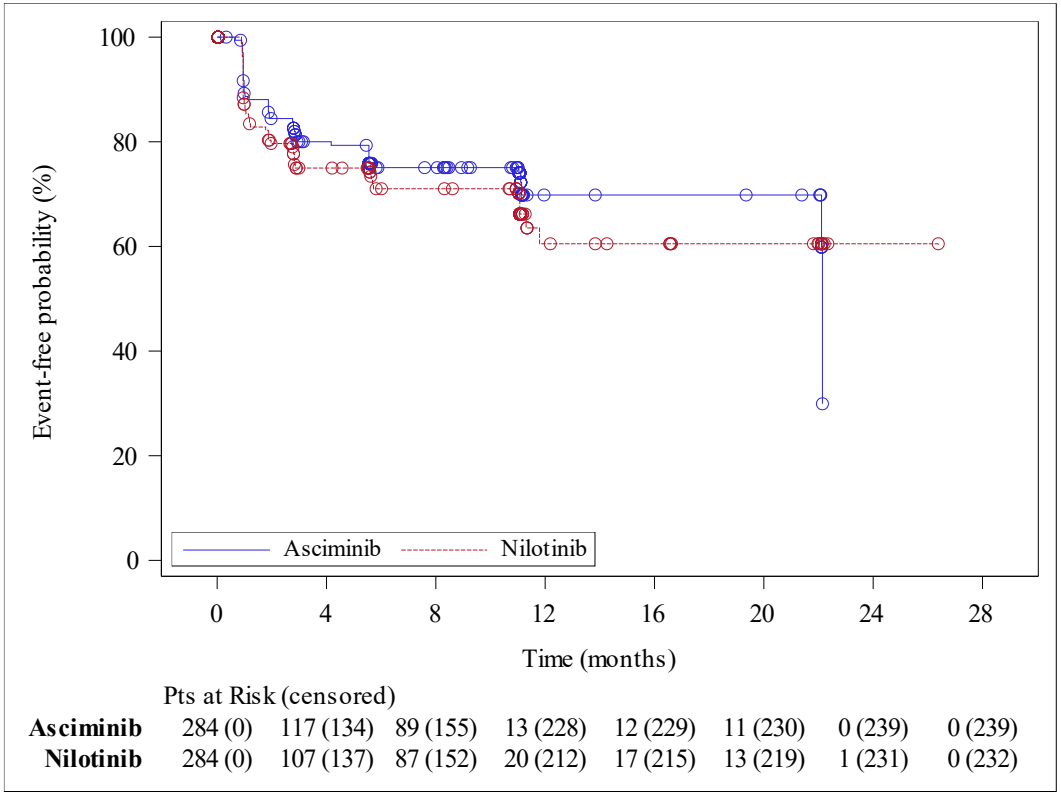
Pain (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

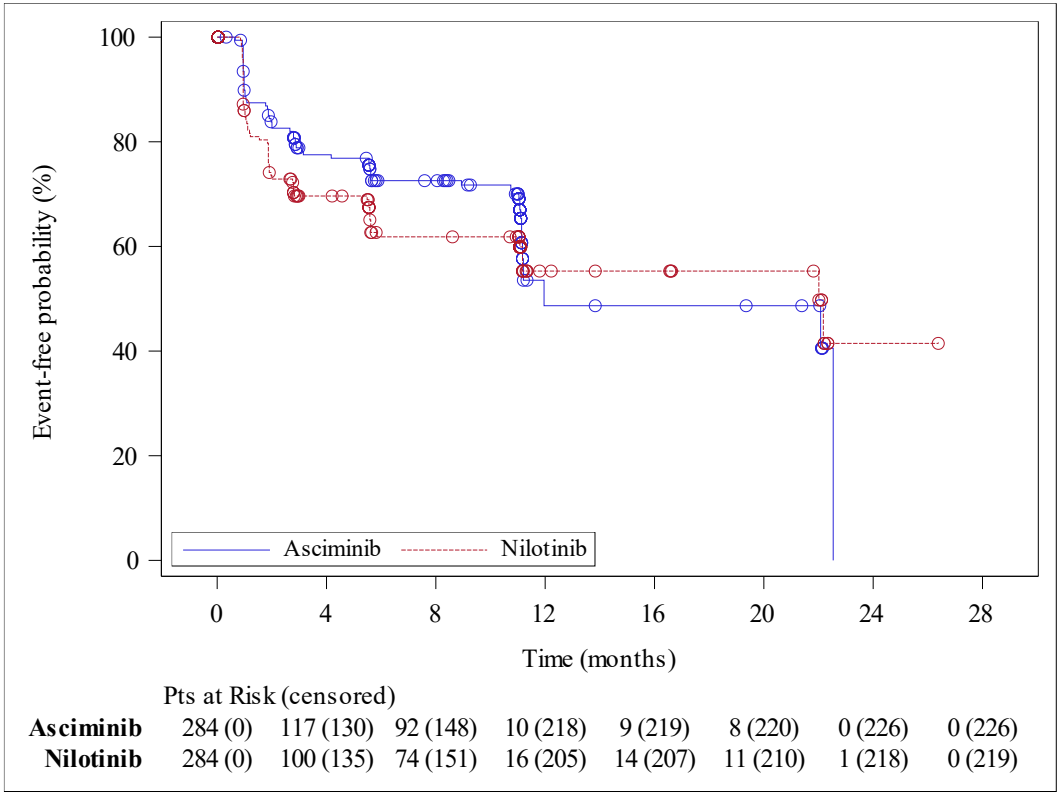
Dyspnoea (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

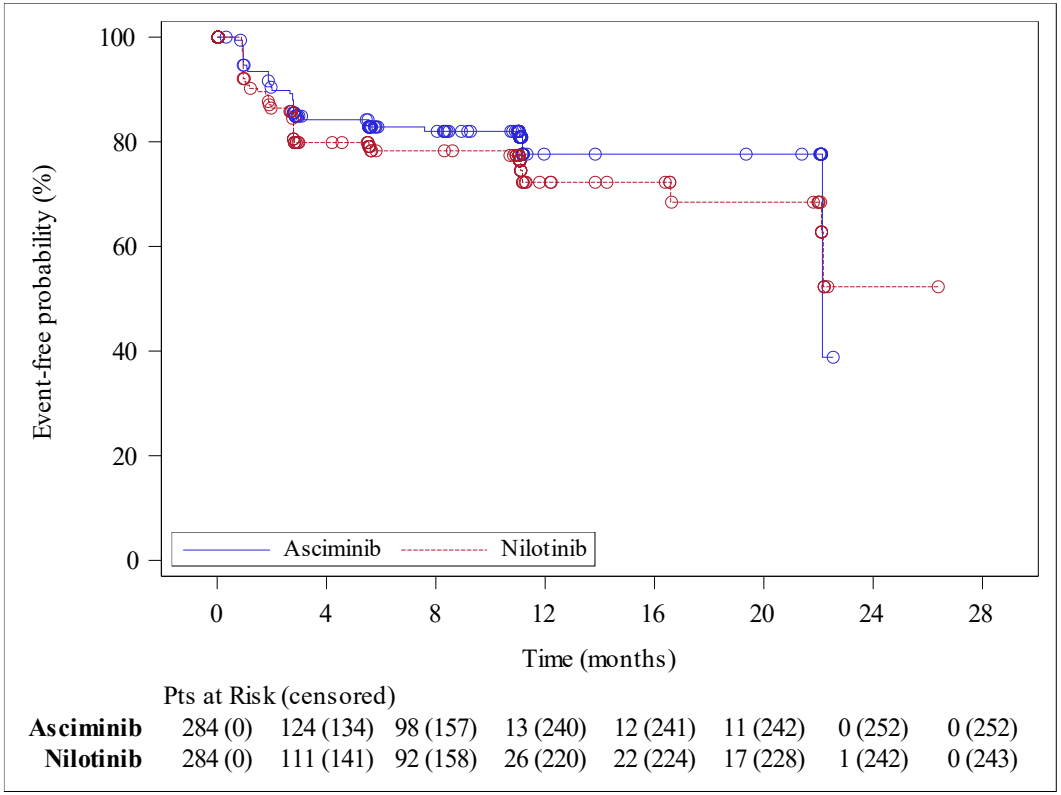
Insomnia (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

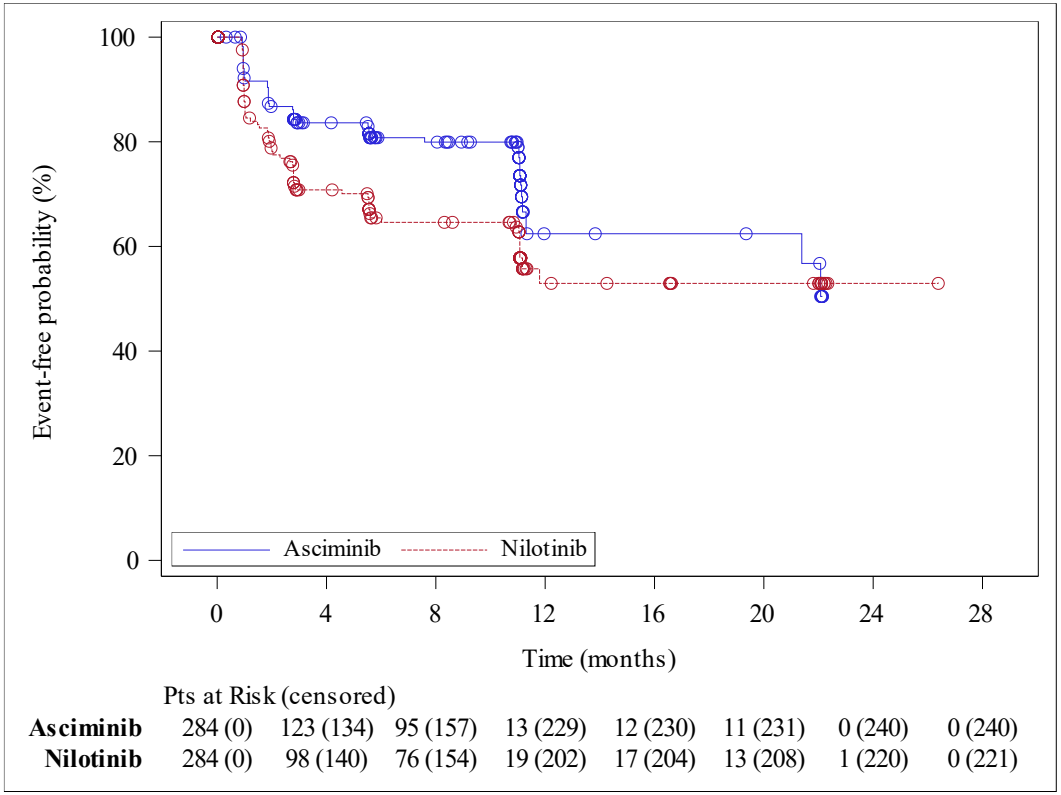
Appetite loss (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

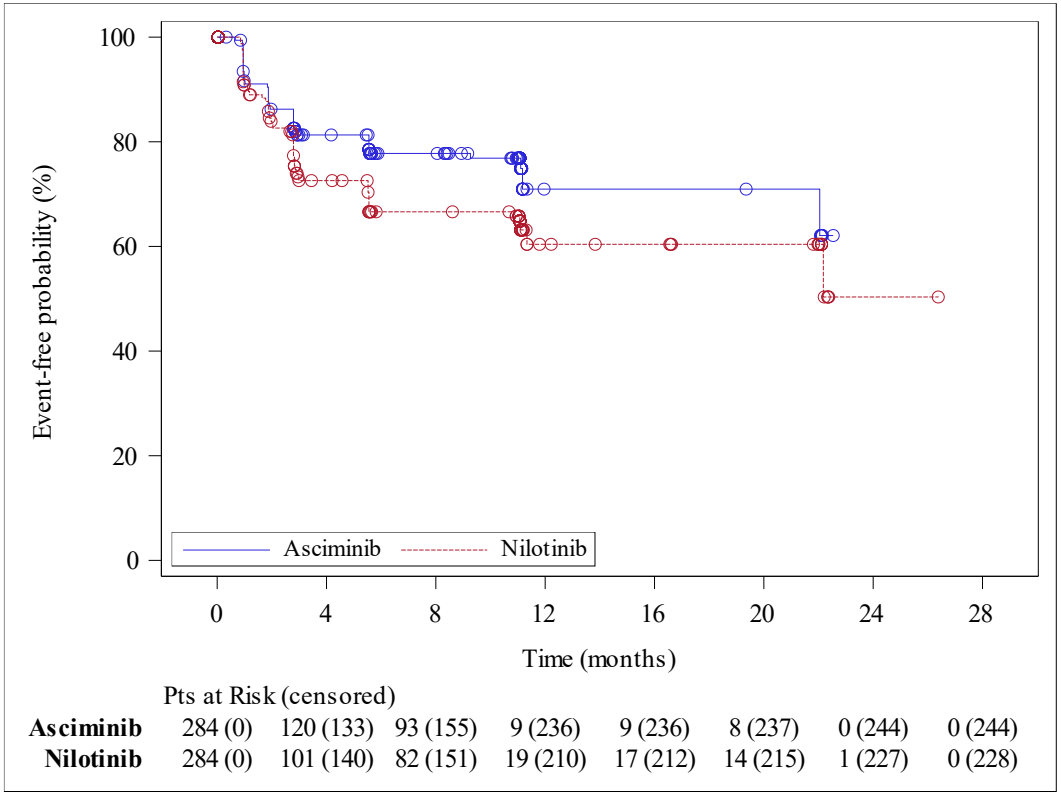
Constipation (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

Diarrhoea (MID=10)

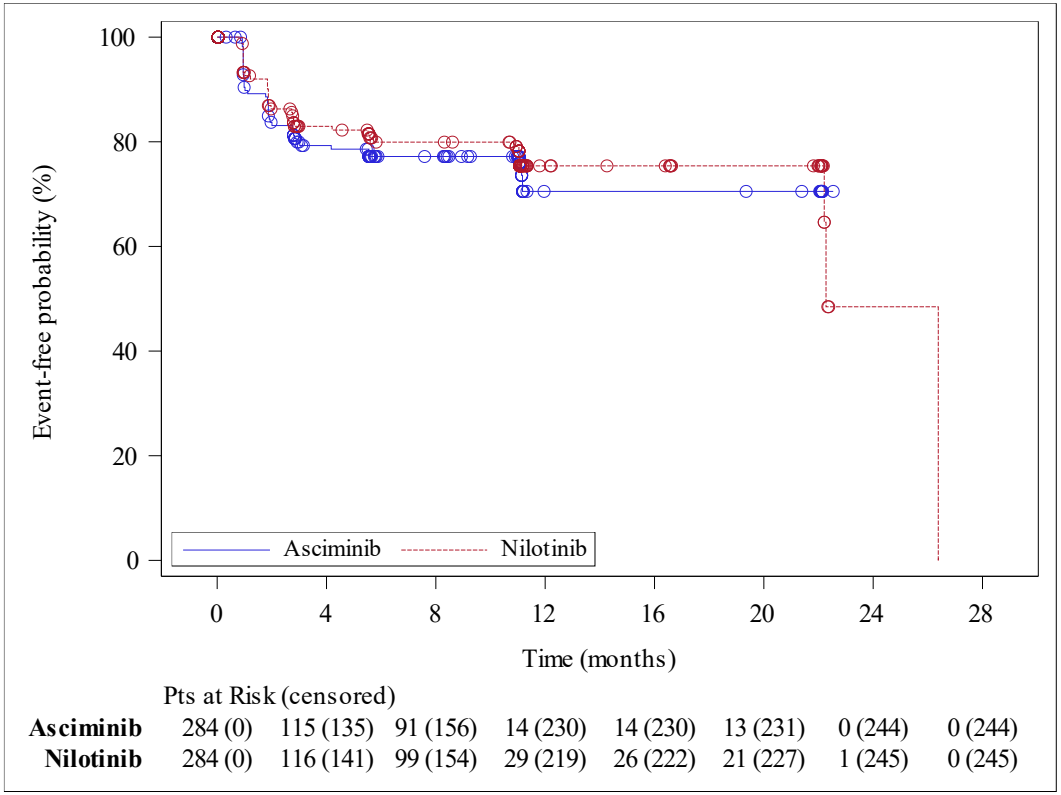


	Pts at Risk (censored)							
Asciminib	284 (0)	120 (133)	93 (155)	9 (236)	9 (236)	8 (237)	0 (244)	0 (244)
Nilotinib	284 (0)	101 (140)	82 (151)	19 (210)	17 (212)	14 (215)	1 (227)	0 (228)

Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.1 EORTC QLQ-C30: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

Financial difficulties (MID=10)



Note: o = Censored observations
Data Cut/15MAY2025

Table 3-6.2 EORTC QLQ-CML24: Time to first deterioration - Sensitivity analysis with alternative definition of baseline (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Body Image Problems (MID=15)			
N*	284	284	1.11
Number of patients with events, n (%)	65 (22.9)	59 (20.8)	[0.78; 1.58]
			0.662
Percentiles (months) [95% CI]			
25th	2.8 [2.0; 5.6]	2.9 [1.9; 5.6]	
Median	N.E. [11.1; N.E.]	22.1 [11.2; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Impact on Daily Life (MID=15)			
N*	284	284	0.71
Number of patients with events, n (%)	44 (15.5)	56 (19.7)	[0.48; 1.06]
			0.144
Percentiles (months) [95% CI]			
25th	11.0 [5.6; 11.2]	2.8 [1.9; 11.0]	
Median	N.E. [N.E.; N.E.]	N.E. [11.3; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Impact on Worry/Mood (MID=15)			
N*	284	284	1.23
Number of patients with events, n (%)	32 (11.3)	24 (8.5)	[0.72; 2.10]
			0.295
Percentiles (months) [95% CI]			
25th	11.2 [8.9; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Symptom Burden (MID=15)			
N*	284	284	0.48
Number of patients with events, n (%)	13 (4.6)	26 (9.2)	[0.24; 0.93]
			0.031
Percentiles (months) [95% CI]			
25th	N.E. [22.1; N.E.]	N.E. [11.2; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Satisfaction with Care and Information (MID=15)			

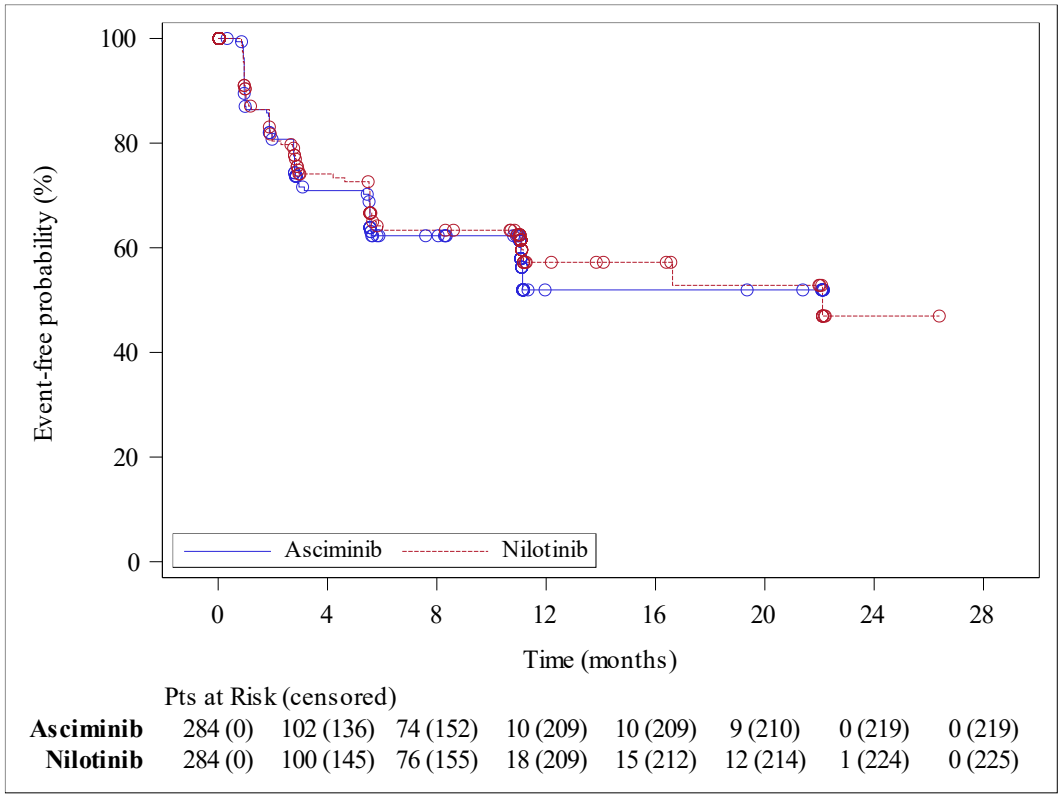
	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
N*	284	284	1.22
Number of patients with events, n (%)	53 (18.7)	40 (14.1)	[0.81; 1.84]
			0.302
Percentiles (months) [95% CI]			
25th	5.6 [2.8; 11.0]	5.6 [2.8; N.E.]	
Median	N.E. [11.2; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Satisfaction with Social Life (MID=15)			
N*	284	284	1.12
Number of patients with events, n (%)	81 (28.5)	73 (25.7)	[0.81; 1.54]
			0.541
Percentiles (months) [95% CI]			
25th	1.8 [1.0; 2.0]	1.9 [1.1; 2.7]	
Median	11.1 [5.6; N.E.]	11.3 [5.5; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [22.1; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**

MID: Minimal important difference
HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
In this sensitivity analysis a missing assessment before randomization is substituted by the last assessment before or on the day of treatment start, if such an assessment is available.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariates baseline score and treatment arm.
P-Values are from a stratified logrank test with stratification factor ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 3-6.2 EORTC QLQ-CML24: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

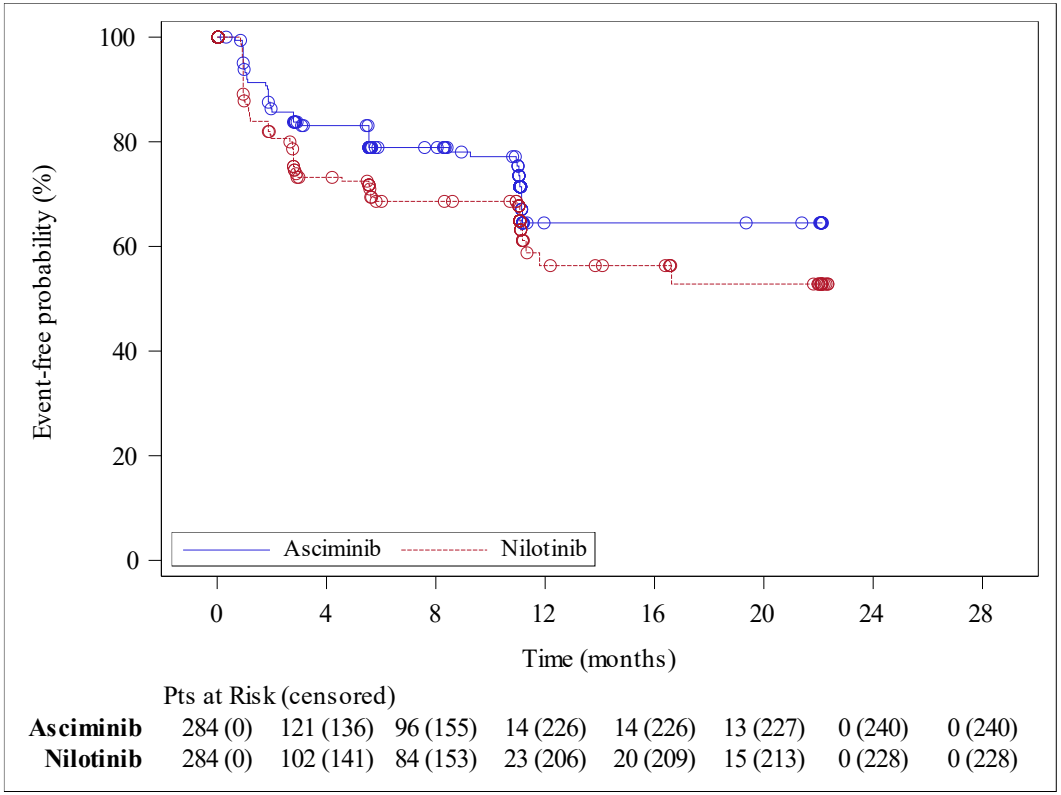
Body Image Problems (MID=15)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.2 EORTC QLQ-CML24: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

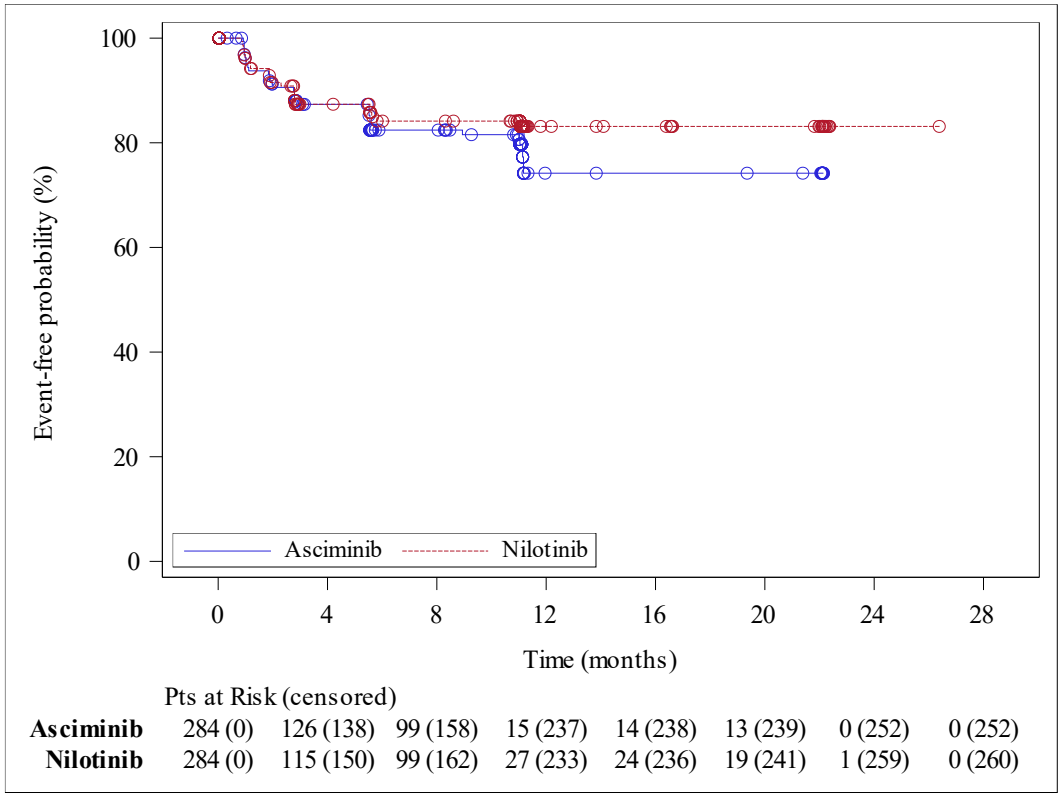
Impact on Daily Life (MID=15)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.2 EORTC QLQ-CML24: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

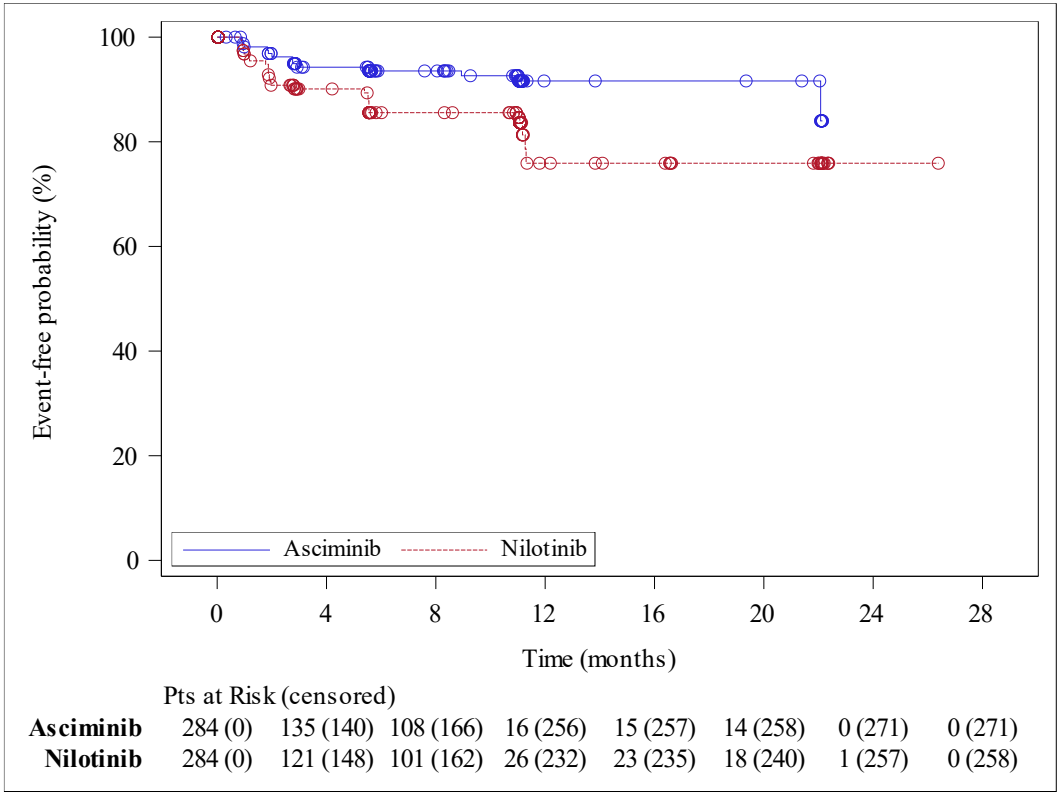
Impact on Worry/Mood (MID=15)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.2 EORTC QLQ-CML24: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

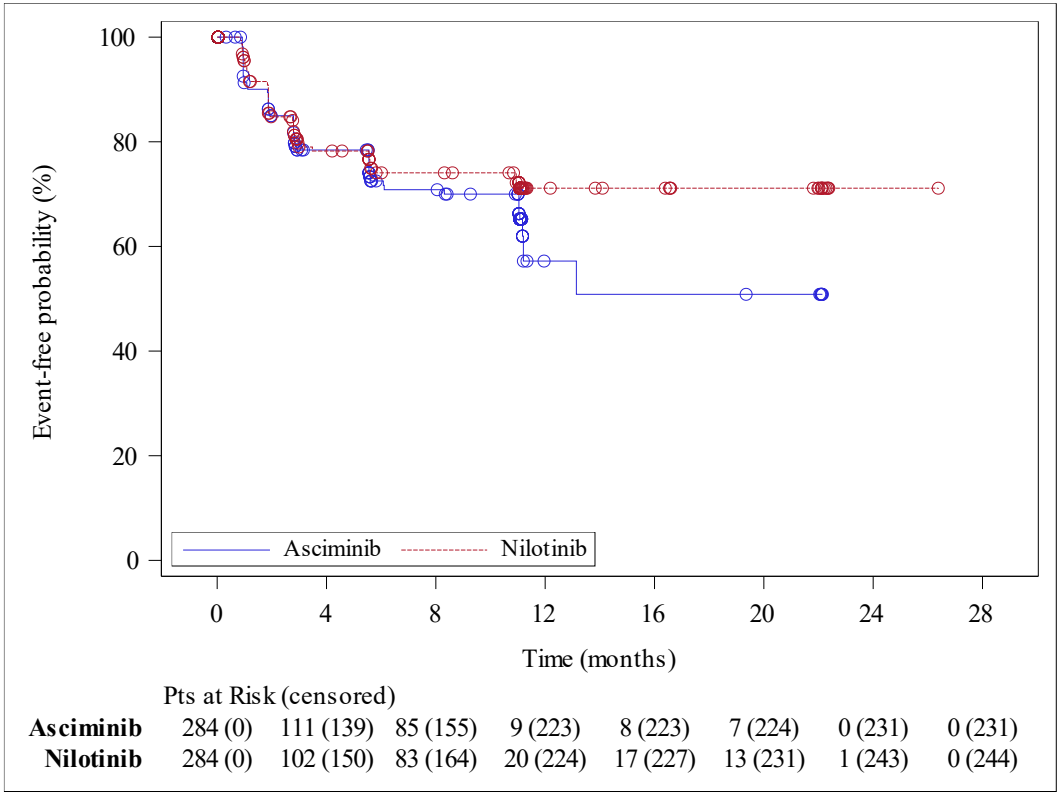
Symptom Burden (MID=15)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.2 EORTC QLQ-CML24: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

Satisfaction with Care and Information (MID=15)

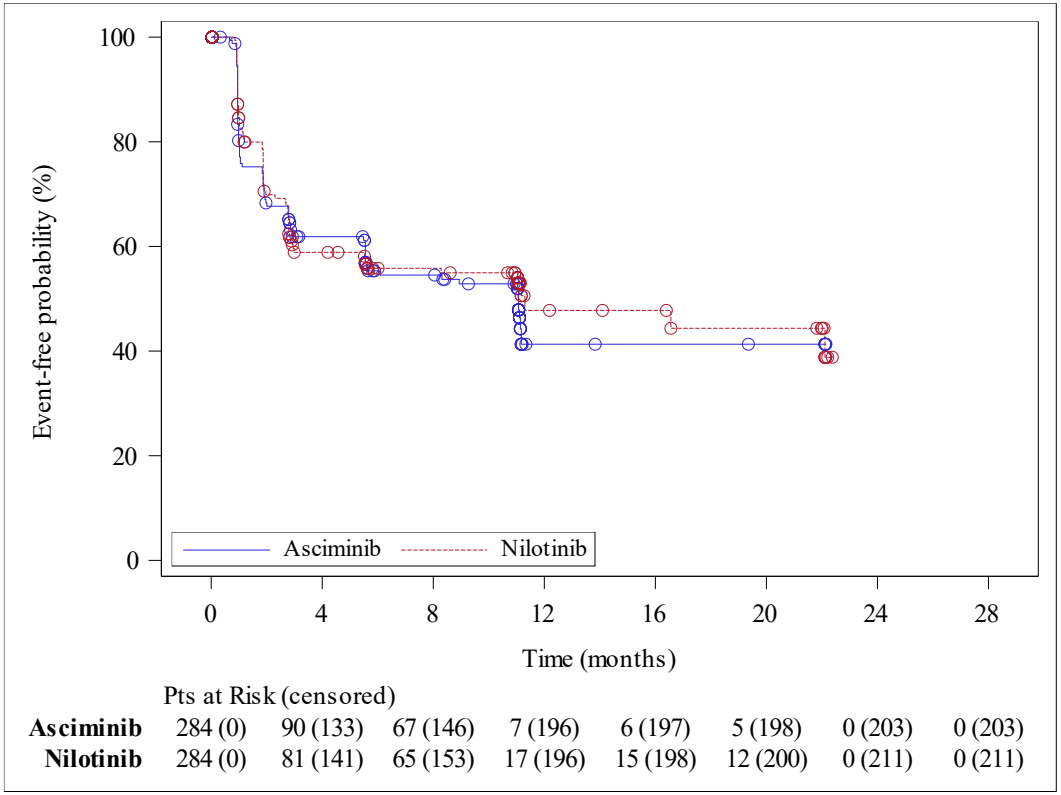


	Pts at Risk (censored)							
Asciminib	284 (0)	111 (139)	85 (155)	9 (223)	8 (223)	7 (224)	0 (231)	0 (231)
Nilotinib	284 (0)	102 (150)	83 (164)	20 (224)	17 (227)	13 (231)	1 (243)	0 (244)

Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.2 EORTC QLQ-CML24: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

Satisfaction with Social Life (MID=15)



	Pts at Risk (censored)							
Asciminib	284 (0)	90 (133)	67 (146)	7 (196)	6 (197)	5 (198)	0 (203)	0 (203)
Nilotinib	284 (0)	81 (141)	65 (153)	17 (196)	15 (198)	12 (200)	0 (211)	0 (211)

Note: o = Censored observations
Data Cut/15MAY2025

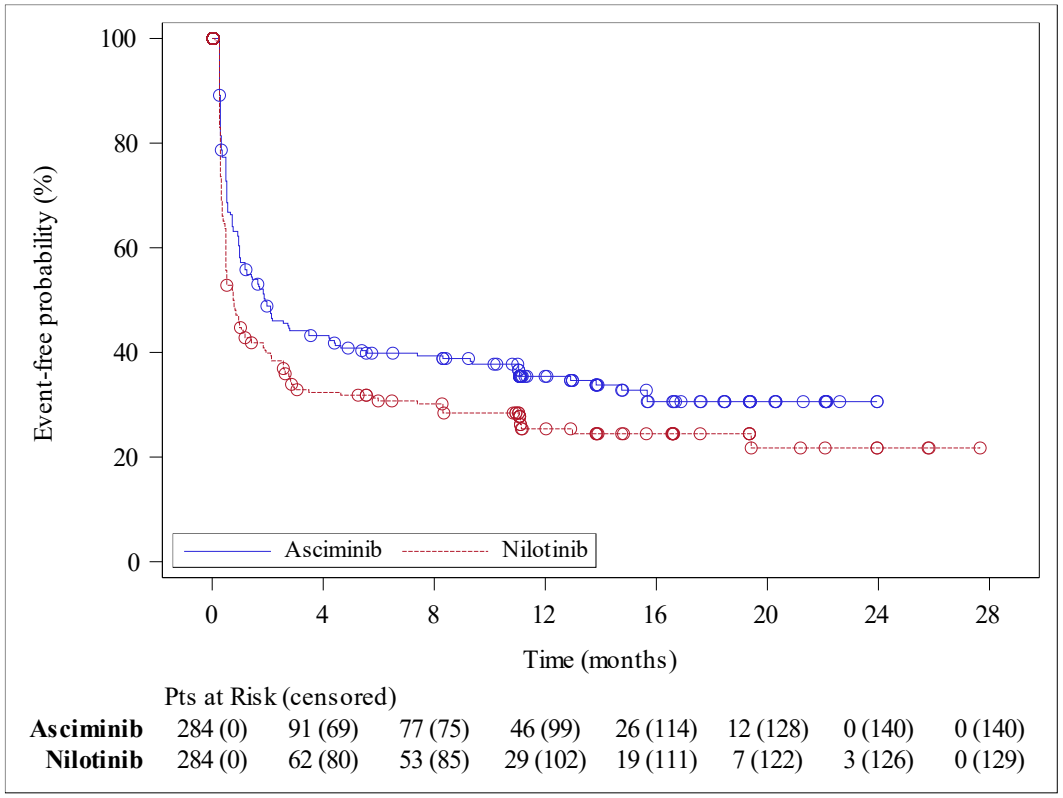
Table 3-6.3 FACT-ITEM GP5: Time to first deterioration - Sensitivity analysis with alternative definition of baseline (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
V4 (MID=1)			
N*	284	284	0.72
Number of patients with events, n (%)	144 (50.7)	155 (54.6)	[0.57; 0.90]
			0.014
Percentiles (months) [95% CI]			
25th	0.5 [0.3; 0.5]	0.3 [0.3; 0.3]	
Median	1.9 [1.2; 3.5]	0.8 [0.5; 1.2]	
75th	N.E. [15.7; N.E.]	13.0 [6.0; N.E.]	

MID: Minimal important difference
HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
In this sensitivity analysis a missing assessment before randomization is substituted by the last assessment before or on the day of treatment start, if such an assessment is available.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariates baseline score and treatment arm.
P-Values are from a stratified logrank test with stratification factor ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 3-6.3 FACT-ITEM GP5: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

V4 (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Table 3-6.4 PRO-CTCAE - Frequency: Time to first deterioration - Sensitivity analysis with alternative definition of baseline (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Headache - Frequency (MID=1)			
N*	284	284	0.69
Number of patients with events, n (%)	144 (50.7)	160 (56.3)	[0.55; 0.86]
			0.004
Percentiles (months) [95% CI]			
25th	0.7 [0.5; 1.0]	0.3 [0.3; 0.5]	
Median	3.2 [2.1; 4.7]	1.4 [0.8; 2.3]	
75th	N.E. [22.1; N.E.]	12.9 [5.5; N.E.]	
Rash - Presence/Absence (MID=1)			
N*	284	284	0.63
Number of patients with events, n (%)	115 (40.5)	128 (45.1)	[0.49; 0.82]
			0.003
Percentiles (months) [95% CI]			
25th	1.6 [1.4; 2.4]	0.6 [0.5; 0.9]	
Median	10.2 [5.6; N.E.]	2.9 [1.7; 5.6]	
75th	N.E. [N.E.; N.E.]	N.E. [19.4; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Diarrhea - Frequency (MID=1)			
N*	284	284	0.93
Number of patients with events, n (%)	132 (46.5)	137 (48.2)	[0.73; 1.18]
			0.352
Percentiles (months) [95% CI]			
25th	0.8 [0.5; 1.0]	0.5 [0.4; 0.9]	
Median	2.9 [2.0; 5.6]	2.8 [2.0; 3.5]	
75th	N.E. [20.3; N.E.]	N.E. [17.5; N.E.]	
Vomiting - Frequency (MID=1)			
N*	284	284	0.49
Number of patients with events, n (%)	40 (14.1)	67 (23.6)	[0.33; 0.73]
			<0.001
Percentiles (months) [95% CI]			
25th	22.1 [14.8; N.E.]	4.7 [2.8; 9.2]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Nausea - Frequency (MID=1)			

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
N*	284	284	0.67
Number of patients with events, n (%)	97 (34.2)	119 (41.9)	[0.51; 0.88]
			0.004
Percentiles (months) [95% CI]			
25th	1.7 [1.0; 2.8]	0.7 [0.4; 1.0]	
Median	22.1 [11.1; N.E.]	4.9 [2.9; 11.1]	
75th	N.E. [25.8; N.E.]	N.E. [24.9; N.E.]	
Edema - Frequency (MID=1)			
N*	284	284	0.85
Number of patients with events, n (%)	91 (32.0)	98 (34.5)	[0.64; 1.13]
			0.226
Percentiles (months) [95% CI]			
25th	2.6 [1.9; 3.9]	2.4 [1.4; 4.0]	
Median	22.1 [17.5; N.E.]	14.8 [11.1; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [24.9; N.E.]	
Muscle Pain - Frequency (MID=1)			
N*	284	284	0.82

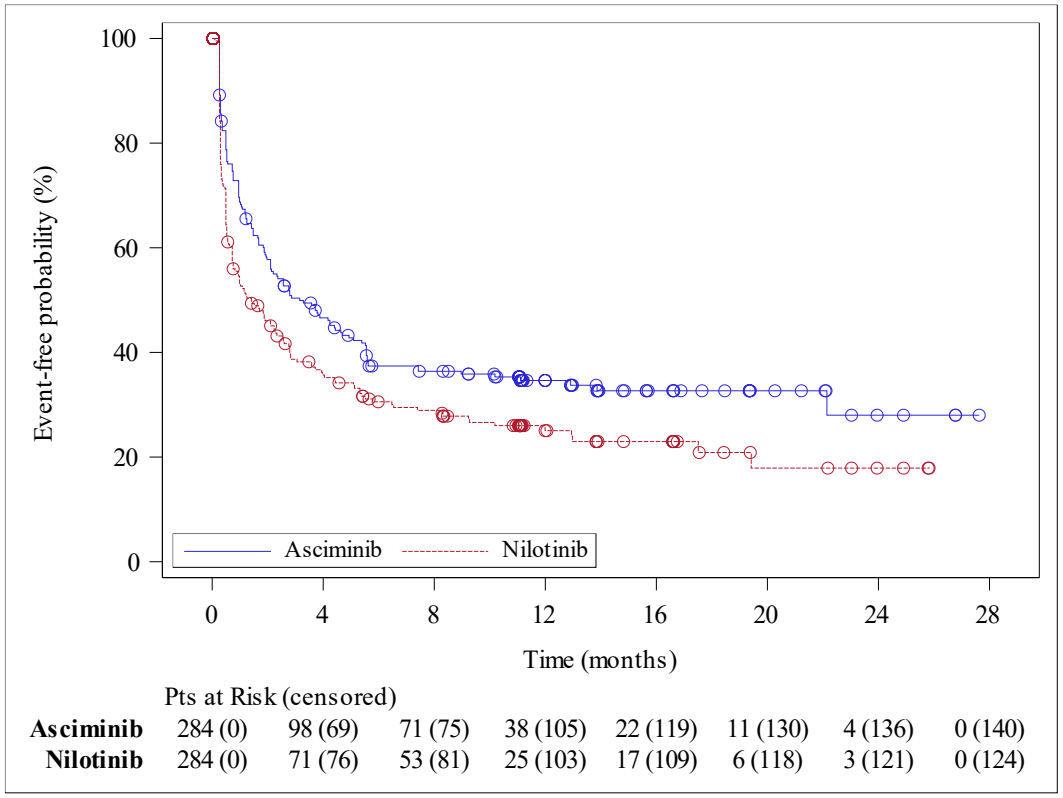
	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Number of patients with events, n (%)	146 (51.4)	161 (56.7)	[0.66; 1.03]
			0.063
Percentiles (months) [95% CI]			
25th	0.5 [0.3; 0.5]	0.3 [0.3; 0.5]	
Median	1.2 [1.0; 2.1]	1.1 [0.7; 1.7]	
75th	N.E. [15.7; N.E.]	11.0 [3.7; N.E.]	
Increased Sweating - Frequency (MID=1)			
N*	284	284	1.01
Number of patients with events, n (%)	115 (40.5)	114 (40.1)	[0.78; 1.30]
			0.846
Percentiles (months) [95% CI]			
25th	1.0 [0.6; 1.4]	0.8 [0.5; 1.4]	
Median	10.2 [5.1; 22.1]	11.1 [5.6; 14.8]	
75th	N.E. [22.1; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**

MID: Minimal important difference
HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
In this sensitivity analysis a missing assessment before randomization is substituted by the last assessment before or on the day of treatment start, if such an assessment is available.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariates baseline score and treatment arm.
P-Values are from a stratified logrank test with stratification factor ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 3-6.4 PRO-CTCAE - Frequency: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

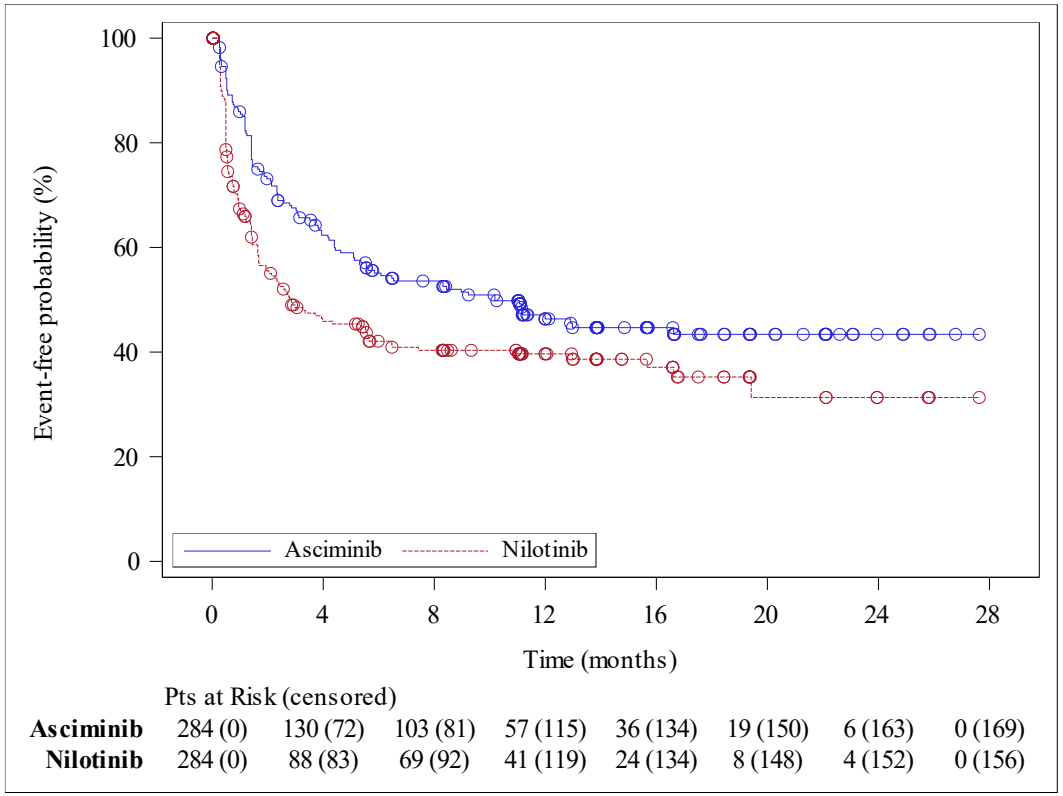
Headache - Frequency (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.4 PRO-CTCAE - Frequency: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

Rash - Presence/Absence (MID=1)

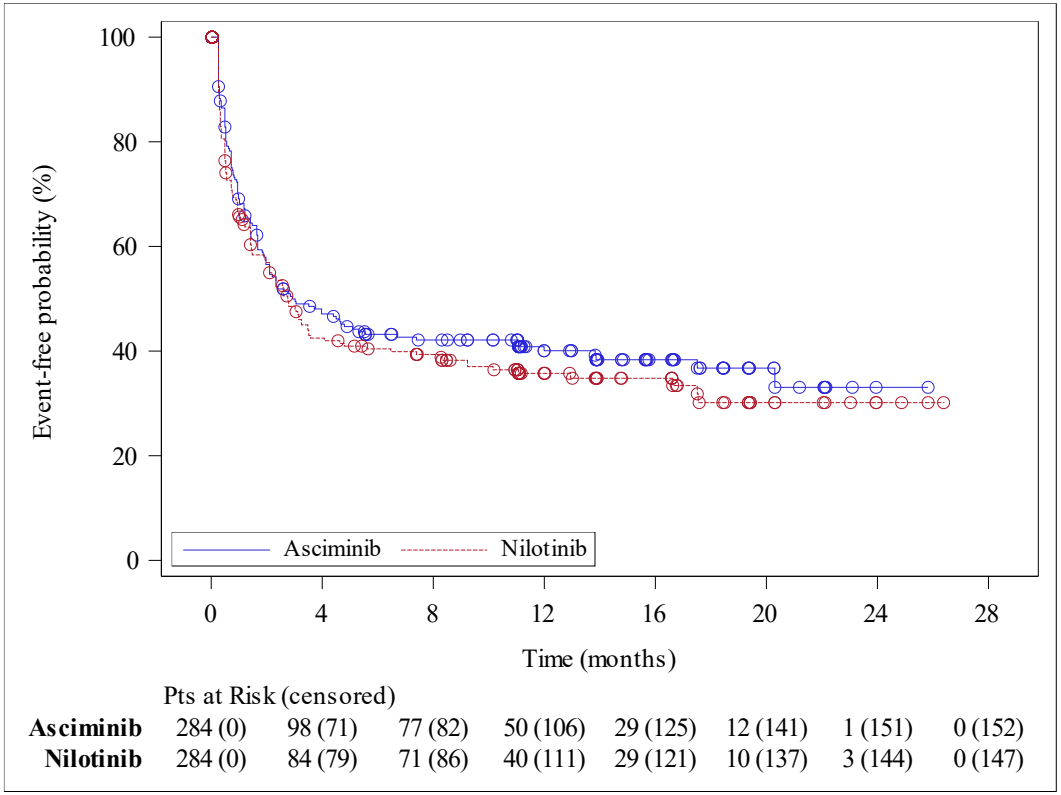


	Pts at Risk (censored)							
Asciminib	284 (0)	130 (72)	103 (81)	57 (115)	36 (134)	19 (150)	6 (163)	0 (169)
Nilotinib	284 (0)	88 (83)	69 (92)	41 (119)	24 (134)	8 (148)	4 (152)	0 (156)

Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.4 PRO-CTCAE - Frequency: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

Diarrhea - Frequency (MID=1)

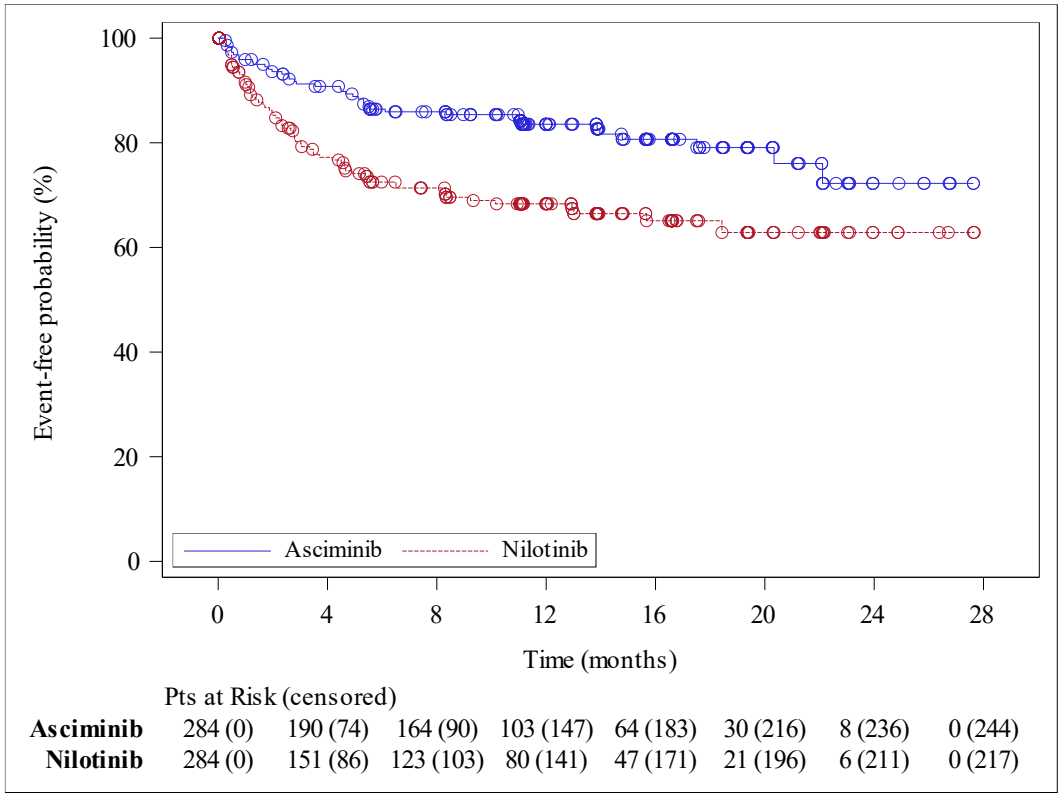


	Pts at Risk (censored)							
Asciminib	284 (0)	98 (71)	77 (82)	50 (106)	29 (125)	12 (141)	1 (151)	0 (152)
Nilotinib	284 (0)	84 (79)	71 (86)	40 (111)	29 (121)	10 (137)	3 (144)	0 (147)

Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.4 PRO-CTCAE - Frequency: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

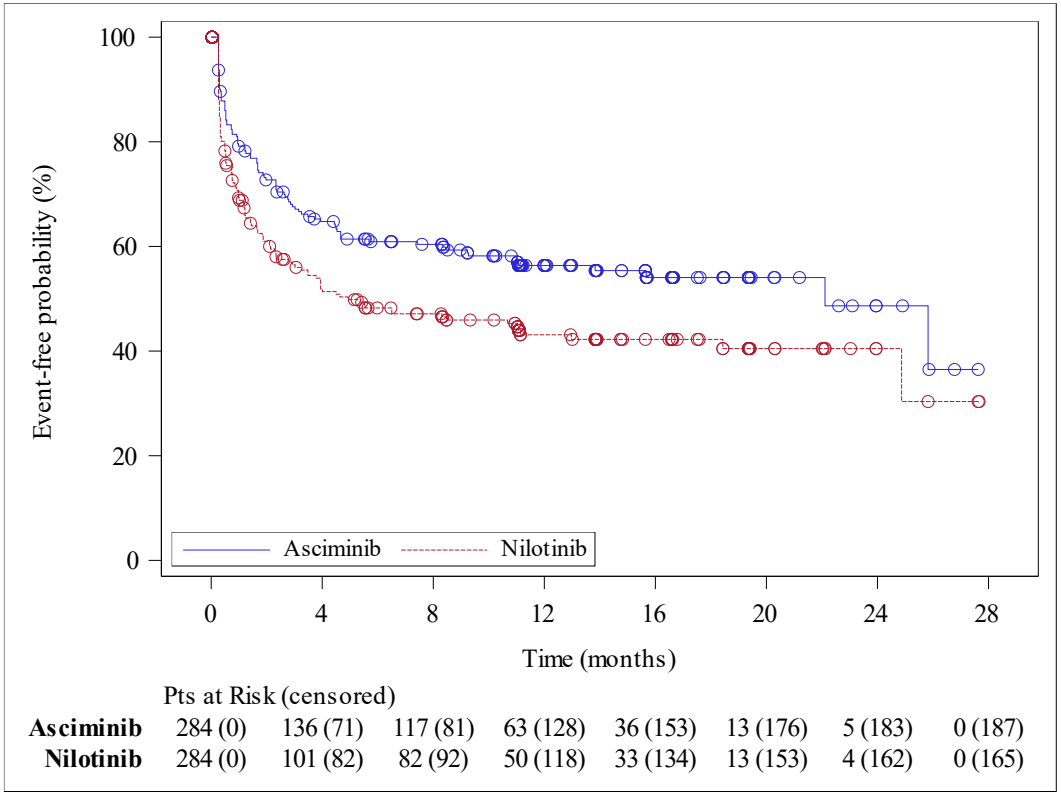
Vomiting - Frequency (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.4 PRO-CTCAE - Frequency: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

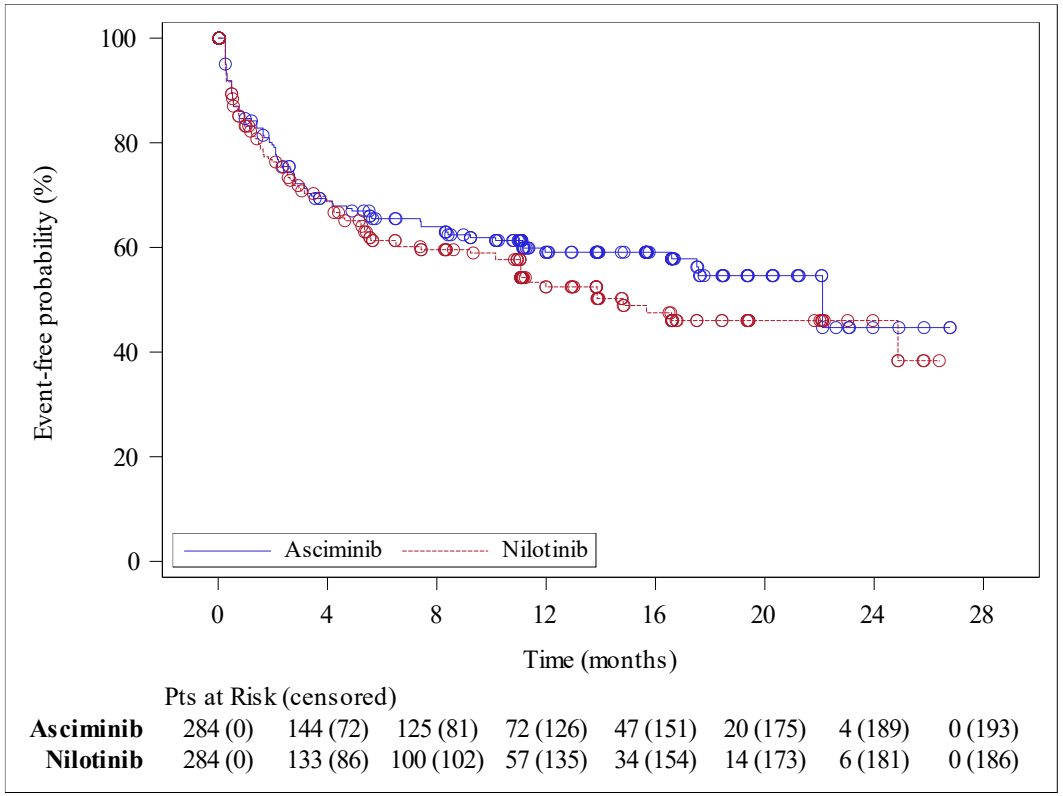
Nausea - Frequency (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.4 PRO-CTCAE - Frequency: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

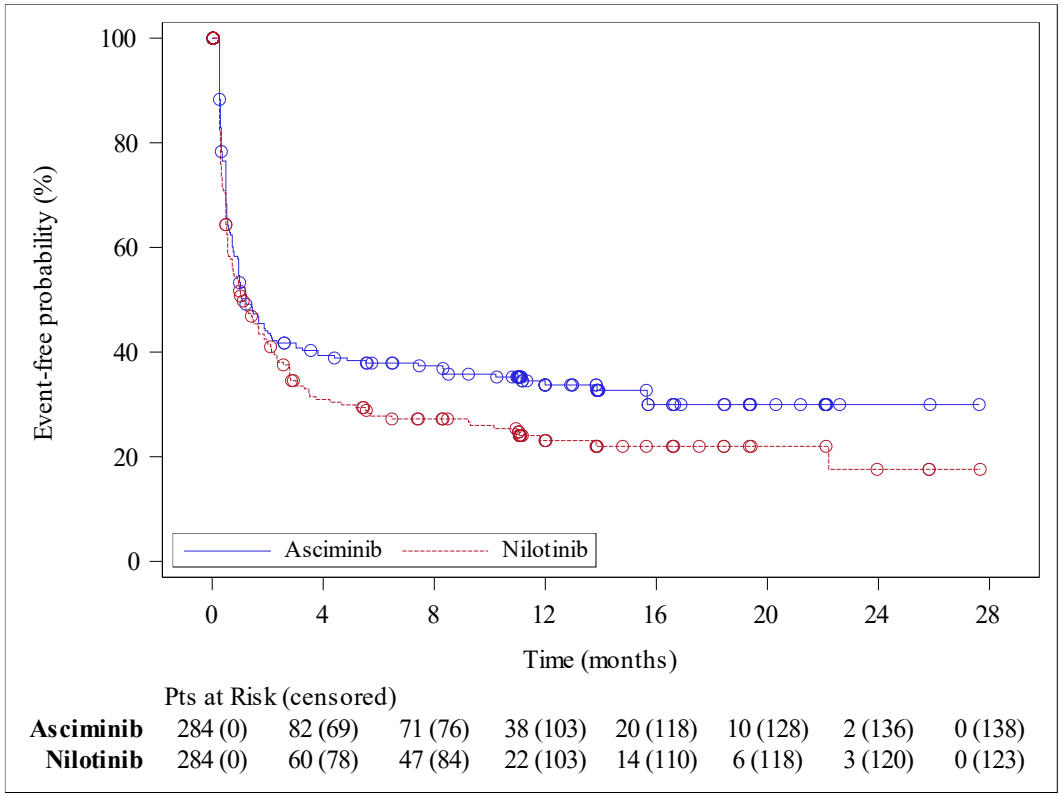
Edema - Frequency (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.4 PRO-CTCAE - Frequency: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

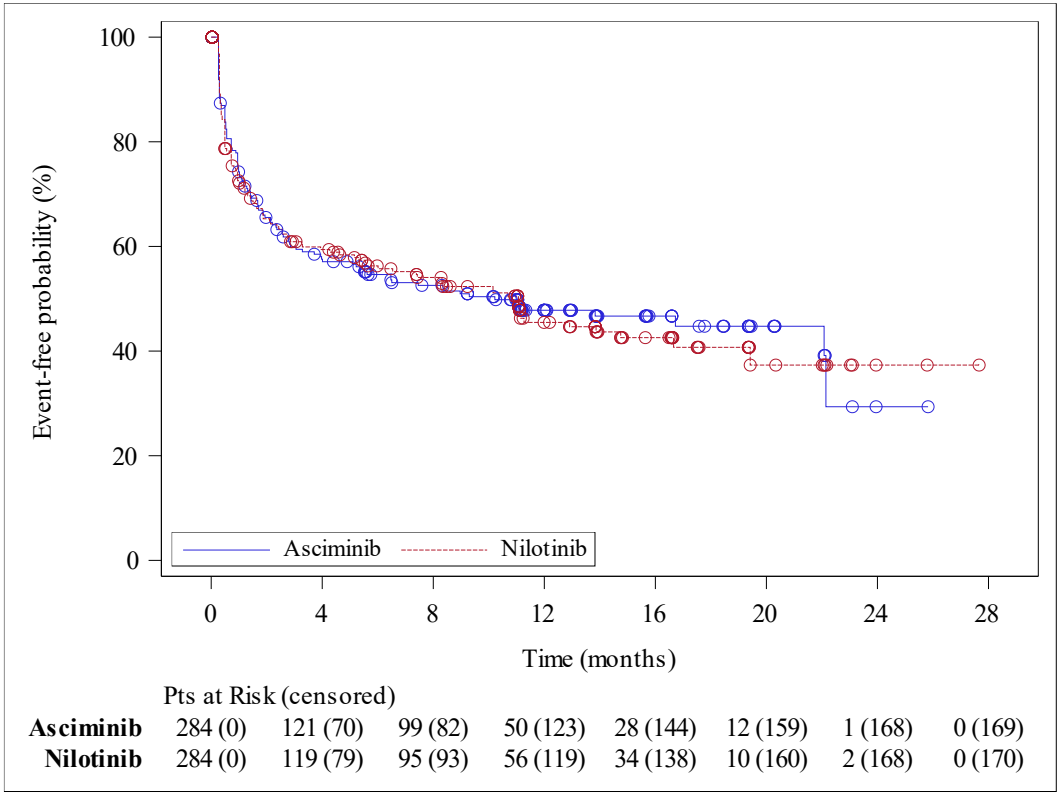
Muscle Pain - Frequency (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.4 PRO-CTCAE - Frequency: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

Increased Sweating - Frequency (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Table 3-6.5 PRO-CTCAE - Severity: Time to first deterioration - Sensitivity analysis with alternative definition of baseline (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Fatigue - Severity (MID=1)			
N*	284	284	0.81
Number of patients with events, n (%)	137 (48.2)	141 (49.6)	[0.64; 1.03]
			0.206
Percentiles (months) [95% CI]			
25th	0.5 [0.3; 1.0]	0.5 [0.3; 0.6]	
Median	3.5 [2.0; 9.2]	2.3 [1.0; 3.7]	
75th	22.1 [18.5; N.E.]	N.E. [14.0; N.E.]	
Headache - Severity (MID=1)			
N*	284	284	0.78
Number of patients with events, n (%)	144 (50.7)	152 (53.5)	[0.62; 0.98]
			0.087
Percentiles (months) [95% CI]			
25th	0.6 [0.5; 1.0]	0.4 [0.3; 0.5]	
Median	2.8 [2.1; 4.4]	1.9 [1.1; 3.0]	
75th	N.E. [22.1; N.E.]	17.5 [10.2; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Vomiting - Severity (MID=1)			
N*	284	284	0.50
Number of patients with events, n (%)	37 (13.0)	62 (21.8)	[0.33; 0.75]
			<0.001
Percentiles (months) [95% CI]			
25th	22.1 [17.5; N.E.]	6.5 [3.5; 13.8]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Nausea - Severity (MID=1)			
N*	284	284	0.65
Number of patients with events, n (%)	90 (31.7)	118 (41.5)	[0.49; 0.85]
			0.001
Percentiles (months) [95% CI]			
25th	1.9 [1.0; 3.5]	0.9 [0.6; 1.4]	
Median	N.E. [15.7; N.E.]	5.6 [3.5; 18.4]	
75th	N.E. [N.E.; N.E.]	24.9 [24.9; N.E.]	
Edema - Severity (MID=1)			

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
N*	284	284	0.77
Number of patients with events, n (%)	78 (27.5)	89 (31.3)	[0.57; 1.05]
			0.093
Percentiles (months) [95% CI]			
25th	3.3 [2.1; 5.6]	2.3 [1.5; 4.2]	
Median	N.E. [22.1; N.E.]	N.E. [11.1; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Muscle Pain - Severity (MID=1)			
N*	284	284	0.74
Number of patients with events, n (%)	137 (48.2)	162 (57.0)	[0.59; 0.93]
			0.004
Percentiles (months) [95% CI]			
25th	0.5 [0.3; 0.5]	0.3 [0.3; 0.5]	
Median	1.9 [1.2; 4.4]	1.3 [0.8; 2.1]	
75th	N.E. [21.2; N.E.]	9.3 [5.5; 19.4]	
Pruritus - Severity (MID=1)			
N*	284	284	0.60

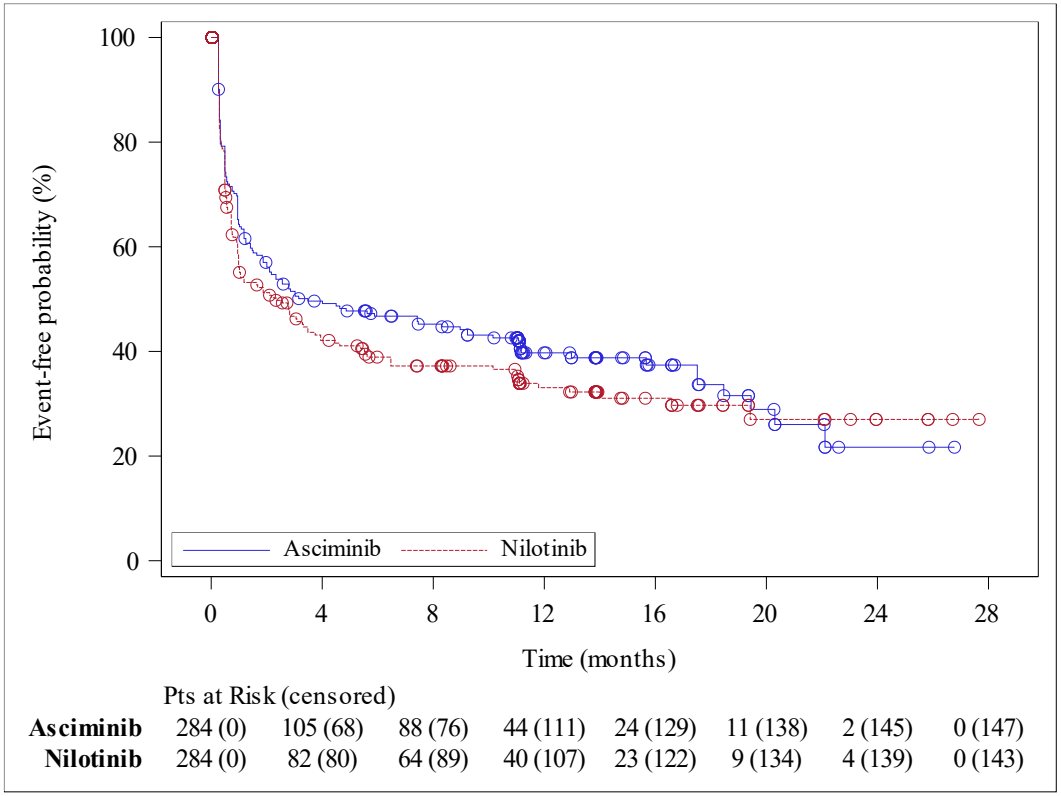
	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Number of patients with events, n (%)	136 (47.9)	165 (58.1)	[0.47; 0.75]
			<0.001
Percentiles (months) [95% CI]			
25th	1.0 [0.8; 1.4]	0.5 [0.5; 0.5]	
Median	3.9 [2.8; 5.6]	1.4 [1.0; 2.0]	
75th	24.0 [22.1; N.E.]	11.1 [5.5; 16.7]	
Increased Sweating - Severity (MID=1)			
N*	284	284	0.98
Number of patients with events, n (%)	106 (37.3)	106 (37.3)	[0.75; 1.28]
			0.760
Percentiles (months) [95% CI]			
25th	1.2 [0.7; 1.9]	1.0 [0.5; 1.7]	
Median	15.8 [7.5; N.E.]	12.9 [5.7; 19.4]	
75th	N.E. [22.1; N.E.]	N.E. [N.E.; N.E.]	
Cough - Severity (MID=1)			
N*	284	284	0.74
Number of patients with events, n (%)	133 (46.8)	146 (51.4)	[0.58; 0.93]

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
			0.006
Percentiles (months) [95% CI]			
25th	1.4 [1.0; 2.0]	0.8 [0.6; 1.1]	
Median	6.5 [4.5; 13.8]	3.0 [2.2; 5.4]	
75th	22.1 [17.5; N.E.]	19.4 [11.2; N.E.]	

MID: Minimal important difference
HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
In this sensitivity analysis a missing assessment before randomization is substituted by the last assessment before or on the day of treatment start, if such an assessment is available.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariates baseline score and treatment arm.
P-Values are from a stratified logrank test with stratification factor ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 3-6.5 PRO-CTCAE - Severity: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

Fatigue - Severity (MID=1)

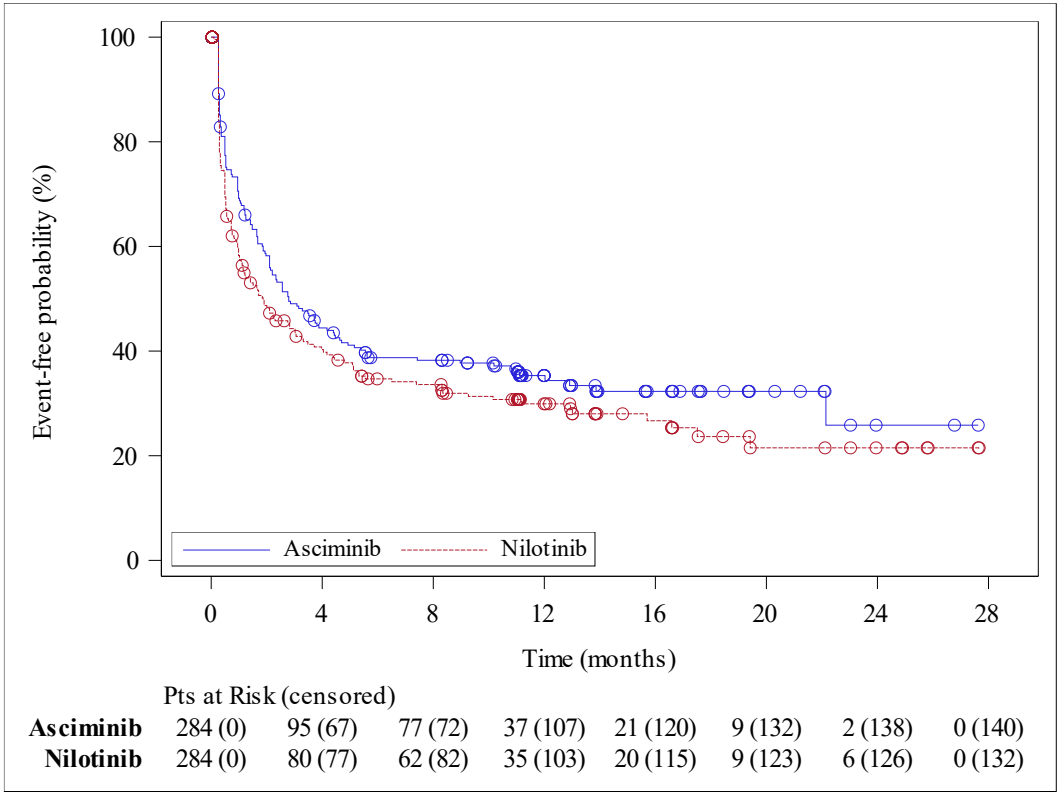


Pts at Risk (censored)								
Asciminib	284 (0)	105 (68)	88 (76)	44 (111)	24 (129)	11 (138)	2 (145)	0 (147)
Nilotinib	284 (0)	82 (80)	64 (89)	40 (107)	23 (122)	9 (134)	4 (139)	0 (143)

Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.5 PRO-CTCAE - Severity: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

Headache - Severity (MID=1)

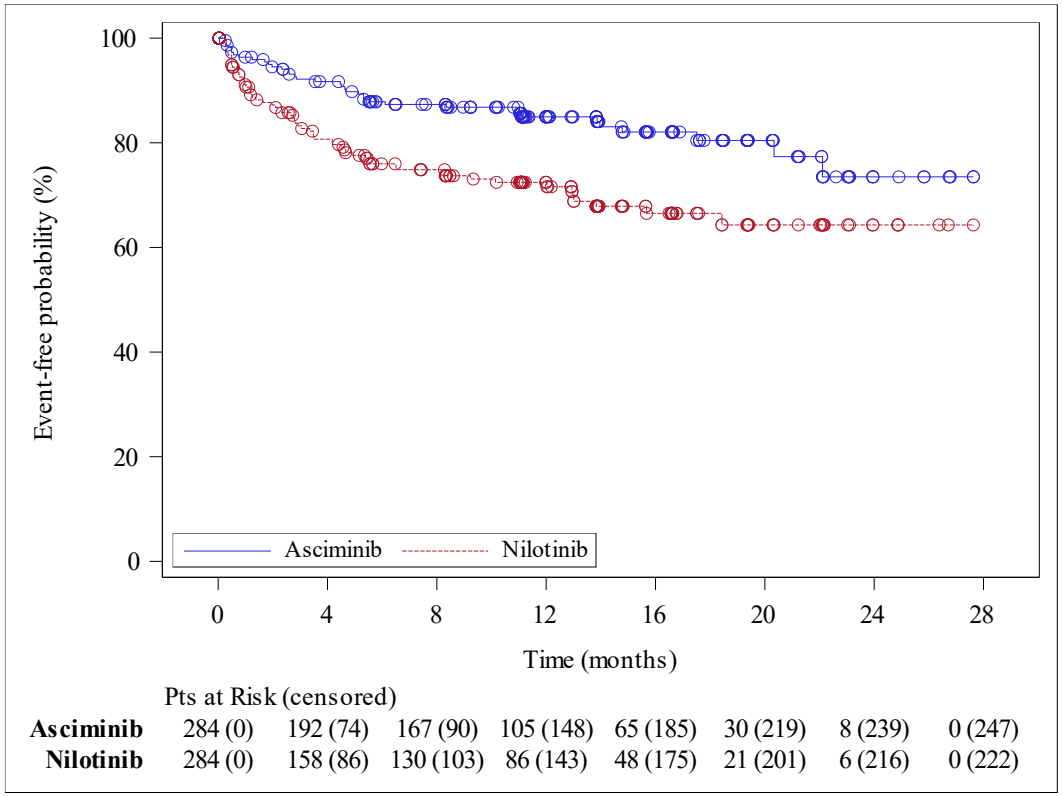


	Pts at Risk (censored)							
Asciminib	284 (0)	95 (67)	77 (72)	37 (107)	21 (120)	9 (132)	2 (138)	0 (140)
Nilotinib	284 (0)	80 (77)	62 (82)	35 (103)	20 (115)	9 (123)	6 (126)	0 (132)

Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.5 PRO-CTCAE - Severity: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

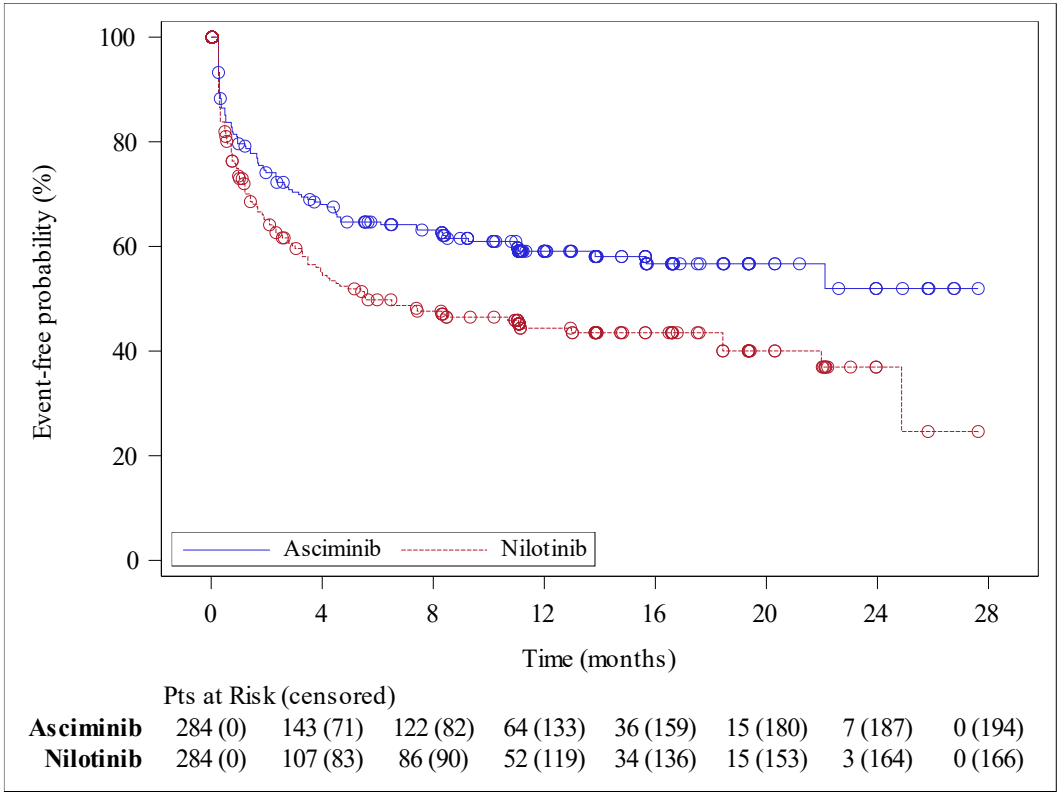
Vomiting - Severity (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.5 PRO-CTCAE - Severity: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

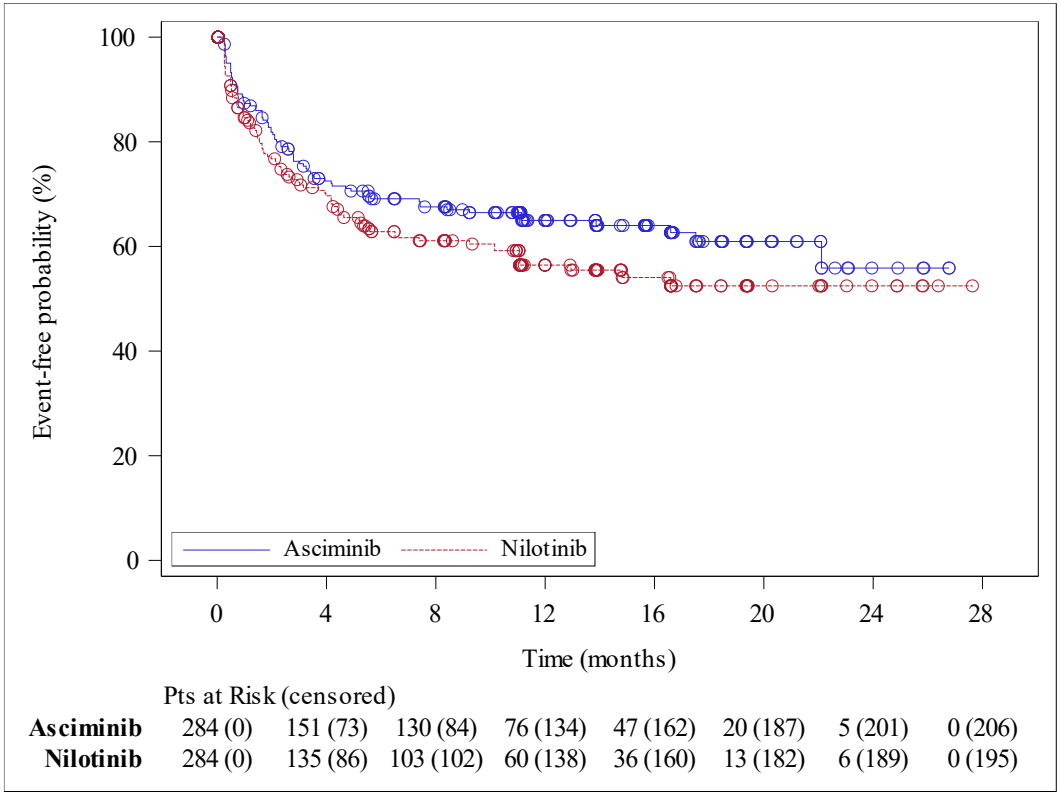
Nausea - Severity (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.5 PRO-CTCAE - Severity: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

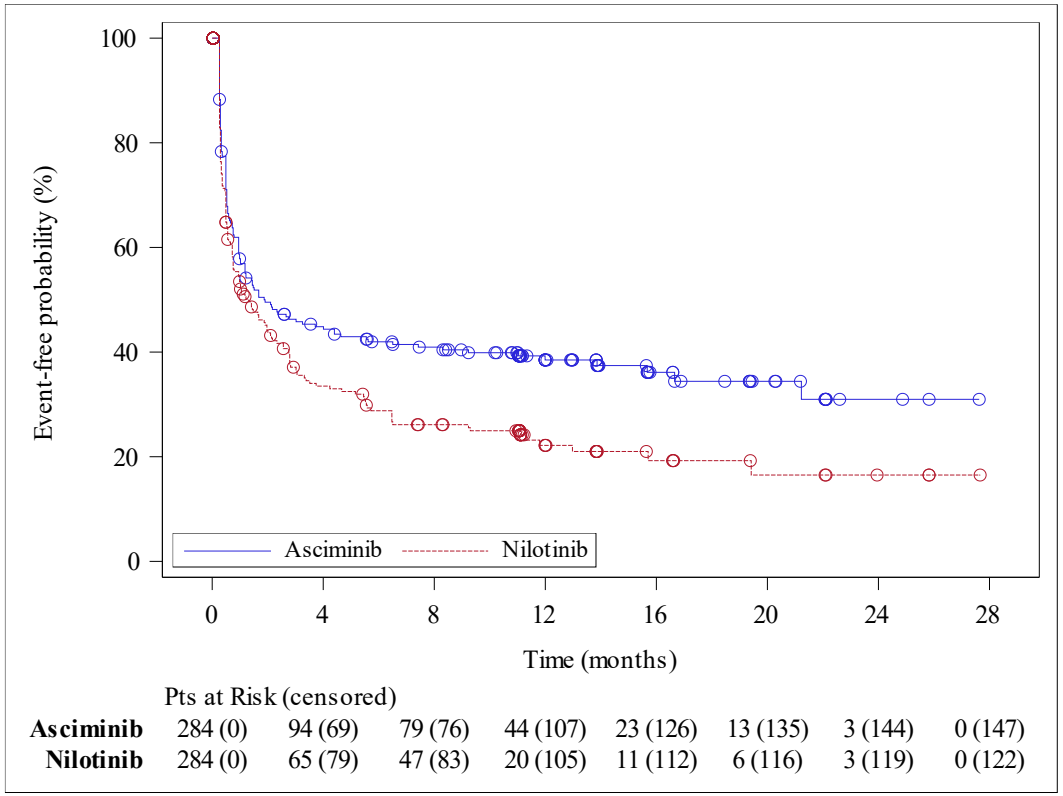
Edema - Severity (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.5 PRO-CTCAE - Severity: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

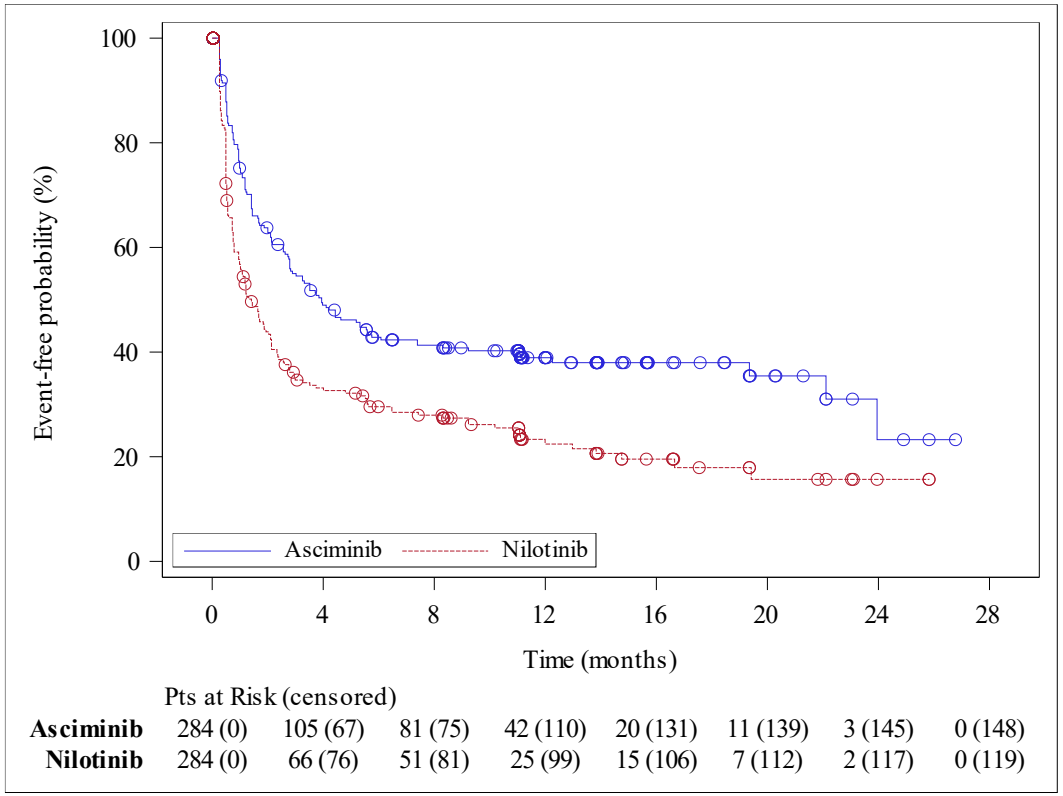
Muscle Pain - Severity (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.5 PRO-CTCAE - Severity: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

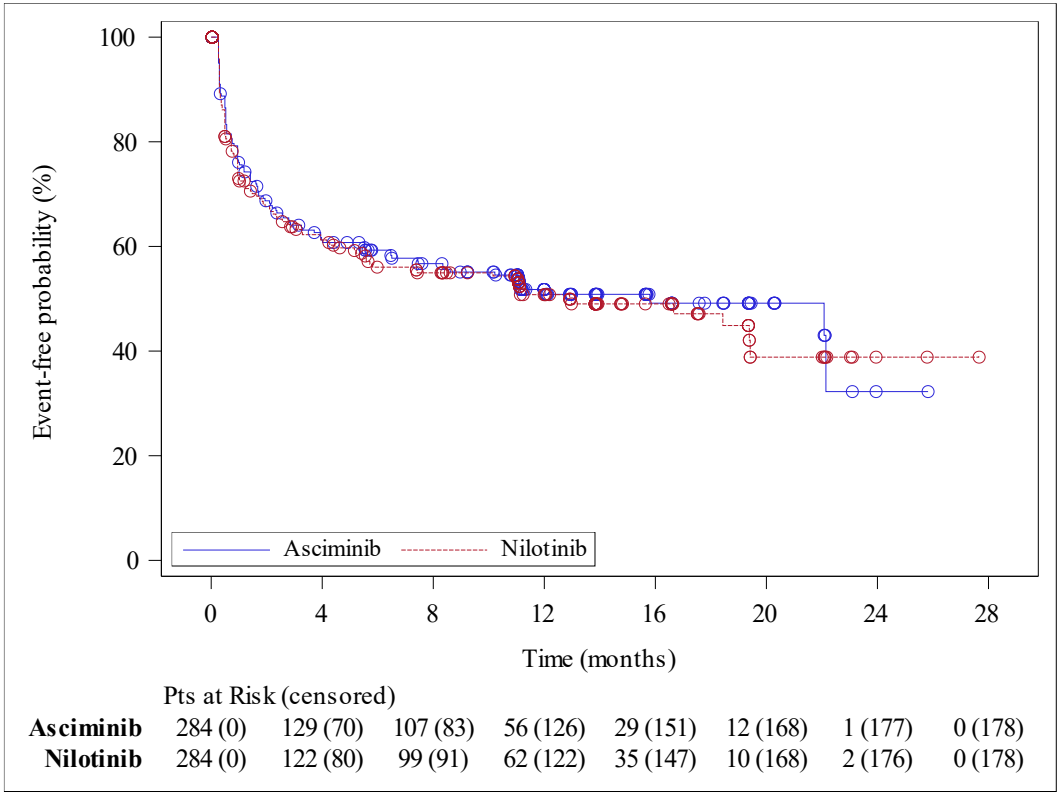
Pruritus - Severity (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.5 PRO-CTCAE - Severity: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

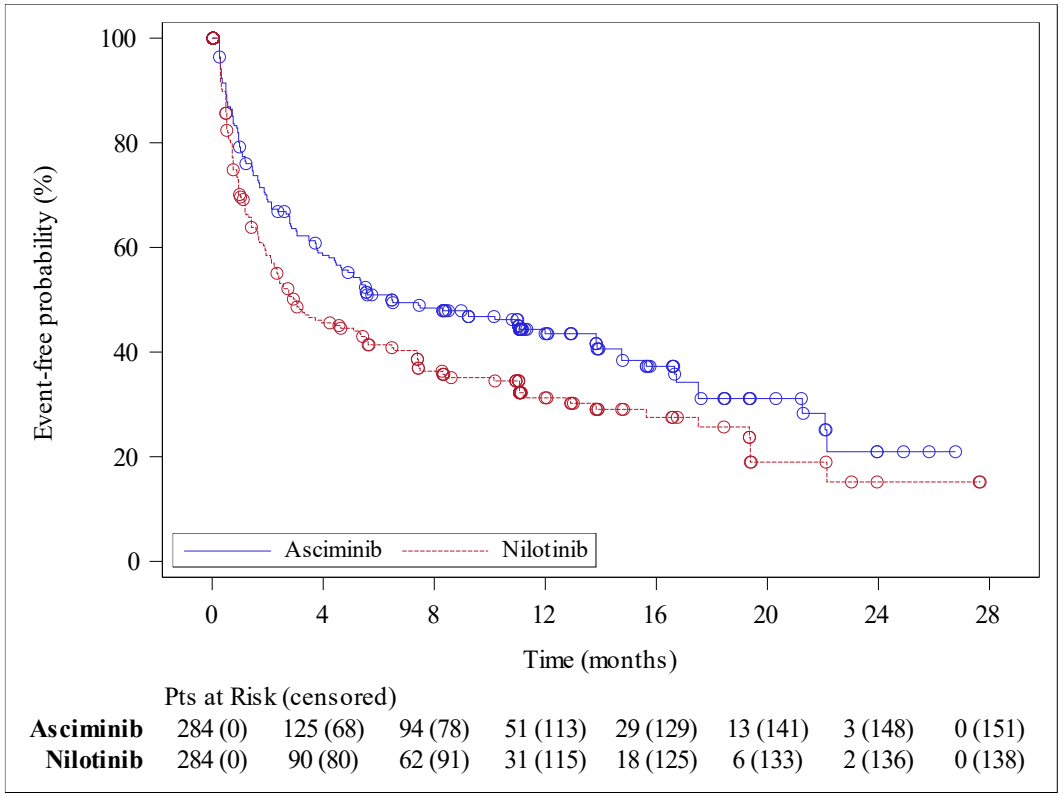
Increased Sweating - Severity (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.5 PRO-CTCAE - Severity: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

Cough - Severity (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Table 3-6.6 PRO-CTCAE - Interference: Time to first deterioration - Sensitivity analysis with alternative definition of baseline (Full Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Fatigue - Interference (MID=1)			
N*	284	284	0.92
Number of patients with events, n (%)	144 (50.7)	138 (48.6)	[0.72; 1.16]
			0.618
Percentiles (months) [95% CI]			
25th	0.7 [0.5; 1.0]	0.4 [0.3; 0.6]	
Median	3.0 [2.1; 5.2]	2.6 [1.0; 3.5]	
75th	22.1 [18.5; N.E.]	N.E. [16.6; N.E.]	
Headache - Interference (MID=1)			
N*	284	284	0.76
Number of patients with events, n (%)	124 (43.7)	133 (46.8)	[0.60; 0.98]
			0.047
Percentiles (months) [95% CI]			
25th	1.9 [1.1; 2.2]	0.5 [0.4; 1.0]	

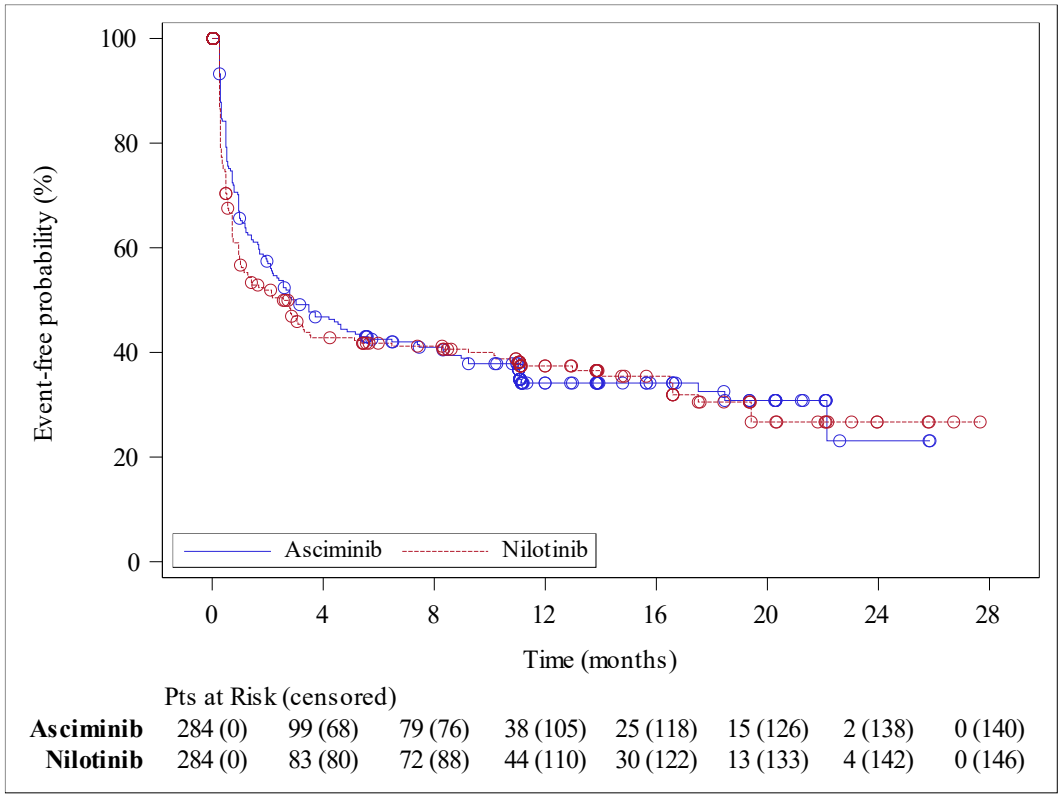
	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	6.5 [4.4; 12.9]	3.1 [2.1; 5.6]	
75th	N.E. [21.3; N.E.]	N.E. [N.E.; N.E.]	
Edema - Interference (MID=1)			
N*	284	284	0.71
Number of patients with events, n (%)	57 (20.1)	70 (24.6)	[0.50; 1.01]
			0.056
Percentiles (months) [95% CI]			
25th	11.2 [4.9; N.E.]	4.2 [2.7; 10.2]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Muscle Pain - Interference (MID=1)			
N*	284	284	0.84
Number of patients with events, n (%)	128 (45.1)	137 (48.2)	[0.66; 1.07]
			0.131
Percentiles (months) [95% CI]			
25th	0.5 [0.5; 0.9]	0.5 [0.3; 0.6]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 284)**	**HR [95% CI] p-value**
Median	3.8 [2.3; 8.3]	2.1 [1.3; 4.2]	
75th	N.E. [N.E.; N.E.]	N.E. [18.4; N.E.]	
Cough - Interference (MID=1)			
N*	284	284	0.89
Number of patients with events, n (%)	103 (36.3)	101 (35.6)	[0.68; 1.17]
			0.479
Percentiles (months) [95% CI]			
25th	2.3 [1.9; 3.5]	2.4 [1.6; 3.2]	
Median	16.7 [11.1; 22.1]	11.2 [7.4; N.E.]	
75th	N.E. [22.1; N.E.]	N.E. [N.E.; N.E.]	

MID: Minimal important difference
HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
In this sensitivity analysis a missing assessment before randomization is substituted by the last assessment before or on the day of treatment start, if such an assessment is available.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariates baseline score and treatment arm.
P-Values are from a stratified logrank test with stratification factor ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 3-6.6 PRO-CTCAE - Interference: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

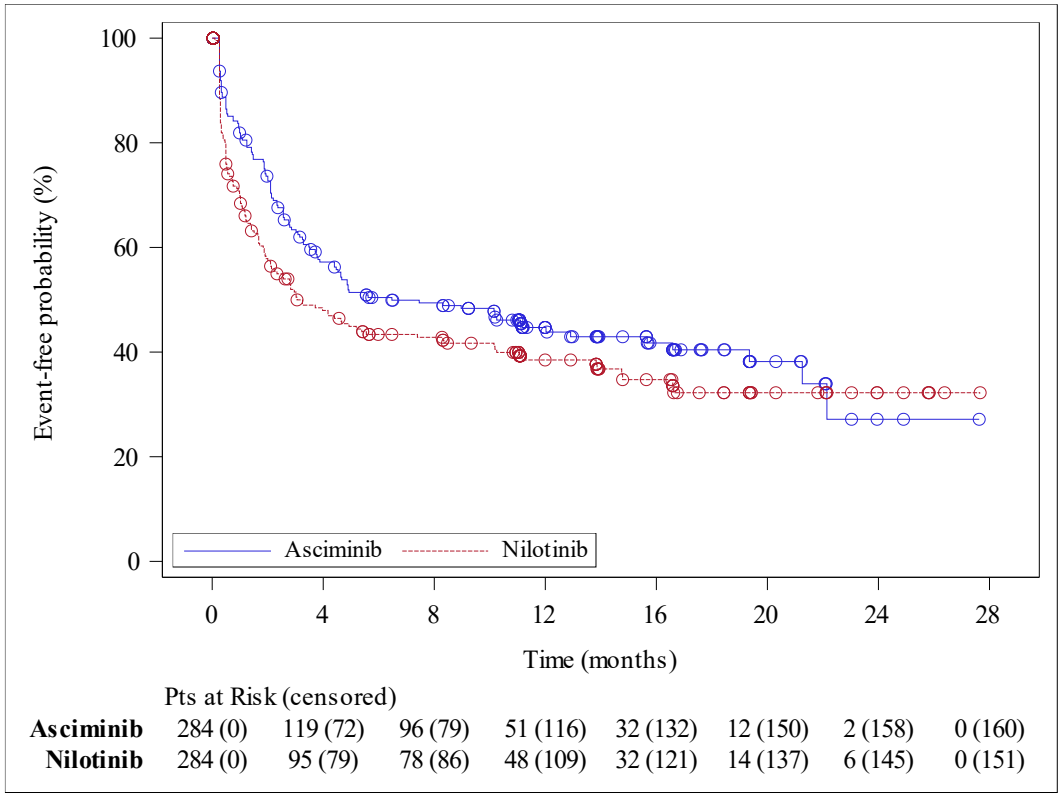
Fatigue - Interference (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.6 PRO-CTCAE - Interference: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

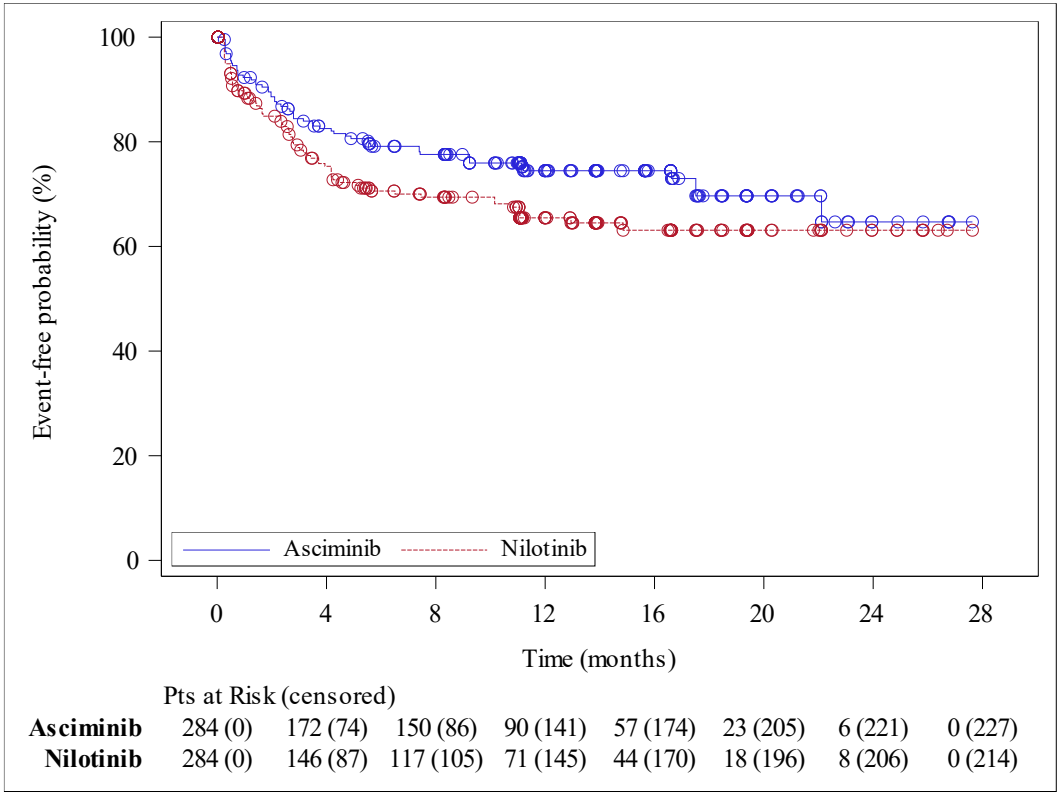
Headache - Interference (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.6 PRO-CTCAE - Interference: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

Edema - Interference (MID=1)

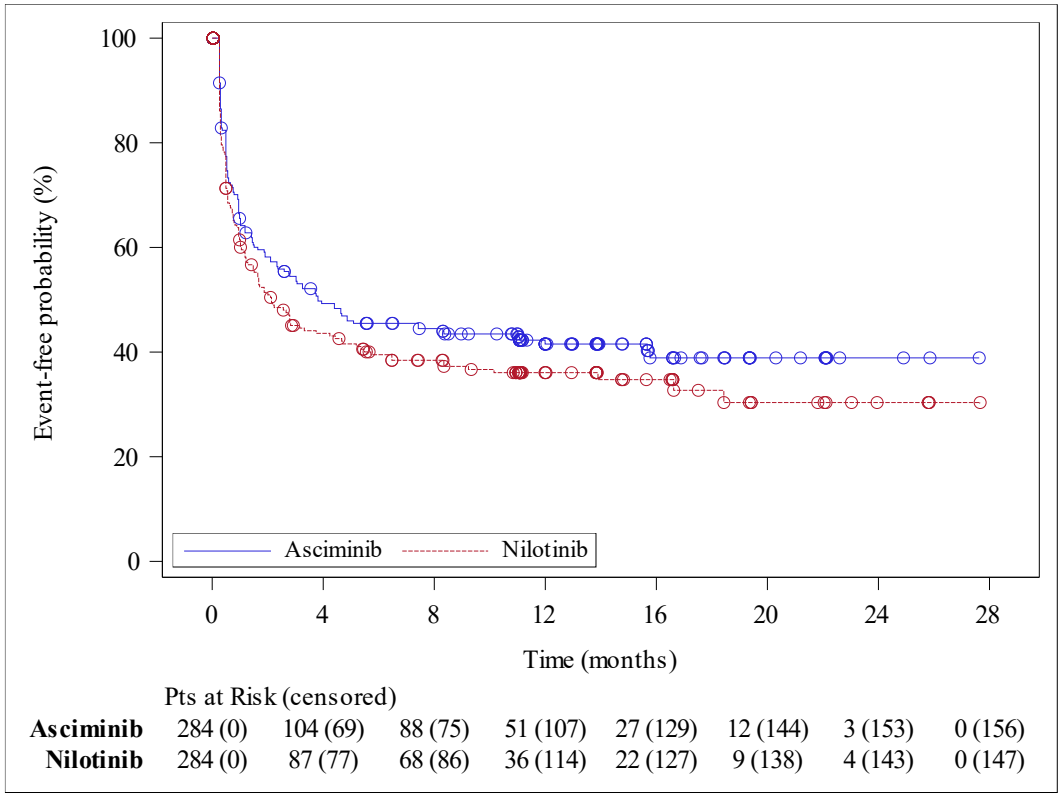


	Pts at Risk (censored)							
Asciminib	284 (0)	172 (74)	150 (86)	90 (141)	57 (174)	23 (205)	6 (221)	0 (227)
Nilotinib	284 (0)	146 (87)	117 (105)	71 (145)	44 (170)	18 (196)	8 (206)	0 (214)

Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.6 PRO-CTCAE - Interference: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

Muscle Pain - Interference (MID=1)

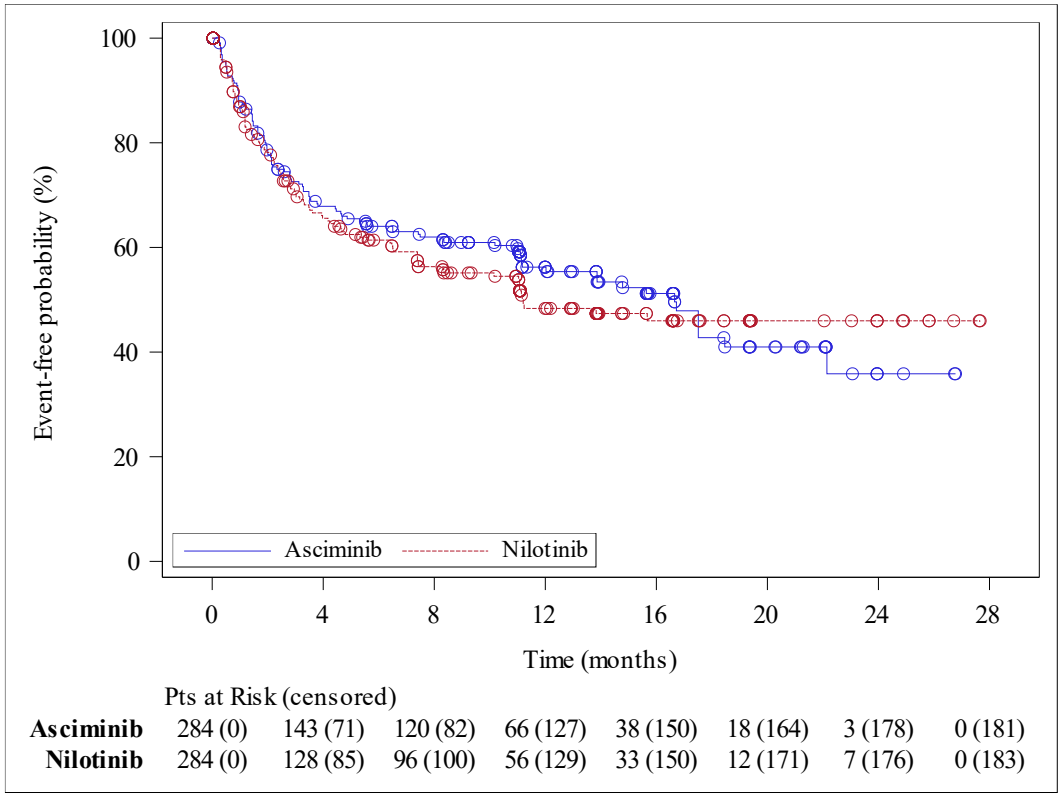


	Pts at Risk (censored)							
Asciminib	284 (0)	104 (69)	88 (75)	51 (107)	27 (129)	12 (144)	3 (153)	0 (156)
Nilotinib	284 (0)	87 (77)	68 (86)	36 (114)	22 (127)	9 (138)	4 (143)	0 (147)

Note: o = Censored observations
Data Cut/15MAY2025

Figure 3-6.6 PRO-CTCAE - Interference: Time to first deterioration - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot (Full Analysis Set)

Cough - Interference (MID=1)



Note: o = Censored observations
Data Cut/15MAY2025

Table 3-7.1 EORTC QLQ-C30: Time to first deterioration analysis by subgroups - Sensitivity analysis with alternative definition of baseline (Full Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Global health status/QoL (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.202)							
Low	45/171 (26.3)	11.2 [11.0; 22.1]	43/172 (25.0)	22.0 [10.7; N.E.]	1.14	[0.75; 1.74]	0.559
Intermediate	12/75 (16.0)	22.1 [11.1; N.E.]	17/75 (22.7)	N.E. [5.5; N.E.]	0.57	[0.27; 1.21]	0.151
High	4/38 (10.5)	N.E. [11.1; N.E.]	6/37 (16.2)	N.E. [5.6; N.E.]	0.39	[0.11; 1.41]	0.189
Sex							
(Interaction test: p = 0.605)							
Female	25/107 (23.4)	11.2 [11.1; N.E.]	28/126 (22.2)	22.0 [5.6; N.E.]	1.00	[0.58; 1.73]	0.956
Male	36/177	22.1 [11.1; N.E.]	38/158	N.E. [11.1; N.E.]	0.84	[0.53; 1.33]	0.465

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(20.3)		(24.1)				
Race							
(Interaction test: p = 0.712)							
Asian	13/40	11.2 [11.0; N.E.]	18/46	10.9 [5.5; N.E.]	0.76	[0.37; 1.60]	0.460
	(32.5)		(39.1)				
White	46/227	22.1 [11.1; N.E.]	47/217	22.0 [11.1; N.E.]	0.93	[0.62; 1.40]	0.595
	(20.3)		(21.7)				
Other	2/17	N.E. [0.9; N.E.]	1/21	N.E. [N.E.; N.E.]	3.52	[0.07; 172.12]	0.134
	(11.8)		(4.8)				
Age groups							
(Interaction test: p = 0.516)							
18 - < 65 years	54/237	12.0 [11.1; 22.1]	59/247	22.0 [11.1; N.E.]	0.96	[0.66; 1.39]	0.803
	(22.8)		(23.9)				
65 - < 75 years	5/38	22.1 [11.1; N.E.]	5/24	N.E. [1.2; N.E.]	0.29	[0.06; 1.46]	0.387
	(13.2)		(20.8)				
>= 75 years	2/9	N.E. [1.0; N.E.]	2/13	1.0 [1.0; N.E.]	0.88	[0.08; 9.40]	0.701
	(22.2)		(15.4)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = 0.758)							
Europe excluding Germany	29/138 (21.0)	22.1 [11.2; N.E.]	35/141 (24.8)	22.0 [10.8; N.E.]	0.86	[0.52; 1.42]	0.588
Germany	11/72 (15.3)	12.0 [11.1; N.E.]	6/53 (11.3)	N.E. [0.9; N.E.]	0.60	[0.20; 1.83]	0.437
Others	21/74 (28.4)	11.2 [11.0; N.E.]	25/90 (27.8)	N.E. [5.7; N.E.]	1.03	[0.57; 1.87]	0.905
Physical functioning (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.097)							
Low	27/171 (15.8)	N.E. [11.2; N.E.]	40/172 (23.3)	11.8 [11.1; N.E.]	0.65	[0.40; 1.07]	0.092
Intermediate	15/75 (20.0)	N.E. [11.1; N.E.]	10/75 (13.3)	N.E. [N.E.; N.E.]	1.71	[0.76; 3.83]	0.349
High	7/38	N.E. [11.1; N.E.]	3/37	N.E. [N.E.; N.E.]	1.56	[0.40; 6.09]	0.370

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(18.4)		(8.1)				
Sex							
(Interaction test: p = 0.706)							
Female	25/107	11.2 [11.1; N.E.]	29/126	11.2 [11.1; N.E.]	1.03	[0.60; 1.77]	0.946
	(23.4)		(23.0)				
Male	24/177	N.E. [N.E.; N.E.]	24/158	N.E. [N.E.; N.E.]	0.87	[0.49; 1.53]	0.619
	(13.6)		(15.2)				
Race							
(Interaction test: p = 0.344)							
Asian	16/40	N.E. [2.0; N.E.]	14/46	N.E. [1.9; N.E.]	1.12	[0.53; 2.35]	0.713
	(40.0)		(30.4)				
White	31/227	N.E. [N.E.; N.E.]	38/217	N.E. [11.8; N.E.]	0.76	[0.47; 1.22]	0.216
	(13.7)		(17.5)				
Other	2/17	N.E. [0.9; N.E.]	1/21	N.E. [11.1; N.E.]	4.39	[0.11; 182.44]	0.180
	(11.8)		(4.8)				
Age groups							
(Interaction test: p = 0.341)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
18 - < 65 years	44/237 (18.6)	N.E. [11.2; N.E.]	47/247 (19.0)	N.E. [11.8; N.E.]	0.95	[0.63; 1.44]	0.822
65 - < 75 years	3/38 (7.9)	N.E. [N.E.; N.E.]	6/24 (25.0)	N.E. [1.2; N.E.]	0.28	[0.07; 1.13]	0.056
>= 75 years	2/9 (22.2)	N.E. [1.0; N.E.]	0/13	N.E. [N.E.; N.E.]	3.29	[0.09; 121.85]	0.199
Geographic region (Interaction test: p = 0.148)							
Europe excluding Germany	21/138 (15.2)	N.E. [11.2; N.E.]	28/141 (19.9)	N.E. [11.2; N.E.]	0.79	[0.44; 1.40]	0.376
Germany	7/72 (9.7)	N.E. [11.1; N.E.]	7/53 (13.2)	5.6 [1.0; N.E.]	0.46	[0.15; 1.43]	0.189
Others	21/74 (28.4)	N.E. [11.0; N.E.]	18/90 (20.0)	N.E. [N.E.; N.E.]	1.35	[0.71; 2.57]	0.336
Role functioning (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.935)							
Low	44/171 (25.7)	11.2 [9.3; N.E.]	39/172 (22.7)	11.8 [11.1; N.E.]	1.17	[0.76; 1.80]	0.441
Intermediate	17/75 (22.7)	N.E. [2.8; N.E.]	19/75 (25.3)	22.1 [5.6; N.E.]	1.07	[0.55; 2.11]	0.936
High	5/38 (13.2)	N.E. [N.E.; N.E.]	4/37 (10.8)	N.E. [5.7; N.E.]	0.82	[0.22; 3.06]	0.888
Sex							
(Interaction test: p = 0.745)							
Female	30/107 (28.0)	11.2 [2.7; N.E.]	31/126 (24.6)	11.2 [5.7; N.E.]	1.25	[0.75; 2.08]	0.507
Male	36/177 (20.3)	22.1 [11.1; N.E.]	31/158 (19.6)	22.1 [22.1; N.E.]	1.09	[0.67; 1.79]	0.592
Race							
(Interaction test: p = 0.945)							
Asian	12/40 (30.0)	N.E. [5.7; N.E.]	15/46 (32.6)	22.3 [5.6; N.E.]	0.93	[0.43; 2.03]	0.875

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
White	52/227 (22.9)	22.1 [11.0; N.E.]	45/217 (20.7)	22.1 [11.2; N.E.]	1.14	[0.76; 1.71]	0.508
Other	2/17 (11.8)	N.E. [1.8; N.E.]	2/21 (9.5)	N.E. [5.7; N.E.]	1.00	[0.14; 7.24]	0.964
Age groups (Interaction test: p = 0.196)							
18 - < 65 years	61/237 (25.7)	22.1 [11.0; N.E.]	55/247 (22.3)	22.3 [11.1; N.E.]	1.21	[0.83; 1.75]	0.241
65 - < 75 years	3/38 (7.9)	N.E. [N.E.; N.E.]	5/24 (20.8)	N.E. [2.8; N.E.]	0.37	[0.08; 1.63]	0.092
>= 75 years	2/9 (22.2)	N.E. [1.0; N.E.]	2/13 (15.4)	22.1 [1.9; N.E.]	14.16	[0.12; 1696.0]	0.541
Geographic region (Interaction test: p = 0.191)							
Europe excluding Germany	33/138 (23.9)	22.5 [11.1; N.E.]	34/141 (24.1)	22.1 [11.1; N.E.]	1.04	[0.64; 1.69]	0.810
Germany	12/72	22.1 [2.8; N.E.]	9/53	2.8 [0.9; N.E.]	0.44	[0.16; 1.19]	0.279

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(16.7)		(17.0)				
Others	21/74	N.E. [5.7; N.E.]	19/90	22.3 [11.1; N.E.]	1.41	[0.75; 2.66]	0.287
	(28.4)		(21.1)				
Emotional functioning (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.498)							
Low	27/171	N.E. [11.2; N.E.]	40/172	11.8 [11.1; N.E.]	0.61	[0.37; 1.00]	0.116
	(15.8)		(23.3)				
Intermediate	17/75	11.1 [11.1; N.E.]	15/75	22.0 [11.0; N.E.]	1.04	[0.52; 2.11]	0.722
	(22.7)		(20.0)				
High	4/38	N.E. [11.1; N.E.]	6/37	N.E. [11.0; N.E.]	0.42	[0.11; 1.53]	0.209
	(10.5)		(16.2)				
Sex							
(Interaction test: p = 0.646)							
Female	21/107	N.E. [11.1; N.E.]	28/126	11.8 [10.7; N.E.]	0.79	[0.45; 1.41]	0.437
	(19.6)		(22.2)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Male	27/177 (15.3)	N.E. [11.1; N.E.]	33/158 (20.9)	22.0 [22.0; N.E.]	0.63	[0.38; 1.06]	0.248
Race							
(Interaction test: p = 0.229)							
Asian	8/40 (20.0)	N.E. [N.E.; N.E.]	15/46 (32.6)	N.E. [2.9; N.E.]	0.44	[0.18; 1.07]	0.101
White	36/227 (15.9)	N.E. [11.2; N.E.]	45/217 (20.7)	22.0 [11.1; N.E.]	0.73	[0.47; 1.14]	0.194
Other	4/17 (23.5)	11.2 [0.9; N.E.]	1/21 (4.8)	N.E. [5.6; N.E.]	8.31	[0.26; 270.24]	0.060
Age groups							
(Interaction test: p = 0.726)							
18 - < 65 years	41/237 (17.3)	N.E. [11.2; N.E.]	56/247 (22.7)	N.E. [11.2; N.E.]	0.68	[0.45; 1.03]	0.175
65 - < 75 years	5/38 (13.2)	N.E. [11.1; N.E.]	4/24 (16.7)	22.0 [2.8; N.E.]	1.03	[0.22; 4.93]	0.837
>= 75 years	2/9	N.E. [1.0; N.E.]	1/13	N.E. [1.0; N.E.]	13.27	[0.09; 1969.7]	0.739

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(22.2)		(7.7)				
Geographic region							
(Interaction test: p = 0.989)							
Europe excluding Germany	26/138	N.E. [11.1; N.E.]	33/141	11.8 [11.1; N.E.]	0.75	[0.45; 1.26]	0.397
	(18.8)		(23.4)				
Germany	5/72	N.E. [11.1; N.E.]	4/53	N.E. [2.7; N.E.]	0.77	[0.19; 3.08]	0.739
	(6.9)		(7.5)				
Others	17/74	11.2 [11.2; N.E.]	24/90	N.E. [11.0; N.E.]	0.71	[0.37; 1.34]	0.473
	(23.0)		(26.7)				
Cognitive functioning (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.776)							
Low	44/171	11.2 [11.0; 22.1]	51/172	11.1 [5.4; N.E.]	0.86	[0.57; 1.29]	0.460
	(25.7)		(29.7)				
Intermediate	23/75	10.8 [4.2; N.E.]	21/75	11.1 [2.8; N.E.]	1.07	[0.59; 1.94]	0.803
	(30.7)		(28.0)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
High	10/38 (26.3)	N.E. [2.8; N.E.]	8/37 (21.6)	N.E. [2.8; N.E.]	0.98	[0.38; 2.49]	0.923
Sex							
(Interaction test: p = 0.093)							
Female	39/107 (36.4)	5.6 [2.8; 11.1]	36/126 (28.6)	11.1 [2.9; 11.8]	1.28	[0.81; 2.04]	0.302
Male	38/177 (21.5)	22.1 [11.1; N.E.]	44/158 (27.8)	11.1 [5.6; N.E.]	0.73	[0.47; 1.13]	0.173
Race							
(Interaction test: p = 0.796)							
Asian	16/40 (40.0)	11.1 [2.8; N.E.]	17/46 (37.0)	11.1 [2.8; N.E.]	0.99	[0.49; 1.99]	0.943
White	58/227 (25.6)	11.1 [10.8; 22.1]	57/217 (26.3)	11.1 [5.6; N.E.]	0.92	[0.64; 1.33]	0.635
Other	3/17 (17.6)	N.E. [0.9; N.E.]	6/21 (28.6)	5.6 [1.0; N.E.]	1.36	[0.21; 8.80]	0.548
Age groups							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.344)							
18 - < 65 years	66/237 (27.8)	11.1 [11.0; 22.1]	74/247 (30.0)	11.1 [5.6; 11.8]	0.90	[0.64; 1.25]	0.521
65 - < 75 years	7/38 (18.4)	N.E. [5.6; N.E.]	5/24 (20.8)	N.E. [2.8; N.E.]	0.82	[0.25; 2.65]	0.743
>= 75 years	4/9 (44.4)	2.8 [1.6; N.E.]	1/13 (7.7)	N.E. [2.8; N.E.]	4.98	[0.14; 177.70]	0.105
Geographic region							
(Interaction test: p = 0.865)							
Europe excluding Germany	35/138 (25.4)	11.2 [11.1; N.E.]	41/141 (29.1)	11.1 [5.6; N.E.]	0.88	[0.56; 1.39]	0.583
Germany	15/72 (20.8)	11.1 [1.9; 22.1]	9/53 (17.0)	5.7 [0.9; N.E.]	0.76	[0.31; 1.86]	0.671
Others	27/74 (36.5)	11.1 [2.8; N.E.]	30/90 (33.3)	11.1 [2.8; N.E.]	1.04	[0.61; 1.77]	0.947
Social functioning (MID=10)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.920)							
Low	35/171 (20.5)	22.1 [11.2; N.E.]	43/172 (25.0)	N.E. [5.6; N.E.]	0.73	[0.46; 1.14]	0.204
Intermediate	16/75 (21.3)	N.E. [2.8; N.E.]	18/75 (24.0)	N.E. [2.8; N.E.]	0.84	[0.43; 1.65]	0.629
High	7/38 (18.4)	N.E. [8.9; N.E.]	6/37 (16.2)	N.E. [2.7; N.E.]	0.84	[0.28; 2.51]	0.691
Sex							
(Interaction test: p = 0.875)							
Female	23/107 (21.5)	N.E. [11.2; N.E.]	30/126 (23.8)	11.2 [2.8; N.E.]	0.81	[0.47; 1.40]	0.272
Male	35/177 (19.8)	22.1 [11.1; N.E.]	37/158 (23.4)	N.E. [11.1; N.E.]	0.78	[0.49; 1.26]	0.415
Race							
(Interaction test: p = 0.281)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Asian	15/40 (37.5)	N.E. [2.8; N.E.]	15/46 (32.6)	N.E. [2.8; N.E.]	0.92	[0.45; 1.90]	0.804
White	41/227 (18.1)	22.1 [11.2; N.E.]	51/217 (23.5)	11.3 [5.6; N.E.]	0.67	[0.44; 1.01]	0.085
Other	2/17 (11.8)	N.E. [0.9; N.E.]	1/21 (4.8)	N.E. [N.E.; N.E.]	5.53	[0.11; 274.09]	0.180
Age groups (Interaction test: p = 0.795)							
18 - < 65 years	52/237 (21.9)	22.1 [11.2; N.E.]	61/247 (24.7)	N.E. [11.0; N.E.]	0.79	[0.54; 1.15]	0.300
65 - < 75 years	5/38 (13.2)	N.E. [N.E.; N.E.]	5/24 (20.8)	N.E. [1.8; N.E.]	0.46	[0.12; 1.73]	0.292
>= 75 years	1/9 (11.1)	N.E. [1.0; N.E.]	1/13 (7.7)	N.E. [1.0; N.E.]	1.55	[0.00; 874.00]	0.739
Geographic region (Interaction test: p = 0.038)							
Europe excluding Germany	30/138	22.5 [11.2; N.E.]	40/141	11.2 [3.0; N.E.]	0.70	[0.43; 1.14]	0.189

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(21.7)		(28.4)				
Germany	5/72	22.1 [N.E.; N.E.]	7/53	N.E. [1.0; N.E.]	0.21	[0.05; 0.82]	0.022
	(6.9)		(13.2)				
Others	23/74	N.E. [5.6; N.E.]	20/90	N.E. [N.E.; N.E.]	1.29	[0.70; 2.36]	0.413
	(31.1)		(22.2)				
Fatigue (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.281)							
Low	31/171	N.E. [11.2; N.E.]	43/172	22.1 [5.6; N.E.]	0.68	[0.43; 1.08]	0.146
	(18.1)		(25.0)				
Intermediate	15/75	22.1 [11.1; N.E.]	11/75	N.E. [22.0; N.E.]	1.20	[0.55; 2.63]	0.566
	(20.0)		(14.7)				
High	5/38	N.E. [11.1; N.E.]	7/37	N.E. [2.7; N.E.]	0.47	[0.14; 1.64]	0.178
	(13.2)		(18.9)				
Sex							
(Interaction test: p = 0.531)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Female	22/107 (20.6)	22.1 [11.2; N.E.]	27/126 (21.4)	N.E. [2.9; N.E.]	0.88	[0.50; 1.56]	0.500
Male	29/177 (16.4)	N.E. [11.1; N.E.]	34/158 (21.5)	22.1 [22.0; N.E.]	0.65	[0.40; 1.08]	0.261
Race							
(Interaction test: p = 0.158)							
Asian	9/40 (22.5)	N.E. [N.E.; N.E.]	15/46 (32.6)	N.E. [2.7; N.E.]	0.50	[0.21; 1.18]	0.128
White	38/227 (16.7)	N.E. [11.2; N.E.]	45/217 (20.7)	22.0 [11.8; N.E.]	0.71	[0.46; 1.10]	0.156
Other	4/17 (23.5)	8.3 [0.9; N.E.]	1/21 (4.8)	N.E. [2.8; N.E.]	1.98	[0.12; 31.50]	0.149
Age groups							
(Interaction test: p = 0.884)							
18 - < 65 years	43/237 (18.1)	N.E. [11.2; N.E.]	55/247 (22.3)	22.1 [11.8; N.E.]	0.73	[0.48; 1.09]	0.175
65 - < 75 years	6/38	N.E. [2.8; N.E.]	6/24	22.0 [1.9; N.E.]	0.55	[0.15; 2.03]	0.633

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(15.8)		(25.0)				
>= 75 years	2/9 (22.2)	22.1 [1.6; N.E.]	0/13	N.E. [N.E.; N.E.]	10.18	[0.12; 884.59]	0.199
Geographic region (Interaction test: p = 0.566)							
Europe excluding Germany	26/138 (18.8)	22.1 [11.2; N.E.]	35/141 (24.8)	22.1 [5.6; N.E.]	0.67	[0.40; 1.12]	0.136
Germany	7/72 (9.7)	N.E. [11.1; N.E.]	6/53 (11.3)	22.0 [1.9; N.E.]	0.41	[0.11; 1.51]	0.407
Others	18/74 (24.3)	N.E. [11.0; N.E.]	20/90 (22.2)	N.E. [N.E.; N.E.]	0.90	[0.46; 1.73]	0.867
Nausea and vomiting (MID=10)							
Stratification factor: ELTS based on randomization data from IRT (Interaction test: p = 0.672)							
Low	23/171 (13.5)	N.E. [N.E.; N.E.]	30/172 (17.4)	22.2 [22.0; N.E.]	0.79	[0.46; 1.37]	0.402

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Intermediate	8/75 (10.7)	22.1 [22.1; N.E.]	14/75 (18.7)	N.E. [5.7; N.E.]	0.55	[0.23; 1.32]	0.104
High	8/38 (21.1)	22.1 [11.1; N.E.]	6/37 (16.2)	N.E. [11.0; N.E.]	0.82	[0.28; 2.44]	0.860
Sex							
(Interaction test: p = 0.824)							
Female	20/107 (18.7)	22.1 [22.1; N.E.]	27/126 (21.4)	22.0 [11.1; N.E.]	0.72	[0.40; 1.31]	0.277
Male	19/177 (10.7)	N.E. [N.E.; N.E.]	23/158 (14.6)	N.E. [N.E.; N.E.]	0.71	[0.39; 1.31]	0.250
Race							
(Interaction test: p = 0.482)							
Asian	13/40 (32.5)	N.E. [5.6; N.E.]	15/46 (32.6)	N.E. [5.5; N.E.]	0.95	[0.44; 2.04]	0.907
White	25/227 (11.0)	22.1 [22.1; N.E.]	35/217 (16.1)	22.2 [22.0; N.E.]	0.62	[0.37; 1.05]	0.059
Other	1/17	N.E. [2.8; N.E.]	0/21	N.E. [N.E.; N.E.]	2.73	[0.02; 467.59]	0.371

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(5.9)						
Age groups							
(Interaction test: p = 0.450)							
18 - < 65 years	34/237	N.E. [N.E.; N.E.]	47/247	N.E. [22.0; N.E.]	0.67	[0.43; 1.05]	0.072
	(14.3)		(19.0)				
65 - < 75 years	3/38	22.1 [11.1; N.E.]	2/24	22.2 [22.2; N.E.]	1.41	[0.12; 16.05]	0.793
	(7.9)		(8.3)				
>= 75 years	2/9	22.1 [1.0; N.E.]	1/13	N.E. [1.0; N.E.]	0.71	[0.04; 11.79]	0.695
	(22.2)		(7.7)				
Geographic region							
(Interaction test: p = 0.132)							
Europe excluding Germany	18/138	22.1 [22.1; N.E.]	27/141	22.2 [11.3; N.E.]	0.63	[0.34; 1.16]	0.118
	(13.0)		(19.1)				
Germany	3/72	N.E. [11.1; N.E.]	5/53	N.E. [2.8; N.E.]	0.19	[0.04; 0.99]	0.022
	(4.2)		(9.4)				
Others	18/74	N.E. [11.1; N.E.]	18/90	N.E. [N.E.; N.E.]	1.17	[0.60; 2.28]	0.658
	(24.3)		(20.0)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Pain (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.183)							
Low	42/171 (24.6)	11.2 [8.3; N.E.]	53/172 (30.8)	11.1 [2.8; N.E.]	0.74	[0.50; 1.12]	0.164
Intermediate	22/75 (29.3)	11.1 [1.0; N.E.]	17/75 (22.7)	N.E. [2.8; N.E.]	1.49	[0.79; 2.82]	0.332
High	12/38 (31.6)	N.E. [1.0; N.E.]	10/37 (27.0)	5.7 [2.0; N.E.]	1.21	[0.52; 2.83]	0.990
Sex							
(Interaction test: p = 0.119)							
Female	37/107 (34.6)	5.6 [1.9; N.E.]	36/126 (28.6)	11.1 [2.8; N.E.]	1.27	[0.79; 2.04]	0.544
Male	39/177 (22.0)	N.E. [11.1; N.E.]	44/158 (27.8)	11.1 [2.9; N.E.]	0.76	[0.50; 1.18]	0.202
Race							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.449)							
Asian	19/40 (47.5)	11.0 [1.8; N.E.]	20/46 (43.5)	5.6 [1.9; N.E.]	0.91	[0.48; 1.71]	0.730
White	54/227 (23.8)	11.2 [10.8; N.E.]	58/217 (26.7)	11.1 [2.8; N.E.]	0.87	[0.60; 1.27]	0.358
Other	3/17 (17.6)	N.E. [0.9; N.E.]	2/21 (9.5)	N.E. [1.0; N.E.]	2.05	[0.20; 21.07]	0.435
Age groups							
(Interaction test: p = 0.574)							
18 - < 65 years	67/237 (28.3)	11.1 [5.6; N.E.]	72/247 (29.1)	11.1 [5.5; N.E.]	0.98	[0.70; 1.37]	0.761
65 - < 75 years	6/38 (15.8)	N.E. [5.6; N.E.]	7/24 (29.2)	5.7 [2.8; N.E.]	0.59	[0.18; 1.90]	0.215
>= 75 years	3/9 (33.3)	1.0 [1.0; N.E.]	1/13 (7.7)	N.E. [1.0; N.E.]	2.12	[0.19; 23.50]	0.485
Geographic region							
(Interaction test: p = 0.159)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Europe excluding Germany	31/138 (22.5)	N.E. [11.1; N.E.]	41/141 (29.1)	11.2 [2.8; N.E.]	0.70	[0.44; 1.13]	0.146
Germany	12/72 (16.7)	N.E. [1.8; N.E.]	8/53 (15.1)	5.7 [1.0; N.E.]	1.09	[0.42; 2.86]	0.952
Others	33/74 (44.6)	5.6 [1.9; N.E.]	31/90 (34.4)	11.1 [2.9; N.E.]	1.26	[0.77; 2.07]	0.426
Dyspnoea (MID=10)							
Stratification factor: ELTS based on randomization data from IRT (Interaction test: p = 0.315)							
Low	30/171 (17.5)	22.1 [22.1; N.E.]	37/172 (21.5)	N.E. [11.8; N.E.]	0.83	[0.51; 1.35]	0.508
Intermediate	10/75 (13.3)	N.E. [11.1; N.E.]	14/75 (18.7)	N.E. [11.0; N.E.]	0.66	[0.29; 1.48]	0.285
High	5/38 (13.2)	N.E. [11.1; N.E.]	1/37 (2.7)	N.E. [N.E.; N.E.]	4.06	[0.47; 34.87]	0.171
Sex							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.698)							
Female	23/107 (21.5)	22.1 [11.1; N.E.]	27/126 (21.4)	11.8 [11.1; N.E.]	0.98	[0.56; 1.71]	0.933
Male	22/177 (12.4)	22.1 [22.1; N.E.]	25/158 (15.8)	N.E. [N.E.; N.E.]	0.79	[0.45; 1.40]	0.448
Race							
(Interaction test: p = 0.841)							
Asian	10/40 (25.0)	N.E. [N.E.; N.E.]	11/46 (23.9)	N.E. [11.1; N.E.]	1.00	[0.41; 2.43]	0.979
White	33/227 (14.5)	22.1 [22.1; N.E.]	38/217 (17.5)	N.E. [11.8; N.E.]	0.79	[0.49; 1.26]	0.354
Other	2/17 (11.8)	N.E. [0.9; N.E.]	3/21 (14.3)	N.E. [2.8; N.E.]	0.65	[0.11; 4.03]	0.676
Age groups							
(Interaction test: p = 0.752)							
18 - < 65 years	38/237 (16.0)	22.1 [22.1; N.E.]	50/247 (20.2)	N.E. [11.3; N.E.]	0.79	[0.51; 1.20]	0.267

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
65 - < 75 years	5/38 (13.2)	N.E. [5.6; N.E.]	2/24 (8.3)	N.E. [2.8; N.E.]	1.34	[0.24; 7.42]	0.792
>= 75 years	2/9 (22.2)	N.E. [1.9; N.E.]	0/13	N.E. [N.E.; N.E.]	1.83	[0.02; 199.10]	0.199
Geographic region (Interaction test: p = 0.601)							
Europe excluding Germany	24/138 (17.4)	N.E. [N.E.; N.E.]	32/141 (22.7)	N.E. [11.1; N.E.]	0.72	[0.42; 1.22]	0.264
Germany	5/72 (6.9)	22.1 [N.E.; N.E.]	4/53 (7.5)	N.E. [2.8; N.E.]	0.78	[0.16; 3.84]	0.663
Others	16/74 (21.6)	22.1 [N.E.; N.E.]	16/90 (17.8)	N.E. [N.E.; N.E.]	1.08	[0.54; 2.19]	0.763
Insomnia (MID=10)							
Stratification factor: ELTS based on randomization data from IRT (Interaction test: p = 0.734)							
Low	34/171	12.0 [11.2; N.E.]	40/172	22.0 [11.1; N.E.]	0.80	[0.50; 1.27]	0.476

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(19.9)		(23.3)				
Intermediate	14/75	22.1 [11.1; N.E.]	19/75	N.E. [2.0; N.E.]	0.69	[0.34; 1.40]	0.139
	(18.7)		(25.3)				
High	10/38	11.1 [5.6; N.E.]	6/37	N.E. [5.6; N.E.]	1.13	[0.41; 3.15]	0.617
	(26.3)		(16.2)				
Sex							
(Interaction test: p = 0.138)							
Female	26/107	11.2 [10.8; N.E.]	26/126	22.2 [11.2; N.E.]	1.15	[0.66; 2.02]	0.703
	(24.3)		(20.6)				
Male	32/177	22.1 [11.1; N.E.]	39/158	22.0 [5.6; N.E.]	0.63	[0.39; 1.02]	0.076
	(18.1)		(24.7)				
Race							
(Interaction test: p = 0.423)							
Asian	11/40	N.E. [11.1; N.E.]	14/46	11.2 [5.6; N.E.]	0.82	[0.37; 1.85]	0.701
	(27.5)		(30.4)				
White	44/227	12.0 [11.1; N.E.]	49/217	22.0 [5.8; N.E.]	0.72	[0.47; 1.10]	0.164
	(19.4)		(22.6)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Other	3/17 (17.6)	N.E. [1.0; N.E.]	2/21 (9.5)	N.E. [1.0; N.E.]	1.11	[0.17; 7.23]	0.752
Age groups (Interaction test: p = 0.428)							
18 - < 65 years	49/237 (20.7)	12.0 [11.1; N.E.]	58/247 (23.5)	22.0 [11.2; N.E.]	0.78	[0.53; 1.15]	0.214
65 - < 75 years	8/38 (21.1)	N.E. [5.6; N.E.]	5/24 (20.8)	22.2 [1.8; N.E.]	1.41	[0.42; 4.77]	0.547
>= 75 years	1/9 (11.1)	N.E. [1.9; N.E.]	2/13 (15.4)	1.9 [1.0; N.E.]	0.56	[0.00; 126.83]	0.116
Geographic region (Interaction test: p = 0.660)							
Europe excluding Germany	33/138 (23.9)	11.2 [11.1; N.E.]	39/141 (27.7)	22.0 [5.6; N.E.]	0.72	[0.44; 1.17]	0.130
Germany	6/72 (8.3)	N.E. [11.1; N.E.]	5/53 (9.4)	N.E. [1.9; N.E.]	0.38	[0.10; 1.43]	0.114

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Others	19/74 (25.7)	N.E. [11.0; N.E.]	21/90 (23.3)	N.E. [11.2; N.E.]	1.06	[0.56; 2.00]	0.829
Appetite loss (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.197)							
Low	23/171 (13.5)	22.1 [22.1; N.E.]	22/172 (12.8)	N.E. [22.2; N.E.]	1.11	[0.62; 2.01]	0.675
Intermediate	6/75 (8.0)	N.E. [N.E.; N.E.]	12/75 (16.0)	N.E. [11.1; N.E.]	0.47	[0.18; 1.27]	0.093
High	3/38 (7.9)	N.E. [N.E.; N.E.]	7/37 (18.9)	16.6 [5.6; N.E.]	0.40	[0.09; 1.74]	0.064
Sex							
(Interaction test: p = 0.942)							
Female	17/107 (15.9)	N.E. [11.2; N.E.]	24/126 (19.0)	22.2 [11.1; N.E.]	0.85	[0.45; 1.61]	0.374
Male	15/177	22.1 [22.1; N.E.]	17/158	N.E. [22.1; N.E.]	0.81	[0.40; 1.62]	0.528

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(8.5)		(10.8)				
Race							
(Interaction test: p = 0.212)							
Asian	6/40	N.E. [N.E.; N.E.]	13/46	N.E. [2.8; N.E.]	0.41	[0.16; 1.08]	0.067
	(15.0)		(28.3)				
White	23/227	22.1 [22.1; N.E.]	26/217	22.2 [22.1; N.E.]	0.90	[0.51; 1.59]	0.553
	(10.1)		(12.0)				
Other	3/17	N.E. [2.0; N.E.]	2/21	11.1 [11.1; N.E.]	3.74	[0.33; 42.12]	0.293
	(17.6)		(9.5)				
Age groups							
(Interaction test: p = 0.178)							
18 - < 65 years	27/237	22.1 [22.1; N.E.]	34/247	N.E. [N.E.; N.E.]	0.83	[0.50; 1.37]	0.434
	(11.4)		(13.8)				
65 - < 75 years	2/38	N.E. [N.E.; N.E.]	5/24	22.2 [1.9; N.E.]	0.29	[0.05; 1.60]	0.127
	(5.3)		(20.8)				
>= 75 years	3/9	2.8 [1.0; N.E.]	2/13	12.5 [2.8; N.E.]	1.89	[0.18; 19.47]	0.629
	(33.3)		(15.4)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = 0.794)							
Europe excluding Germany	14/138 (10.1)	N.E. [N.E.; N.E.]	19/141 (13.5)	22.2 [22.1; N.E.]	0.84	[0.42; 1.70]	0.503
Germany	3/72 (4.2)	22.1 [N.E.; N.E.]	4/53 (7.5)	N.E. [5.6; N.E.]	0.37	[0.06; 2.13]	0.180
Others	15/74 (20.3)	N.E. [N.E.; N.E.]	18/90 (20.0)	N.E. [N.E.; N.E.]	0.82	[0.41; 1.64]	0.757
Constipation (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.997)							
Low	27/171 (15.8)	N.E. [11.2; N.E.]	41/172 (23.8)	11.8 [11.1; N.E.]	0.60	[0.37; 0.97]	0.065
Intermediate	13/75 (17.3)	22.1 [11.1; N.E.]	17/75 (22.7)	N.E. [2.8; N.E.]	0.63	[0.30; 1.30]	0.197
High	4/38	N.E. [N.E.; N.E.]	5/37	N.E. [5.6; N.E.]	0.64	[0.17; 2.38]	0.468

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(10.5)		(13.5)				
Sex							
(Interaction test: p = 0.645)							
Female	17/107	21.4 [11.2; N.E.]	30/126	11.2 [5.6; N.E.]	0.55	[0.30; 1.00]	0.048
	(15.9)		(23.8)				
Male	27/177	N.E. [11.3; N.E.]	33/158	N.E. [11.1; N.E.]	0.65	[0.39; 1.09]	0.159
	(15.3)		(20.9)				
Race							
(Interaction test: p = 0.151)							
Asian	7/40	N.E. [11.1; N.E.]	17/46	11.1 [2.0; N.E.]	0.36	[0.15; 0.88]	0.021
	(17.5)		(37.0)				
White	34/227	N.E. [11.3; N.E.]	45/217	N.E. [11.1; N.E.]	0.65	[0.41; 1.02]	0.068
	(15.0)		(20.7)				
Other	3/17	N.E. [5.6; N.E.]	1/21	N.E. [5.6; N.E.]	5.39	[0.12; 234.85]	0.079
	(17.6)		(4.8)				
Age groups							
(Interaction test: p = 0.622)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
18 - < 65 years	37/237 (15.6)	N.E. [11.3; N.E.]	59/247 (23.9)	N.E. [11.1; N.E.]	0.58	[0.38; 0.88]	0.012
65 - < 75 years	6/38 (15.8)	N.E. [21.4; N.E.]	3/24 (12.5)	N.E. [2.8; N.E.]	0.99	[0.24; 4.12]	0.841
>= 75 years	1/9 (11.1)	N.E. [1.0; N.E.]	1/13 (7.7)	N.E. [1.0; N.E.]	0.34	[0.00; 23.19]	0.739
Geographic region (Interaction test: p = 0.076)							
Europe excluding Germany	25/138 (18.1)	21.4 [11.2; N.E.]	30/141 (21.3)	N.E. [11.2; N.E.]	0.78	[0.45; 1.33]	0.408
Germany	2/72 (2.8)	N.E. [N.E.; N.E.]	7/53 (13.2)	N.E. [0.9; N.E.]	0.13	[0.03; 0.67]	0.004
Others	17/74 (23.0)	N.E. [11.1; N.E.]	26/90 (28.9)	N.E. [11.0; N.E.]	0.68	[0.36; 1.27]	0.326
Diarrhoea (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.657)							
Low	23/171 (13.5)	N.E. [N.E.; N.E.]	39/172 (22.7)	22.2 [11.1; N.E.]	0.66	[0.39; 1.10]	0.035
Intermediate	11/75 (14.7)	N.E. [N.E.; N.E.]	13/75 (17.3)	N.E. [11.1; N.E.]	0.83	[0.37; 1.86]	0.560
High	6/38 (15.8)	22.0 [11.1; N.E.]	4/37 (10.8)	N.E. [N.E.; N.E.]	1.08	[0.30; 3.84]	0.893
Sex							
(Interaction test: p = 0.312)							
Female	17/107 (15.9)	N.E. [11.2; N.E.]	21/126 (16.7)	22.2 [11.3; N.E.]	0.91	[0.47; 1.75]	0.596
Male	23/177 (13.0)	N.E. [22.0; N.E.]	35/158 (22.2)	N.E. [11.1; N.E.]	0.60	[0.35; 1.02]	0.033
Race							
(Interaction test: p = 0.786)							
Asian	7/40 (17.5)	N.E. [11.1; N.E.]	12/46 (26.1)	N.E. [5.6; N.E.]	0.66	[0.26; 1.69]	0.206

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
White	31/227 (13.7)	N.E. [22.0; N.E.]	42/217 (19.4)	22.2 [11.3; N.E.]	0.73	[0.45; 1.16]	0.121
Other	2/17 (11.8)	N.E. [2.8; N.E.]	2/21 (9.5)	N.E. [2.8; N.E.]	1.03	[0.14; 7.42]	0.747
Age groups (Interaction test: p = 0.554)							
18 - < 65 years	35/237 (14.8)	N.E. [22.0; N.E.]	53/247 (21.5)	N.E. [11.3; N.E.]	0.70	[0.45; 1.08]	0.040
65 - < 75 years	5/38 (13.2)	N.E. [N.E.; N.E.]	2/24 (8.3)	22.2 [22.2; N.E.]	3.55	[0.39; 32.61]	0.269
>= 75 years	0/9	N.E. [N.E.; N.E.]	1/13 (7.7)	N.E. [1.0; N.E.]	0.17	[0.00; 18.51]	0.221
Geographic region (Interaction test: p = 0.229)							
Europe excluding Germany	23/138 (16.7)	N.E. [11.2; N.E.]	33/141 (23.4)	22.2 [11.1; N.E.]	0.77	[0.45; 1.32]	0.239
Germany	3/72	22.0 [22.0; N.E.]	6/53	N.E. [1.9; N.E.]	0.14	[0.03; 0.81]	0.008

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(4.2)		(11.3)				
Others	14/74	N.E. [11.1; N.E.]	17/90	N.E. [N.E.; N.E.]	0.97	[0.47; 1.99]	0.671
	(18.9)		(18.9)				
Financial difficulties (MID=10)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.148)							
Low	24/171	N.E. [N.E.; N.E.]	26/172	22.2 [22.2; N.E.]	1.02	[0.58; 1.78]	0.934
	(14.0)		(15.1)				
Intermediate	14/75	N.E. [11.1; N.E.]	9/75	26.4 [22.3; N.E.]	2.23	[0.89; 5.57]	0.090
	(18.7)		(12.0)				
High	2/38	N.E. [N.E.; N.E.]	4/37	N.E. [N.E.; N.E.]	0.30	[0.05; 1.66]	0.178
	(5.3)		(10.8)				
Sex							
(Interaction test: p = 0.616)							
Female	16/107	N.E. [11.2; N.E.]	15/126	N.E. [22.2; N.E.]	1.35	[0.65; 2.80]	0.527
	(15.0)		(11.9)				

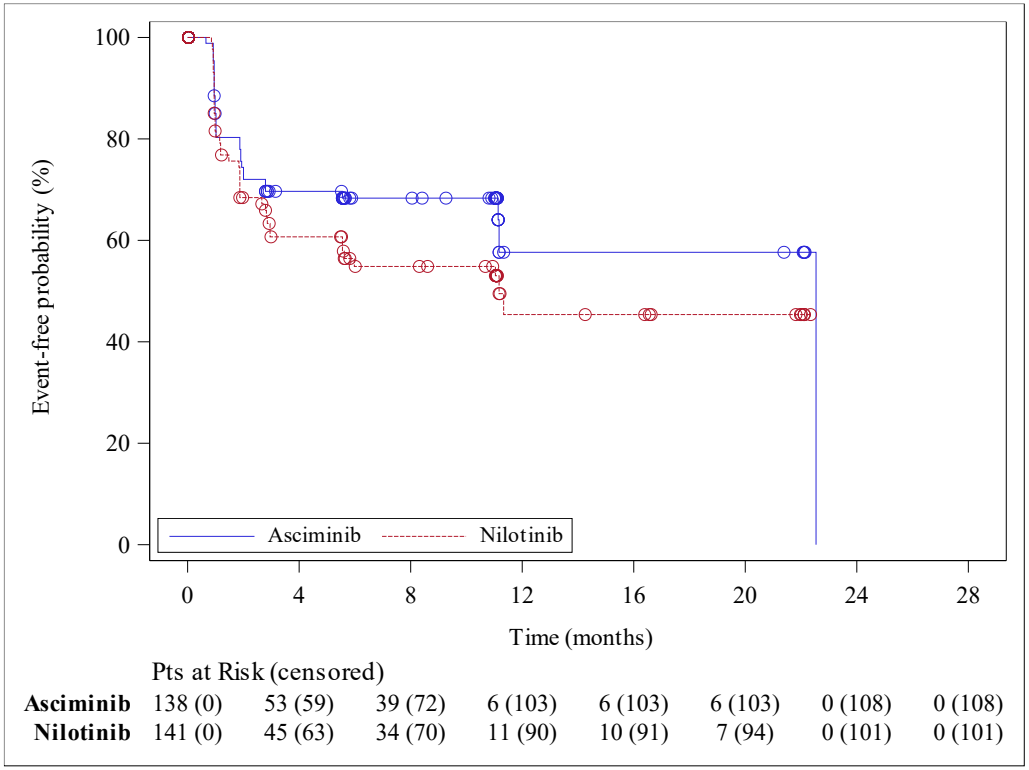
	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Male	24/177 (13.6)	N.E. [N.E.; N.E.]	24/158 (15.2)	22.3 [22.3; N.E.]	1.06	[0.60; 1.90]	0.819
Race							
(Interaction test: p = 0.255)							
Asian	12/40 (30.0)	N.E. [5.6; N.E.]	10/46 (21.7)	22.3 [22.3; N.E.]	1.31	[0.54; 3.15]	0.369
White	25/227 (11.0)	N.E. [N.E.; N.E.]	28/217 (12.9)	26.4 [22.2; N.E.]	0.92	[0.53; 1.59]	0.823
Other	3/17 (17.6)	N.E. [1.0; N.E.]	1/21 (4.8)	N.E. [N.E.; N.E.]	9.86	[0.29; 336.31]	0.078
Age groups							
(Interaction test: p = 0.506)							
18 - < 65 years	35/237 (14.8)	N.E. [N.E.; N.E.]	34/247 (13.8)	22.3 [22.2; N.E.]	1.22	[0.76; 1.97]	0.410
65 - < 75 years	3/38 (7.9)	N.E. [N.E.; N.E.]	5/24 (20.8)	26.4 [1.8; N.E.]	0.64	[0.10; 3.98]	0.193
>= 75 years	2/9	N.E. [1.0; N.E.]	0/13	N.E. [N.E.; N.E.]	3.00	[0.04; 207.39]	0.182

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(22.2)						
Geographic region							
(Interaction test: p = 0.587)							
Europe excluding Germany	18/138	N.E. [N.E.; N.E.]	19/141	N.E. [22.2; N.E.]	1.03	[0.53; 1.97]	0.887
	(13.0)		(13.5)				
Germany	4/72	N.E. [N.E.; N.E.]	5/53	26.4 [1.0; N.E.]	0.71	[0.17; 2.94]	0.539
	(5.6)		(9.4)				
Others	18/74	N.E. [N.E.; N.E.]	15/90	22.3 [N.E.; N.E.]	1.46	[0.72; 2.95]	0.242
	(24.3)		(16.7)				

MID: Minimally important difference
N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
In this sensitivity analysis a missing assessment before randomization is substituted by the last assessment before or on the day of treatment start, if such an assessment is available.
If there are not at least 10 patients in every subgroup or not more than 10 events per subgroup per treatment arm, no subgroup analyses were performed for the corresponding attribute.
If there are not more than 10 events per subgroup per treatment arm, no Cox PH hazard analysis is carried out.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variables ELTS Score (IRT) and covariates treatment arm and baseline PRO score.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variables ELTS Score (IRT).
For the subgroup of Stratification factor: ELTS based on IRT randomisation data not stratification factor was included in the Cox PH model and an unstratitfied log-rank test was applied
The reference group in the (stratified) Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/2025-05-15

Figure 3-7.1 EORTC QLQ-C30: Time to first deterioration analysis by subgroups - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot by subgroups (Full Analysis Set)

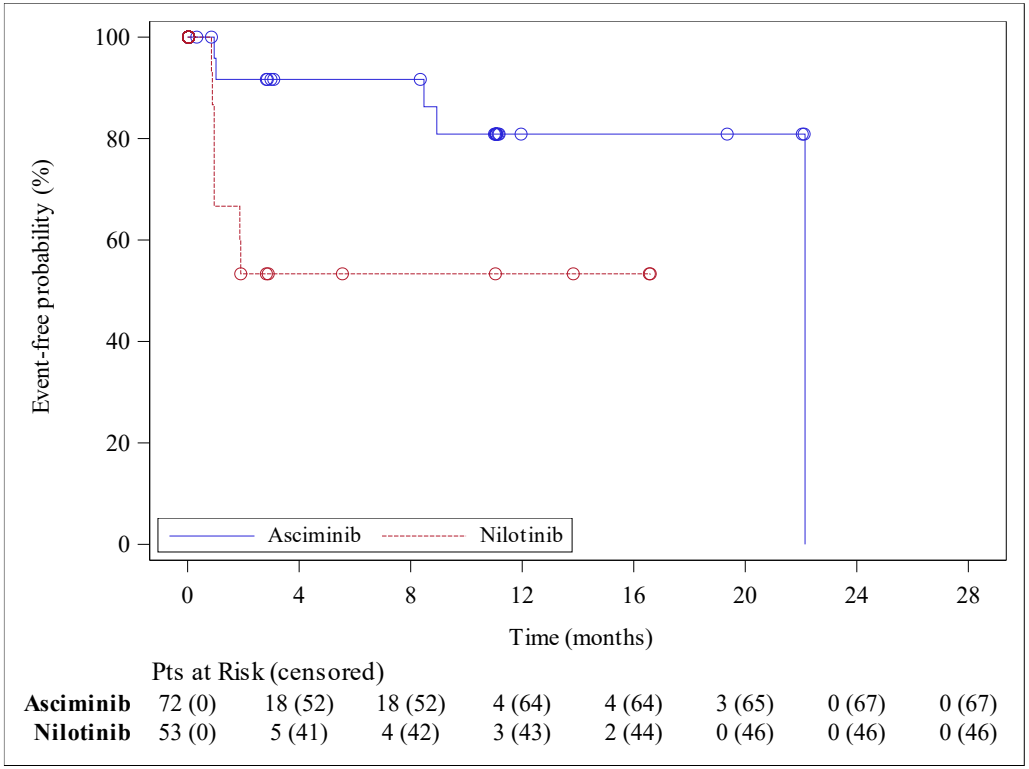
Social functioning (MID=10): Geographic region: Europe excluding Germany



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Figure 3-7.1 EORTC QLQ-C30: Time to first deterioration analysis by subgroups - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot by subgroups (Full Analysis Set)

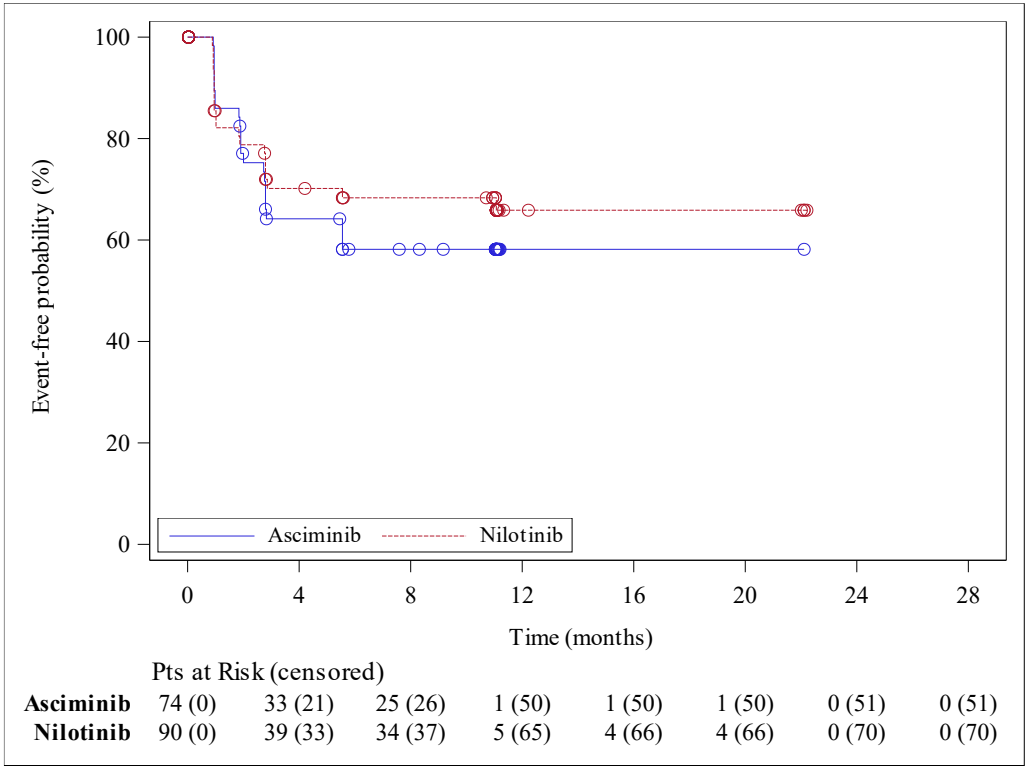
Social functioning (MID=10): Geographic region: Germany



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Figure 3-7.1 EORTC QLQ-C30: Time to first deterioration analysis by subgroups - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot by subgroups (Full Analysis Set)

Social functioning (MID=10): Geographic region: Others



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Table 3-7.2 EORTC QLQ-CML24: Time to first deterioration analysis by subgroups - Sensitivity analysis with alternative definition of baseline (Full Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Body Image Problems (MID=15)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.768)							
Low	37/171 (21.6)	N.E. [11.0; N.E.]	32/172 (18.6)	N.E. [11.2; N.E.]	1.25	[0.78; 2.01]	0.311
Intermediate	19/75 (25.3)	11.1 [5.5; N.E.]	21/75 (28.0)	11.1 [2.8; N.E.]	0.97	[0.51; 1.81]	0.628
High	9/38 (23.7)	N.E. [5.6; N.E.]	6/37 (16.2)	N.E. [5.6; N.E.]	0.82	[0.29; 2.36]	0.890
Sex							
(Interaction test: p = 0.845)							
Female	31/107 (29.0)	11.0 [2.8; N.E.]	31/126 (24.6)	11.2 [5.5; N.E.]	1.16	[0.69; 1.95]	0.768
Male	34/177	N.E. [11.1; N.E.]	28/158	N.E. [22.1; N.E.]	1.10	[0.67; 1.83]	0.702

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(19.2)		(17.7)				
Race							
(Interaction test: p = 0.916)							
Asian	15/40	11.1 [2.8; N.E.]	13/46	N.E. [2.9; N.E.]	1.17	[0.55; 2.48]	0.659
	(37.5)		(28.3)				
White	48/227	N.E. [11.1; N.E.]	43/217	22.1 [11.1; N.E.]	1.08	[0.71; 1.64]	0.932
	(21.1)		(19.8)				
Other	2/17	N.E. [1.8; N.E.]	3/21	11.1 [5.6; N.E.]	5.72	[0.14; 242.57]	0.134
	(11.8)		(14.3)				
Age groups							
(Interaction test: p = 0.810)							
18 - < 65 years	56/237	N.E. [11.1; N.E.]	55/247	22.1 [11.1; N.E.]	1.07	[0.74; 1.57]	0.644
	(23.6)		(22.3)				
65 - < 75 years	6/38	N.E. [5.6; N.E.]	3/24	N.E. [2.8; N.E.]	2.43	[0.53; 11.23]	0.644
	(15.8)		(12.5)				
>= 75 years	3/9	2.8 [1.0; N.E.]	1/13	N.E. [1.9; N.E.]	1.45	[0.12; 17.57]	0.455
	(33.3)		(7.7)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = 0.817)							
Europe excluding Germany	32/138 (23.2)	N.E. [11.0; N.E.]	33/141 (23.4)	16.6 [10.9; N.E.]	1.08	[0.66; 1.78]	0.914
Germany	11/72 (15.3)	11.1 [2.8; N.E.]	6/53 (11.3)	N.E. [1.0; N.E.]	0.79	[0.27; 2.30]	0.935
Others	22/74 (29.7)	N.E. [5.5; N.E.]	20/90 (22.2)	N.E. [11.1; N.E.]	1.27	[0.69; 2.35]	0.383
Impact on Daily Life (MID=15)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.538)							
Low	31/171 (18.1)	N.E. [11.2; N.E.]	36/172 (20.9)	N.E. [11.2; N.E.]	0.84	[0.52; 1.36]	0.640
Intermediate	8/75 (10.7)	N.E. [N.E.; N.E.]	16/75 (21.3)	16.6 [11.0; N.E.]	0.46	[0.20; 1.08]	0.056
High	5/38	N.E. [11.1; N.E.]	4/37	N.E. [2.8; N.E.]	0.56	[0.14; 2.18]	0.651

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(13.2)		(10.8)				
Sex							
(Interaction test: p = 0.633)							
Female	20/107	N.E. [11.2; N.E.]	32/126	11.2 [4.6; N.E.]	0.69	[0.39; 1.21]	0.118
	(18.7)		(25.4)				
Male	24/177	N.E. [N.E.; N.E.]	24/158	N.E. [N.E.; N.E.]	0.80	[0.45; 1.42]	0.711
	(13.6)		(15.2)				
Race							
(Interaction test: p = 0.134)							
Asian	12/40	N.E. [2.8; N.E.]	10/46	N.E. [11.1; N.E.]	1.38	[0.59; 3.22]	0.405
	(30.0)		(21.7)				
White	30/227	N.E. [N.E.; N.E.]	42/217	16.6 [11.2; N.E.]	0.60	[0.37; 0.96]	0.045
	(13.2)		(19.4)				
Other	2/17	N.E. [1.8; N.E.]	4/21	11.1 [2.8; N.E.]	0.81	[0.11; 6.00]	0.765
	(11.8)		(19.0)				
Age groups							
(Interaction test: p = 0.922)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
18 - < 65 years	39/237 (16.5)	N.E. [11.2; N.E.]	52/247 (21.1)	N.E. [11.3; N.E.]	0.70	[0.46; 1.07]	0.174
65 - < 75 years	4/38 (10.5)	N.E. [N.E.; N.E.]	4/24 (16.7)	N.E. [1.2; N.E.]	0.31	[0.06; 1.77]	0.325
>= 75 years	1/9 (11.1)	N.E. [1.0; N.E.]	0/13	N.E. [N.E.; N.E.]	27.00	[0.00; 6.53E6]	0.480
Geographic region (Interaction test: p = 0.085)							
Europe excluding Germany	22/138 (15.9)	N.E. [11.2; N.E.]	36/141 (25.5)	11.8 [11.1; N.E.]	0.58	[0.34; 0.99]	0.051
Germany	3/72 (4.2)	N.E. [N.E.; N.E.]	3/53 (5.7)	N.E. [11.0; N.E.]	0.50	[0.09; 2.76]	0.556
Others	19/74 (25.7)	N.E. [11.0; N.E.]	17/90 (18.9)	N.E. [N.E.; N.E.]	1.31	[0.68; 2.54]	0.381
Impact on Worry/Mood (MID=15)							
Stratification factor: ELTS based on randomization data from IRT							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.792)							
Low	18/171 (10.5)	N.E. [N.E.; N.E.]	15/172 (8.7)	N.E. [N.E.; N.E.]	1.20	[0.60; 2.39]	0.533
Intermediate	11/75 (14.7)	N.E. [11.1; N.E.]	7/75 (9.3)	N.E. [N.E.; N.E.]	1.50	[0.58; 3.89]	0.305
High	3/38 (7.9)	N.E. [N.E.; N.E.]	2/37 (5.4)	N.E. [N.E.; N.E.]	0.79	[0.13; 4.86]	0.956
Sex							
(Interaction test: p = 0.069)							
Female	16/107 (15.0)	N.E. [11.2; N.E.]	8/126 (6.3)	N.E. [N.E.; N.E.]	2.24	[0.95; 5.27]	0.061
Male	16/177 (9.0)	N.E. [N.E.; N.E.]	16/158 (10.1)	N.E. [N.E.; N.E.]	0.84	[0.42; 1.70]	0.801
Race							
(Interaction test: p = 0.237)							
Asian	10/40 (25.0)	N.E. [11.0; N.E.]	5/46 (10.9)	N.E. [N.E.; N.E.]	1.98	[0.66; 5.94]	0.129

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
White	19/227 (8.4)	N.E. [N.E.; N.E.]	18/217 (8.3)	N.E. [N.E.; N.E.]	0.96	[0.50; 1.84]	0.994
Other	3/17 (17.6)	11.0 [2.8; N.E.]	1/21 (4.8)	N.E. [5.6; N.E.]	6.16	[0.18; 208.31]	0.121
Age groups (Interaction test: p = 0.998)							
18 - < 65 years	30/237 (12.7)	N.E. [N.E.; N.E.]	23/247 (9.3)	N.E. [N.E.; N.E.]	1.28	[0.73; 2.22]	0.221
65 - < 75 years	2/38 (5.3)	N.E. [N.E.; N.E.]	1/24 (4.2)	N.E. [N.E.; N.E.]	0.93	[0.08; 10.28]	0.757
>= 75 years	0/9	N.E. [N.E.; N.E.]	0/13	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.
Geographic region (Interaction test: p = 0.093)							
Europe excluding Germany	15/138 (10.9)	N.E. [N.E.; N.E.]	12/141 (8.5)	N.E. [N.E.; N.E.]	1.29	[0.60; 2.78]	0.412
Germany	2/72	N.E. [N.E.; N.E.]	4/53	N.E. [1.9; N.E.]	0.08	[0.01; 0.83]	0.026

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(2.8)		(7.5)				
Others	15/74 (20.3)	N.E. [N.E.; N.E.]	8/90 (8.9)	N.E. [N.E.; N.E.]	2.04	[0.85; 4.90]	0.063
Symptom Burden (MID=15)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.603)							
Low	7/171 (4.1)	N.E. [N.E.; N.E.]	18/172 (10.5)	N.E. [N.E.; N.E.]	0.40	[0.17; 0.97]	0.037
Intermediate	4/75 (5.3)	N.E. [22.1; N.E.]	7/75 (9.3)	N.E. [N.E.; N.E.]	0.53	[0.15; 1.81]	0.285
High	2/38 (5.3)	N.E. [N.E.; N.E.]	1/37 (2.7)	N.E. [11.2; N.E.]	1.22	[0.11; 13.97]	0.768
Sex							
(Interaction test: p = 0.727)							
Female	7/107 (6.5)	N.E. [N.E.; N.E.]	17/126 (13.5)	N.E. [11.3; N.E.]	0.43	[0.18; 1.05]	0.050

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Male	6/177 (3.4)	N.E. [22.1; N.E.]	9/158 (5.7)	N.E. [N.E.; N.E.]	0.54	[0.19; 1.54]	0.291
Race							
(Interaction test: p = 0.875)							
Asian	4/40 (10.0)	N.E. [N.E.; N.E.]	9/46 (19.6)	N.E. [11.2; N.E.]	0.54	[0.16; 1.80]	0.314
White	7/227 (3.1)	N.E. [N.E.; N.E.]	17/217 (7.8)	N.E. [N.E.; N.E.]	0.36	[0.15; 0.88]	0.020
Other	2/17 (11.8)	N.E. [0.9; N.E.]	0/21	N.E. [N.E.; N.E.]	3.51	[0.05; 263.62]	0.187
Age groups							
(Interaction test: p = 1.000)							
18 - < 65 years	13/237 (5.5)	N.E. [22.1; N.E.]	23/247 (9.3)	N.E. [N.E.; N.E.]	0.57	[0.28; 1.13]	0.127
65 - < 75 years	0/38	N.E. [N.E.; N.E.]	3/24 (12.5)	N.E. [1.2; N.E.]	0.00	[0.00; 6.70]	0.018
>= 75 years	0/9	N.E. [N.E.; N.E.]	0/13	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = 0.729)							
Europe excluding Germany	6/138 (4.3)	N.E. [N.E.; N.E.]	14/141 (9.9)	N.E. [N.E.; N.E.]	0.42	[0.16; 1.12]	0.076
Germany	1/72 (1.4)	N.E. [N.E.; N.E.]	2/53 (3.8)	N.E. [5.4; N.E.]	0.05	[0.00; 4.16]	0.201
Others	6/74 (8.1)	N.E. [N.E.; N.E.]	10/90 (11.1)	N.E. [11.2; N.E.]	0.67	[0.24; 1.91]	0.501
Satisfaction with Care and Information (MID=15)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.800)							
Low	25/171 (14.6)	N.E. [11.2; N.E.]	21/172 (12.2)	N.E. [N.E.; N.E.]	1.21	[0.68; 2.16]	0.403
Intermediate	18/75 (24.0)	11.2 [8.3; N.E.]	15/75 (20.0)	N.E. [3.5; N.E.]	1.09	[0.54; 2.18]	0.861

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
High	10/38 (26.3)	N.E. [2.8; N.E.]	4/37 (10.8)	N.E. [2.8; N.E.]	1.76	[0.55; 5.64]	0.378
Sex							
(Interaction test: p = 0.900)							
Female	26/107 (24.3)	11.2 [6.1; N.E.]	20/126 (15.9)	N.E. [N.E.; N.E.]	1.18	[0.65; 2.13]	0.394
Male	27/177 (15.3)	N.E. [11.2; N.E.]	20/158 (12.7)	N.E. [N.E.; N.E.]	1.22	[0.68; 2.18]	0.528
Race							
(Interaction test: p = 0.733)							
Asian	18/40 (45.0)	5.6 [2.8; N.E.]	10/46 (21.7)	N.E. [N.E.; N.E.]	1.52	[0.68; 3.40]	0.087
White	33/227 (14.5)	N.E. [11.2; N.E.]	26/217 (12.0)	N.E. [N.E.; N.E.]	1.18	[0.70; 1.99]	0.653
Other	2/17 (11.8)	N.E. [1.0; N.E.]	4/21 (19.0)	N.E. [2.8; N.E.]	0.25	[0.02; 2.81]	0.328
Age groups							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.264)							
18 - < 65 years	47/237 (19.8)	N.E. [11.2; N.E.]	34/247 (13.8)	N.E. [N.E.; N.E.]	1.39	[0.89; 2.17]	0.107
65 - < 75 years	5/38 (13.2)	N.E. [13.1; N.E.]	5/24 (20.8)	5.6 [0.9; N.E.]	0.61	[0.17; 2.18]	0.299
>= 75 years	1/9 (11.1)	N.E. [2.8; N.E.]	1/13 (7.7)	N.E. [1.0; N.E.]	0.71	[0.03; 17.62]	0.515
Geographic region							
(Interaction test: p = 0.136)							
Europe excluding Germany	20/138 (14.5)	13.1 [11.2; N.E.]	22/141 (15.6)	N.E. [N.E.; N.E.]	0.83	[0.45; 1.54]	0.435
Germany	7/72 (9.7)	N.E. [6.1; N.E.]	2/53 (3.8)	N.E. [11.1; N.E.]	2.39	[0.48; 11.95]	0.338
Others	26/74 (35.1)	11.0 [5.6; N.E.]	16/90 (17.8)	N.E. [N.E.; N.E.]	1.71	[0.91; 3.23]	0.044
Satisfaction with Social Life (MID=15)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.488)							
Low	44/171 (25.7)	11.1 [2.9; N.E.]	44/172 (25.6)	11.2 [5.5; N.E.]	0.98	[0.65; 1.49]	0.796
Intermediate	26/75 (34.7)	5.6 [2.0; 11.1]	25/75 (33.3)	2.9 [2.7; 16.6]	1.22	[0.69; 2.14]	0.874
High	11/38 (28.9)	11.1 [2.8; N.E.]	4/37 (10.8)	N.E. [1.9; N.E.]	1.83	[0.58; 5.75]	0.298
Sex							
(Interaction test: p = 0.483)							
Female	35/107 (32.7)	11.0 [2.9; 11.2]	29/126 (23.0)	11.2 [3.0; N.E.]	1.33	[0.80; 2.20]	0.157
Male	46/177 (26.0)	11.1 [5.6; N.E.]	44/158 (27.8)	16.6 [2.8; N.E.]	1.00	[0.65; 1.51]	0.773
Race							
(Interaction test: p = 0.690)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Asian	20/40 (50.0)	5.6 [1.8; N.E.]	15/46 (32.6)	11.3 [2.3; N.E.]	1.38	[0.69; 2.78]	0.173
White	57/227 (25.1)	11.1 [5.6; N.E.]	54/217 (24.9)	11.2 [2.8; N.E.]	1.04	[0.71; 1.52]	0.873
Other	4/17 (23.5)	11.1 [0.9; N.E.]	4/21 (19.0)	5.6 [1.0; N.E.]	0.86	[0.15; 4.82]	0.613
Age groups (Interaction test: p = 0.756)							
18 - < 65 years	71/237 (30.0)	11.1 [5.6; 11.2]	68/247 (27.5)	11.2 [3.0; N.E.]	1.08	[0.77; 1.51]	0.485
65 - < 75 years	8/38 (21.1)	N.E. [2.0; N.E.]	4/24 (16.7)	N.E. [1.9; N.E.]	2.56	[0.62; 10.55]	0.954
>= 75 years	2/9 (22.2)	N.E. [1.0; N.E.]	1/13 (7.7)	N.E. [1.0; N.E.]	1.62	[0.14; 18.31]	0.861
Geographic region (Interaction test: p = 0.336)							
Europe excluding Germany	41/138	11.1 [2.9; N.E.]	40/141	11.2 [2.9; N.E.]	1.26	[0.80; 1.96]	0.756

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Germany	(29.7) 10/72	N.E. [5.6; N.E.]	(28.4) 9/53	2.8 [1.0; N.E.]	0.54	[0.18; 1.66]	0.535
Others	(13.9) 30/74	5.6 [2.8; N.E.]	(17.0) 24/90	N.E. [2.8; N.E.]	1.21	[0.70; 2.09]	0.230
	(40.5)		(26.7)				

MID: Minimally important difference
N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
In this sensitivity analysis a missing assessment before randomization is substituted by the last assessment before or on the day of treatment start, if such an assessment is available.
If there are not at least 10 patients in every subgroup or not more than 10 events per subgroup per treatment arm, no subgroup analyses were performed for the corresponding attribute.
If there are not more than 10 events per subgroup per treatment arm, no Cox PH hazard analysis is carried out.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variables ELTS Score (IRT) and covariates treatment arm and baseline PRO score.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variables ELTS Score (IRT).
For the subgroup of Stratification factor: ELTS based on IRT randomisation data not stratification factor was included in the Cox PH model and an unstratitfied log-rank test was applied
The reference group in the (stratified) Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/2025-05-15

Table 3-7.3 FACIT GP5: Time to first deterioration analysis by subgroups - Sensitivity analysis with alternative definition of baseline (Full Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
V4 (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.742)							
Low	91/171 (53.2)	1.6 [0.9; 3.5]	98/172 (57.0)	0.5 [0.5; 1.0]	0.76	[0.57; 1.02]	0.111
Intermediate	34/75 (45.3)	5.4 [1.0; N.E.]	34/75 (45.3)	1.8 [0.5; 8.3]	0.71	[0.44; 1.14]	0.224
High	19/38 (50.0)	1.7 [0.5; N.E.]	23/37 (62.2)	0.5 [0.3; 1.9]	0.57	[0.31; 1.05]	0.097
Sex							
(Interaction test: p = 0.484)							
Female	56/107 (52.3)	1.0 [0.5; 2.8]	74/126 (58.7)	0.5 [0.4; 1.0]	0.70	[0.49; 0.99]	0.065
Male	88/177	2.1 [1.4; 8.3]	81/158	1.0 [0.5; 2.6]	0.78	[0.57; 1.05]	0.146

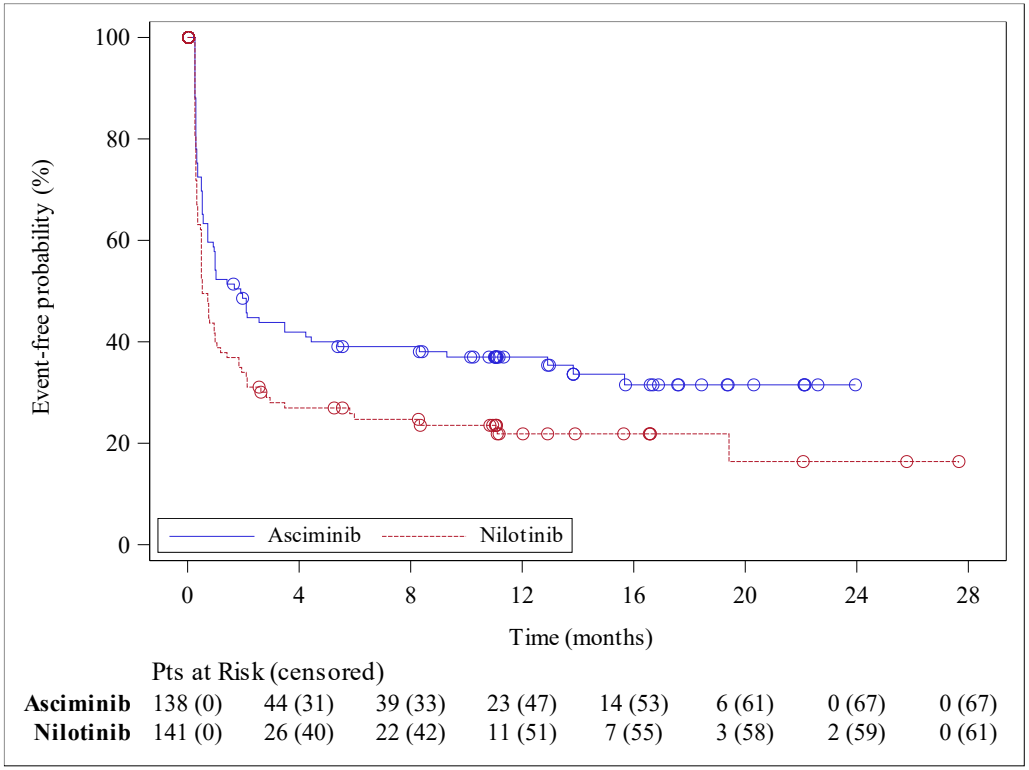
	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(49.7)		(51.3)				
Race							
(Interaction test: p = 0.352)							
Asian	20/40	2.8 [1.0; N.E.]	27/46	2.9 [0.5; 13.0]	0.94	[0.51; 1.75]	0.573
	(50.0)		(58.7)				
White	117/227	1.8 [1.0; 3.5]	117/217	0.5 [0.5; 0.9]	0.66	[0.51; 0.86]	0.007
	(51.5)		(53.9)				
Other	7/17	2.1 [0.5; N.E.]	11/21	1.0 [0.4; 7.4]	0.47	[0.16; 1.34]	0.154
	(41.2)		(52.4)				
Age groups							
(Interaction test: p = 0.595)							
18 - < 65 years	122/237	1.9 [1.2; 4.2]	133/247	0.8 [0.5; 1.8]	0.74	[0.58; 0.95]	0.046
	(51.5)		(53.8)				
65 - < 75 years	20/38	2.0 [0.5; 9.4]	12/24	1.8 [0.3; N.E.]	0.70	[0.32; 1.52]	0.831
	(52.6)		(50.0)				
>= 75 years	2/9	N.E. [0.3; N.E.]	10/13	0.5 [0.3; 0.8]	0.80	[0.13; 5.02]	0.333
	(22.2)		(76.9)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = <0.001)							
Europe excluding Germany	71/138 (51.4)	1.9 [0.7; 4.4]	80/141 (56.7)	0.5 [0.5; 1.0]	0.66	[0.48; 0.91]	0.019
Germany	32/72 (44.4)	1.7 [0.7; 11.1]	31/53 (58.5)	0.3 [0.3; 0.5]	0.31	[0.17; 0.55]	<0.001
Others	41/74 (55.4)	2.1 [1.2; 11.0]	44/90 (48.9)	4.6 [2.6; 13.0]	1.19	[0.77; 1.84]	0.374

MID: Minimally important difference
N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
In this sensitivity analysis a missing assessment before randomization is substituted by the last assessment before or on the day of treatment start, if such an assessment is available.
If there are not at least 10 patients in every subgroup or not more than 10 events per subgroup per treatment arm, no subgroup analyses were performed for the corresponding attribute.
If there are not more than 10 events per subgroup per treatment arm, no Cox PH hazard analysis is carried out.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variables ELTS Score (IRT) and covariates treatment arm and baseline PRO score.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variables ELTS Score (IRT).
For the subgroup of Stratification factor: ELTS based on IRT randomisation data not stratification factor was included in the Cox PH model and an unstratitfied log-rank test was applied
The reference group in the (stratified) Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/2025-05-15

Figure 3-7.3 FACIT GP5: Time to first deterioration analysis by subgroups - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot by subgroups (Full Analysis Set)

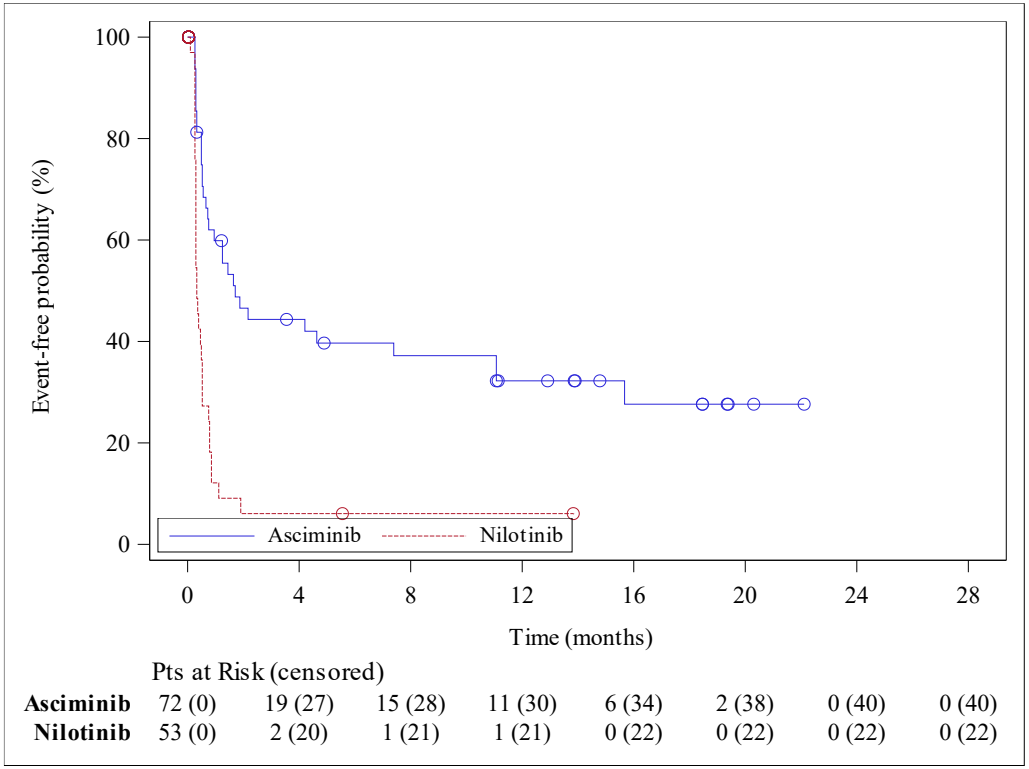
V4 (MID=1): Geographic region: Europe excluding Germany



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Figure 3-7.3 FACIT GP5: Time to first deterioration analysis by subgroups - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot by subgroups (Full Analysis Set)

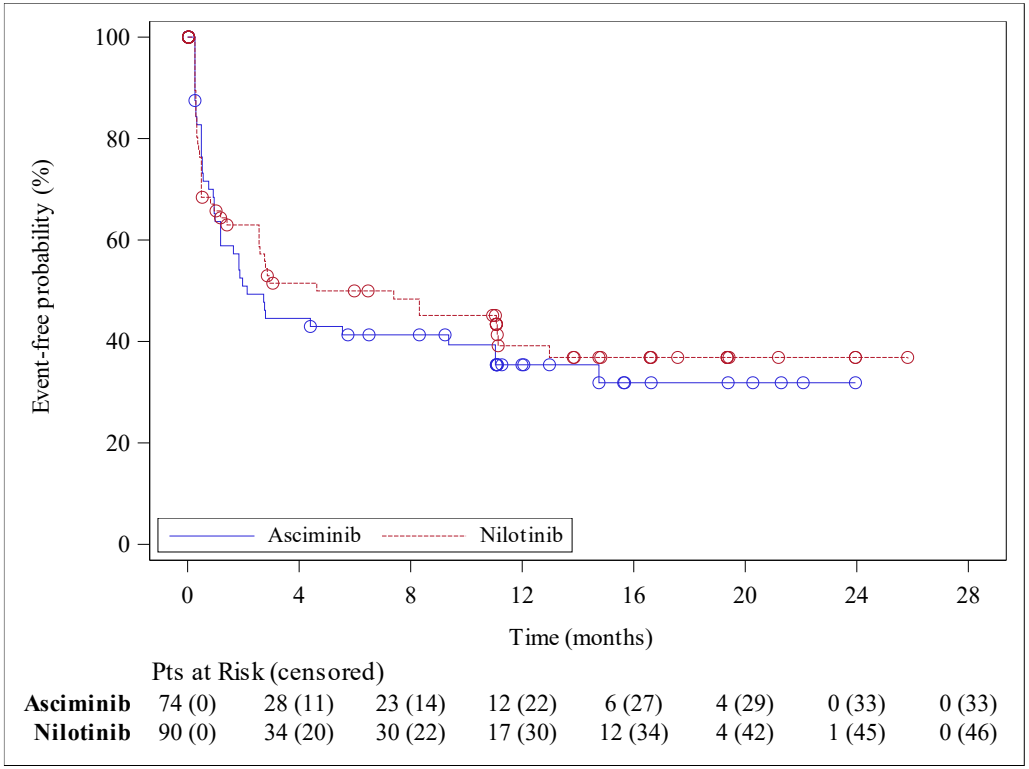
V4 (MID=1): Geographic region: Germany



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Figure 3-7.3 FACIT GP5: Time to first deterioration analysis by subgroups - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot by subgroups (Full Analysis Set)

V4 (MID=1): Geographic region: Others



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Table 3-7.4 PRO-CTCAE - Frequency: Time to first deterioration analysis by subgroups - Sensitivity analysis with alternative definition of baseline (Full Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Headache - Frequency (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.425)							
Low	87/171 (50.9)	2.8 [2.0; 5.6]	105/172 (61.0)	1.2 [0.7; 2.8]	0.63	[0.48; 0.84]	0.009
Intermediate	37/75 (49.3)	3.2 [1.0; 5.6]	33/75 (44.0)	1.9 [0.5; 9.2]	0.91	[0.57; 1.45]	0.645
High	20/38 (52.6)	3.7 [1.2; 11.1]	22/37 (59.5)	0.7 [0.5; 2.6]	0.61	[0.33; 1.13]	0.096
Sex							
(Interaction test: p = 0.944)							
Female	57/107 (53.3)	2.1 [1.0; 5.1]	75/126 (59.5)	1.0 [0.5; 2.3]	0.71	[0.50; 1.01]	0.042
Male	87/177	3.8 [2.2; 5.6]	85/158	2.1 [0.7; 3.9]	0.69	[0.51; 0.94]	0.045

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(49.2)		(53.8)				
Race							
(Interaction test: p = 0.043)							
Asian	20/40	5.6 [1.0; N.E.]	35/46	1.9 [0.5; 4.4]	0.52	[0.30; 0.91]	0.020
	(50.0)		(76.1)				
White	119/227	2.8 [1.9; 4.2]	112/217	1.5 [0.8; 2.8]	0.79	[0.61; 1.02]	0.143
	(52.4)		(51.6)				
Other	5/17	N.E. [0.4; N.E.]	13/21	0.5 [0.3; 1.4]	0.28	[0.09; 0.91]	0.028
	(29.4)		(61.9)				
Age groups							
(Interaction test: p = 0.215)							
18 - < 65 years	121/237	3.3 [2.1; 5.1]	138/247	1.8 [0.8; 2.6]	0.70	[0.55; 0.90]	0.017
	(51.1)		(55.9)				
65 - < 75 years	18/38	4.2 [1.2; N.E.]	14/24	0.6 [0.3; 5.3]	0.56	[0.27; 1.18]	0.114
	(47.4)		(58.3)				
>= 75 years	5/9	0.5 [0.3; N.E.]	8/13	1.1 [0.3; N.E.]	12.84	[1.39; 118.50]	0.039
	(55.6)		(61.5)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = 0.317)							
Europe excluding Germany	73/138 (52.9)	2.9 [1.5; 5.6]	74/141 (52.5)	2.2 [0.8; 4.0]	0.80	[0.58; 1.11]	0.293
Germany	33/72 (45.8)	3.8 [1.9; 5.1]	27/53 (50.9)	0.5 [0.3; 1.5]	0.41	[0.23; 0.73]	0.009
Others	38/74 (51.4)	2.8 [1.0; N.E.]	59/90 (65.6)	1.4 [0.7; 2.8]	0.64	[0.43; 0.97]	0.022
Rash - Presence/Absence (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.354)							
Low	73/171 (42.7)	8.3 [4.4; N.E.]	75/172 (43.6)	4.3 [1.9; N.E.]	0.75	[0.54; 1.04]	0.313
Intermediate	29/75 (38.7)	11.1 [4.2; N.E.]	35/75 (46.7)	2.3 [1.4; 5.6]	0.51	[0.31; 0.83]	0.006
High	13/38	N.E. [4.6; N.E.]	18/37	2.0 [0.7; N.E.]	0.45	[0.22; 0.92]	0.020

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(34.2)		(48.6)				
Sex							
(Interaction test: p = 0.996)							
Female	54/107	4.4 [1.9; 11.2]	63/126	1.7 [1.1; 3.7]	0.66	[0.45; 0.95]	0.171
	(50.5)		(50.0)				
Male	61/177	N.E. [8.3; N.E.]	65/158	5.5 [2.1; 19.4]	0.64	[0.45; 0.91]	0.014
	(34.5)		(41.1)				
Race							
(Interaction test: p = 0.283)							
Asian	14/40	N.E. [10.2; N.E.]	26/46	2.8 [1.2; N.E.]	0.32	[0.16; 0.65]	0.009
	(35.0)		(56.5)				
White	97/227	6.5 [4.4; 13.0]	93/217	2.8 [1.6; 6.5]	0.71	[0.53; 0.94]	0.047
	(42.7)		(42.9)				
Other	4/17	N.E. [0.5; N.E.]	9/21	3.4 [0.6; N.E.]	0.75	[0.21; 2.60]	0.478
	(23.5)		(42.9)				
Age groups							
(Interaction test: p = 0.698)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
18 - < 65 years	99/237 (41.8)	9.2 [4.6; N.E.]	112/247 (45.3)	2.9 [1.9; 5.6]	0.66	[0.50; 0.87]	0.013
65 - < 75 years	14/38 (36.8)	16.6 [3.9; N.E.]	9/24 (37.5)	6.5 [1.0; N.E.]	0.66	[0.28; 1.58]	0.584
>= 75 years	2/9 (22.2)	N.E. [1.2; N.E.]	7/13 (53.8)	1.4 [0.3; N.E.]	0.15	[0.02; 1.35]	0.032
Geographic region (Interaction test: p = 0.793)							
Europe excluding Germany	60/138 (43.5)	6.5 [4.2; N.E.]	61/141 (43.3)	3.0 [1.4; 13.0]	0.68	[0.48; 0.98]	0.089
Germany	24/72 (33.3)	13.0 [2.3; N.E.]	23/53 (43.4)	2.0 [1.2; 15.7]	0.67	[0.37; 1.22]	0.078
Others	31/74 (41.9)	12.0 [5.4; N.E.]	44/90 (48.9)	2.8 [1.7; N.E.]	0.48	[0.29; 0.79]	0.052
Diarrhea - Frequency (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.774)							
Low	81/171 (47.4)	2.9 [1.7; 11.1]	93/172 (54.1)	2.6 [1.4; 3.5]	0.87	[0.64; 1.17]	0.220
Intermediate	34/75 (45.3)	4.0 [1.8; N.E.]	28/75 (37.3)	3.2 [1.4; N.E.]	1.00	[0.61; 1.65]	0.959
High	17/38 (44.7)	2.9 [0.7; N.E.]	16/37 (43.2)	2.1 [1.2; N.E.]	1.12	[0.57; 2.23]	0.820
Sex							
(Interaction test: p = 0.518)							
Female	47/107 (43.9)	3.5 [1.7; N.E.]	61/126 (48.4)	2.3 [1.4; 6.5]	0.83	[0.56; 1.22]	0.283
Male	85/177 (48.0)	2.9 [1.8; 5.1]	76/158 (48.1)	3.0 [2.0; 4.6]	1.00	[0.73; 1.37]	0.724
Race							
(Interaction test: p = 0.411)							
Asian	24/40 (60.0)	2.4 [1.2; 11.1]	25/46 (54.3)	4.6 [1.5; N.E.]	1.17	[0.65; 2.09]	0.570

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
White	102/227 (44.9)	2.9 [1.8; 11.1]	104/217 (47.9)	2.6 [1.4; 3.5]	0.85	[0.65; 1.12]	0.151
Other	6/17 (35.3)	3.7 [0.5; N.E.]	8/21 (38.1)	3.2 [0.5; N.E.]	1.01	[0.32; 3.23]	0.936
Age groups (Interaction test: p = 0.494)							
18 - < 65 years	107/237 (45.1)	3.7 [2.1; 11.1]	120/247 (48.6)	2.8 [2.1; 4.1]	0.89	[0.69; 1.16]	0.234
65 - < 75 years	21/38 (55.3)	2.0 [1.0; 17.5]	9/24 (37.5)	7.4 [0.9; N.E.]	1.42	[0.64; 3.17]	0.365
>= 75 years	4/9 (44.4)	2.0 [0.3; N.E.]	8/13 (61.5)	1.1 [0.5; 2.6]	0.69	[0.18; 2.71]	0.615
Geographic region (Interaction test: p = 0.141)							
Europe excluding Germany	70/138 (50.7)	1.7 [1.2; 3.0]	70/141 (49.6)	2.6 [1.4; 3.5]	1.02	[0.73; 1.42]	0.877
Germany	21/72	N.E. [4.6; N.E.]	21/53	2.8 [0.8; N.E.]	0.60	[0.32; 1.12]	0.072

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(29.2)		(39.6)				
Others	41/74	2.4 [1.2; 11.1]	46/90	3.2 [2.1; 12.9]	1.17	[0.76; 1.81]	0.592
	(55.4)		(51.1)				
Vomiting - Frequency (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.431)							
Low	22/171	N.E. [N.E.; N.E.]	45/172	N.E. [N.E.; N.E.]	0.42	[0.25; 0.70]	<0.001
	(12.9)		(26.2)				
Intermediate	14/75	N.E. [20.3; N.E.]	14/75	N.E. [12.9; N.E.]	0.70	[0.33; 1.48]	0.424
	(18.7)		(18.7)				
High	4/38	N.E. [13.9; N.E.]	8/37	N.E. [8.3; N.E.]	0.39	[0.11; 1.37]	0.133
	(10.5)		(21.6)				
Sex							
(Interaction test: p = 0.188)							
Female	17/107	N.E. [22.1; N.E.]	39/126	N.E. [6.5; N.E.]	0.39	[0.22; 0.69]	<0.001
	(15.9)		(31.0)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Male	23/177 (13.0)	N.E. [N.E.; N.E.]	28/158 (17.7)	N.E. [N.E.; N.E.]	0.64	[0.37; 1.12]	0.114
Race							
(Interaction test: p = 0.407)							
Asian	8/40 (20.0)	20.3 [17.5; N.E.]	17/46 (37.0)	N.E. [5.5; N.E.]	0.48	[0.20; 1.12]	0.079
White	31/227 (13.7)	N.E. [N.E.; N.E.]	42/217 (19.4)	N.E. [N.E.; N.E.]	0.57	[0.36; 0.91]	0.017
Other	1/17 (5.9)	N.E. [N.E.; N.E.]	8/21 (38.1)	15.7 [1.2; N.E.]	0.17	[0.02; 1.47]	0.073
Age groups							
(Interaction test: p = 0.594)							
18 - < 65 years	32/237 (13.5)	N.E. [N.E.; N.E.]	61/247 (24.7)	N.E. [N.E.; N.E.]	0.45	[0.29; 0.69]	<0.001
65 - < 75 years	7/38 (18.4)	N.E. [14.0; N.E.]	4/24 (16.7)	N.E. [1.5; N.E.]	0.79	[0.22; 2.78]	0.717
>= 75 years	1/9	22.1 [N.E.; N.E.]	2/13	N.E. [1.4; N.E.]	0.87	[0.05; 13.95]	0.919

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(11.1)		(15.4)				
Geographic region							
(Interaction test: p = 0.444)							
Europe excluding Germany	21/138	N.E. [N.E.; N.E.]	26/141	N.E. [18.4; N.E.]	0.68	[0.38; 1.22]	0.200
	(15.2)		(18.4)				
Germany	5/72	N.E. [N.E.; N.E.]	8/53	N.E. [N.E.; N.E.]	0.33	[0.11; 1.03]	0.046
	(6.9)		(15.1)				
Others	14/74	20.3 [17.5; N.E.]	33/90	N.E. [5.4; N.E.]	0.34	[0.17; 0.68]	0.001
	(18.9)		(36.7)				
Nausea - Frequency (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.654)							
Low	62/171	25.8 [4.7; N.E.]	74/172	3.9 [1.7; N.E.]	0.73	[0.52; 1.03]	0.083
	(36.3)		(43.0)				
Intermediate	22/75	22.1 [8.4; N.E.]	30/75	4.9 [1.9; 13.0]	0.48	[0.27; 0.85]	0.007
	(29.3)		(40.0)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
High	13/38 (34.2)	N.E. [1.7; N.E.]	15/37 (40.5)	6.5 [2.1; N.E.]	0.75	[0.36; 1.59]	0.519
Sex							
(Interaction test: p = 0.305)							
Female	44/107 (41.1)	13.8 [3.0; N.E.]	62/126 (49.2)	1.8 [0.8; 3.9]	0.59	[0.40; 0.87]	0.010
Male	53/177 (29.9)	25.8 [25.8; N.E.]	57/158 (36.1)	18.4 [4.6; N.E.]	0.78	[0.54; 1.14]	0.147
Race							
(Interaction test: p = 0.855)							
Asian	14/40 (35.0)	N.E. [3.2; N.E.]	22/46 (47.8)	5.6 [1.8; N.E.]	0.70	[0.36; 1.38]	0.276
White	78/227 (34.4)	22.1 [9.2; N.E.]	91/217 (41.9)	3.9 [2.1; 11.1]	0.65	[0.48; 0.88]	0.004
Other	5/17 (29.4)	N.E. [0.5; N.E.]	6/21 (28.6)	18.4 [0.3; N.E.]	0.72	[0.18; 2.87]	0.797
Age groups							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.586)							
18 - < 65 years	81/237 (34.2)	25.8 [11.0; N.E.]	102/247 (41.3)	6.5 [3.3; 18.4]	0.70	[0.52; 0.94]	0.018
65 - < 75 years	14/38 (36.8)	15.7 [4.4; N.E.]	11/24 (45.8)	2.1 [0.8; N.E.]	0.50	[0.21; 1.19]	0.178
>= 75 years	2/9 (22.2)	22.1 [0.5; N.E.]	6/13 (46.2)	1.0 [0.3; N.E.]	0.32	[0.03; 2.91]	0.208
Geographic region							
(Interaction test: p = 0.563)							
Europe excluding Germany	47/138 (34.1)	22.1 [9.2; N.E.]	60/141 (42.6)	3.9 [1.4; 18.4]	0.61	[0.41; 0.89]	0.008
Germany	24/72 (33.3)	7.4 [2.7; N.E.]	24/53 (45.3)	4.0 [0.8; 8.5]	0.60	[0.34; 1.09]	0.113
Others	26/74 (35.1)	N.E. [11.0; N.E.]	35/90 (38.9)	N.E. [3.5; N.E.]	0.86	[0.51; 1.44]	0.536
Edema - Frequency (MID=1)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.331)							
Low	54/171 (31.6)	N.E. [12.0; N.E.]	69/172 (40.1)	11.3 [6.5; N.E.]	0.73	[0.51; 1.04]	0.069
Intermediate	23/75 (30.7)	22.1 [11.1; N.E.]	20/75 (26.7)	N.E. [5.6; N.E.]	0.98	[0.54; 1.79]	0.917
High	14/38 (36.8)	16.6 [2.1; N.E.]	9/37 (24.3)	N.E. [2.8; N.E.]	1.30	[0.56; 3.01]	0.366
Sex							
(Interaction test: p = 0.677)							
Female	47/107 (43.9)	7.4 [3.3; N.E.]	54/126 (42.9)	5.4 [3.0; 11.1]	0.93	[0.62; 1.37]	0.648
Male	44/177 (24.9)	N.E. [22.1; N.E.]	44/158 (27.8)	N.E. [13.9; N.E.]	0.82	[0.54; 1.25]	0.354
Race							
(Interaction test: p = 0.830)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Asian	17/40 (42.5)	10.2 [5.6; N.E.]	25/46 (54.3)	5.2 [2.0; N.E.]	0.74	[0.40; 1.38]	0.303
White	69/227 (30.4)	22.1 [17.5; N.E.]	66/217 (30.4)	24.9 [11.1; N.E.]	0.90	[0.64; 1.26]	0.501
Other	5/17 (29.4)	11.1 [0.5; N.E.]	7/21 (33.3)	15.7 [1.5; N.E.]	0.96	[0.26; 3.46]	0.957
Age groups (Interaction test: p = 0.681)							
18 - < 65 years	77/237 (32.5)	22.1 [16.6; N.E.]	89/247 (36.0)	13.9 [10.2; N.E.]	0.82	[0.60; 1.11]	0.180
65 - < 75 years	13/38 (34.2)	N.E. [2.8; N.E.]	6/24 (25.0)	N.E. [0.7; N.E.]	1.10	[0.41; 2.95]	0.782
>= 75 years	1/9 (11.1)	22.1 [N.E.; N.E.]	3/13 (23.1)	N.E. [1.1; N.E.]	0.44	[0.04; 4.43]	0.472
Geographic region (Interaction test: p = 0.962)							
Europe excluding Germany	42/138	22.1 [17.5; N.E.]	43/141	24.9 [11.1; N.E.]	0.88	[0.58; 1.36]	0.535

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(30.4)		(30.5)				
Germany	19/72	22.1 [4.7; N.E.]	16/53	13.9 [4.6; N.E.]	0.76	[0.39; 1.50]	0.425
	(26.4)		(30.2)				
Others	30/74	16.6 [7.4; N.E.]	39/90	11.1 [2.8; N.E.]	0.89	[0.55; 1.46]	0.674
	(40.5)		(43.3)				
Muscle Pain - Frequency (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.474)							
Low	89/171	1.2 [0.9; 3.0]	101/172	1.0 [0.6; 2.0]	0.79	[0.59; 1.05]	0.125
	(52.0)		(58.7)				
Intermediate	41/75	1.0 [0.7; 2.3]	38/75	1.3 [0.5; 3.0]	1.01	[0.64; 1.57]	0.723
	(54.7)		(50.7)				
High	16/38	1.0 [0.5; N.E.]	22/37	1.4 [0.5; 2.3]	0.67	[0.35; 1.28]	0.178
	(42.1)		(59.5)				
Sex							
(Interaction test: p = 0.712)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Female	61/107 (57.0)	1.0 [0.5; 1.9]	78/126 (61.9)	0.7 [0.5; 1.2]	0.79	[0.56; 1.12]	0.126
Male	85/177 (48.0)	1.7 [1.0; 5.6]	83/158 (52.5)	2.0 [1.0; 3.5]	0.86	[0.64; 1.17]	0.315
Race							
(Interaction test: p = 0.388)							
Asian	21/40 (52.5)	3.8 [0.8; N.E.]	37/46 (80.4)	1.0 [0.5; 1.9]	0.60	[0.35; 1.05]	0.030
White	117/227 (51.5)	1.2 [0.8; 1.9]	115/217 (53.0)	1.2 [0.6; 2.0]	0.85	[0.66; 1.10]	0.209
Other	8/17 (47.1)	0.6 [0.3; N.E.]	9/21 (42.9)	2.3 [0.4; N.E.]	1.01	[0.33; 3.05]	0.614
Age groups							
(Interaction test: p = 0.830)							
18 - < 65 years	119/237 (50.2)	1.2 [1.0; 3.0]	137/247 (55.5)	1.2 [0.7; 2.0]	0.83	[0.65; 1.07]	0.126
65 - < 75 years	22/38	1.0 [0.5; 8.3]	15/24	1.3 [0.3; 2.3]	0.57	[0.27; 1.18]	0.175

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(57.9)		(62.5)				
>= 75 years	5/9	1.2 [0.3; N.E.]	9/13	0.6 [0.3; 4.2]	0.41	[0.09; 1.88]	0.286
	(55.6)		(69.2)				
Geographic region							
(Interaction test: p = 0.896)							
Europe excluding Germany	70/138	1.6 [1.0; 4.4]	72/141	1.2 [0.7; 2.8]	0.87	[0.63; 1.21]	0.433
	(50.7)		(51.1)				
Germany	33/72	0.8 [0.5; 1.9]	28/53	0.6 [0.4; 1.0]	0.74	[0.43; 1.25]	0.232
	(45.8)		(52.8)				
Others	43/74	1.4 [0.7; 7.4]	61/90	1.3 [0.6; 2.3]	0.78	[0.52; 1.16]	0.115
	(58.1)		(67.8)				
Increased Sweating - Frequency (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.802)							
Low	75/171	5.2 [2.6; 22.1]	79/172	7.4 [2.6; 11.1]	0.98	[0.72; 1.35]	0.841
	(43.9)		(45.9)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Intermediate	28/75 (37.3)	16.7 [2.1; N.E.]	23/75 (30.7)	16.7 [4.3; N.E.]	1.14	[0.65; 1.97]	0.781
High	12/38 (31.6)	13.8 [6.5; N.E.]	12/37 (32.4)	N.E. [4.6; N.E.]	0.92	[0.41; 2.05]	0.618
Sex							
(Interaction test: p = 0.804)							
Female	49/107 (45.8)	5.1 [1.4; N.E.]	57/126 (45.2)	5.2 [1.8; 11.1]	1.02	[0.69; 1.50]	0.901
Male	66/177 (37.3)	16.7 [6.5; N.E.]	57/158 (36.1)	13.9 [10.2; N.E.]	1.07	[0.75; 1.53]	0.994
Race							
(Interaction test: p = 0.412)							
Asian	13/40 (32.5)	N.E. [2.8; N.E.]	24/46 (52.2)	11.1 [1.8; N.E.]	0.59	[0.30; 1.17]	0.151
White	96/227 (42.3)	8.3 [3.7; 22.1]	81/217 (37.3)	11.1 [5.2; 19.4]	1.09	[0.81; 1.46]	0.650
Other	6/17	N.E. [0.3; N.E.]	9/21	5.3 [1.0; N.E.]	1.07	[0.36; 3.14]	0.835

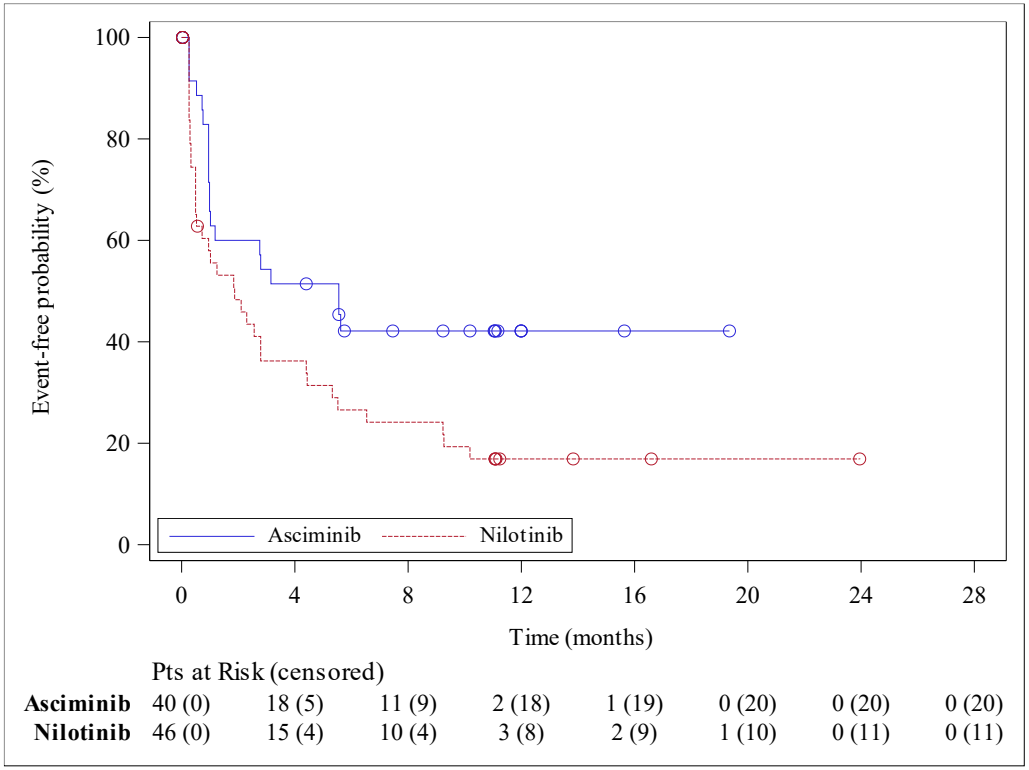
	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(35.3)		(42.9)				
Age groups							
(Interaction test: p = 0.318)							
18 - < 65 years	96/237	10.2 [3.9; 22.1]	99/247	11.1 [6.0; 16.7]	1.00	[0.76; 1.33]	0.923
	(40.5)		(40.1)				
65 - < 75 years	17/38	6.5 [1.4; N.E.]	7/24	19.4 [0.3; N.E.]	1.15	[0.46; 2.88]	0.452
	(44.7)		(29.2)				
>= 75 years	2/9	N.E. [2.1; N.E.]	8/13	1.0 [0.3; 5.2]	0.05	[0.00; 0.79]	0.011
	(22.2)		(61.5)				
Geographic region							
(Interaction test: p = 0.431)							
Europe excluding Germany	58/138	6.5 [2.3; N.E.]	58/141	8.3 [3.9; 19.4]	1.03	[0.72; 1.49]	0.953
	(42.0)		(41.1)				
Germany	29/72	6.5 [1.7; 22.1]	22/53	2.8 [0.5; 16.7]	0.65	[0.37; 1.16]	0.265
	(40.3)		(41.5)				
Others	28/74	16.7 [3.3; N.E.]	34/90	N.E. [5.6; N.E.]	0.98	[0.59; 1.63]	0.835
	(37.8)		(37.8)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			

MID: Minimally important difference
N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
In this sensitivity analysis a missing assessment before randomization is substituted by the last assessment before or on the day of treatment start, if such an assessment is available.
If there are not at least 10 patients in every subgroup or not more than 10 events per subgroup per treatment arm, no subgroup analyses were performed for the corresponding attribute.
If there are not more than 10 events per subgroup per treatment arm, no Cox PH hazard analysis is carried out.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variables ELTS Score (IRT) and covariates treatment arm and baseline PRO score.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variables ELTS Score (IRT).
For the subgroup of Stratification factor: ELTS based on IRT randomisation data not stratification factor was included in the Cox PH model and an unstratitfied log-rank test was applied
The reference group in the (stratified) Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/2025-05-15

Figure 3-7.4 PRO-CTCAE - Frequency: Time to first deterioration analysis by subgroups - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot by subgroups (Full Analysis Set)

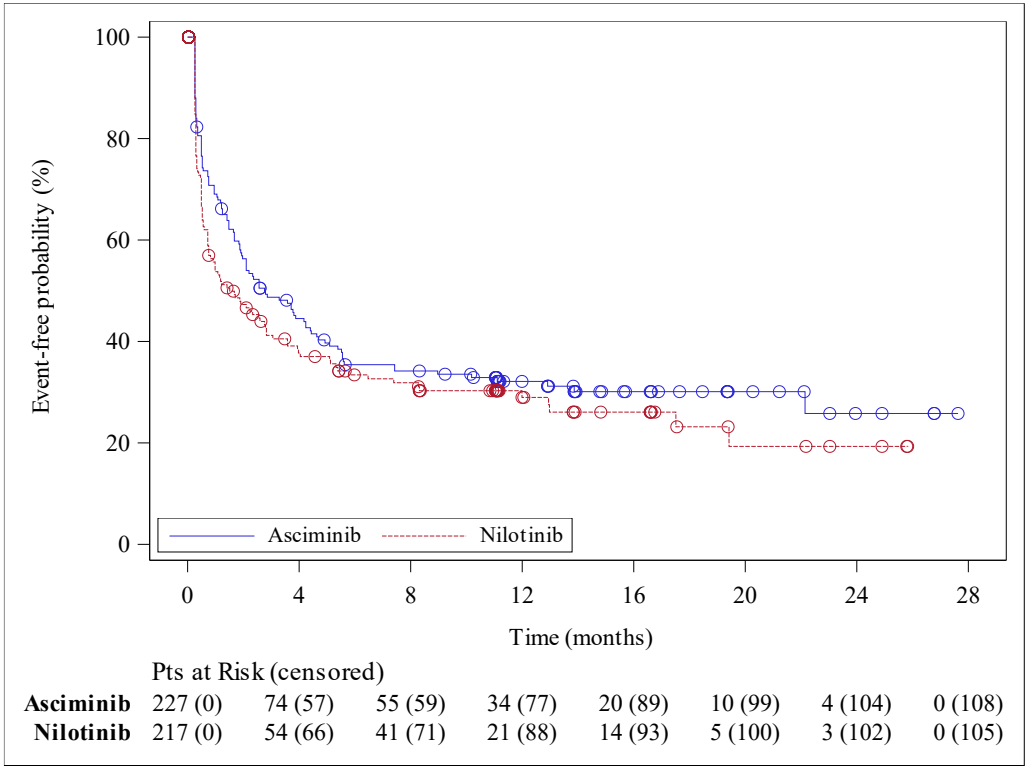
Headache - Frequency (MID=1): Race: Asian



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Figure 3-7.4 PRO-CTCAE - Frequency: Time to first deterioration analysis by subgroups - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot by subgroups (Full Analysis Set)

Headache - Frequency (MID=1): Race: White

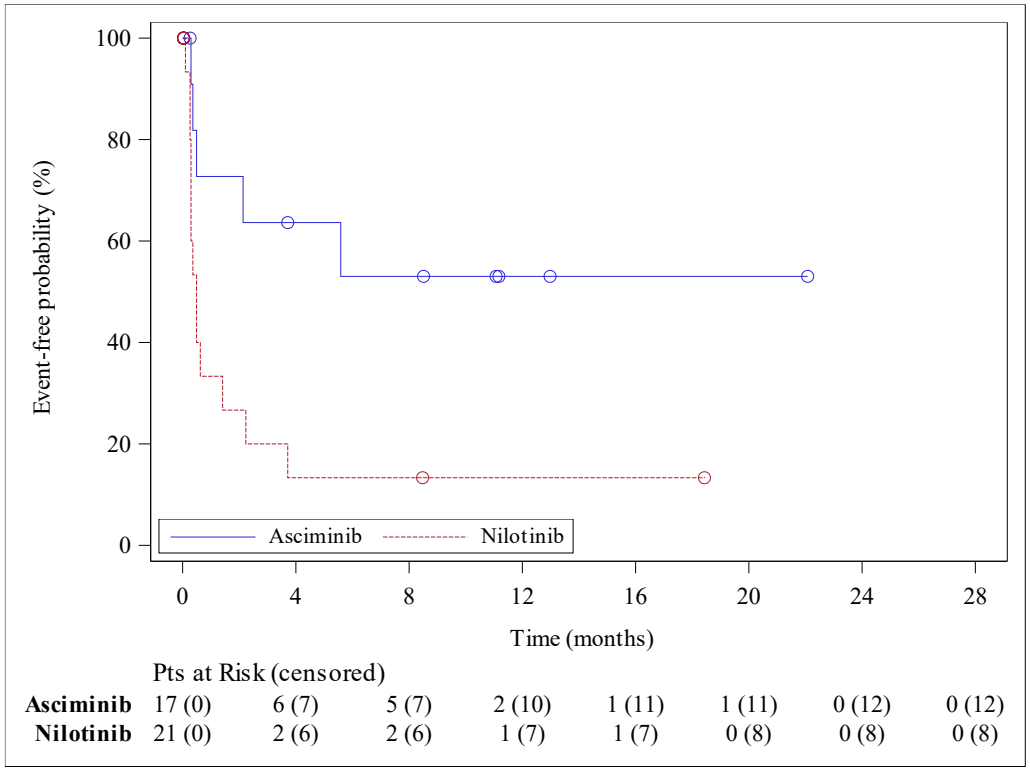


	Pts at Risk (censored)							
Asciminib	227 (0)	74 (57)	55 (59)	34 (77)	20 (89)	10 (99)	4 (104)	0 (108)
Nilotinib	217 (0)	54 (66)	41 (71)	21 (88)	14 (93)	5 (100)	3 (102)	0 (105)

Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Figure 3-7.4 PRO-CTCAE - Frequency: Time to first deterioration analysis by subgroups - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot by subgroups (Full Analysis Set)

Headache - Frequency (MID=1): Race: Other



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Table 3-7.5 PRO-CTCAE - Severity: Time to first deterioration analysis by subgroups - Sensitivity analysis with alternative definition of baseline (Full Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Fatigue - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.473)							
Low	89/171 (52.0)	1.6 [1.0; 2.9]	93/172 (54.1)	1.9 [1.0; 3.3]	0.93	[0.69; 1.24]	0.901
Intermediate	33/75 (44.0)	11.1 [3.2; 18.5]	33/75 (44.0)	2.8 [0.7; 11.1]	0.64	[0.39; 1.05]	0.056
High	15/38 (39.5)	11.1 [1.2; N.E.]	15/37 (40.5)	11.0 [0.5; N.E.]	0.53	[0.25; 1.11]	0.444
Sex							
(Interaction test: p = 0.564)							
Female	57/107 (53.3)	1.9 [1.0; 9.2]	69/126 (54.8)	1.2 [0.8; 3.3]	0.79	[0.55; 1.14]	0.373
Male	80/177	5.9 [2.3; 13.0]	72/158	3.1 [1.0; 10.2]	0.87	[0.63; 1.20]	0.447

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(45.2)		(45.6)				
Race							
(Interaction test: p = 0.342)							
Asian	22/40	2.8 [1.0; N.E.]	27/46	5.5 [0.9; 16.6]	0.77	[0.42; 1.39]	0.830
	(55.0)		(58.7)				
White	109/227	4.6 [1.9; 11.1]	110/217	1.1 [0.8; 2.8]	0.76	[0.58; 0.99]	0.051
	(48.0)		(50.7)				
Other	6/17	2.8 [0.3; N.E.]	4/21	N.E. [11.0; N.E.]	1.78	[0.33; 9.65]	0.066
	(35.3)		(19.0)				
Age groups							
(Interaction test: p = 0.627)							
18 - < 65 years	116/237	2.8 [1.6; 9.2]	123/247	2.8 [1.0; 4.5]	0.85	[0.65; 1.09]	0.449
	(48.9)		(49.8)				
65 - < 75 years	17/38	15.7 [0.8; 19.4]	12/24	0.7 [0.3; N.E.]	0.76	[0.35; 1.66]	0.585
	(44.7)		(50.0)				
>= 75 years	4/9	8.3 [0.5; N.E.]	6/13	1.3 [0.3; N.E.]	0.61	[0.12; 3.02]	0.686
	(44.4)		(46.2)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = 0.693)							
Europe excluding Germany	65/138 (47.1)	4.9 [1.5; 17.5]	71/141 (50.4)	1.1 [0.8; 3.3]	0.75	[0.54; 1.06]	0.154
Germany	34/72 (47.2)	2.2 [0.8; 11.1]	24/53 (45.3)	1.0 [0.4; 3.1]	0.65	[0.38; 1.13]	0.408
Others	38/74 (51.4)	4.0 [1.8; 17.5]	46/90 (51.1)	5.6 [1.2; 12.9]	0.95	[0.61; 1.47]	0.956
Headache - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.785)							
Low	92/171 (53.8)	2.6 [1.7; 3.7]	97/172 (56.4)	1.9 [1.0; 3.3]	0.81	[0.61; 1.09]	0.434
Intermediate	33/75 (44.0)	3.9 [1.2; N.E.]	33/75 (44.0)	2.3 [0.7; 8.3]	0.79	[0.48; 1.28]	0.286
High	19/38	3.7 [1.9; 11.1]	22/37	1.0 [0.5; 3.7]	0.62	[0.33; 1.16]	0.110

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(50.0)		(59.5)				
Sex							
(Interaction test: p = 0.752)							
Female	59/107	1.9 [1.0; 3.5]	72/126	1.2 [0.6; 3.0]	0.83	[0.59; 1.18]	0.335
	(55.1)		(57.1)				
Male	85/177	3.7 [2.3; 10.2]	80/158	2.2 [1.2; 4.8]	0.77	[0.57; 1.05]	0.196
	(48.0)		(50.6)				
Race							
(Interaction test: p = 0.111)							
Asian	20/40	5.6 [1.0; N.E.]	35/46	1.2 [0.5; 4.4]	0.54	[0.31; 0.95]	0.025
	(50.0)		(76.1)				
White	120/227	2.6 [1.9; 3.8]	106/217	1.9 [1.1; 3.3]	0.88	[0.68; 1.14]	0.668
	(52.9)		(48.8)				
Other	4/17	N.E. [0.5; N.E.]	11/21	2.2 [0.4; 15.7]	0.48	[0.13; 1.78]	0.254
	(23.5)		(52.4)				
Age groups							
(Interaction test: p = 0.236)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
18 - < 65 years	121/237 (51.1)	2.8 [2.1; 4.5]	131/247 (53.0)	1.9 [1.1; 3.5]	0.81	[0.63; 1.04]	0.199
65 - < 75 years	18/38 (47.4)	4.2 [1.2; N.E.]	13/24 (54.2)	2.1 [0.3; 5.3]	0.67	[0.30; 1.47]	0.461
>= 75 years	5/9 (55.6)	0.6 [0.3; N.E.]	8/13 (61.5)	1.1 [0.3; N.E.]	19.45	[0.92; 409.25]	0.045
Geographic region (Interaction test: p = 0.905)							
Europe excluding Germany	69/138 (50.0)	2.9 [1.9; 10.2]	69/141 (48.9)	2.1 [0.9; 6.5]	0.80	[0.57; 1.12]	0.418
Germany	37/72 (51.4)	3.1 [1.6; 4.4]	24/53 (45.3)	1.2 [0.5; 5.1]	0.70	[0.40; 1.24]	0.615
Others	38/74 (51.4)	2.8 [1.2; N.E.]	59/90 (65.6)	2.0 [1.0; 3.7]	0.71	[0.47; 1.06]	0.074
Vomiting - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.508)							
Low	21/171 (12.3)	N.E. [N.E.; N.E.]	43/172 (25.0)	N.E. [N.E.; N.E.]	0.43	[0.25; 0.72]	0.001
Intermediate	12/75 (16.0)	N.E. [20.3; N.E.]	12/75 (16.0)	N.E. [N.E.; N.E.]	0.70	[0.31; 1.59]	0.463
High	4/38 (10.5)	N.E. [13.9; N.E.]	7/37 (18.9)	N.E. [13.8; N.E.]	0.47	[0.13; 1.70]	0.254
Sex							
(Interaction test: p = 0.286)							
Female	15/107 (14.0)	N.E. [22.1; N.E.]	34/126 (27.0)	N.E. [13.0; N.E.]	0.41	[0.22; 0.76]	0.003
Male	22/177 (12.4)	N.E. [N.E.; N.E.]	28/158 (17.7)	N.E. [N.E.; N.E.]	0.62	[0.35; 1.08]	0.086
Race							
(Interaction test: p = 0.507)							
Asian	7/40 (17.5)	20.3 [17.5; N.E.]	13/46 (28.3)	N.E. [13.0; N.E.]	0.66	[0.26; 1.72]	0.392

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
White	29/227 (12.8)	N.E. [N.E.; N.E.]	42/217 (19.4)	N.E. [N.E.; N.E.]	0.53	[0.33; 0.86]	0.007
Other	1/17 (5.9)	N.E. [N.E.; N.E.]	7/21 (33.3)	18.4 [1.2; N.E.]	0.18	[0.02; 1.54]	0.083
Age groups (Interaction test: p = 0.367)							
18 - < 65 years	29/237 (12.2)	N.E. [N.E.; N.E.]	57/247 (23.1)	N.E. [N.E.; N.E.]	0.44	[0.28; 0.69]	<0.001
65 - < 75 years	7/38 (18.4)	N.E. [14.0; N.E.]	3/24 (12.5)	N.E. [N.E.; N.E.]	1.18	[0.30; 4.66]	0.824
>= 75 years	1/9 (11.1)	22.1 [N.E.; N.E.]	2/13 (15.4)	N.E. [1.4; N.E.]	0.87	[0.05; 13.95]	0.919
Geographic region (Interaction test: p = 0.811)							
Europe excluding Germany	19/138 (13.8)	N.E. [N.E.; N.E.]	26/141 (18.4)	N.E. [18.4; N.E.]	0.61	[0.33; 1.10]	0.096
Germany	5/72	N.E. [N.E.; N.E.]	7/53	N.E. [N.E.; N.E.]	0.36	[0.11; 1.16]	0.076

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(6.9)		(13.2)				
Others	13/74	20.3 [17.5; N.E.]	29/90	N.E. [12.0; N.E.]	0.38	[0.19; 0.78]	0.006
	(17.6)		(32.2)				
Nausea - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.718)							
Low	57/171	N.E. [11.0; N.E.]	74/172	5.5 [2.8; 24.9]	0.70	[0.49; 0.99]	0.042
	(33.3)		(43.0)				
Intermediate	21/75	22.1 [13.8; N.E.]	29/75	5.6 [3.9; 18.4]	0.45	[0.25; 0.82]	0.010
	(28.0)		(38.7)				
High	12/38	N.E. [1.9; N.E.]	15/37	6.5 [2.3; N.E.]	0.74	[0.34; 1.58]	0.403
	(31.6)		(40.5)				
Sex							
(Interaction test: p = 0.596)							
Female	39/107	22.1 [4.4; N.E.]	58/126	3.3 [1.5; 10.7]	0.61	[0.40; 0.92]	0.021
	(36.4)		(46.0)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Male	51/177 (28.8)	N.E. [N.E.; N.E.]	60/158 (38.0)	11.1 [4.5; N.E.]	0.70	[0.48; 1.01]	0.041
Race (Interaction test: p = 0.865)							
Asian	12/40 (30.0)	N.E. [11.1; N.E.]	21/46 (45.7)	5.6 [1.9; N.E.]	0.65	[0.32; 1.33]	0.212
White	73/227 (32.2)	N.E. [11.0; N.E.]	90/217 (41.5)	5.4 [3.3; 11.1]	0.63	[0.46; 0.86]	0.003
Other	5/17 (29.4)	N.E. [0.5; N.E.]	7/21 (33.3)	18.4 [0.3; N.E.]	0.75	[0.21; 2.71]	0.981
Age groups (Interaction test: p = 0.948)							
18 - < 65 years	74/237 (31.2)	N.E. [15.7; N.E.]	104/247 (42.1)	5.5 [3.5; 18.4]	0.64	[0.47; 0.86]	0.002
65 - < 75 years	13/38 (34.2)	N.E. [4.4; N.E.]	9/24 (37.5)	7.4 [1.0; N.E.]	0.80	[0.32; 1.99]	0.623
>= 75 years	3/9	22.1 [0.5; N.E.]	5/13	1.2 [0.3; N.E.]	0.27	[0.02; 3.82]	0.407

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(33.3)		(38.5)				
Geographic region							
(Interaction test: p = 0.501)							
Europe excluding Germany	43/138	N.E. [13.8; N.E.]	61/141	4.3 [2.1; 13.0]	0.54	[0.36; 0.81]	0.002
	(31.2)		(43.3)				
Germany	23/72	7.4 [2.6; N.E.]	23/53	6.5 [1.0; 18.4]	0.67	[0.37; 1.22]	0.233
	(31.9)		(43.4)				
Others	24/74	N.E. [11.1; N.E.]	34/90	N.E. [3.5; N.E.]	0.83	[0.49; 1.41]	0.428
	(32.4)		(37.8)				
Edema - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.920)							
Low	46/171	N.E. [N.E.; N.E.]	58/172	N.E. [10.2; N.E.]	0.73	[0.50; 1.08]	0.130
	(26.9)		(33.7)				
Intermediate	21/75	22.1 [17.5; N.E.]	21/75	N.E. [4.2; N.E.]	0.79	[0.43; 1.44]	0.375
	(28.0)		(28.0)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
High	11/38 (28.9)	N.E. [4.2; N.E.]	10/37 (27.0)	N.E. [4.2; N.E.]	0.84	[0.35; 2.00]	0.913
Sex							
(Interaction test: p = 0.511)							
Female	44/107 (41.1)	9.2 [3.5; N.E.]	51/126 (40.5)	6.5 [3.9; N.E.]	0.90	[0.60; 1.35]	0.604
Male	34/177 (19.2)	N.E. [22.1; N.E.]	38/158 (24.1)	N.E. [N.E.; N.E.]	0.72	[0.46; 1.15]	0.152
Race							
(Interaction test: p = 0.705)							
Asian	13/40 (32.5)	N.E. [7.4; N.E.]	22/46 (47.8)	10.2 [2.4; N.E.]	0.59	[0.30; 1.17]	0.130
White	61/227 (26.9)	N.E. [22.1; N.E.]	61/217 (28.1)	N.E. [11.1; N.E.]	0.84	[0.59; 1.19]	0.312
Other	4/17 (23.5)	N.E. [2.8; N.E.]	6/21 (28.6)	N.E. [1.5; N.E.]	0.65	[0.17; 2.49]	0.585
Age groups							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.990)							
18 - < 65 years	67/237 (28.3)	N.E. [17.5; N.E.]	77/247 (31.2)	N.E. [11.1; N.E.]	0.82	[0.59; 1.13]	0.223
65 - < 75 years	11/38 (28.9)	N.E. [4.2; N.E.]	7/24 (29.2)	N.E. [0.7; N.E.]	0.75	[0.28; 1.96]	0.569
>= 75 years	0/9	N.E. [N.E.; N.E.]	5/13 (38.5)	12.9 [0.5; N.E.]	0.11	[0.00; 2.69]	0.045
Geographic region							
(Interaction test: p = 0.992)							
Europe excluding Germany	35/138 (25.4)	N.E. [N.E.; N.E.]	39/141 (27.7)	N.E. [11.1; N.E.]	0.77	[0.48; 1.22]	0.275
Germany	18/72 (25.0)	22.1 [4.7; N.E.]	16/53 (30.2)	12.9 [4.4; N.E.]	0.73	[0.37; 1.45]	0.384
Others	25/74 (33.8)	N.E. [8.4; N.E.]	34/90 (37.8)	N.E. [4.2; N.E.]	0.76	[0.45; 1.29]	0.357
Muscle Pain - Severity (MID=1)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.484)							
Low	86/171 (50.3)	1.9 [1.0; 7.4]	105/172 (61.0)	1.1 [0.7; 2.0]	0.70	[0.53; 0.94]	0.015
Intermediate	37/75 (49.3)	1.4 [0.8; 5.6]	37/75 (49.3)	2.0 [0.6; 5.6]	0.94	[0.59; 1.49]	0.419
High	14/38 (36.8)	N.E. [0.7; N.E.]	20/37 (54.1)	1.6 [0.5; 2.8]	0.62	[0.31; 1.24]	0.112
Sex							
(Interaction test: p = 0.590)							
Female	57/107 (53.3)	1.2 [0.6; 4.6]	79/126 (62.7)	1.0 [0.6; 1.6]	0.66	[0.47; 0.94]	0.011
Male	80/177 (45.2)	3.0 [1.2; 9.2]	83/158 (52.5)	2.0 [1.0; 3.7]	0.79	[0.58; 1.07]	0.087
Race							
(Interaction test: p = 0.854)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Asian	19/40 (47.5)	9.2 [1.0; N.E.]	34/46 (73.9)	1.6 [0.6; 2.8]	0.64	[0.36; 1.14]	0.054
White	110/227 (48.5)	1.7 [1.0; 4.4]	115/217 (53.0)	1.2 [0.7; 2.3]	0.76	[0.59; 0.99]	0.028
Other	8/17 (47.1)	0.6 [0.3; N.E.]	13/21 (61.9)	2.2 [0.4; 5.5]	0.64	[0.22; 1.88]	0.289
Age groups (Interaction test: p = 0.739)							
18 - < 65 years	112/237 (47.3)	2.2 [1.0; 7.4]	138/247 (55.9)	1.4 [0.8; 2.3]	0.74	[0.58; 0.96]	0.012
65 - < 75 years	20/38 (52.6)	1.4 [0.7; 13.9]	15/24 (62.5)	1.3 [0.3; 2.6]	0.49	[0.23; 1.03]	0.059
>= 75 years	5/9 (55.6)	1.2 [0.3; N.E.]	9/13 (69.2)	0.7 [0.3; 4.7]	0.70	[0.17; 2.93]	0.958
Geographic region (Interaction test: p = 0.793)							
Europe excluding Germany	65/138	2.1 [1.2; 13.9]	72/141	1.5 [0.8; 3.1]	0.76	[0.54; 1.07]	0.119

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(47.1)		(51.1)				
Germany	32/72	0.8 [0.5; 6.5]	30/53	0.7 [0.3; 1.0]	0.63	[0.37; 1.08]	0.056
	(44.4)		(56.6)				
Others	40/74	2.7 [0.6; 11.0]	60/90	2.0 [0.6; 2.8]	0.75	[0.50; 1.12]	0.075
	(54.1)		(66.7)				
Pruritus - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.156)							
Low	87/171	3.5 [2.1; 5.6]	105/172	1.2 [0.8; 2.1]	0.65	[0.49; 0.87]	0.003
	(50.9)		(61.0)				
Intermediate	35/75	4.2 [2.7; N.E.]	35/75	2.1 [1.0; 3.5]	0.63	[0.39; 1.01]	0.086
	(46.7)		(46.7)				
High	14/38	11.1 [1.7; N.E.]	25/37	1.0 [0.5; 2.0]	0.34	[0.17; 0.66]	<0.001
	(36.8)		(67.6)				
Sex							
(Interaction test: p = 0.191)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Female	53/107 (49.5)	3.3 [2.1; 5.7]	78/126 (61.9)	0.8 [0.6; 1.7]	0.51	[0.36; 0.73]	<0.001
Male	83/177 (46.9)	4.4 [2.7; 9.2]	87/158 (55.1)	1.9 [1.2; 3.3]	0.68	[0.50; 0.92]	0.019
Race							
(Interaction test: p = 0.243)							
Asian	13/40 (32.5)	N.E. [2.8; N.E.]	30/46 (65.2)	1.8 [0.7; 5.3]	0.35	[0.18; 0.69]	0.003
White	114/227 (50.2)	3.5 [2.1; 4.6]	122/217 (56.2)	1.4 [1.0; 2.1]	0.65	[0.50; 0.84]	<0.001
Other	9/17 (52.9)	3.3 [0.3; N.E.]	13/21 (61.9)	1.1 [0.5; 2.1]	0.62	[0.22; 1.70]	0.297
Age groups							
(Interaction test: p = 0.205)							
18 - < 65 years	115/237 (48.5)	3.9 [2.6; 6.1]	140/247 (56.7)	1.6 [1.1; 2.1]	0.64	[0.50; 0.82]	<0.001
65 - < 75 years	18/38	3.9 [1.7; N.E.]	15/24	1.1 [0.5; 5.3]	0.46	[0.22; 0.96]	0.027

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(47.4)		(62.5)				
>= 75 years	3/9	N.E. [1.0; N.E.]	10/13	0.5 [0.3; 1.7]	0.18	[0.03; 0.93]	0.027
	(33.3)		(76.9)				
Geographic region							
(Interaction test: p = 0.919)							
Europe excluding Germany	69/138	3.9 [2.1; 7.4]	80/141	1.4 [0.8; 2.6]	0.62	[0.44; 0.85]	0.004
	(50.0)		(56.7)				
Germany	31/72	3.5 [1.2; 19.4]	29/53	1.2 [0.6; 2.0]	0.52	[0.30; 0.89]	0.009
	(43.1)		(54.7)				
Others	36/74	5.6 [2.8; N.E.]	56/90	1.7 [0.8; 2.8]	0.60	[0.39; 0.92]	0.020
	(48.6)		(62.2)				
Increased Sweating - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.571)							
Low	70/171	11.1 [3.9; 22.1]	72/172	11.1 [3.3; 19.4]	1.00	[0.72; 1.40]	0.935
	(40.9)		(41.9)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Intermediate	26/75 (34.7)	15.8 [2.8; N.E.]	21/75 (28.0)	19.4 [5.7; N.E.]	1.10	[0.62; 1.96]	0.844
High	10/38 (26.3)	N.E. [6.5; N.E.]	13/37 (35.1)	11.0 [1.0; N.E.]	0.68	[0.30; 1.55]	0.312
Sex							
(Interaction test: p = 0.266)							
Female	45/107 (42.1)	10.2 [1.9; N.E.]	57/126 (45.2)	5.2 [1.9; 12.9]	0.88	[0.59; 1.31]	0.686
Male	61/177 (34.5)	22.1 [8.4; N.E.]	49/158 (31.0)	19.4 [11.1; N.E.]	1.16	[0.79; 1.69]	0.665
Race							
(Interaction test: p = 0.153)							
Asian	9/40 (22.5)	N.E. [N.E.; N.E.]	22/46 (47.8)	11.1 [2.3; N.E.]	0.46	[0.21; 1.00]	0.065
White	91/227 (40.1)	11.1 [4.0; 22.1]	76/217 (35.0)	16.7 [5.6; N.E.]	1.09	[0.80; 1.47]	0.672
Other	6/17	N.E. [0.3; N.E.]	8/21	5.6 [1.0; N.E.]	1.17	[0.39; 3.51]	0.906

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(35.3)		(38.1)				
Age groups							
(Interaction test: p = 0.615)							
18 - < 65 years	89/237	22.1 [7.4; N.E.]	91/247	13.0 [7.4; N.E.]	1.00	[0.75; 1.34]	0.946
	(37.6)		(36.8)				
65 - < 75 years	15/38	12.0 [2.9; N.E.]	8/24	19.4 [0.3; N.E.]	0.79	[0.32; 2.00]	0.983
	(39.5)		(33.3)				
>= 75 years	2/9	N.E. [1.0; N.E.]	7/13	1.0 [0.3; N.E.]	0.25	[0.04; 1.49]	0.107
	(22.2)		(53.8)				
Geographic region							
(Interaction test: p = 0.912)							
Europe excluding Germany	55/138	11.1 [3.9; N.E.]	56/141	11.1 [3.3; 19.4]	0.98	[0.67; 1.42]	0.761
	(39.9)		(39.7)				
Germany	28/72	6.5 [1.6; N.E.]	19/53	5.6 [0.8; N.E.]	0.83	[0.46; 1.51]	0.776
	(38.9)		(35.8)				
Others	23/74	N.E. [15.8; N.E.]	31/90	N.E. [11.0; N.E.]	0.88	[0.51; 1.52]	0.597
	(31.1)		(34.4)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Cough - Severity (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.208)							
Low	80/171 (46.8)	7.4 [4.5; 14.8]	104/172 (60.5)	2.4 [1.7; 3.5]	0.64	[0.48; 0.86]	<0.001
Intermediate	36/75 (48.0)	5.4 [2.1; 15.6]	26/75 (34.7)	12.9 [1.8; N.E.]	1.02	[0.61; 1.70]	0.731
High	17/38 (44.7)	5.5 [1.9; N.E.]	16/37 (43.2)	5.3 [1.7; N.E.]	0.97	[0.48; 1.96]	0.854
Sex							
(Interaction test: p = 0.518)							
Female	57/107 (53.3)	4.2 [1.9; 9.2]	67/126 (53.2)	2.6 [1.7; 5.6]	0.81	[0.56; 1.16]	0.223
Male	76/177 (42.9)	11.0 [5.4; 16.7]	79/158 (50.0)	3.3 [2.2; 7.4]	0.72	[0.52; 0.99]	0.020
Race							

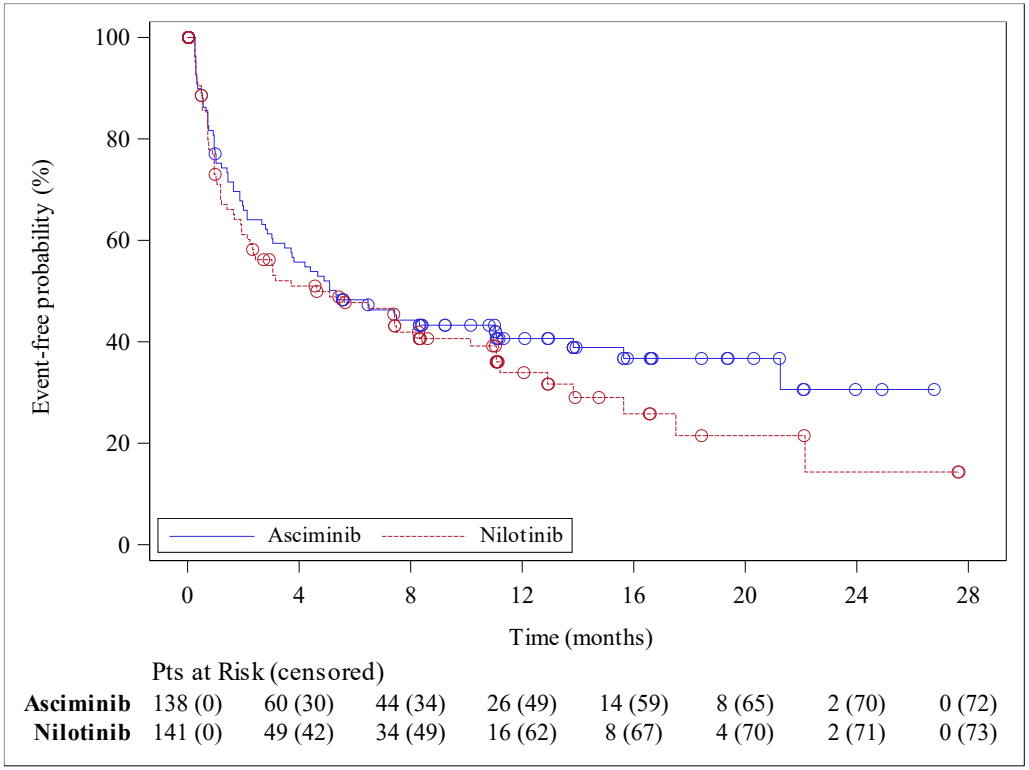
	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.809)							
Asian	20/40 (50.0)	12.0 [4.0; 17.5]	31/46 (67.4)	4.4 [2.3; 7.4]	0.81	[0.45; 1.47]	0.194
White	107/227 (47.1)	6.5 [3.8; 13.8]	106/217 (48.8)	2.8 [1.7; 5.6]	0.74	[0.57; 0.97]	0.026
Other	6/17 (35.3)	22.1 [1.9; N.E.]	9/21 (42.9)	2.2 [0.6; N.E.]	0.31	[0.09; 1.07]	0.070
Age groups							
(Interaction test: p = 0.103)							
18 - < 65 years	113/237 (47.7)	5.6 [4.2; 12.0]	129/247 (52.2)	3.0 [2.1; 5.3]	0.77	[0.60; 1.00]	0.013
65 - < 75 years	16/38 (42.1)	11.1 [3.0; N.E.]	12/24 (50.0)	2.1 [0.6; 5.6]	0.36	[0.15; 0.82]	0.018
>= 75 years	4/9 (44.4)	2.8 [1.0; N.E.]	5/13 (38.5)	22.1 [0.3; N.E.]	0.41	[0.03; 6.62]	0.590
Geographic region							
(Interaction test: p = 0.036)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Europe excluding Germany	66/138 (47.8)	5.3 [3.1; 11.1]	68/141 (48.2)	4.6 [2.2; 10.2]	0.84	[0.60; 1.19]	0.299
Germany	31/72 (43.1)	4.6 [1.7; 14.8]	28/53 (52.8)	0.8 [0.5; 1.7]	0.42	[0.24; 0.72]	0.012
Others	36/74 (48.6)	12.0 [5.6; 17.5]	50/90 (55.6)	3.3 [2.4; 6.5]	0.78	[0.50; 1.22]	0.119

MID: Minimally important difference
N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
In this sensitivity analysis a missing assessment before randomization is substituted by the last assessment before or on the day of treatment start, if such an assessment is available.
If there are not at least 10 patients in every subgroup or not more than 10 events per subgroup per treatment arm, no subgroup analyses were performed for the corresponding attribute.
If there are not more than 10 events per subgroup per treatment arm, no Cox PH hazard analysis is carried out.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variables ELTS Score (IRT) and covariates treatment arm and baseline PRO score.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variables ELTS Score (IRT).
For the subgroup of Stratification factor: ELTS based on IRT randomisation data not stratification factor was included in the Cox PH model and an unstratitfied log-rank test was applied
The reference group in the (stratified) Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/2025-05-15

Figure 3-7.5 PRO-CTCAE - Severity: Time to first deterioration analysis by subgroups - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot by subgroups (Full Analysis Set)

Cough - Severity (MID=1): Geographic region: Europe excluding Germany

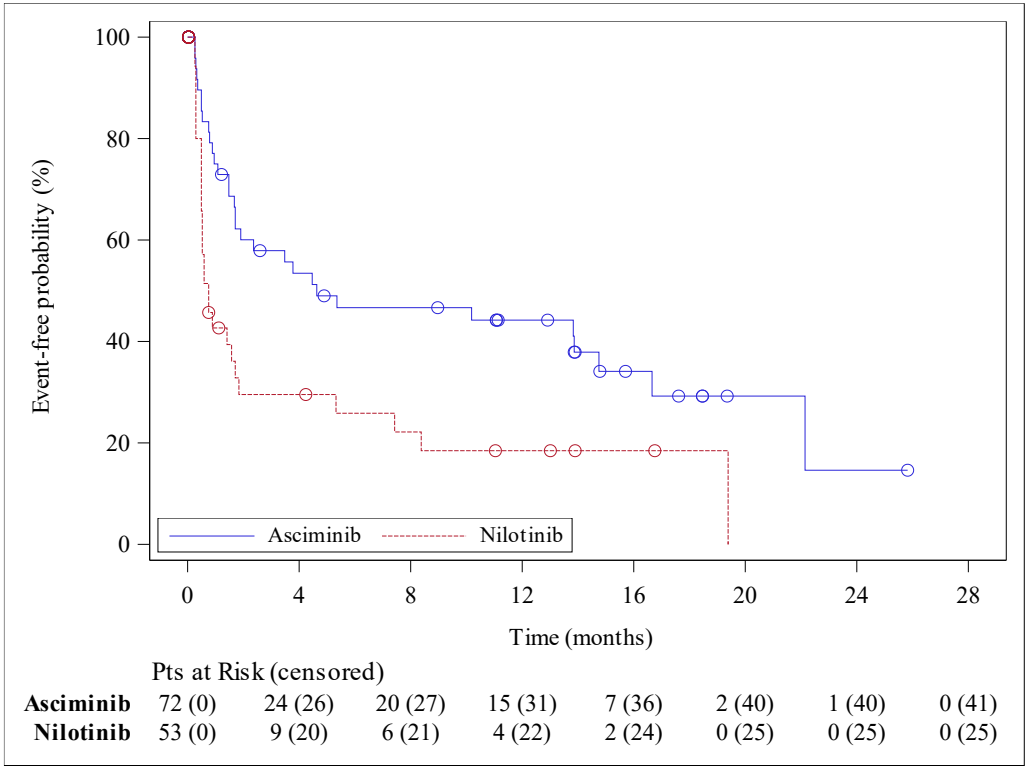


Pts at Risk (censored)								
Asciminib	138 (0)	60 (30)	44 (34)	26 (49)	14 (59)	8 (65)	2 (70)	0 (72)
Nilotinib	141 (0)	49 (42)	34 (49)	16 (62)	8 (67)	4 (70)	2 (71)	0 (73)

Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Figure 3-7.5 PRO-CTCAE - Severity: Time to first deterioration analysis by subgroups - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot by subgroups (Full Analysis Set)

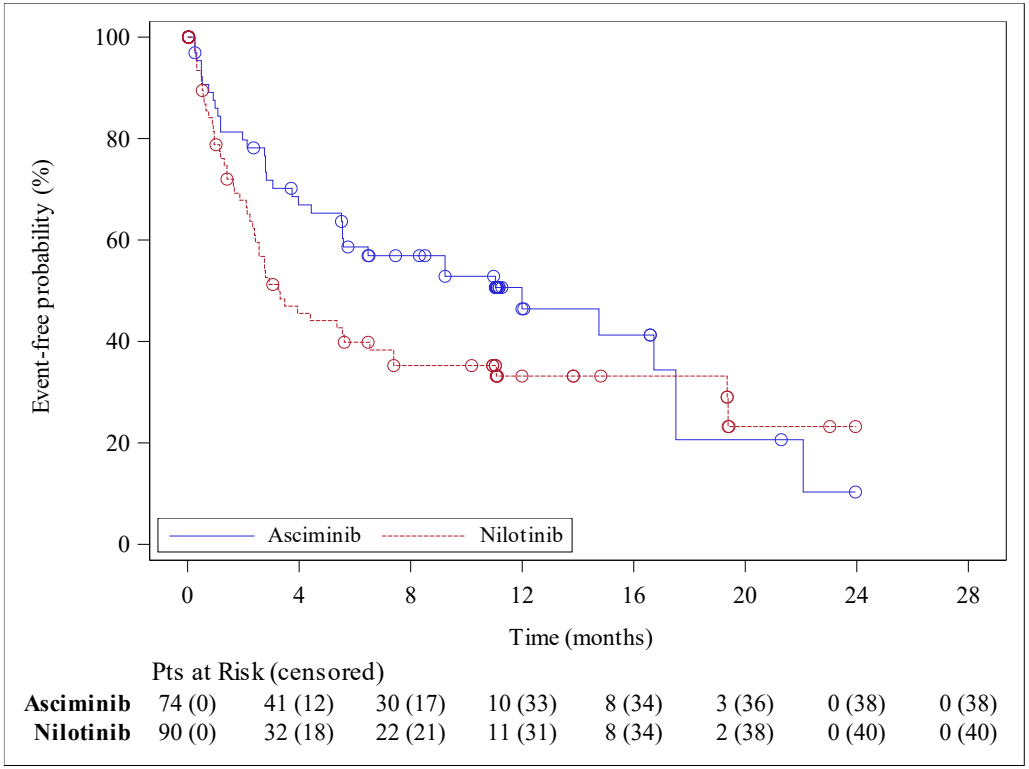
Cough - Severity (MID=1): Geographic region: Germany



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Figure 3-7.5 PRO-CTCAE - Severity: Time to first deterioration analysis by subgroups - Sensitivity analysis with alternative definition of baseline: Kaplan-Meier plot by subgroups (Full Analysis Set)

Cough - Severity (MID=1): Geographic region: Others



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/2025-05-15

Table 3-7.6 PRO-CTCAE - Interference: Time to first deterioration analysis by subgroups - Sensitivity analysis with alternative definition of baseline (Full Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Fatigue - Interference (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.664)							
Low	93/171 (54.4)	2.2 [1.3; 3.7]	88/172 (51.2)	2.1 [1.0; 3.3]	0.98	[0.73; 1.31]	0.863
Intermediate	37/75 (49.3)	4.5 [1.7; 11.1]	36/75 (48.0)	2.8 [0.7; 11.1]	0.88	[0.56; 1.39]	0.431
High	14/38 (36.8)	N.E. [3.5; N.E.]	14/37 (37.8)	11.0 [0.7; N.E.]	0.61	[0.29; 1.31]	0.448
Sex							
(Interaction test: p = 0.969)							
Female	60/107 (56.1)	1.8 [1.0; 4.9]	67/126 (53.2)	1.7 [0.8; 3.0]	0.94	[0.66; 1.34]	0.899
Male	84/177	3.7 [2.2; 9.2]	71/158	3.3 [1.0; 14.0]	0.94	[0.68; 1.29]	0.702

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(47.5)		(44.9)				
Race							
(Interaction test: p = 0.648)							
Asian	22/40	4.4 [1.0; N.E.]	31/46	2.8 [0.5; 9.2]	0.75	[0.43; 1.32]	0.398
	(55.0)		(67.4)				
White	115/227	3.0 [1.7; 5.3]	99/217	2.6 [1.0; 3.5]	0.97	[0.74; 1.27]	0.848
	(50.7)		(45.6)				
Other	7/17	2.1 [1.1; N.E.]	8/21	16.5 [0.4; N.E.]	0.79	[0.26; 2.40]	0.773
	(41.2)		(38.1)				
Age groups							
(Interaction test: p = 0.669)							
18 - < 65 years	124/237	2.9 [2.0; 5.3]	121/247	2.8 [1.0; 3.5]	0.93	[0.72; 1.19]	0.801
	(52.3)		(49.0)				
65 - < 75 years	18/38	2.6 [0.5; N.E.]	10/24	1.4 [0.3; N.E.]	0.86	[0.37; 2.01]	0.853
	(47.4)		(41.7)				
>= 75 years	2/9	N.E. [0.5; N.E.]	7/13	1.1 [0.3; N.E.]	0.43	[0.08; 2.30]	0.076
	(22.2)		(53.8)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = 0.418)							
Europe excluding Germany	70/138 (50.7)	2.8 [1.0; 5.6]	66/141 (46.8)	2.1 [1.0; 3.5]	1.00	[0.71; 1.41]	0.963
Germany	36/72 (50.0)	2.2 [1.2; 8.3]	24/53 (45.3)	0.8 [0.3; 9.2]	0.62	[0.35; 1.07]	0.382
Others	38/74 (51.4)	4.5 [2.4; 17.5]	48/90 (53.3)	3.5 [1.0; 11.1]	0.87	[0.56; 1.34]	0.519
Headache - Interference (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.184)							
Low	79/171 (46.2)	4.9 [3.3; 12.9]	96/172 (55.8)	2.1 [1.5; 3.3]	0.66	[0.49; 0.89]	0.012
Intermediate	28/75 (37.3)	16.6 [3.8; N.E.]	21/75 (28.0)	N.E. [4.2; N.E.]	1.15	[0.65; 2.02]	0.637
High	17/38	9.0 [2.1; N.E.]	16/37	4.6 [1.0; N.E.]	0.89	[0.45; 1.77]	0.739

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(44.7)		(43.2)				
Sex							
(Interaction test: p = 0.826)							
Female	56/107	3.8 [2.1; 8.3]	65/126	2.3 [1.2; 4.2]	0.80	[0.56; 1.14]	0.269
	(52.3)		(51.6)				
Male	68/177	11.1 [4.9; N.E.]	68/158	7.4 [2.2; 14.8]	0.78	[0.55; 1.09]	0.147
	(38.4)		(43.0)				
Race							
(Interaction test: p = 0.458)							
Asian	18/40	8.3 [2.0; N.E.]	30/46	2.1 [1.0; 8.3]	0.65	[0.36; 1.17]	0.125
	(45.0)		(65.2)				
White	102/227	4.9 [3.8; 12.0]	94/217	4.0 [2.1; 11.2]	0.82	[0.62; 1.09]	0.242
	(44.9)		(43.3)				
Other	4/17	N.E. [0.4; N.E.]	9/21	3.7 [0.4; N.E.]	0.50	[0.15; 1.67]	0.305
	(23.5)		(42.9)				
Age groups							
(Interaction test: p = 0.767)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
18 - < 65 years	105/237 (44.3)	5.6 [3.7; 12.9]	119/247 (48.2)	3.1 [1.9; 5.4]	0.75	[0.57; 0.97]	0.043
65 - < 75 years	16/38 (42.1)	10.2 [2.3; N.E.]	7/24 (29.2)	N.E. [0.6; N.E.]	0.99	[0.38; 2.59]	0.779
>= 75 years	3/9 (33.3)	19.4 [0.3; N.E.]	7/13 (53.8)	1.7 [0.3; 14.8]	0.42	[0.08; 2.16]	0.289
Geographic region (Interaction test: p = 0.806)							
Europe excluding Germany	62/138 (44.9)	7.5 [3.7; 16.6]	62/141 (44.0)	3.1 [2.1; 11.2]	0.80	[0.56; 1.14]	0.322
Germany	31/72 (43.1)	4.7 [3.3; 10.3]	23/53 (43.4)	3.3 [1.0; 14.8]	0.62	[0.35; 1.10]	0.171
Others	31/74 (41.9)	N.E. [2.6; N.E.]	48/90 (53.3)	3.3 [1.4; 10.2]	0.69	[0.44; 1.08]	0.101
Edema - Interference (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.727)							
Low	33/171 (19.3)	N.E. [N.E.; N.E.]	45/172 (26.2)	N.E. [N.E.; N.E.]	0.67	[0.43; 1.06]	0.096
Intermediate	18/75 (24.0)	22.1 [17.5; N.E.]	16/75 (21.3)	N.E. [10.7; N.E.]	0.85	[0.43; 1.69]	0.698
High	6/38 (15.8)	N.E. [N.E.; N.E.]	9/37 (24.3)	N.E. [2.8; N.E.]	0.48	[0.17; 1.38]	0.243
Sex							
(Interaction test: p = 0.921)							
Female	29/107 (27.1)	N.E. [17.5; N.E.]	40/126 (31.7)	N.E. [10.2; N.E.]	0.72	[0.44; 1.17]	0.183
Male	28/177 (15.8)	N.E. [N.E.; N.E.]	30/158 (19.0)	N.E. [N.E.; N.E.]	0.73	[0.44; 1.23]	0.251
Race							
(Interaction test: p = 0.807)							
Asian	12/40 (30.0)	17.5 [11.2; N.E.]	20/46 (43.5)	N.E. [3.0; N.E.]	0.58	[0.28; 1.19]	0.121

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
White	41/227 (18.1)	N.E. [N.E.; N.E.]	45/217 (20.7)	N.E. [N.E.; N.E.]	0.74	[0.48; 1.13]	0.174
Other	4/17 (23.5)	N.E. [2.8; N.E.]	5/21 (23.8)	N.E. [1.5; N.E.]	1.04	[0.24; 4.41]	0.865
Age groups (Interaction test: p = 0.342)							
18 - < 65 years	49/237 (20.7)	N.E. [N.E.; N.E.]	59/247 (23.9)	N.E. [N.E.; N.E.]	0.78	[0.53; 1.14]	0.200
65 - < 75 years	7/38 (18.4)	N.E. [N.E.; N.E.]	6/24 (25.0)	N.E. [2.7; N.E.]	0.54	[0.18; 1.64]	0.255
>= 75 years	1/9 (11.1)	22.1 [N.E.; N.E.]	5/13 (38.5)	12.9 [0.5; N.E.]	0.13	[0.01; 2.75]	0.045
Geographic region (Interaction test: p = 0.763)							
Europe excluding Germany	25/138 (18.1)	N.E. [22.1; N.E.]	28/141 (19.9)	N.E. [N.E.; N.E.]	0.73	[0.42; 1.28]	0.350
Germany	12/72	N.E. [N.E.; N.E.]	10/53	N.E. [12.9; N.E.]	0.72	[0.31; 1.70]	0.496

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Others	(16.7) 20/74 (27.0)	N.E. [17.5; N.E.]	(18.9) 32/90 (35.6)	N.E. [5.1; N.E.]	0.61	[0.34; 1.08]	0.096
Muscle Pain - Interference (MID=1)							
Stratification factor: ELTS based on randomization data from IRT (Interaction test: p = 0.087)							
Low	74/171 (43.3)	5.1 [3.0; 15.8]	89/172 (51.7)	1.7 [1.0; 3.7]	0.71	[0.52; 0.97]	0.033
Intermediate	39/75 (52.0)	1.4 [0.8; 3.8]	30/75 (40.0)	4.7 [0.9; N.E.]	1.32	[0.81; 2.13]	0.303
High	15/38 (39.5)	7.4 [1.0; N.E.]	18/37 (48.6)	2.7 [1.0; N.E.]	0.71	[0.35; 1.41]	0.300
Sex (Interaction test: p = 0.404)							
Female	58/107 (54.2)	1.5 [0.7; 3.0]	66/126 (52.4)	1.5 [1.0; 2.1]	0.96	[0.67; 1.37]	0.723

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Male	70/177 (39.5)	7.4 [3.7; N.E.]	71/158 (44.9)	4.7 [1.7; 13.9]	0.79	[0.57; 1.10]	0.163
Race (Interaction test: p = 0.465)							
Asian	24/40 (60.0)	2.8 [1.0; 4.9]	30/46 (65.2)	1.9 [0.6; 4.7]	0.90	[0.52; 1.55]	0.713
White	96/227 (42.3)	4.7 [2.4; 15.8]	99/217 (45.6)	2.1 [1.2; 4.7]	0.79	[0.60; 1.05]	0.089
Other	8/17 (47.1)	1.5 [0.3; N.E.]	8/21 (38.1)	5.5 [0.4; N.E.]	1.81	[0.51; 6.45]	0.614
Age groups (Interaction test: p = 0.750)							
18 - < 65 years	104/237 (43.9)	4.4 [2.6; 15.7]	115/247 (46.6)	2.2 [1.2; 5.5]	0.84	[0.64; 1.09]	0.181
65 - < 75 years	19/38 (50.0)	2.8 [1.0; N.E.]	14/24 (58.3)	2.1 [0.4; 3.2]	0.52	[0.25; 1.10]	0.282
>= 75 years	5/9	1.8 [0.5; N.E.]	8/13	1.2 [0.3; 4.7]	0.35	[0.07; 1.91]	0.222

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(55.6)		(61.5)				
Geographic region							
(Interaction test: p = 0.488)							
Europe excluding Germany	56/138	12.0 [2.3; N.E.]	62/141	2.7 [1.5; 13.9]	0.79	[0.55; 1.13]	0.197
	(40.6)		(44.0)				
Germany	31/72	3.1 [0.6; 11.1]	28/53	0.8 [0.5; 1.5]	0.69	[0.40; 1.20]	0.173
	(43.1)		(52.8)				
Others	41/74	3.3 [1.2; 7.4]	47/90	2.8 [1.0; 10.2]	1.01	[0.66; 1.54]	0.964
	(55.4)		(52.2)				
Cough - Interference (MID=1)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.408)							
Low	61/171	17.5 [11.0; N.E.]	68/172	11.1 [6.5; N.E.]	0.84	[0.60; 1.19]	0.302
	(35.7)		(39.5)				
Intermediate	31/75	13.9 [2.9; 17.5]	20/75	N.E. [4.2; N.E.]	1.14	[0.64; 2.02]	0.371
	(41.3)		(26.7)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
High	11/38 (28.9)	N.E. [11.1; N.E.]	13/37 (35.1)	11.0 [2.8; N.E.]	0.65	[0.29; 1.46]	0.334
Sex							
(Interaction test: p = 0.323)							
Female	47/107 (43.9)	11.2 [3.5; 17.5]	45/126 (35.7)	11.1 [4.4; N.E.]	1.04	[0.69; 1.57]	0.563
Male	56/177 (31.6)	18.5 [14.8; N.E.]	56/158 (35.4)	11.2 [6.5; N.E.]	0.79	[0.55; 1.15]	0.196
Race							
(Interaction test: p = 0.970)							
Asian	14/40 (35.0)	17.5 [14.8; N.E.]	19/46 (41.3)	N.E. [4.4; N.E.]	0.78	[0.38; 1.60]	0.538
White	83/227 (36.6)	16.7 [11.1; N.E.]	74/217 (34.1)	11.2 [7.4; N.E.]	0.88	[0.64; 1.21]	0.440
Other	6/17 (35.3)	2.8 [0.5; N.E.]	8/21 (38.1)	15.7 [2.2; N.E.]	0.96	[0.32; 2.87]	0.772
Age groups							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.150)							
18 - < 65 years	88/237 (37.1)	16.7 [11.1; 22.1]	85/247 (34.4)	13.8 [10.2; N.E.]	0.99	[0.74; 1.34]	0.965
65 - < 75 years	11/38 (28.9)	17.5 [13.9; N.E.]	10/24 (41.7)	5.6 [0.7; N.E.]	0.45	[0.19; 1.07]	0.065
>= 75 years	4/9 (44.4)	6.5 [1.0; N.E.]	6/13 (46.2)	6.5 [0.5; N.E.]	0.29	[0.05; 1.75]	0.260
Geographic region							
(Interaction test: p = 0.649)							
Europe excluding Germany	44/138 (31.9)	N.E. [11.2; N.E.]	47/141 (33.3)	11.2 [7.4; N.E.]	0.82	[0.54; 1.24]	0.321
Germany	32/72 (44.4)	4.5 [2.6; 13.9]	22/53 (41.5)	2.2 [1.2; 5.3]	0.65	[0.37; 1.15]	0.362
Others	27/74 (36.5)	17.5 [12.0; N.E.]	32/90 (35.6)	N.E. [7.4; N.E.]	0.95	[0.56; 1.61]	0.889

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=284)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			

MID: Minimally important difference
N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
In this sensitivity analysis a missing assessment before randomization is substituted by the last assessment before or on the day of treatment start, if such an assessment is available.
If there are not at least 10 patients in every subgroup or not more than 10 events per subgroup per treatment arm, no subgroup analyses were performed for the corresponding attribute.
If there are not more than 10 events per subgroup per treatment arm, no Cox PH hazard analysis is carried out.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variables ELTS Score (IRT) and covariates treatment arm and baseline PRO score.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variables ELTS Score (IRT).
For the subgroup of Stratification factor: ELTS based on IRT randomisation data not stratification factor was included in the Cox PH model and an unstratitfied log-rank test was applied
The reference group in the (stratified) Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/2025-05-15

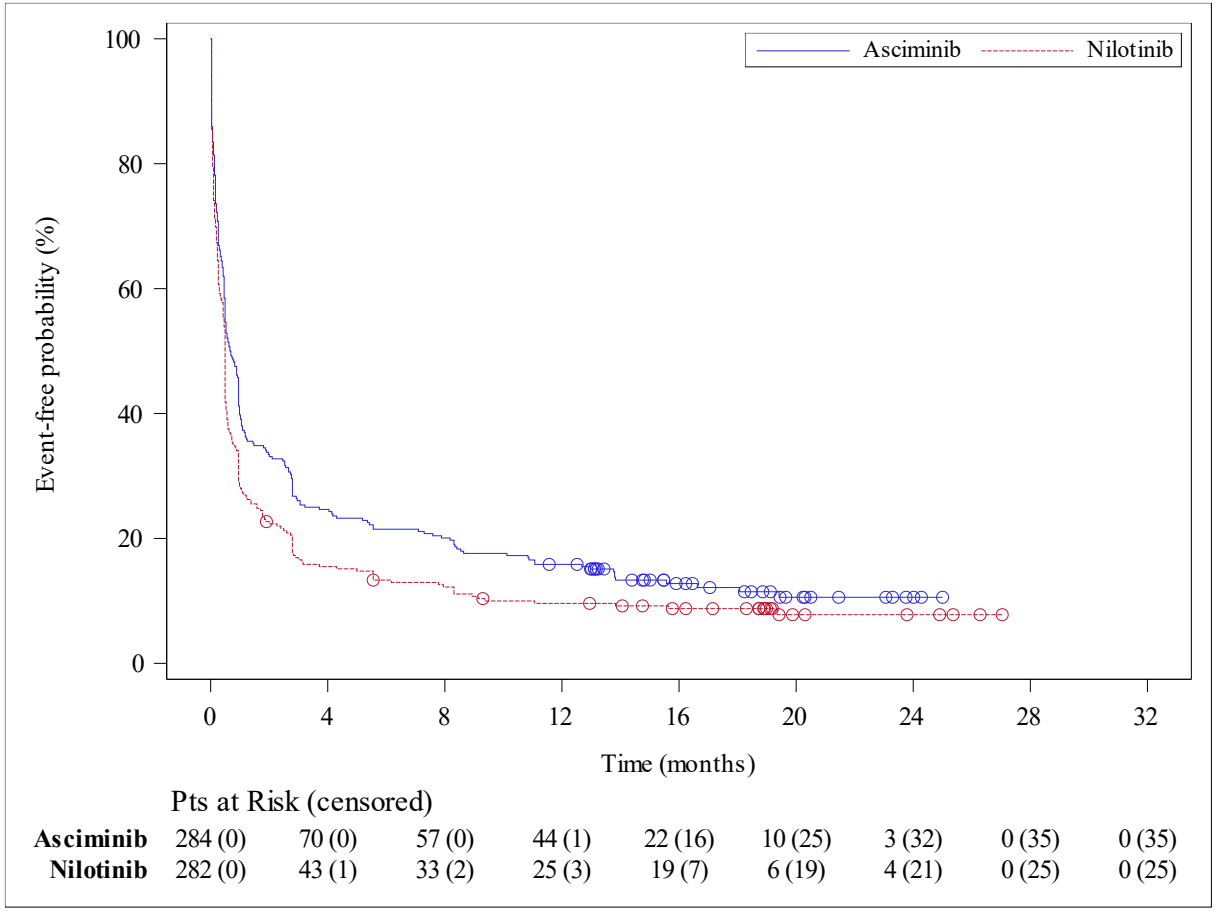
4. Safety

Table 4-1.1 Any AE: time to first occurrence (Safety Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
N*	284	282	0.78
Number of patients with events, n (%)	249 (87.7)	257 (91.1)	[0.66; 0.93]
			0.007
Percentiles (months) [95% CI]			
25th	0.2 [0.1; 0.3]	0.1 [0.1; 0.2]	
Median	0.7 [0.5; 1.0]	0.5 [0.4; 0.5]	
75th	3.5 [2.8; 7.9]	1.6 [1.0; 2.8]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 4-1.1 Any AE: Kaplan-Meier plot (Safety Analysis Set)



Note: o = Censored observations
Data Cut/15MAY2025

Table 4-1.2 Any AE by SOC: time to first occurrence (Safety Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Blood and lymphatic system disorders			
N*	284	282	1.08
Number of patients with events, n (%)	66 (23.2)	60 (21.3)	[0.76; 1.53]
			0.674
Percentiles (months) [95% CI]			
25th	N.E. [2.8; N.E.]	N.E. [3.0; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Cardiac disorders			
N*	284	282	0.72
Number of patients with events, n (%)	14 (4.9)	18 (6.4)	[0.36; 1.45]
			0.359
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Eye disorders			
N*	284	282	0.94
Number of patients with events, n (%)	26 (9.2)	26 (9.2)	[0.54; 1.61]
			0.817
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Gastrointestinal disorders			
N*	284	282	0.92
Number of patients with events, n (%)	98 (34.5)	102 (36.2)	[0.70; 1.22]
			0.564
Percentiles (months) [95% CI]			
25th	5.3 [2.5; 10.7]	2.1 [0.7; 5.5]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
General disorders and administration site conditions			

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
N*	284	282	0.91
Number of patients with events, n (%)	76 (26.8)	79 (28.0)	[0.66; 1.25]
			0.563
Percentiles (months) [95% CI]			
25th	13.8 [5.4; 19.9]	9.1 [4.2; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Hepatobiliary disorders			
N*	284	282	0.39
Number of patients with events, n (%)	11 (3.9)	26 (9.2)	[0.19; 0.79]
			0.007
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Infections and infestations			
N*	284	282	1.14

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Number of patients with events, n (%)	109 (38.4)	92 (32.6)	[0.86; 1.51]
			0.349
Percentiles (months) [95% CI]			
25th	7.1 [4.0; 8.9]	8.0 [4.7; 10.8]	
Median	N.E. [24.8; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Injury, poisoning and procedural complications			
N*	284	282	2.29
Number of patients with events, n (%)	19 (6.7)	8 (2.8)	[1.00; 5.23]
			0.043
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Investigations			
N*	284	282	0.70
Number of patients with events, n (%)	96 (33.8)	121 (42.9)	[0.54; 0.92]

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
			0.010
Percentiles (months) [95% CI]			
25th	5.6 [2.8; 11.1]	1.8 [0.9; 2.8]	
Median	N.E. [N.E.; N.E.]	N.E. [14.9; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Metabolism and nutrition disorders			
N*	284	282	0.72
Number of patients with events, n (%)	38 (13.4)	50 (17.7)	[0.47; 1.10]
			0.129
Percentiles (months) [95% CI]			
25th	N.E. [26.7; N.E.]	N.E. [13.8; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Musculoskeletal and connective tissue disorders			
N*	284	282	1.13
Number of patients with events, n (%)	103 (36.3)	91 (32.3)	[0.85; 1.50]
			0.399

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Percentiles (months) [95% CI]			
25th	5.6 [1.5; 8.3]	5.6 [2.7; 11.0]	
Median	N.E. [24.4; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
N*	284	282	1.01
Number of patients with events, n (%)	10 (3.5)	9 (3.2)	[0.41; 2.49]
			0.984
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Nervous system disorders			
N*	284	282	0.97
Number of patients with events, n (%)	66 (23.2)	64 (22.7)	[0.69; 1.37]
			0.870
Percentiles (months) [95% CI]			

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
25th	20.8 [10.6; N.E.]	N.E. [7.2; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Psychiatric disorders			
N*	284	282	1.97
Number of patients with events, n (%)	24 (8.5)	12 (4.3)	[0.99; 3.95]
			0.050
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Renal and urinary disorders			
N*	284	282	0.60
Number of patients with events, n (%)	9 (3.2)	14 (5.0)	[0.26; 1.38]
			0.221
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Reproductive system and breast disorders			
N*	284	282	0.88
Number of patients with events, n (%)	16 (5.6)	17 (6.0)	[0.44; 1.73]
			0.705
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Respiratory, thoracic and mediastinal disorders			
N*	284	282	0.98
Number of patients with events, n (%)	40 (14.1)	39 (13.8)	[0.63; 1.53]
			0.947
Percentiles (months) [95% CI]			
25th	N.E. [26.2; N.E.]	N.E. [23.6; N.E.]	

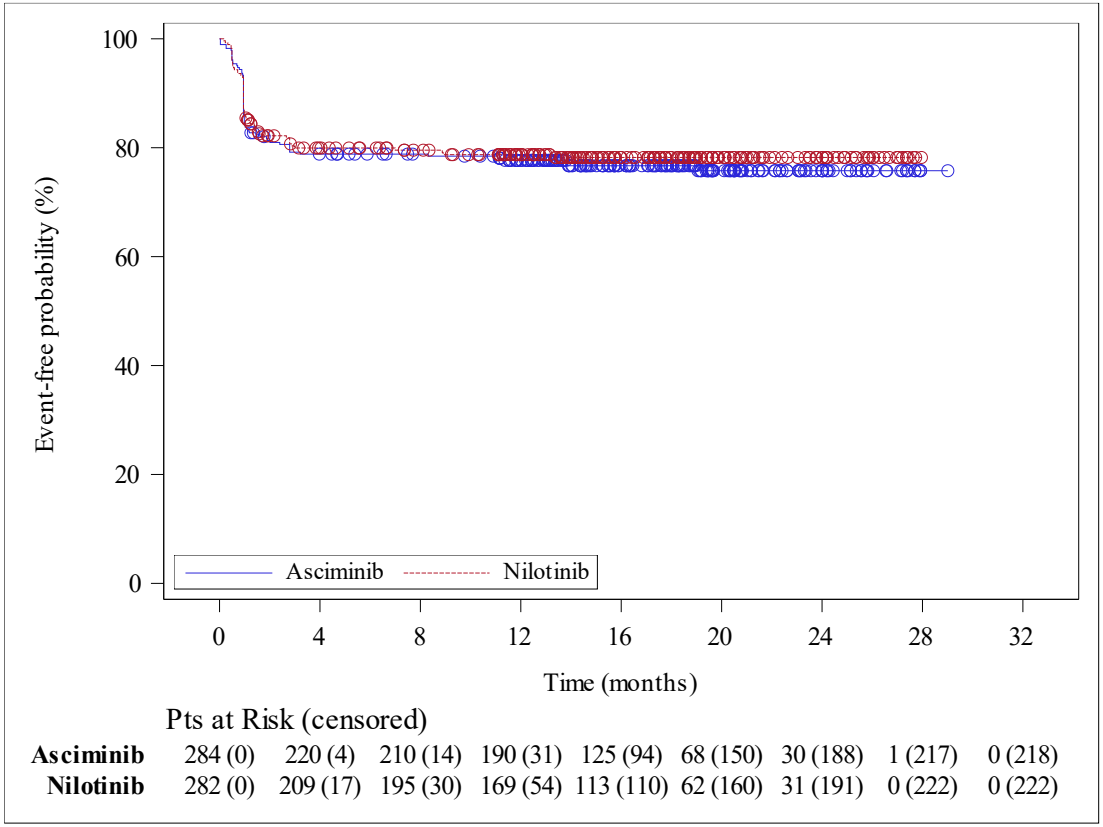
	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Skin and subcutaneous tissue disorders			
N*	284	282	0.54
Number of patients with events, n (%)	88 (31.0)	132 (46.8)	[0.41; 0.70]
			<0.001
Percentiles (months) [95% CI]			
25th	6.0 [4.2; 12.1]	1.0 [0.5; 1.7]	
Median	N.E. [N.E.; N.E.]	N.E. [8.3; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Vascular disorders			
N*	284	282	1.35
Number of patients with events, n (%)	40 (14.1)	29 (10.3)	[0.83; 2.17]
			0.222
Percentiles (months) [95% CI]			
25th	24.8 [23.2; N.E.]	N.E. [26.4; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
SOC: System Organ Class
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factor ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 4-1.2 Any AE by SOC: Kaplan-Meier plot (Safety Analysis Set)

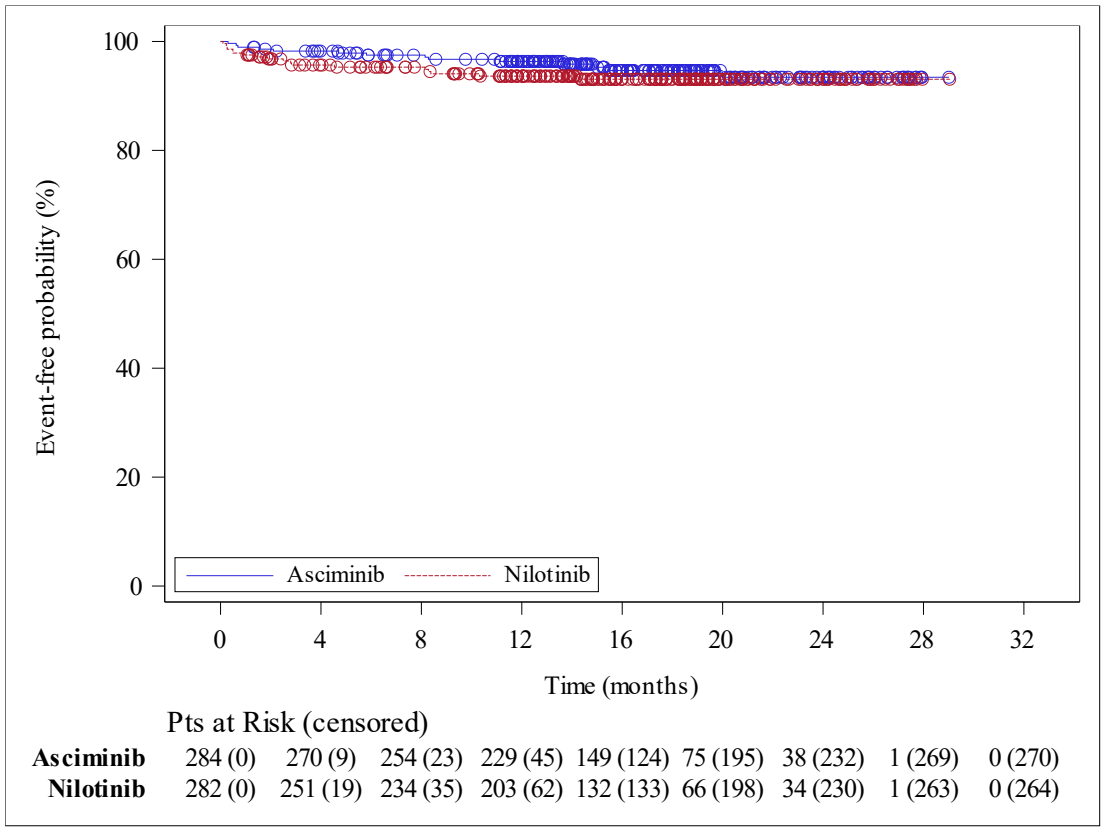
Blood and lymphatic system disorders



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.2 Any AE by SOC: Kaplan-Meier plot (Safety Analysis Set)

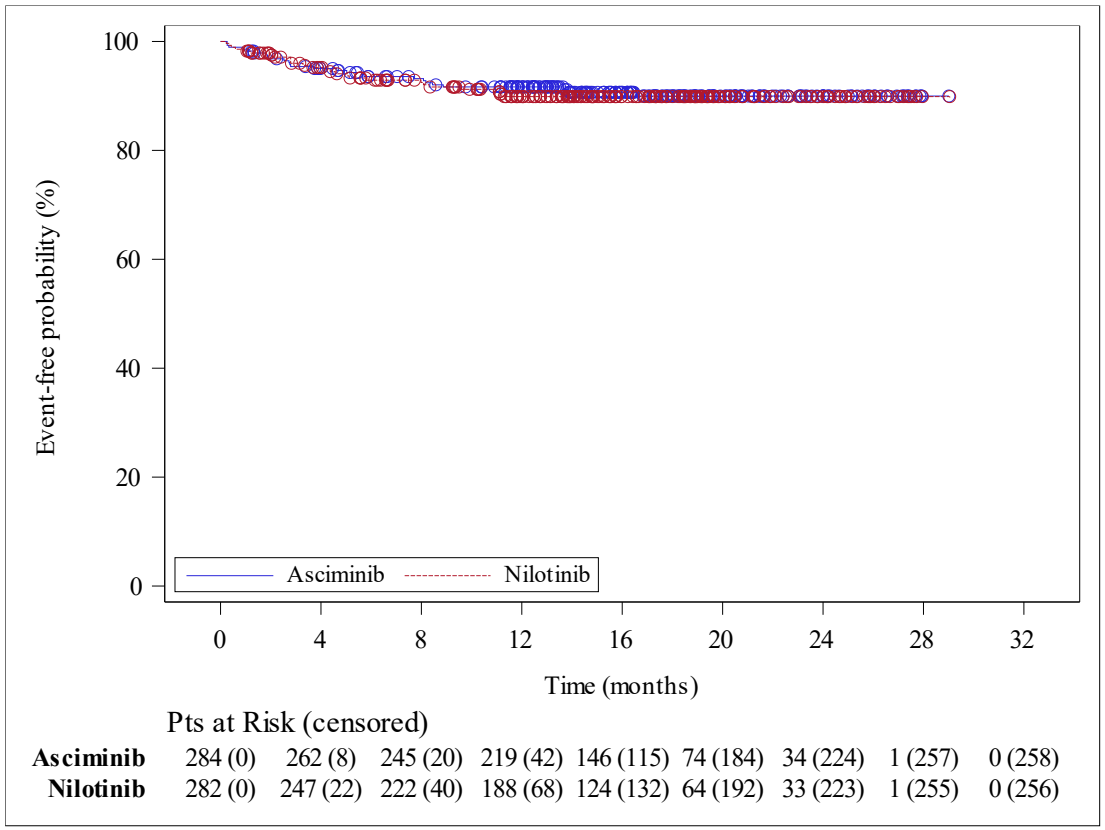
Cardiac disorders



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.2 Any AE by SOC: Kaplan-Meier plot (Safety Analysis Set)

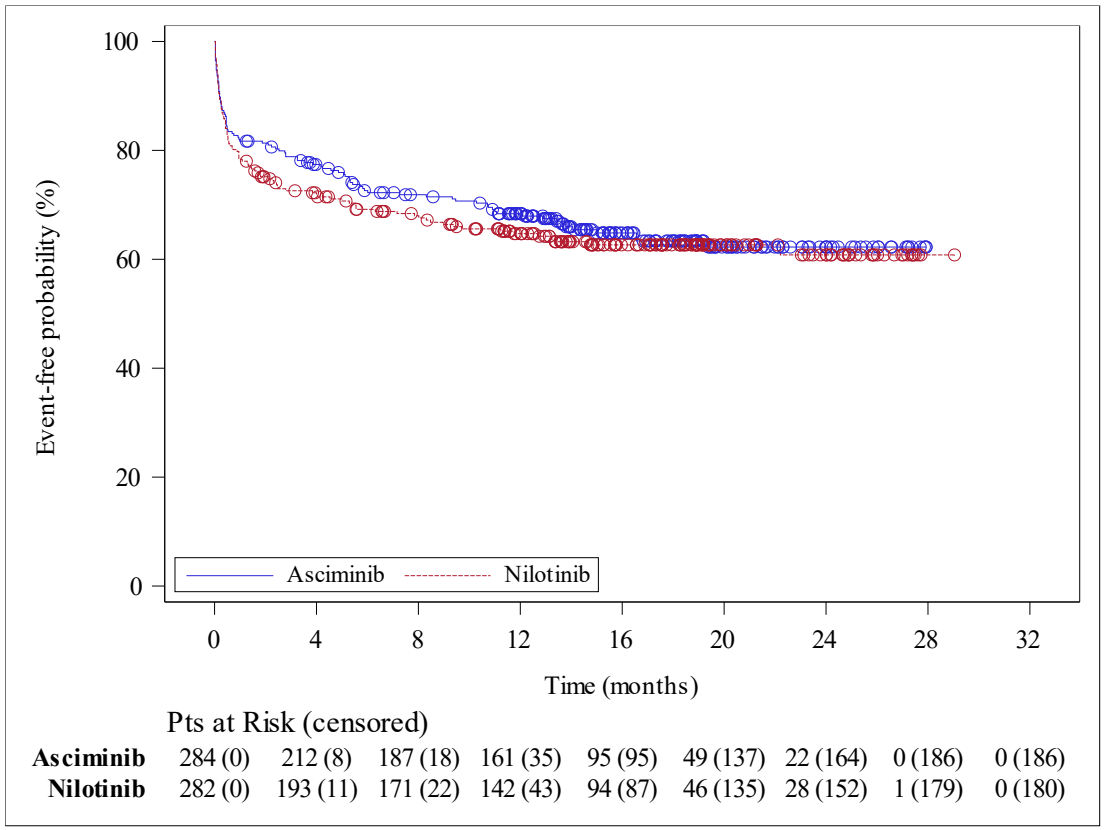
Eye disorders



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.2 Any AE by SOC: Kaplan-Meier plot (Safety Analysis Set)

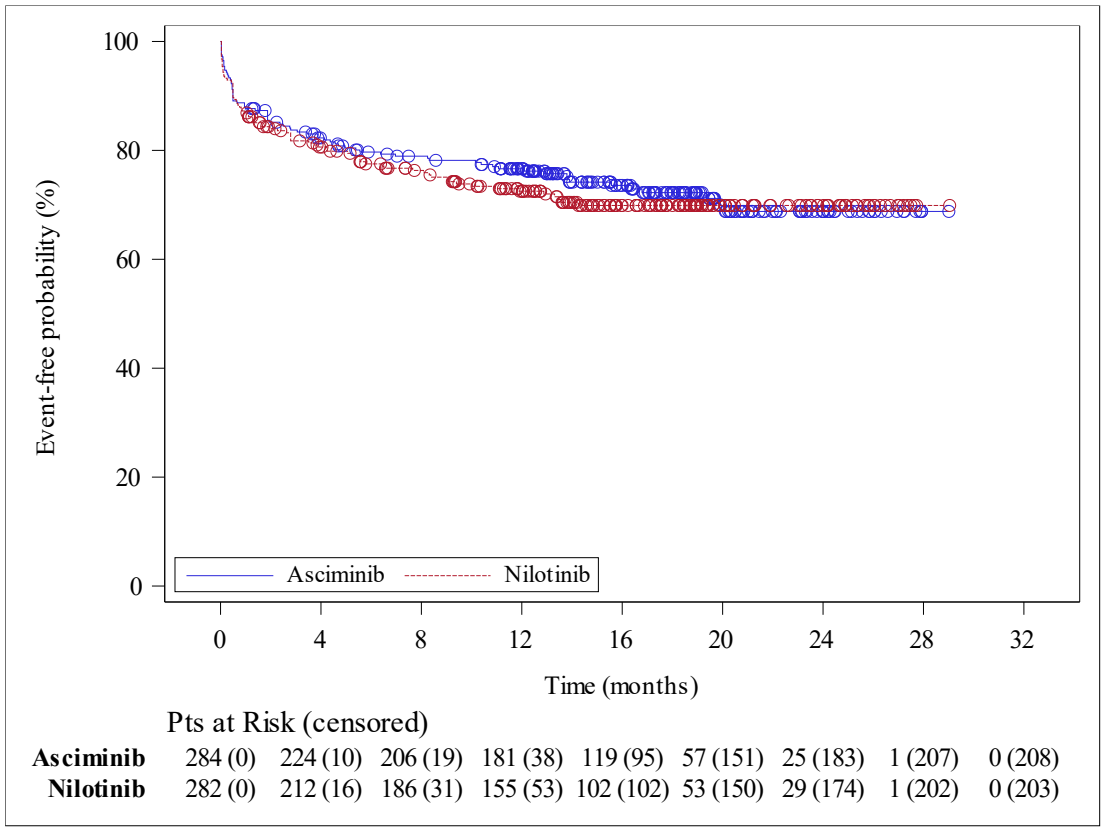
Gastrointestinal disorders



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.2 Any AE by SOC: Kaplan-Meier plot (Safety Analysis Set)

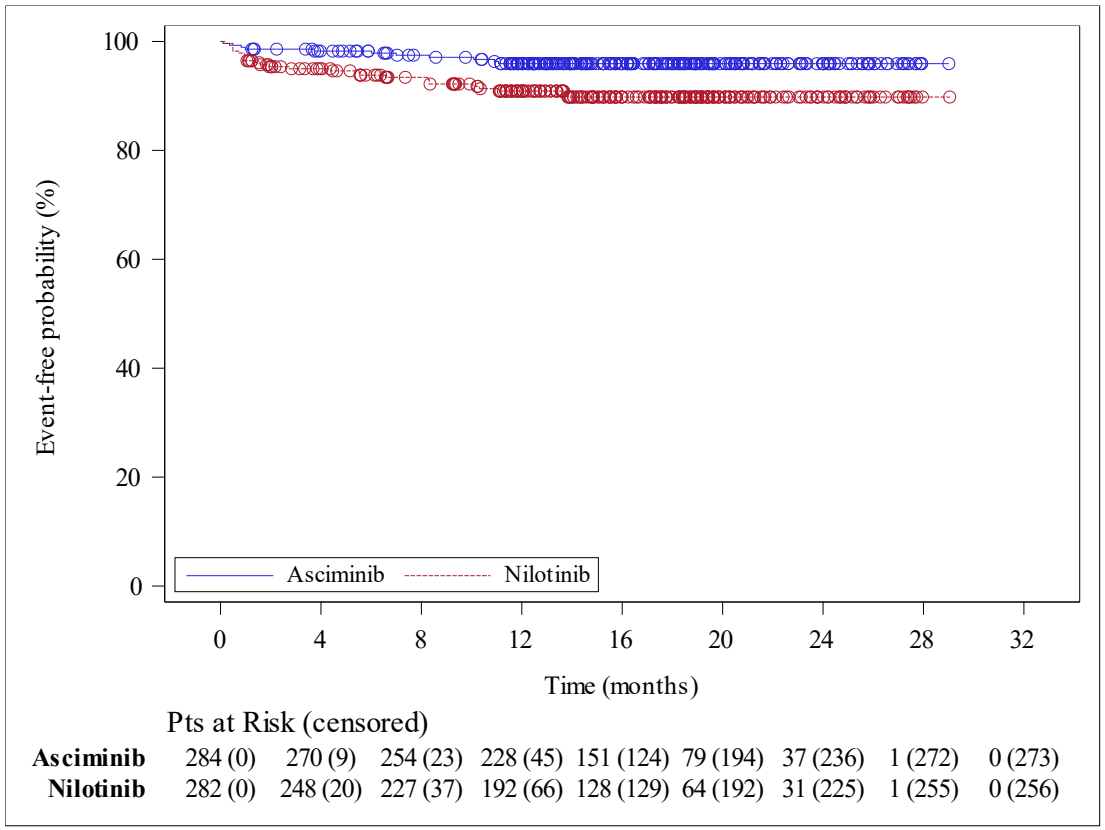
General disorders and administration site conditions



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.2 Any AE by SOC: Kaplan-Meier plot (Safety Analysis Set)

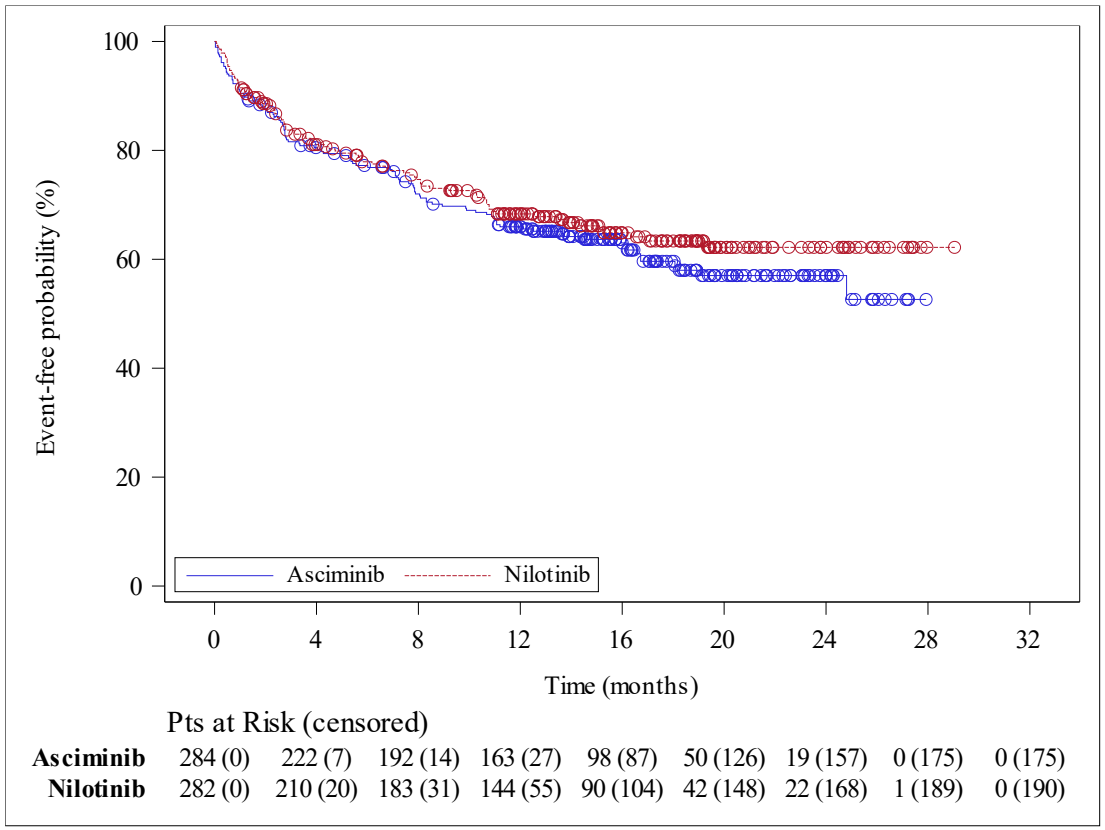
Hepatobiliary disorders



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.2 Any AE by SOC: Kaplan-Meier plot (Safety Analysis Set)

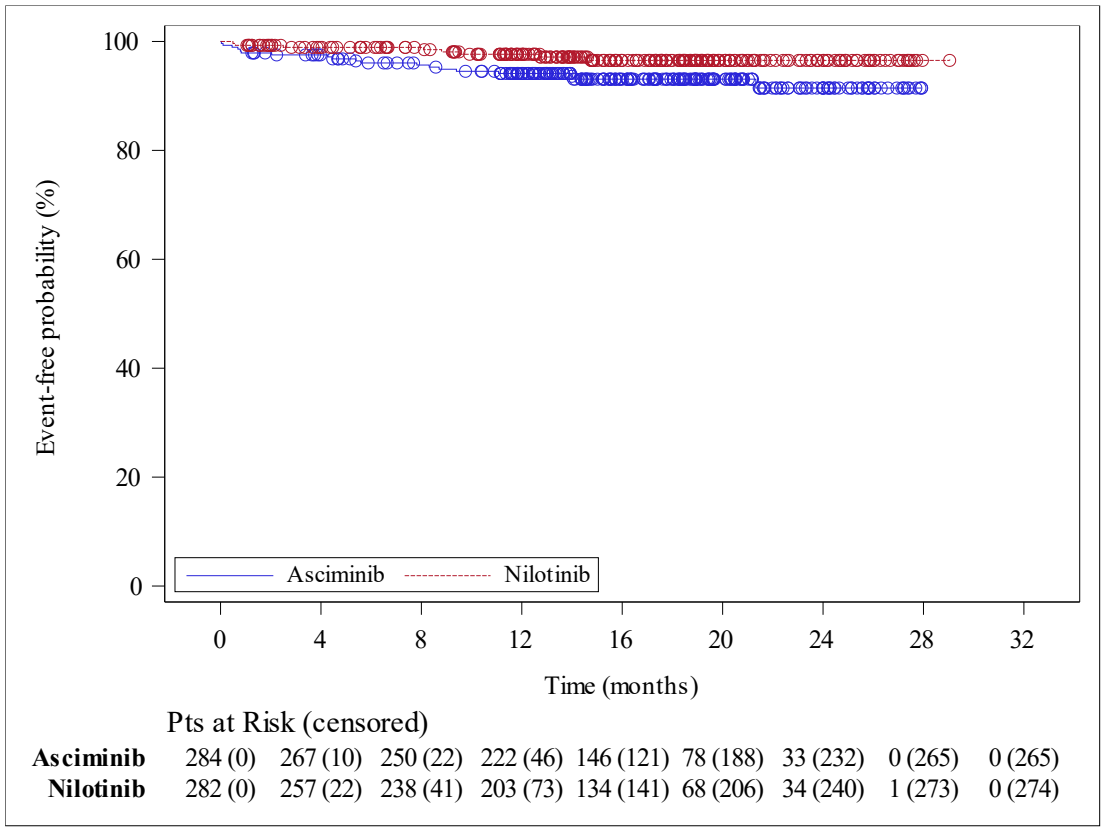
Infections and infestations



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.2 Any AE by SOC: Kaplan-Meier plot (Safety Analysis Set)

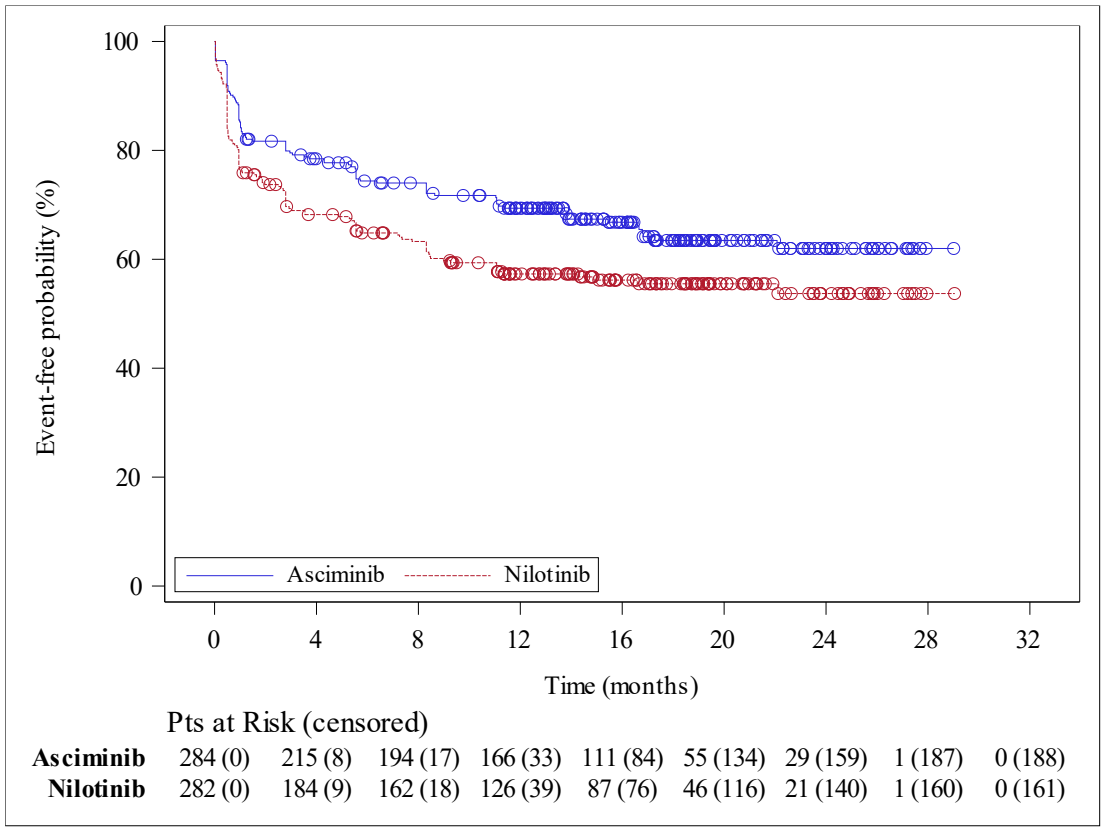
Injury, poisoning and procedural complications



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.2 Any AE by SOC: Kaplan-Meier plot (Safety Analysis Set)

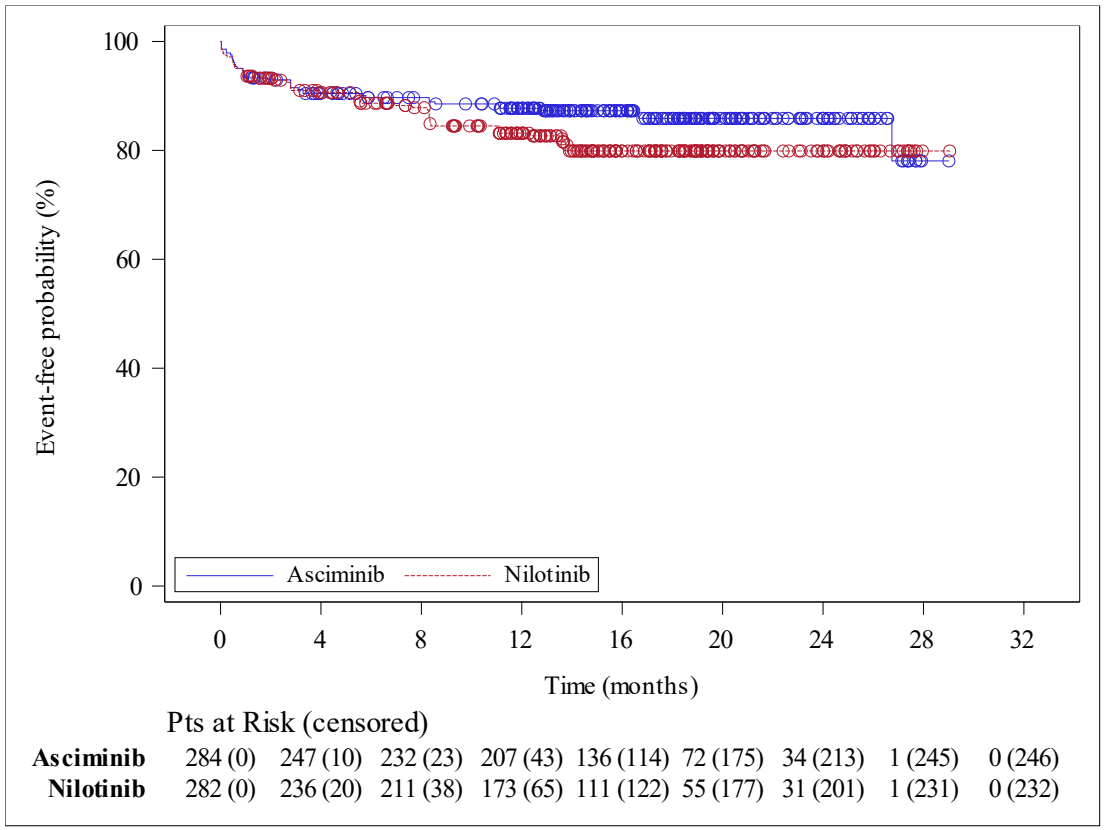
Investigations



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.2 Any AE by SOC: Kaplan-Meier plot (Safety Analysis Set)

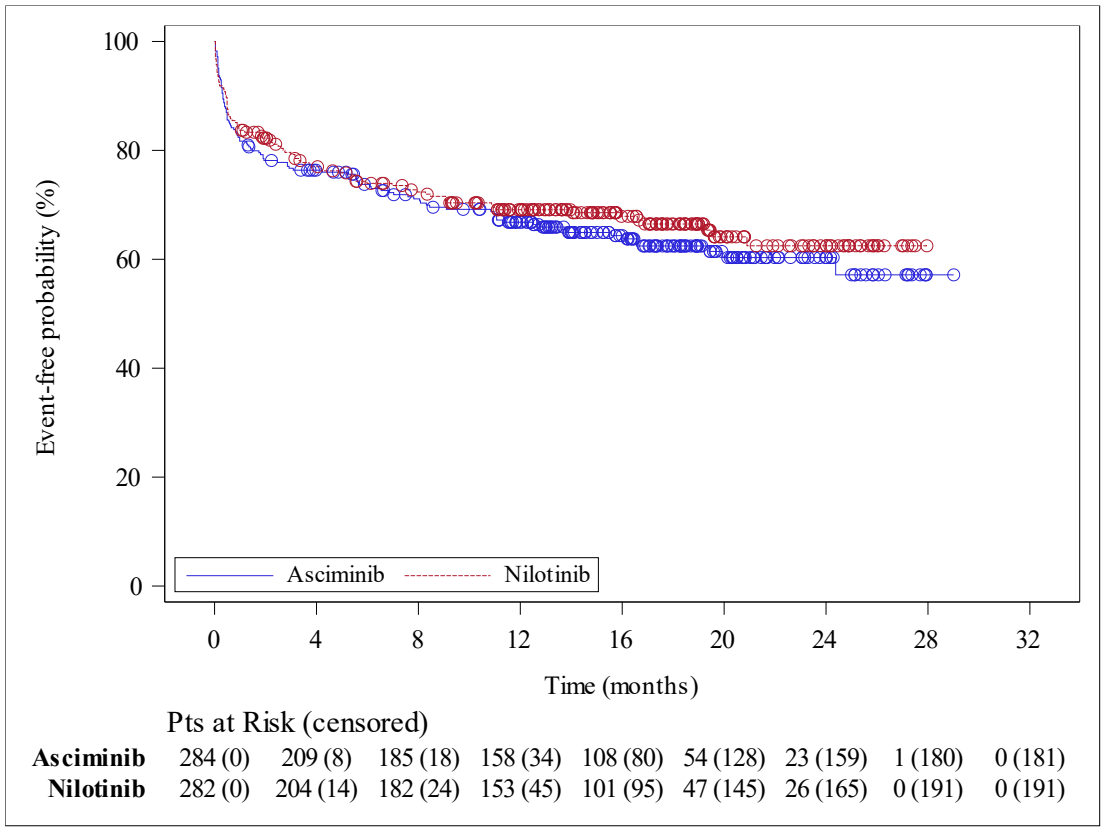
Metabolism and nutrition disorders



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.2 Any AE by SOC: Kaplan-Meier plot (Safety Analysis Set)

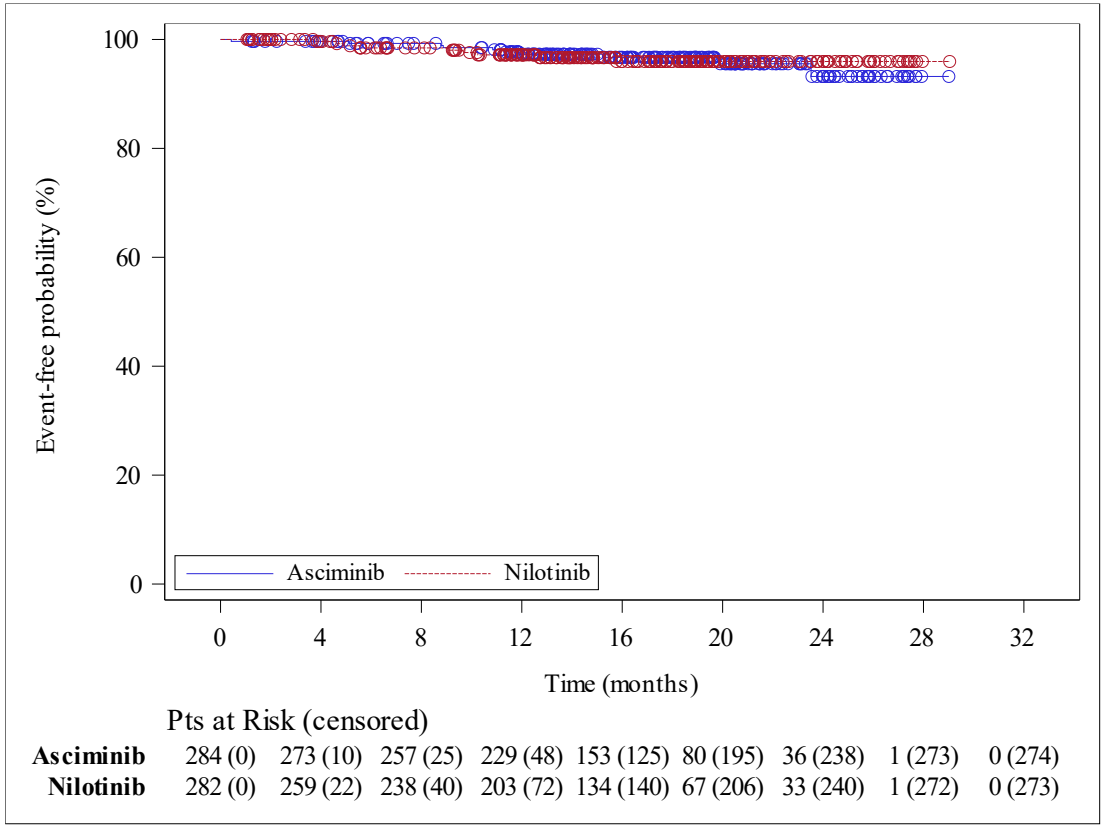
Musculoskeletal and connective tissue disorders



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.2 Any AE by SOC: Kaplan-Meier plot (Safety Analysis Set)

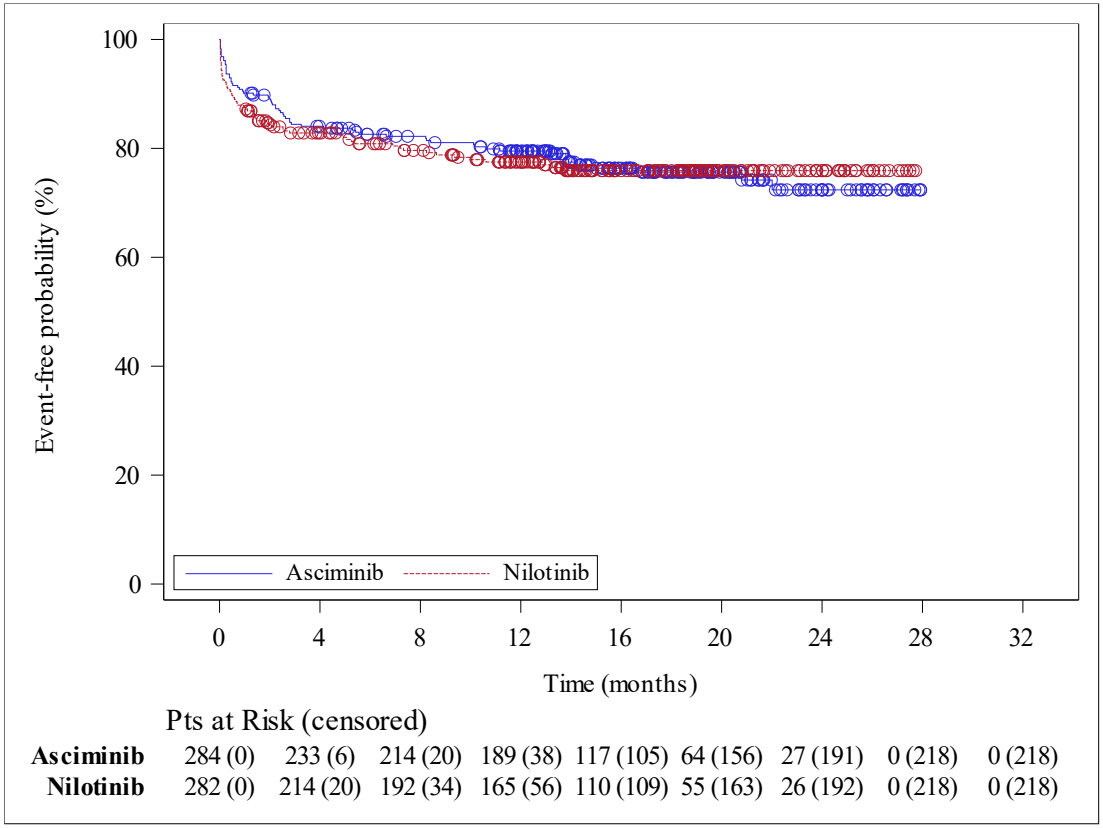
Neoplasms benign, malignant and unspecified (incl cysts and polyps)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.2 Any AE by SOC: Kaplan-Meier plot (Safety Analysis Set)

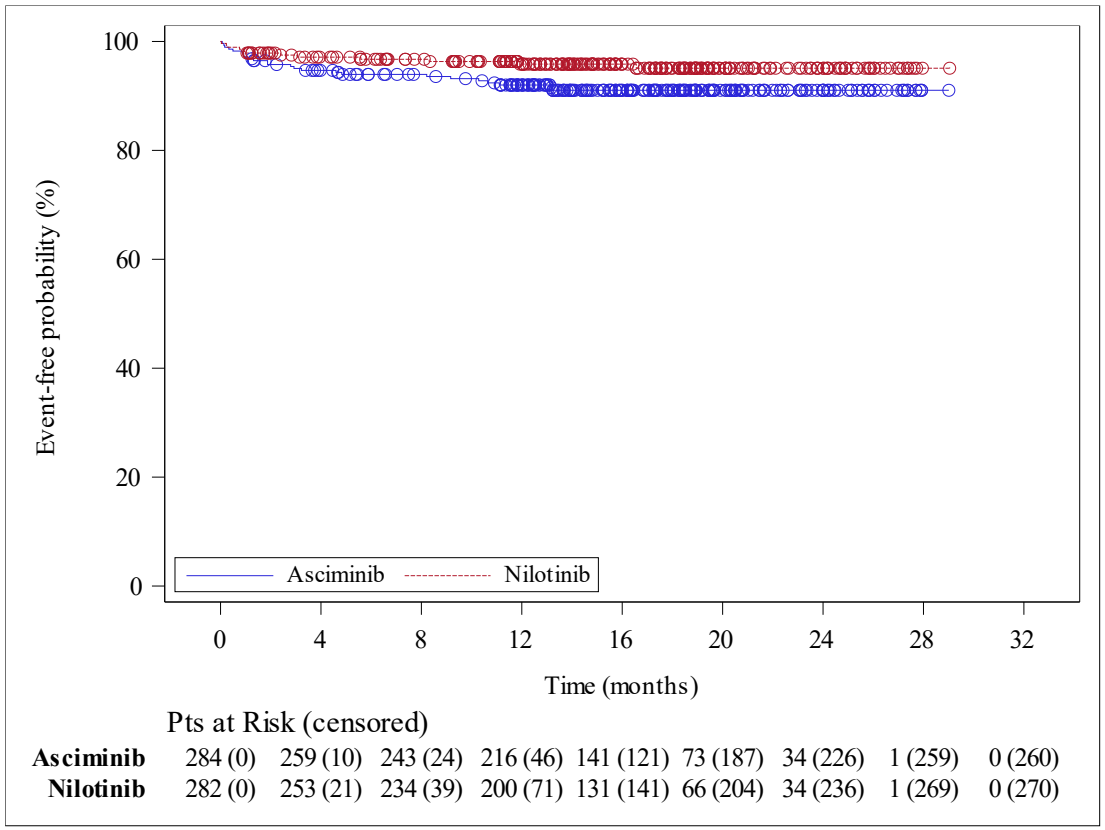
Nervous system disorders



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.2 Any AE by SOC: Kaplan-Meier plot (Safety Analysis Set)

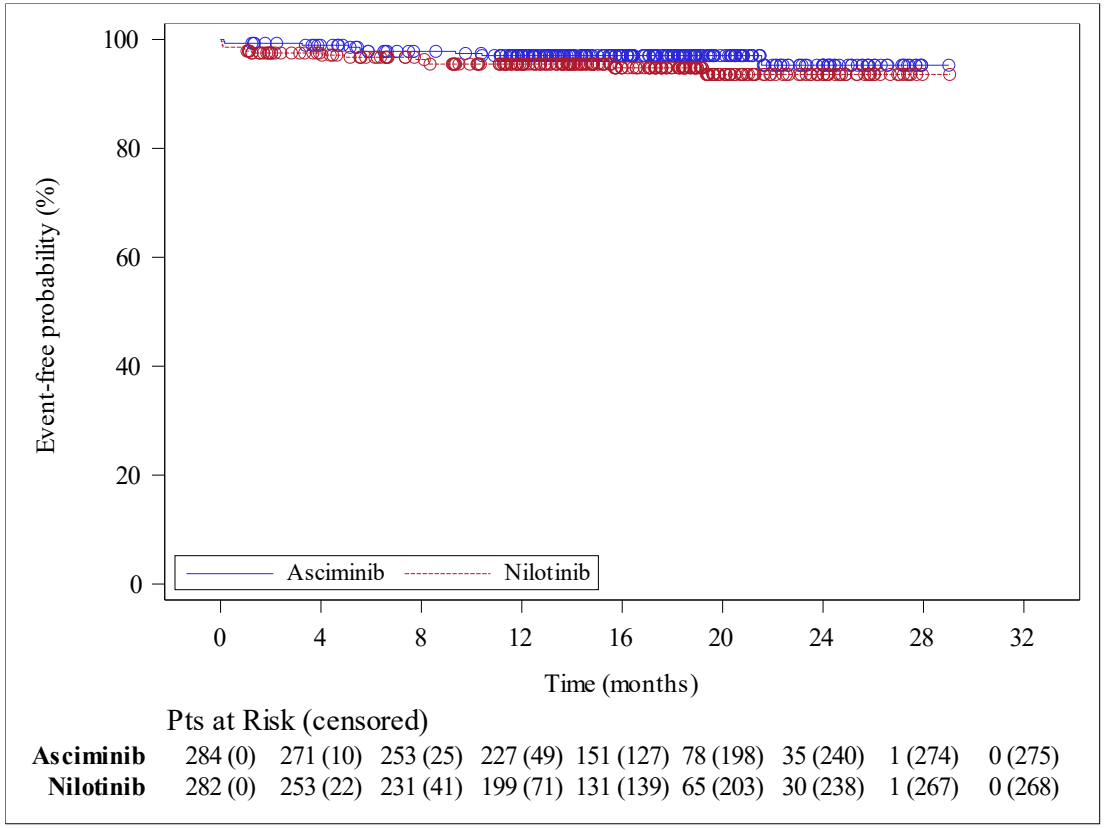
Psychiatric disorders



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.2 Any AE by SOC: Kaplan-Meier plot (Safety Analysis Set)

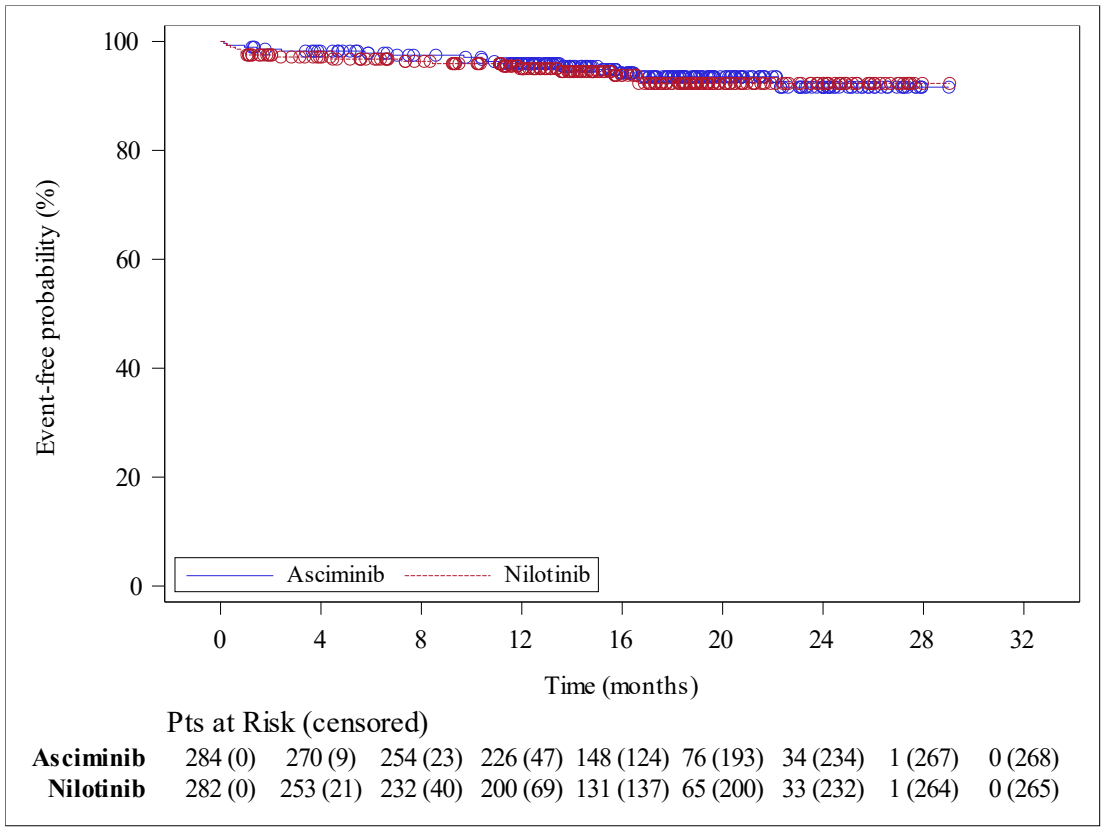
Renal and urinary disorders



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.2 Any AE by SOC: Kaplan-Meier plot (Safety Analysis Set)

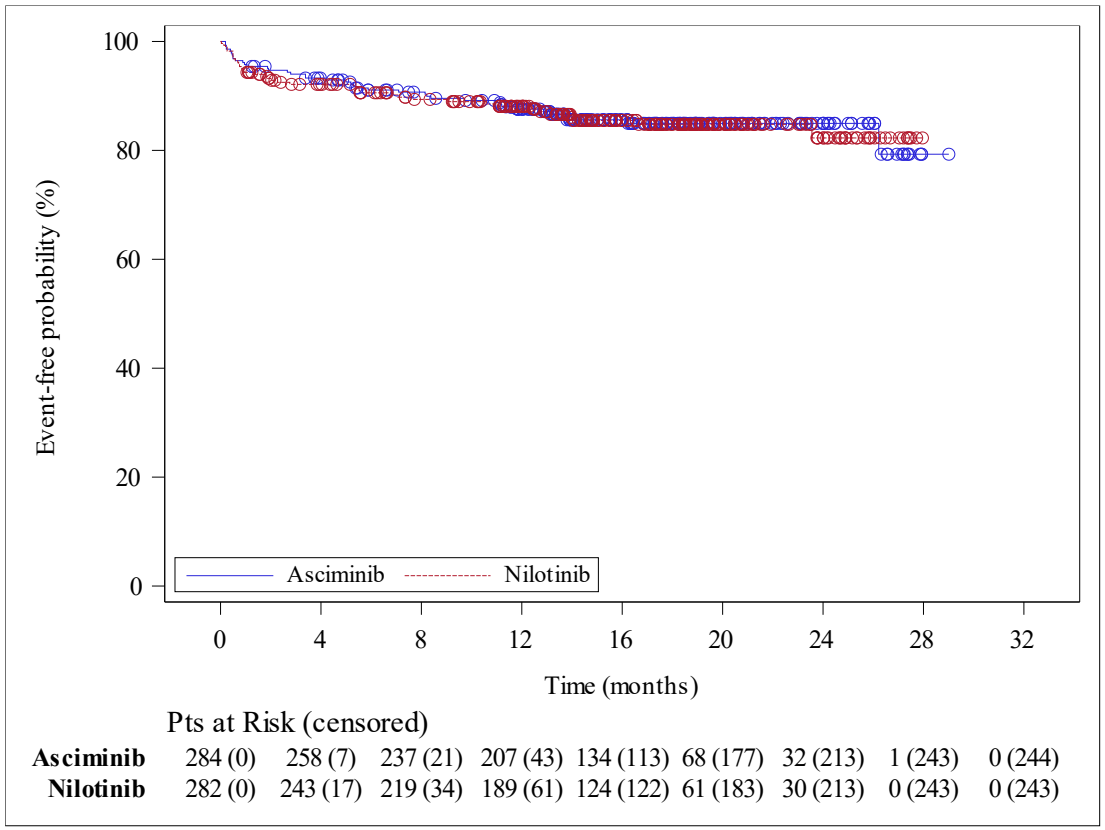
Reproductive system and breast disorders



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.2 Any AE by SOC: Kaplan-Meier plot (Safety Analysis Set)

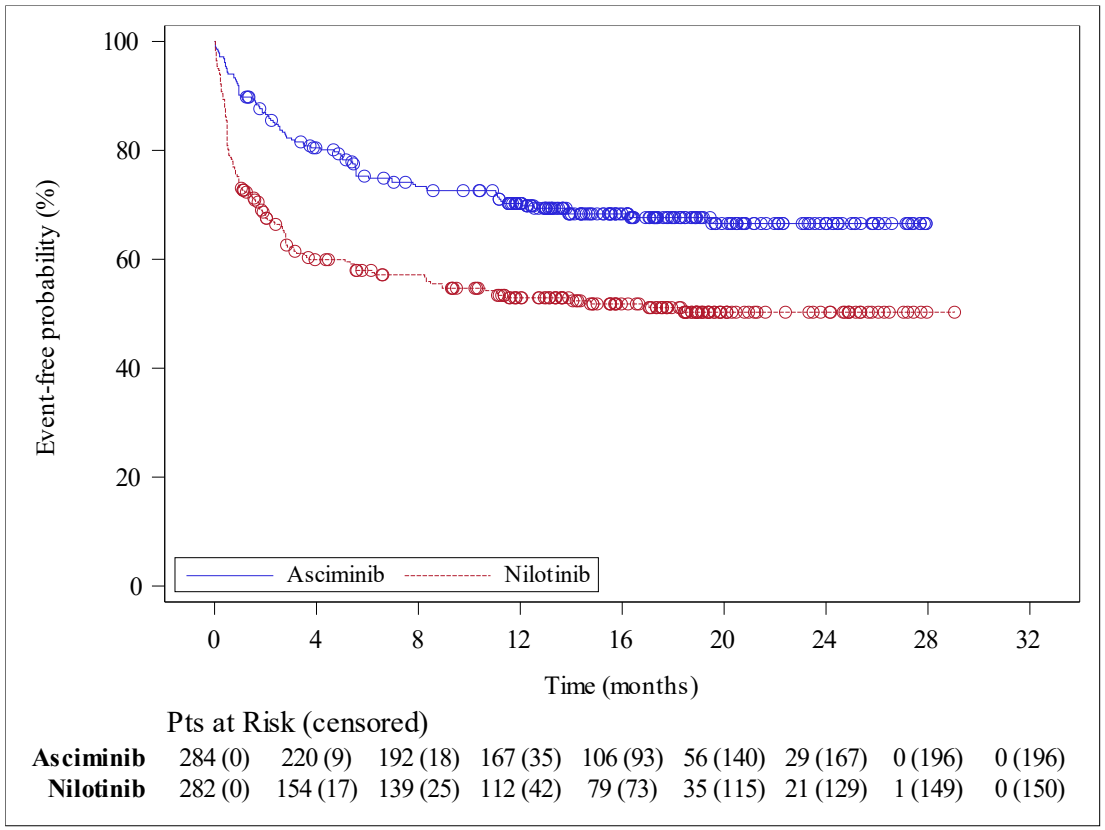
Respiratory, thoracic and mediastinal disorders



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.2 Any AE by SOC: Kaplan-Meier plot (Safety Analysis Set)

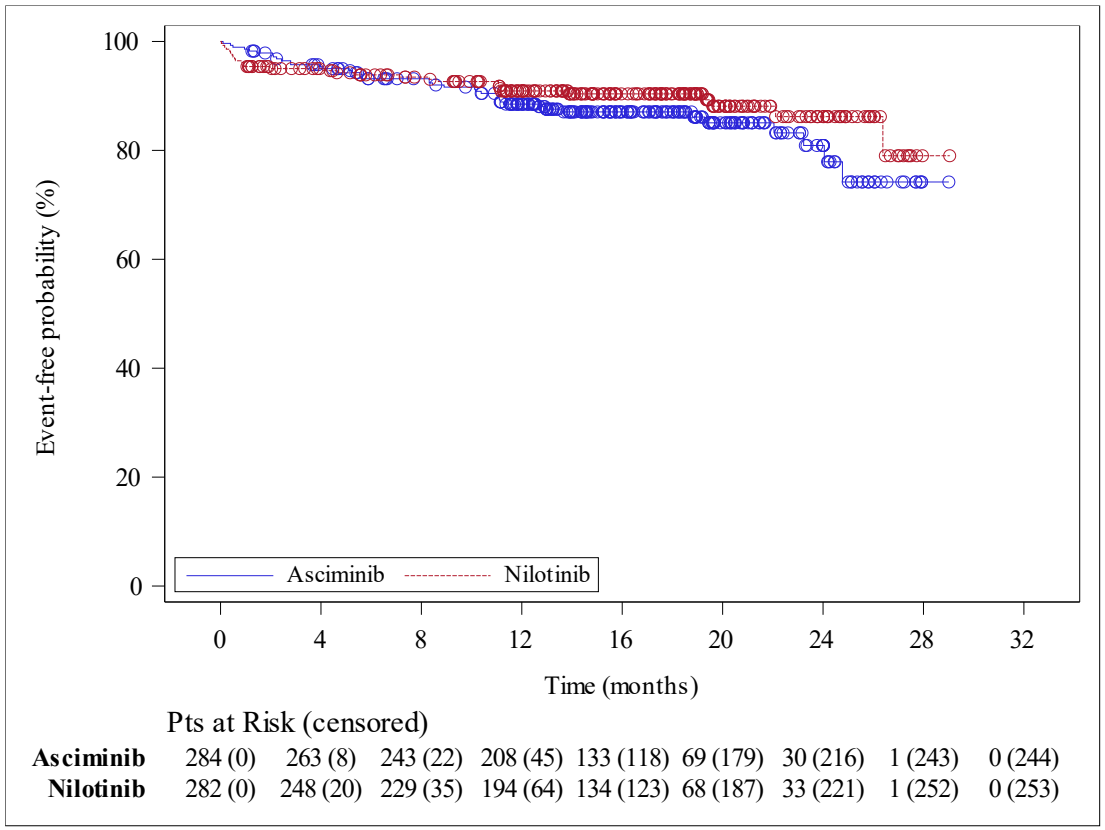
Skin and subcutaneous tissue disorders



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.2 Any AE by SOC: Kaplan-Meier plot (Safety Analysis Set)

Vascular disorders



Note: o = Censored observations
Data Cut/15MAY2025

Table 4-1.3 Any AE by PT: time to first occurrence (Safety Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Abdominal pain			
N*	284	282	0.90
Number of patients with events, n (%)	18 (6.3)	19 (6.7)	[0.47; 1.72]
			0.757
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Abdominal pain upper			
N*	284	282	1.50
Number of patients with events, n (%)	14 (4.9)	9 (3.2)	[0.65; 3.46]
			0.342
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Alanine aminotransferase increased			
N*	284	282	0.32
Number of patients with events, n (%)	15 (5.3)	42 (14.9)	[0.18; 0.58]
			<0.001
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Alopecia			
N*	284	282	0.31
Number of patients with events, n (%)	10 (3.5)	30 (10.6)	[0.15; 0.64]
			<0.001
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Amylase increased			

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
N*	284	282	0.53
Number of patients with events, n (%)	9 (3.2)	16 (5.7)	[0.23; 1.19]
			0.118
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Anaemia			
N*	284	282	1.06
Number of patients with events, n (%)	24 (8.5)	22 (7.8)	[0.59; 1.88]
			0.860
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Arthralgia			
N*	284	282	0.65

	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
Number of patients with events, n (%)	22 (7.7)	32 (11.3)	[0.38; 1.13]
			0.122
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Aspartate aminotransferase increased			
N*	284	282	0.45
Number of patients with events, n (%)	13 (4.6)	27 (9.6)	[0.23; 0.87]
			0.015
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Asthenia			
N*	284	282	0.98
Number of patients with events, n (%)	21 (7.4)	21 (7.4)	[0.53; 1.79]

	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
			0.939
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Back pain			
N*	284	282	1.94
Number of patients with events, n (%)	24 (8.5)	12 (4.3)	[0.97; 3.88]
			0.056
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Blood bilirubin increased			
N*	284	282	0.14
Number of patients with events, n (%)	6 (2.1)	39 (13.8)	[0.06; 0.33]
			<0.001

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Blood cholesterol increased			
N*	284	282	0.43
Number of patients with events, n (%)	5 (1.8)	11 (3.9)	[0.15; 1.23]
			0.104
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Bone pain			
N*	284	282	5.46
Number of patients with events, n (%)	11 (3.9)	2 (0.7)	[1.21; 24.61]
			0.013
Percentiles (months) [95% CI]			

	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Bronchitis			
N*	284	282	0.38
Number of patients with events, n (%)	4 (1.4)	10 (3.5)	[0.12; 1.20]
			0.087
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
COVID-19			
N*	284	282	1.20
Number of patients with events, n (%)	19 (6.7)	15 (5.3)	[0.61; 2.37]
			0.591
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Constipation			
N*	284	282	0.45
Number of patients with events, n (%)	10 (3.5)	21 (7.4)	[0.21; 0.96]
			0.034
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Cough			
N*	284	282	1.40
Number of patients with events, n (%)	19 (6.7)	13 (4.6)	[0.69; 2.84]
			0.344
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Diarrhoea			
N*	284	282	1.26
Number of patients with events, n (%)	31 (10.9)	24 (8.5)	[0.74; 2.15]
			0.396
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Dizziness			
N*	284	282	0.57
Number of patients with events, n (%)	9 (3.2)	15 (5.3)	[0.25; 1.29]
			0.172
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Dry eye			
N*	284	282	0.66
Number of patients with events, n (%)	7 (2.5)	10 (3.5)	[0.25; 1.73]
			0.394
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Dry skin			
N*	284	282	0.66
Number of patients with events, n (%)	11 (3.9)	16 (5.7)	[0.31; 1.42]
			0.282
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Dyspnoea			
N*	284	282	2.42
Number of patients with events, n (%)	12 (4.2)	5 (1.8)	[0.85; 6.86]
			0.087
Percentiles (months) [95% CI]			
25th	N.E. [26.2; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Fatigue			
N*	284	282	0.86
Number of patients with events, n (%)	32 (11.3)	35 (12.4)	[0.53; 1.39]
			0.535
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Gamma-glutamyltransferase increased			
N*	284	282	0.53
Number of patients with events, n (%)	13 (4.6)	23 (8.2)	[0.27; 1.05]
			0.064
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Headache			
N*	284	282	0.87
Number of patients with events, n (%)	38 (13.4)	41 (14.5)	[0.56; 1.35]
			0.533
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Hyperbilirubinaemia			
N*	284	282	0.19
Number of patients with events, n (%)	2 (0.7)	10 (3.5)	[0.04; 0.85]
			0.015
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Hypercholesterolaemia			
N*	284	282	0.25
Number of patients with events, n (%)	4 (1.4)	15 (5.3)	[0.08; 0.75]
			0.008
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Hypertension			
N*	284	282	2.58
Number of patients with events, n (%)	27 (9.5)	10 (3.5)	[1.25; 5.34]
			0.008
Percentiles (months) [95% CI]			
25th	N.E. [24.0; N.E.]	N.E. [26.5; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Influenza like illness			
N*	284	282	1.91
Number of patients with events, n (%)	10 (3.5)	5 (1.8)	[0.65; 5.60]
			0.227
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Lipase increased			
N*	284	282	1.03
Number of patients with events, n (%)	30 (10.6)	28 (9.9)	[0.61; 1.72]
			0.916
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Low density lipoprotein increased			
N*	284	282	0.37
Number of patients with events, n (%)	4 (1.4)	10 (3.5)	[0.12; 1.18]
			0.081
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Muscle spasms			
N*	284	282	0.69
Number of patients with events, n (%)	10 (3.5)	14 (5.0)	[0.31; 1.56]
			0.370
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Myalgia			
N*	284	282	1.33
Number of patients with events, n (%)	35 (12.3)	26 (9.2)	[0.80; 2.20]
			0.273
Percentiles (months) [95% CI]			
25th	N.E. [25.0; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Nasopharyngitis			
N*	284	282	1.44
Number of patients with events, n (%)	15 (5.3)	10 (3.5)	[0.65; 3.20]
			0.371
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Nausea			
N*	284	282	1.52
Number of patients with events, n (%)	32 (11.3)	21 (7.4)	[0.88; 2.63]
			0.134
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Neutropenia			
N*	284	282	1.14
Number of patients with events, n (%)	28 (9.9)	24 (8.5)	[0.66; 1.97]
			0.632
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Pain in extremity			
N*	284	282	1.16
Number of patients with events, n (%)	10 (3.5)	8 (2.8)	[0.46; 2.95]
			0.752
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Platelet count decreased			
N*	284	282	2.58
Number of patients with events, n (%)	13 (4.6)	5 (1.8)	[0.92; 7.23]
			0.062
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Pruritus			
N*	284	282	0.69
Number of patients with events, n (%)	22 (7.7)	30 (10.6)	[0.40; 1.20]
			0.187
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Pyrexia			
N*	284	282	0.58
Number of patients with events, n (%)	6 (2.1)	10 (3.5)	[0.21; 1.59]
			0.280
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Rash			
N*	284	282	0.62
Number of patients with events, n (%)	33 (11.6)	48 (17.0)	[0.40; 0.96]
			0.032
Percentiles (months) [95% CI]			
25th	N.E. [24.9; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Rash maculo-papular			
N*	284	282	0.24
Number of patients with events, n (%)	3 (1.1)	12 (4.3)	[0.07; 0.83]
			0.015
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Thrombocytopenia			
N*	284	282	1.13
Number of patients with events, n (%)	46 (16.2)	40 (14.2)	[0.74; 1.73]
			0.569
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

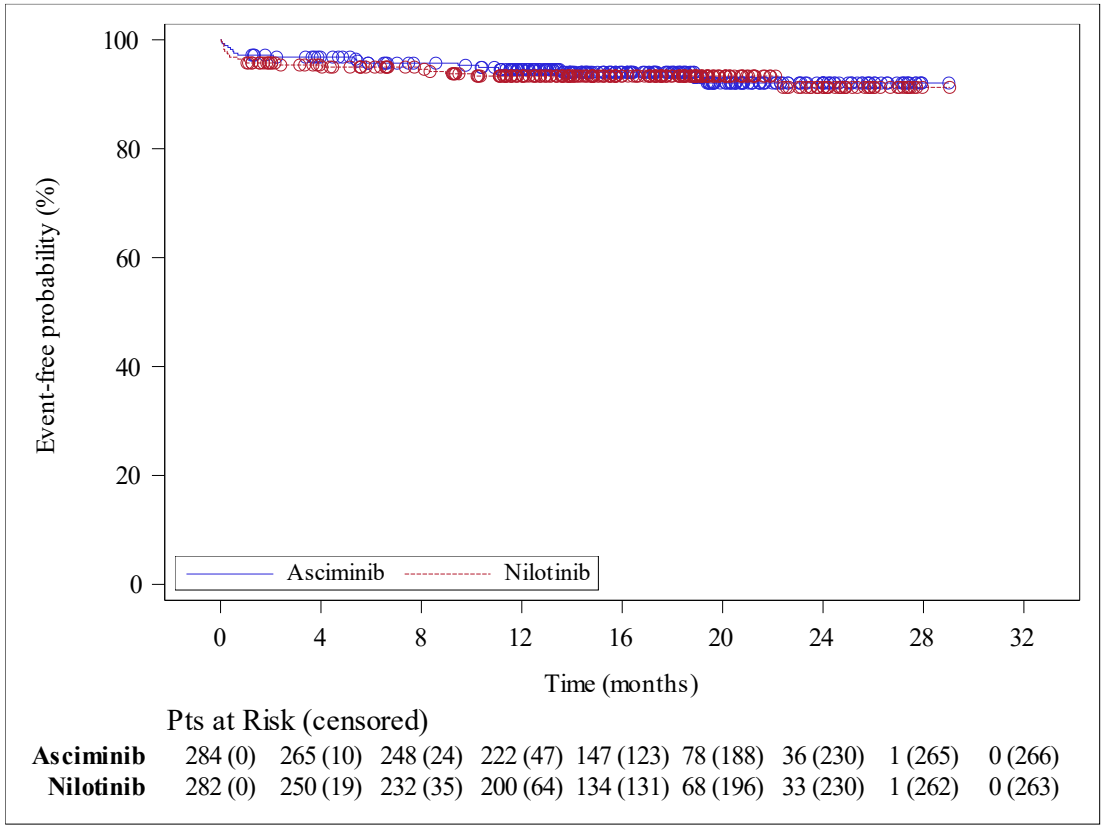
	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Upper respiratory tract infection			
N*	284	282	1.22
Number of patients with events, n (%)	13 (4.6)	10 (3.5)	[0.54; 2.78]
			0.635
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Vomiting			
N*	284	282	0.97
Number of patients with events, n (%)	14 (4.9)	14 (5.0)	[0.46; 2.03]
			0.926
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Weight increased			
N*	284	282	1.88
Number of patients with events, n (%)	14 (4.9)	7 (2.5)	[0.76; 4.67]
			0.164
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
PT: Preferred Term
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

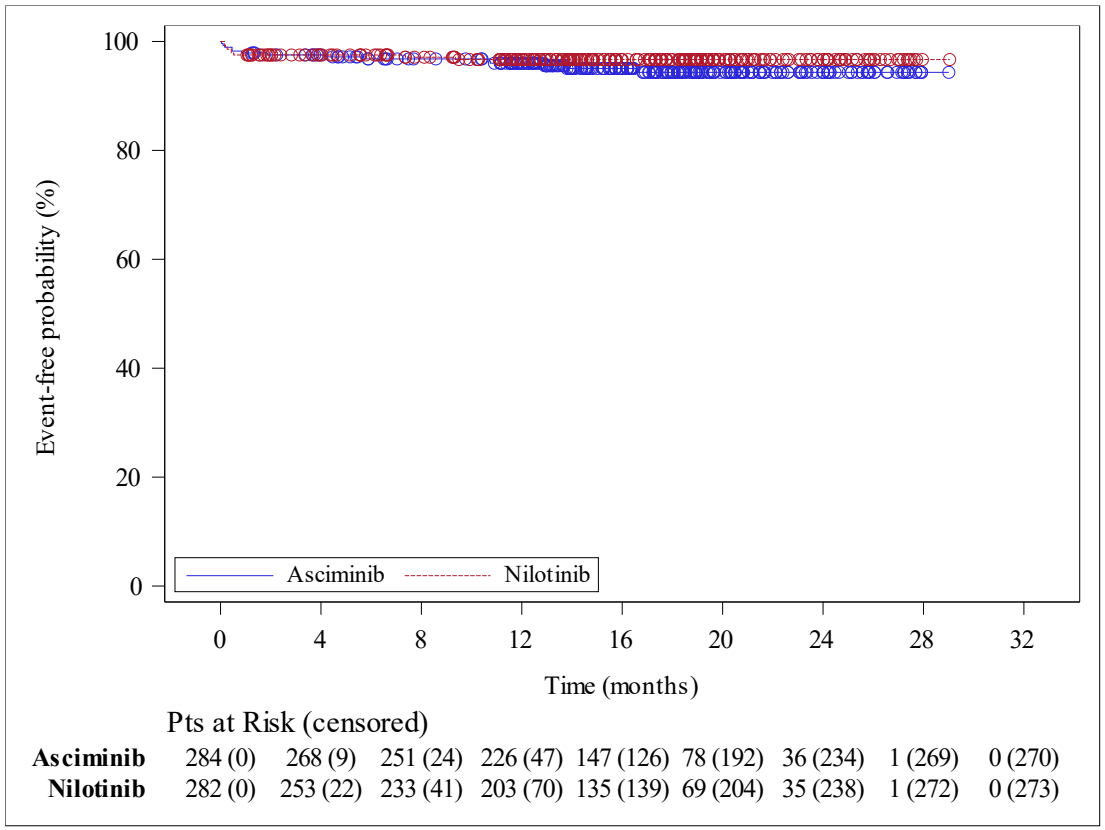
Abdominal pain



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

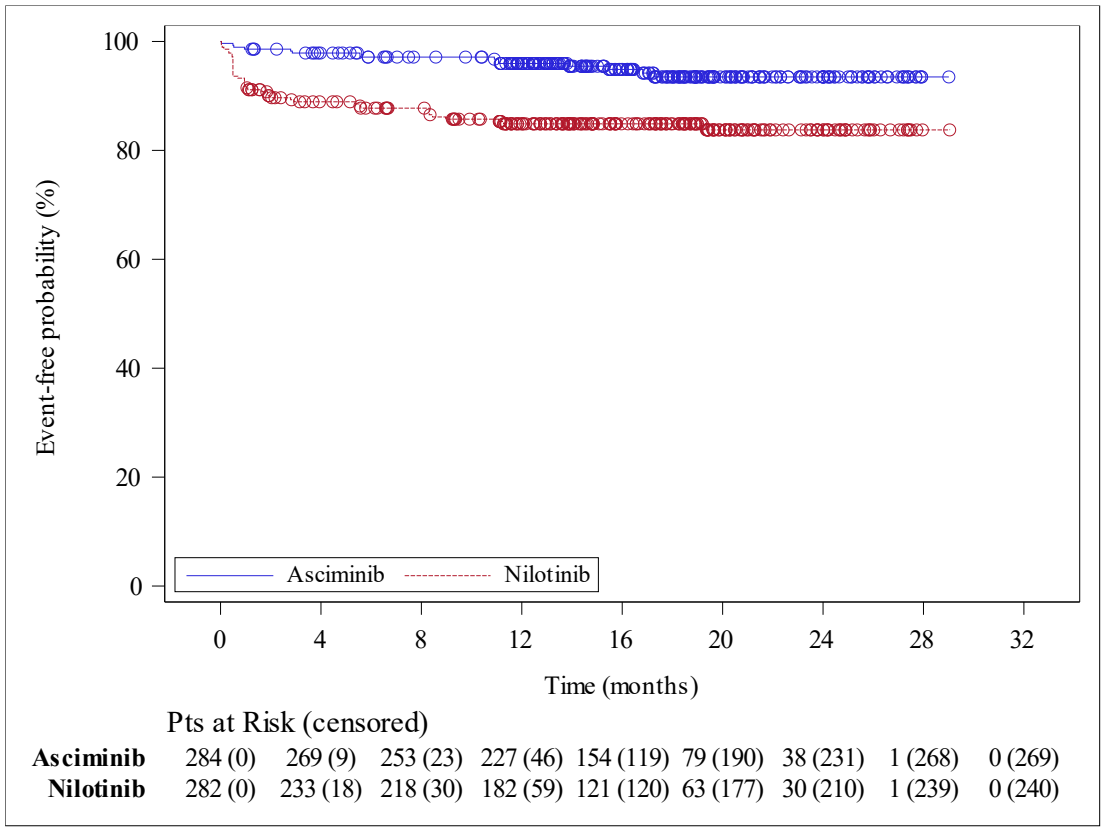
Abdominal pain upper



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

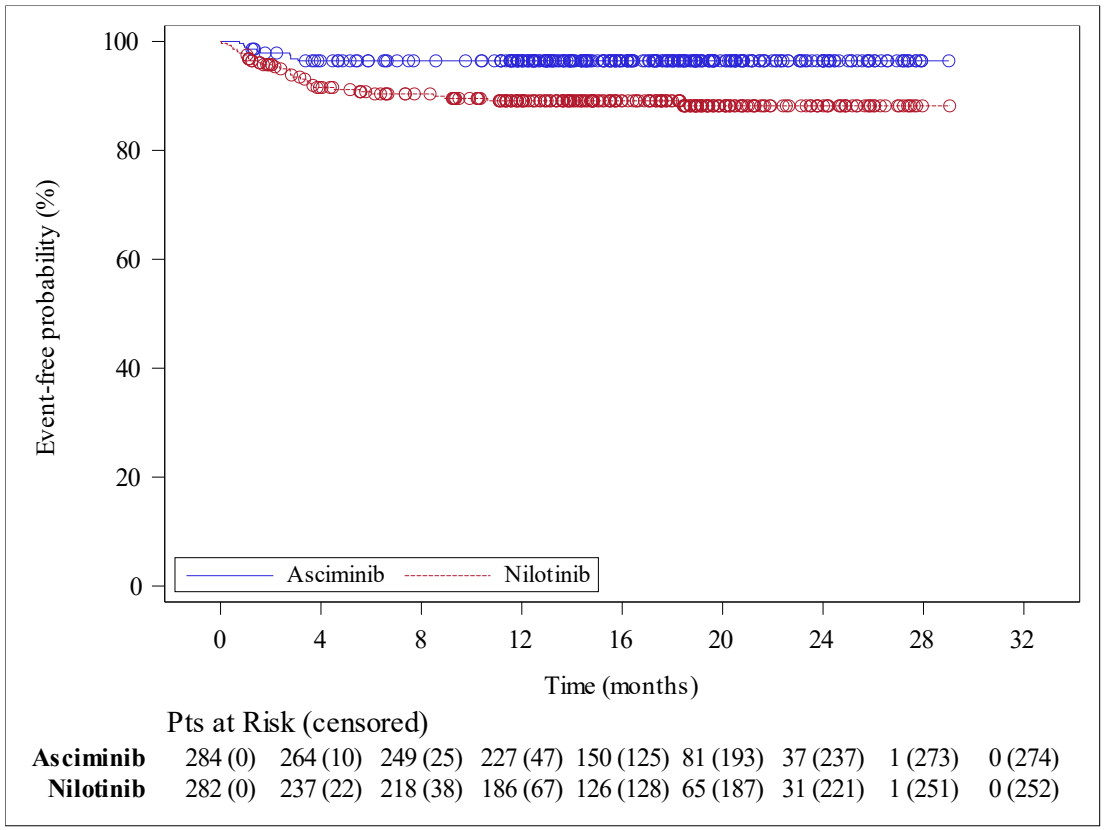
Alanine aminotransferase increased



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

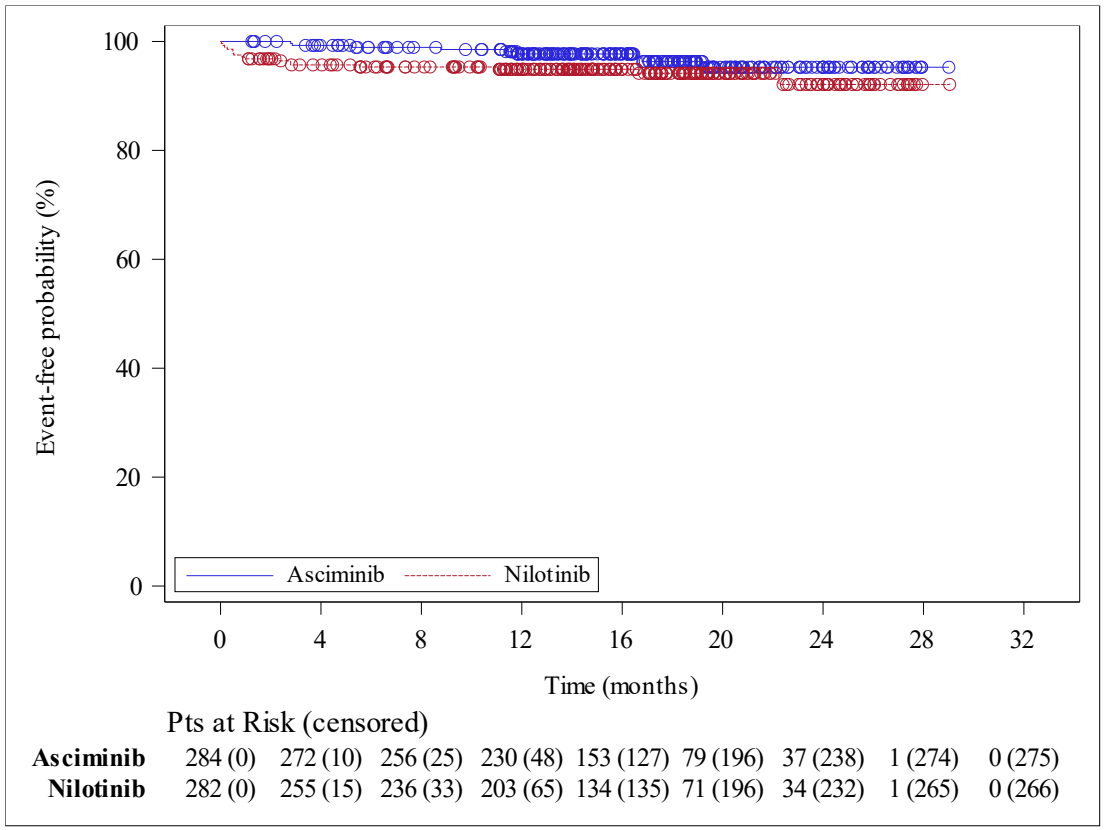
Alopecia



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

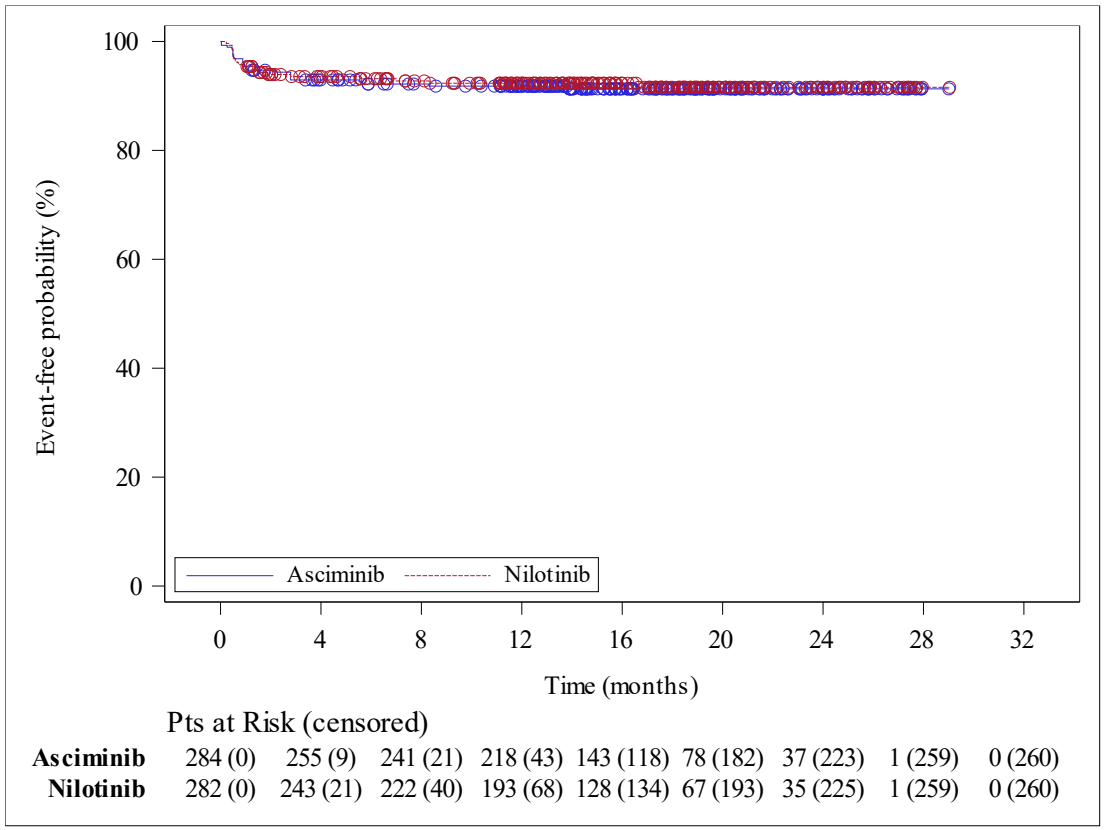
Amylase increased



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

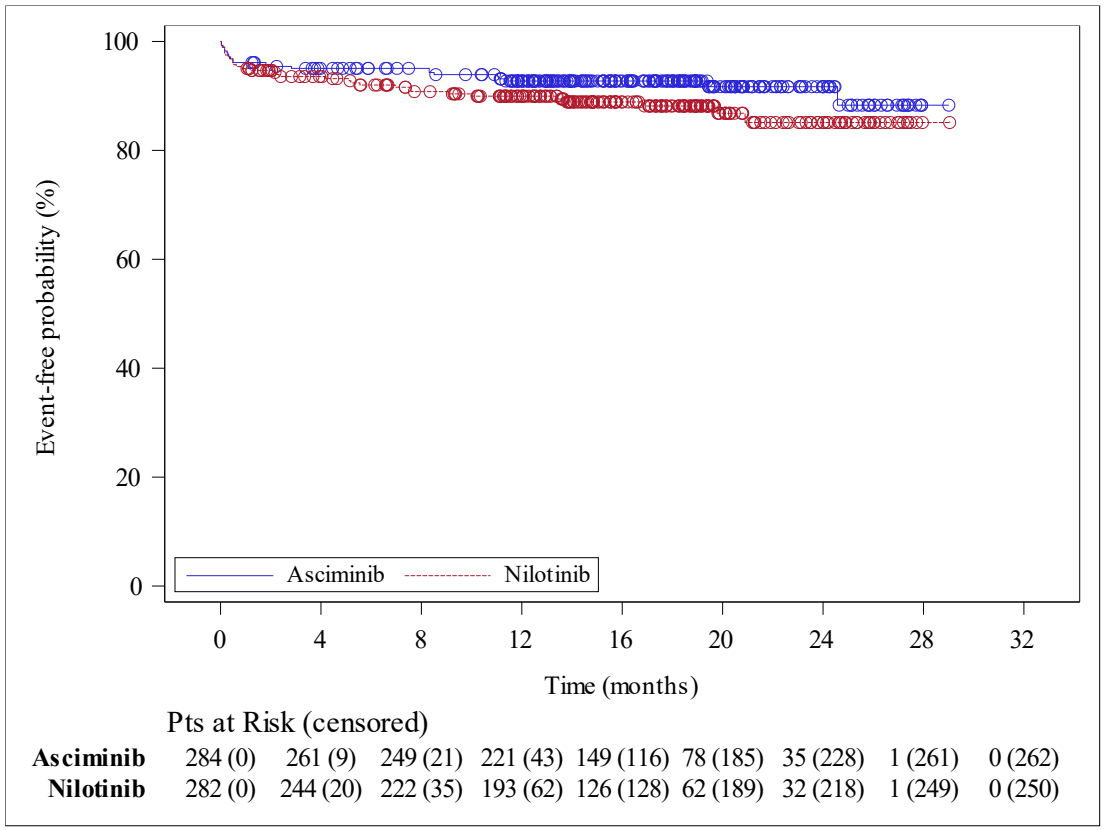
Anaemia



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

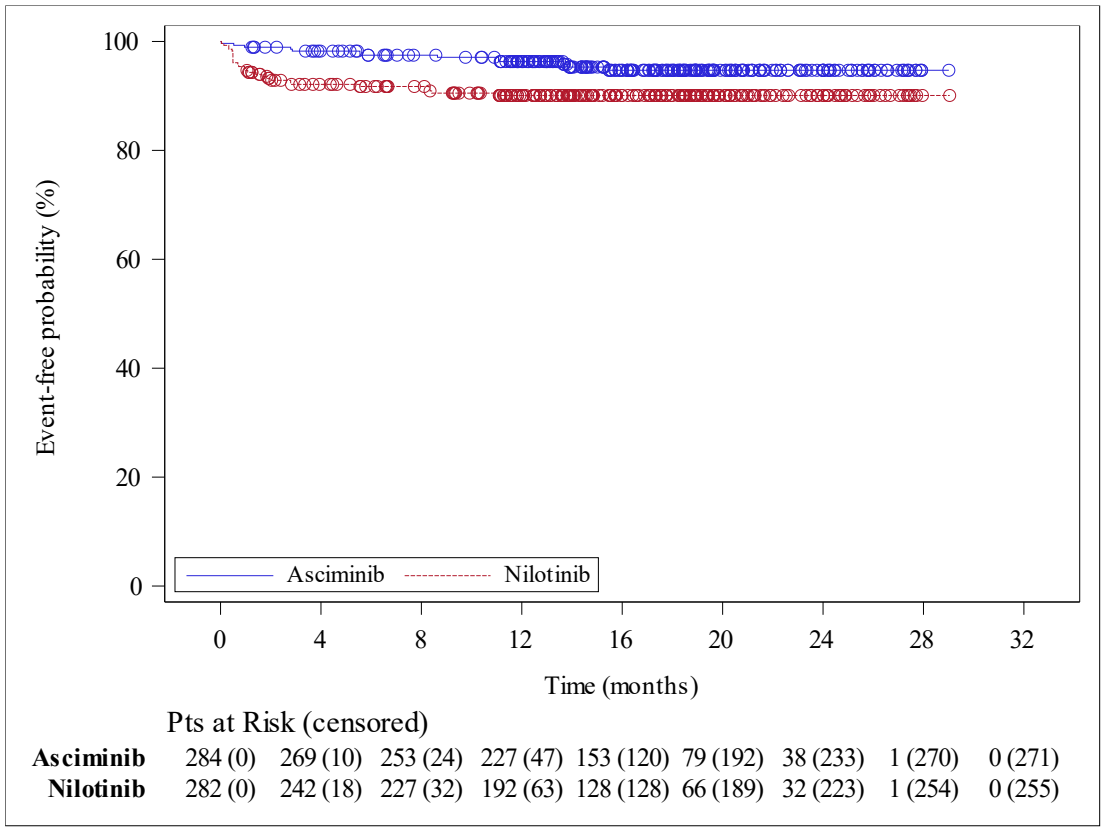
Arthralgia



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

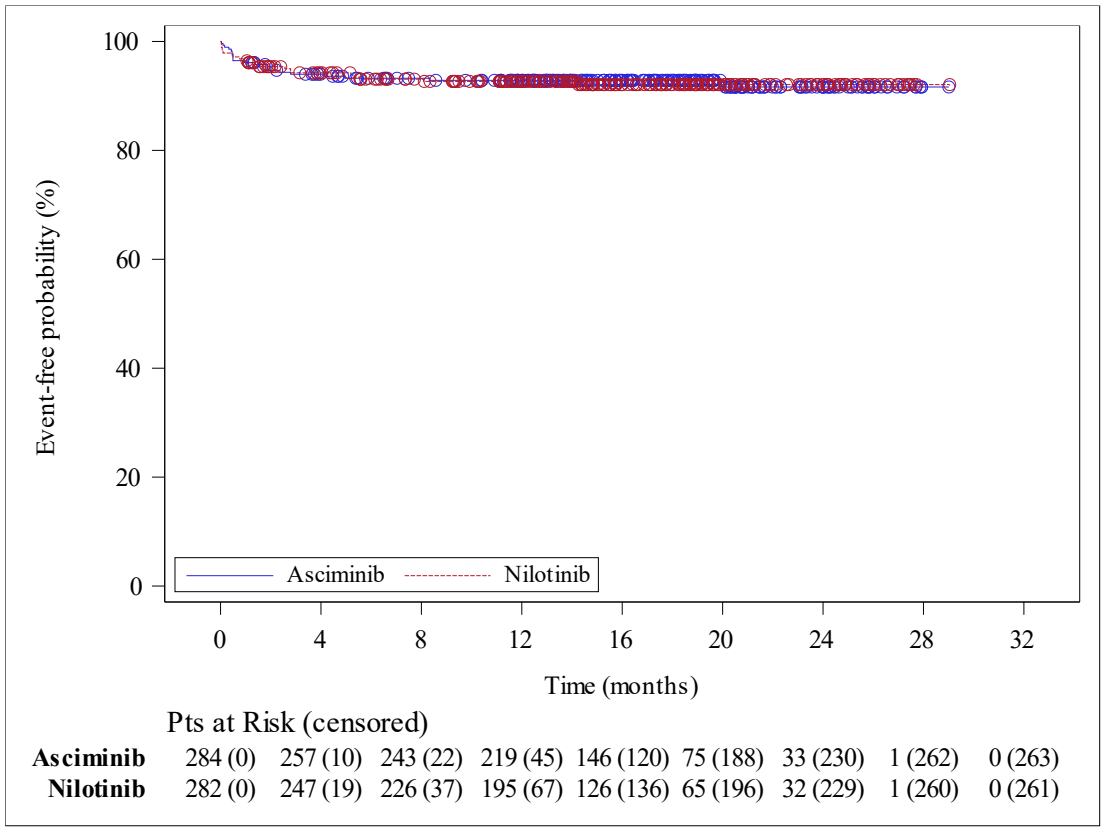
Aspartate aminotransferase increased



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

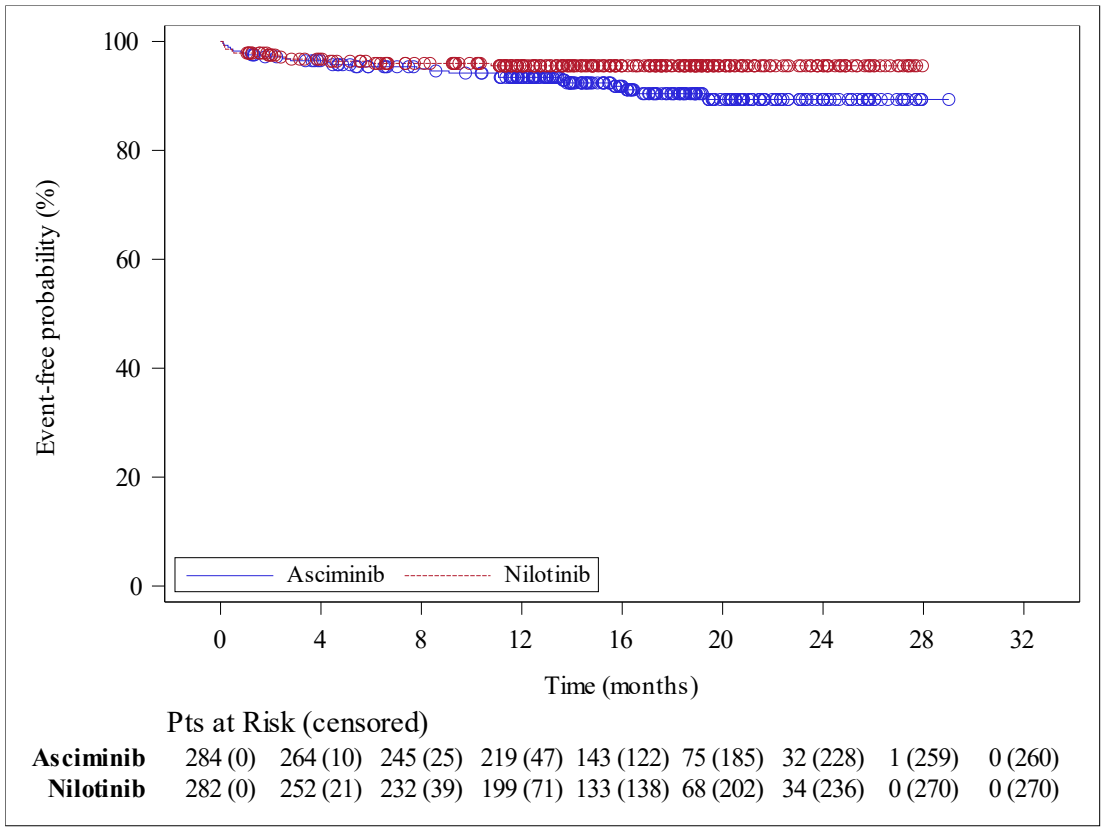
Asthenia



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

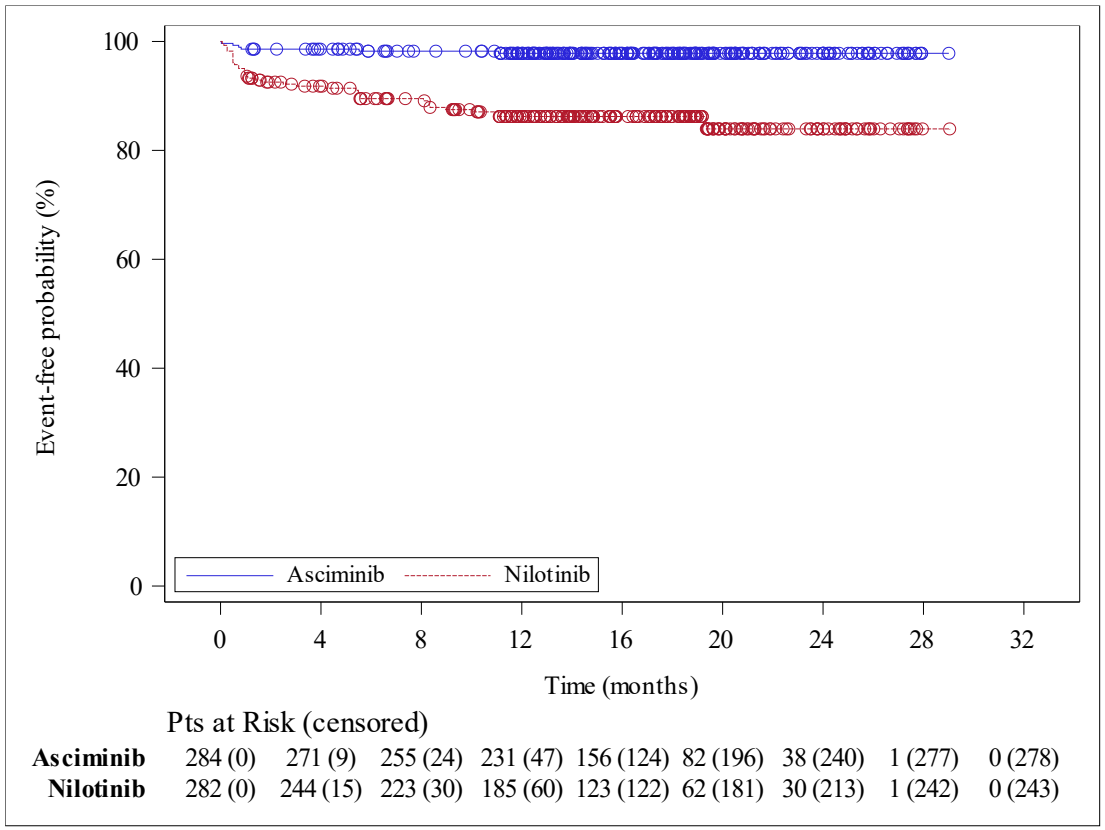
Back pain



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

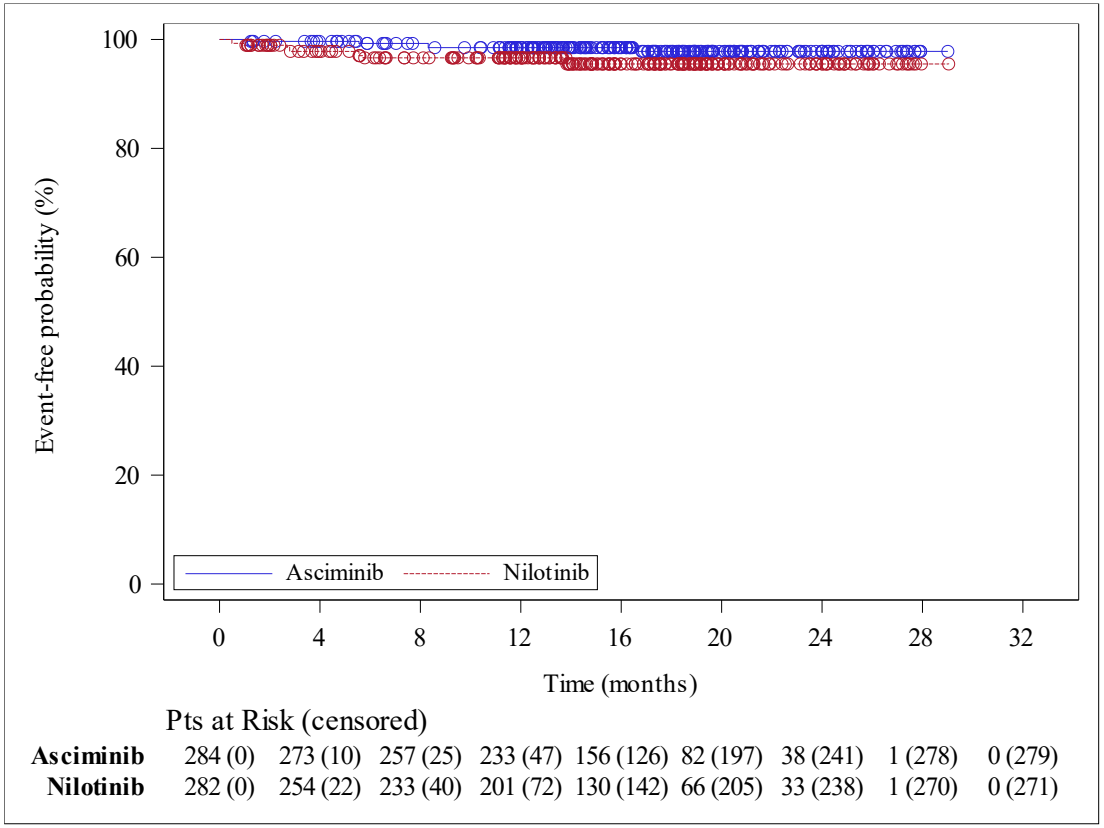
Blood bilirubin increased



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

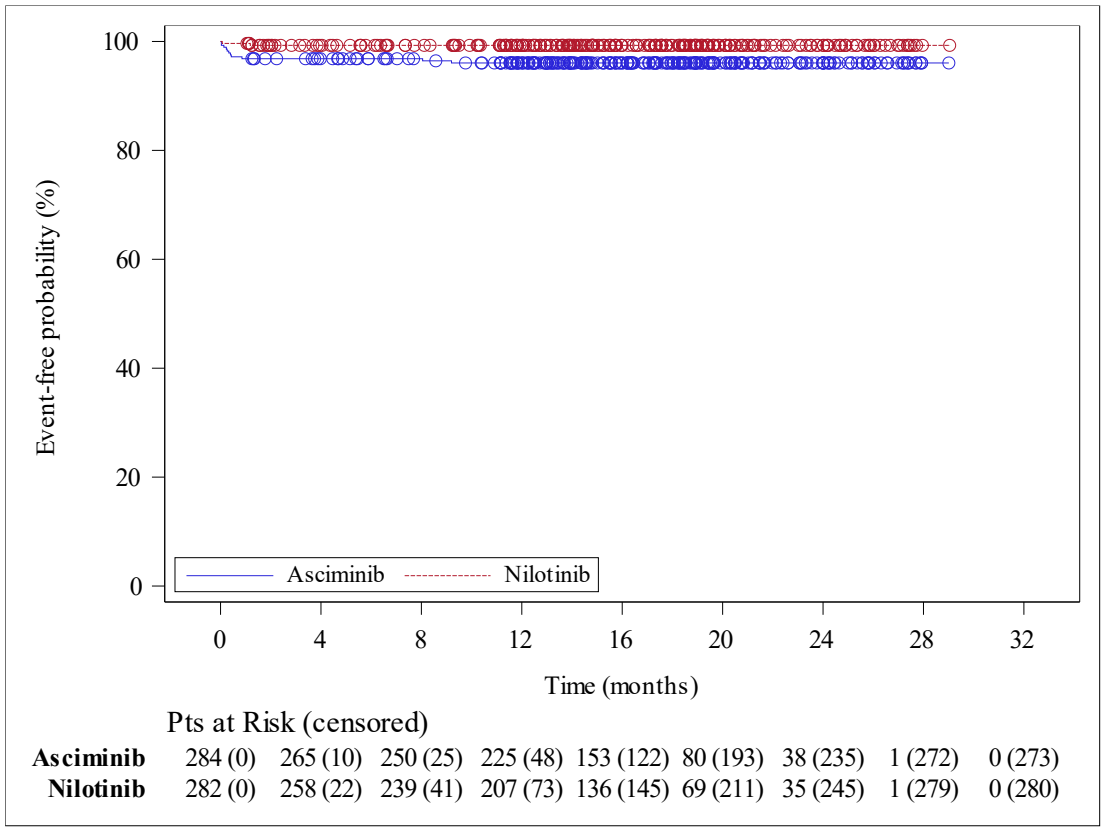
Blood cholesterol increased



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

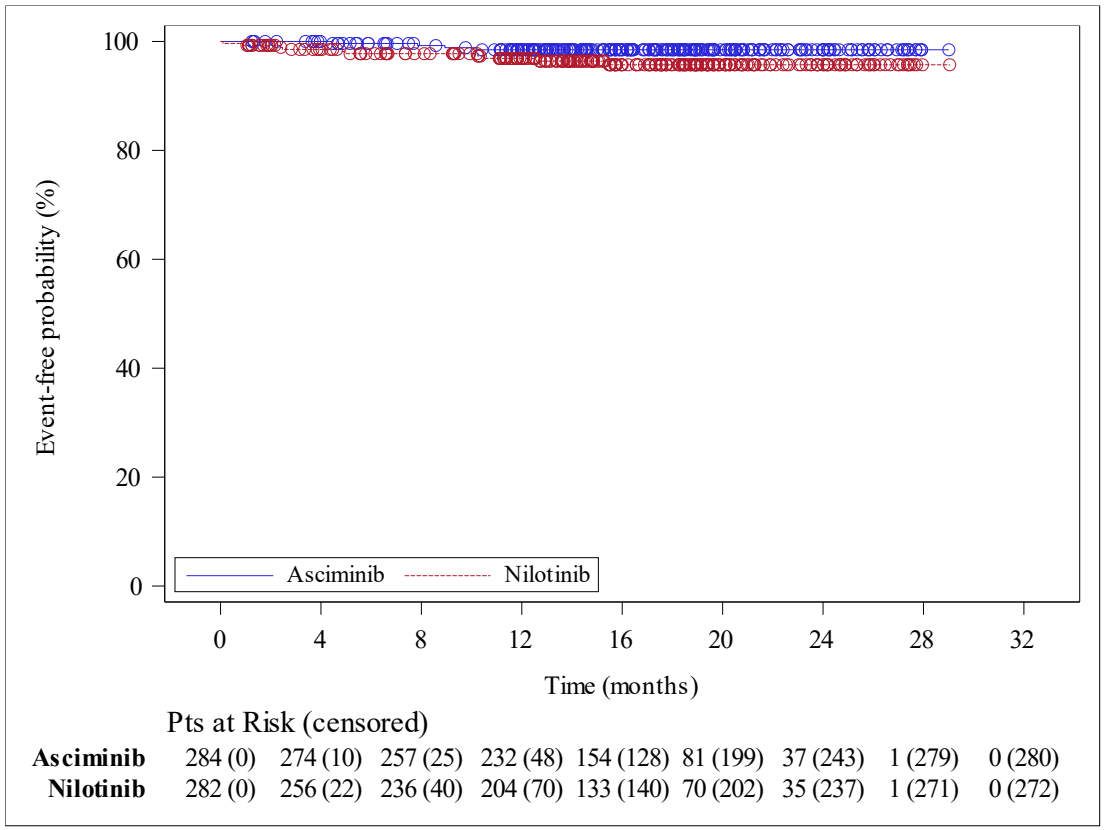
Bone pain



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

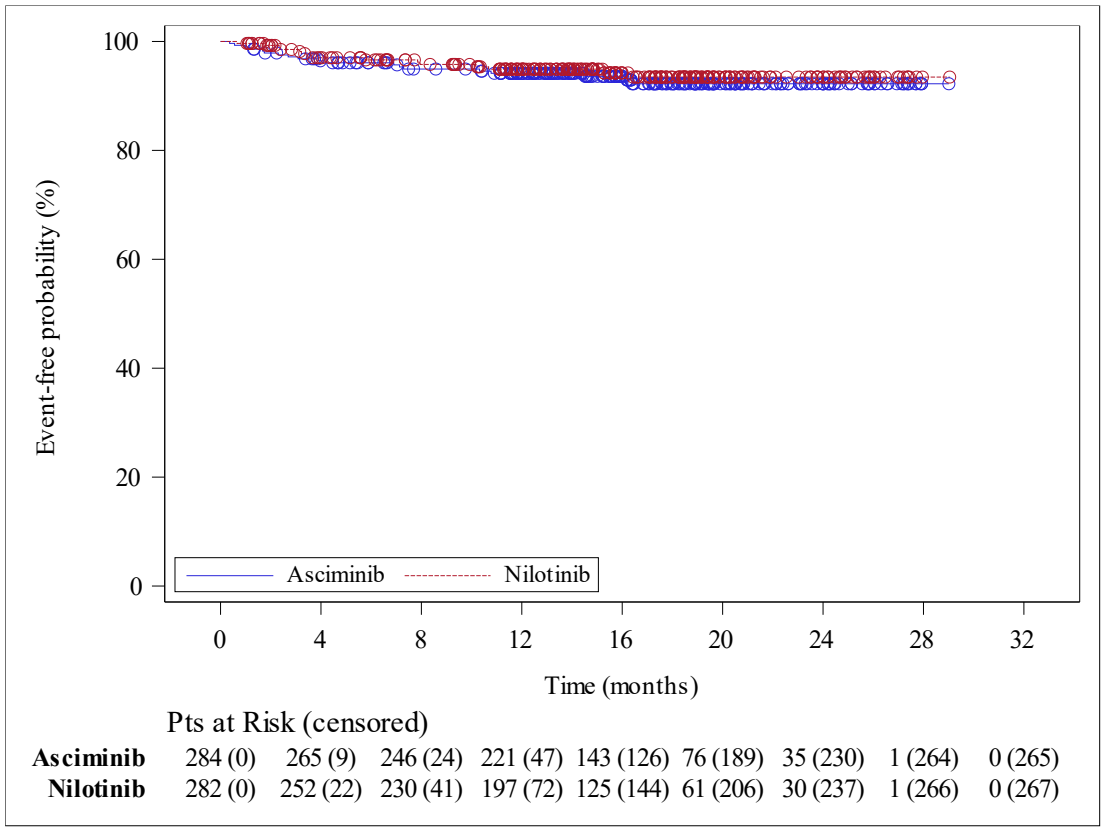
Bronchitis



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

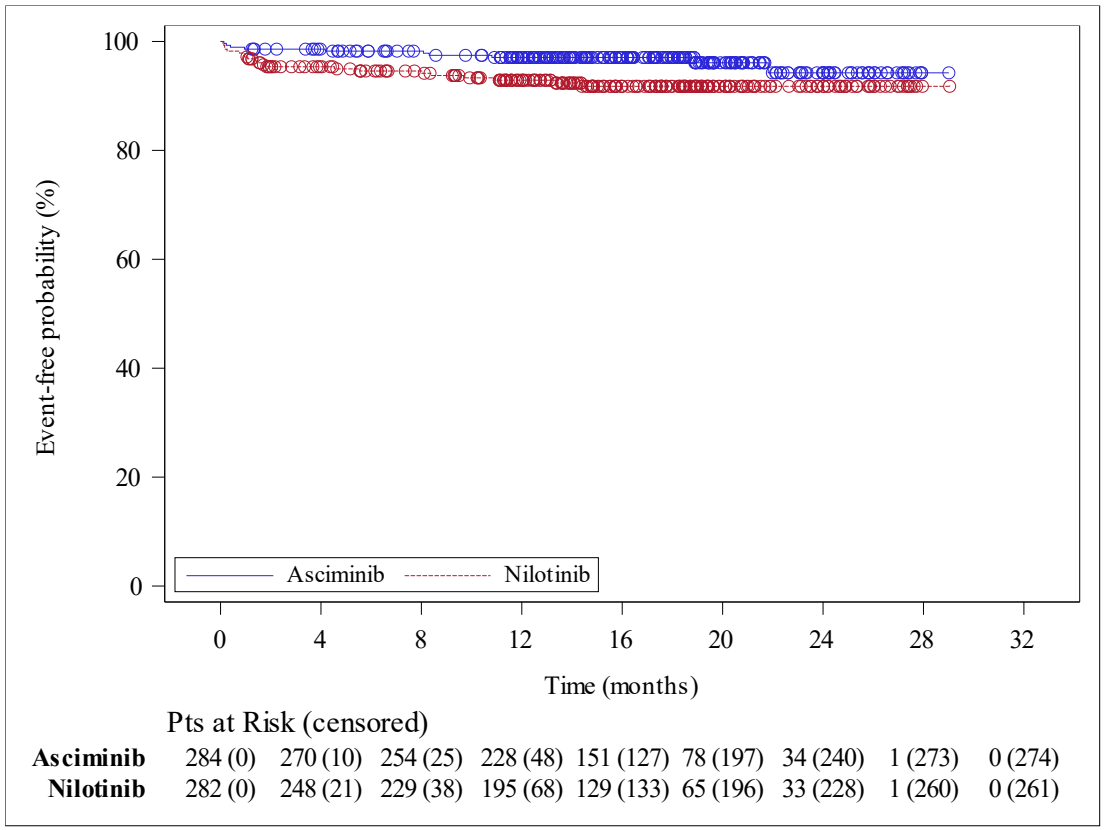
COVID-19



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

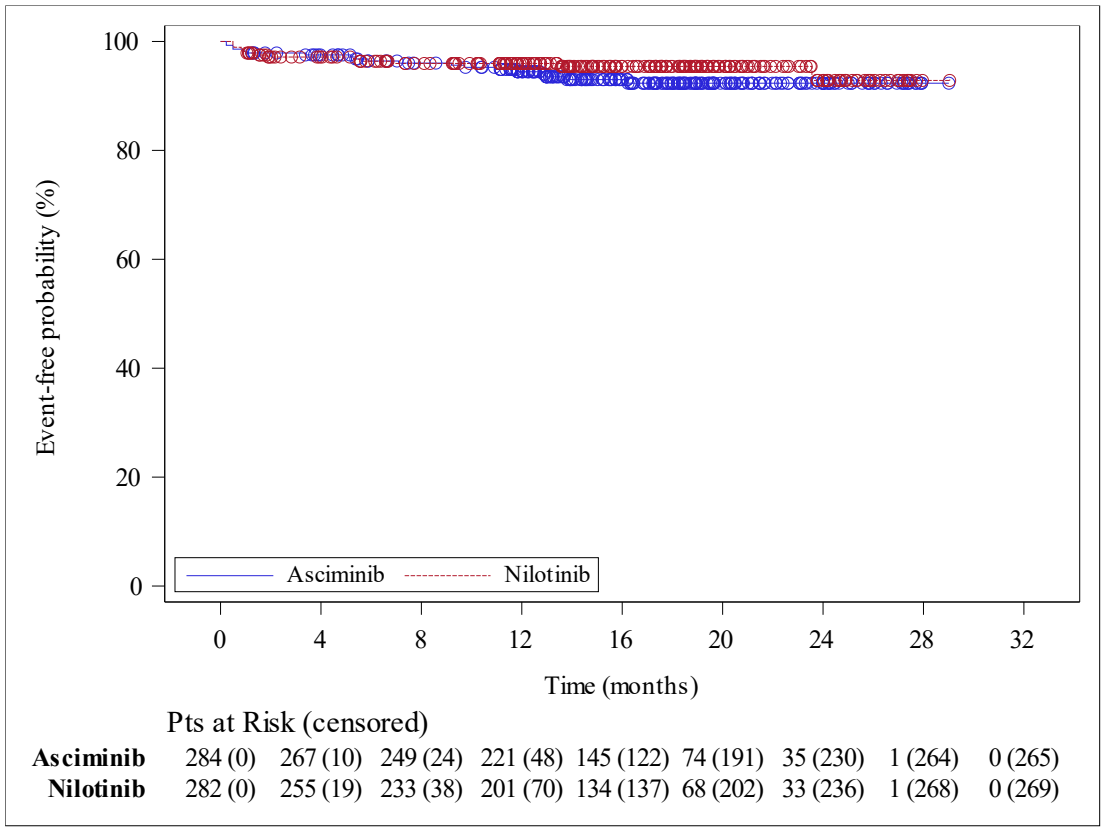
Constipation



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

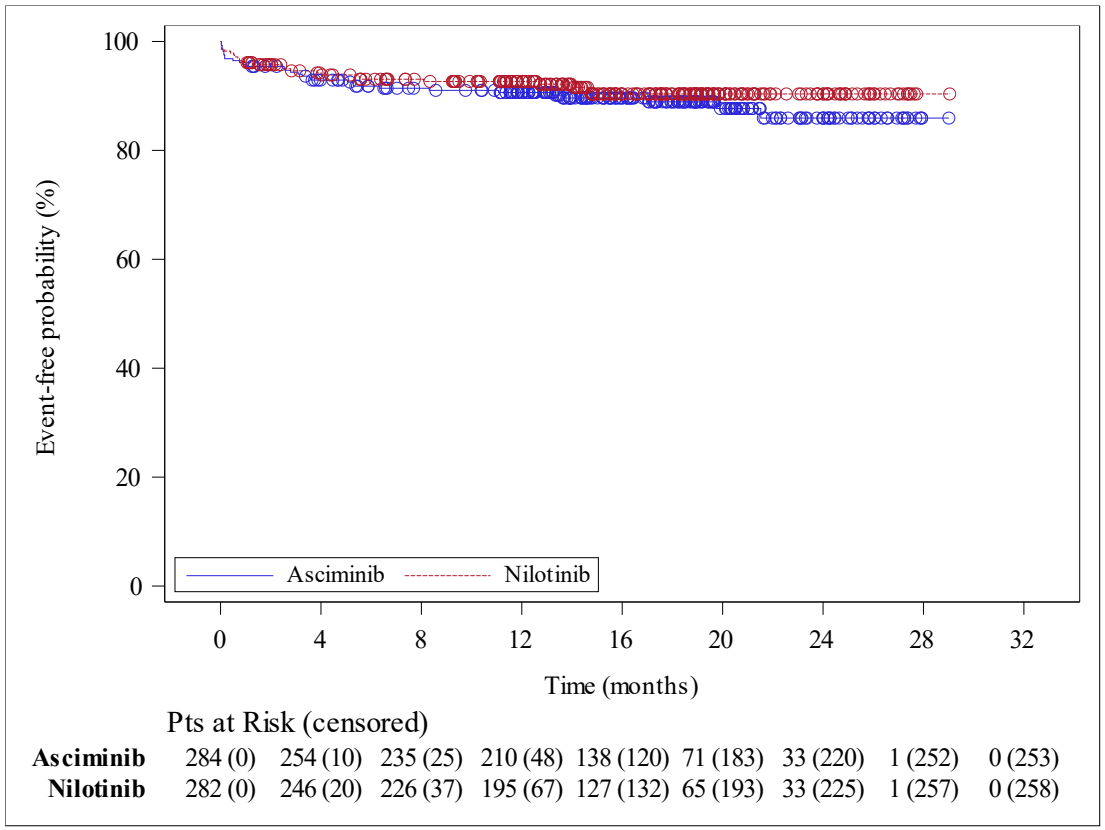
Cough



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

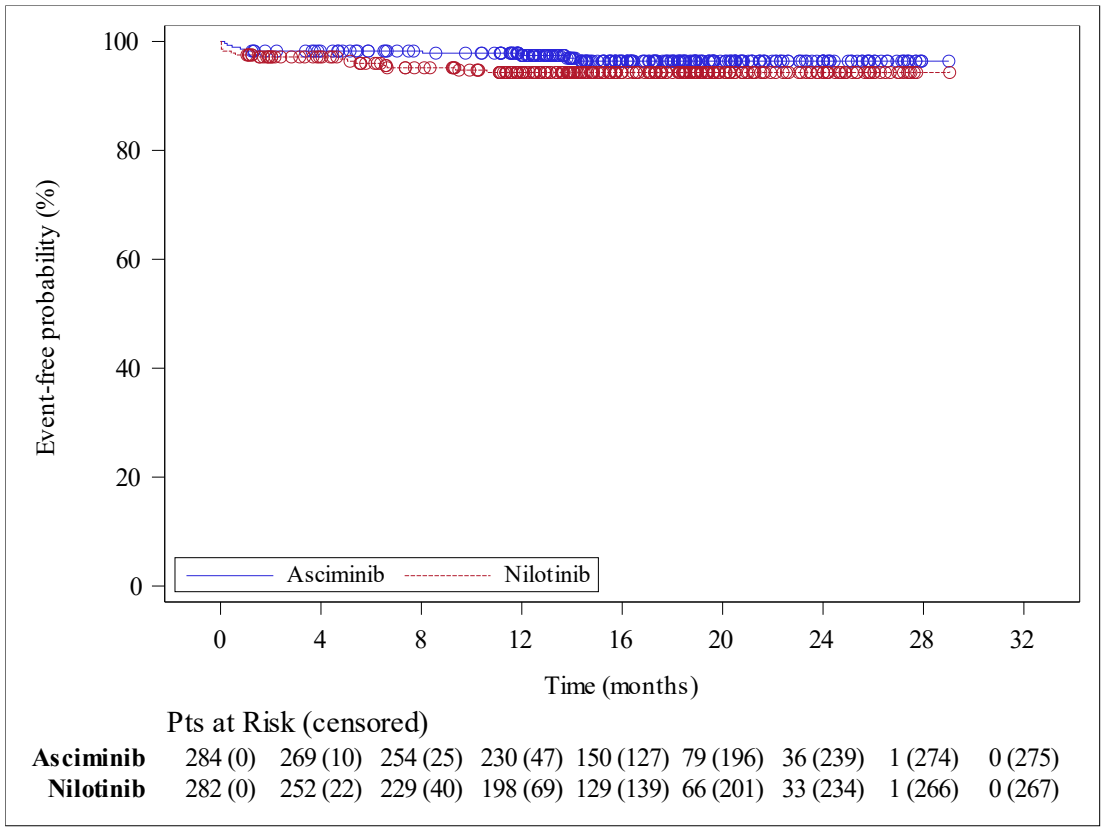
Diarrhoea



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

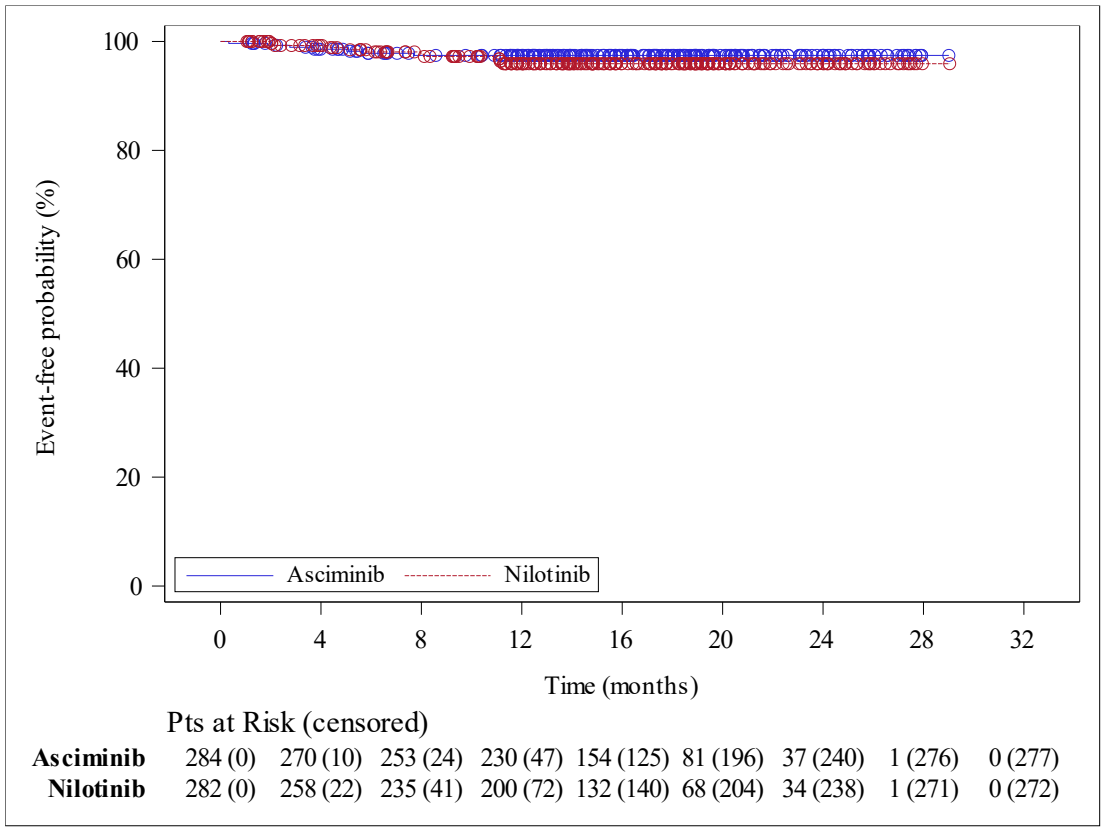
Dizziness



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

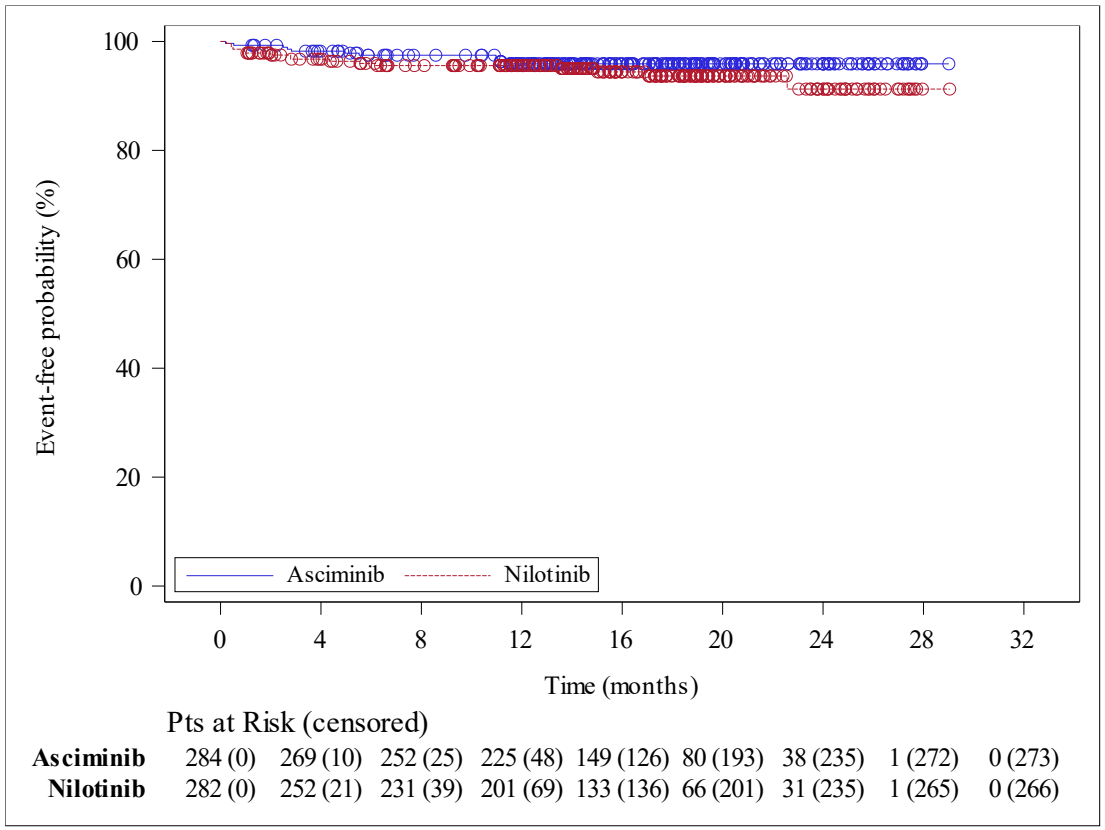
Dry eye



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

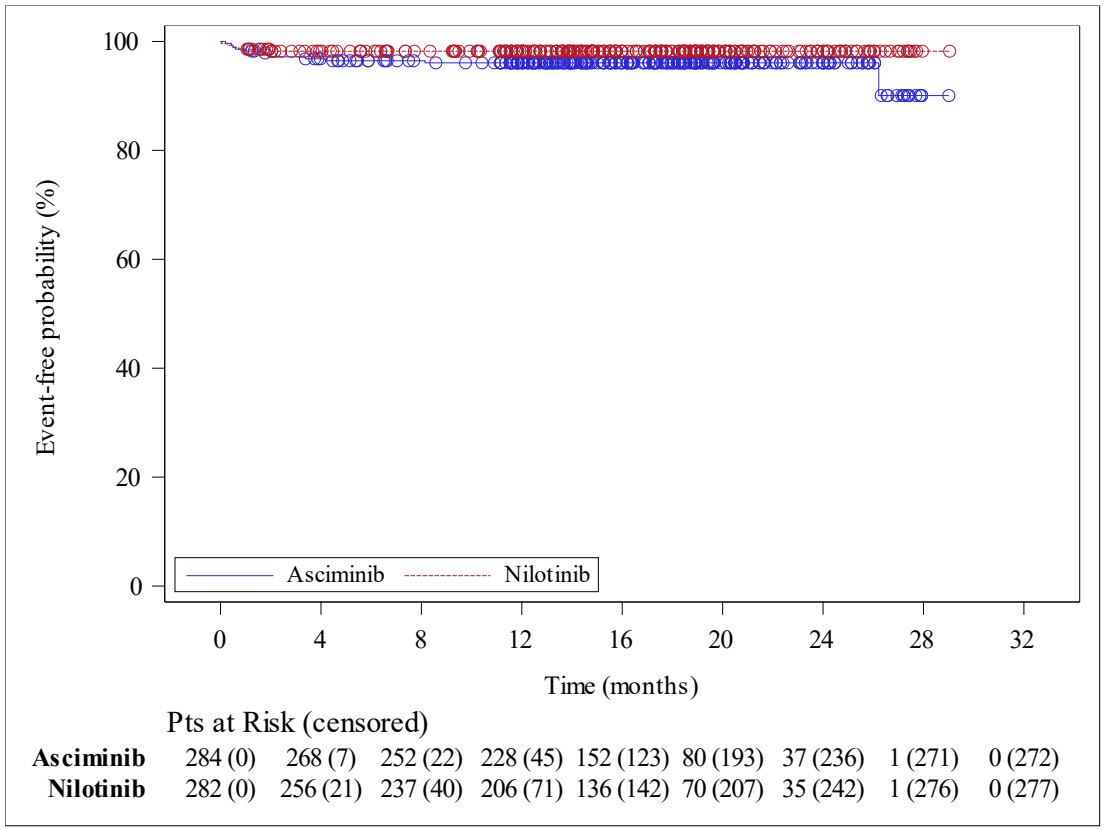
Dry skin



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

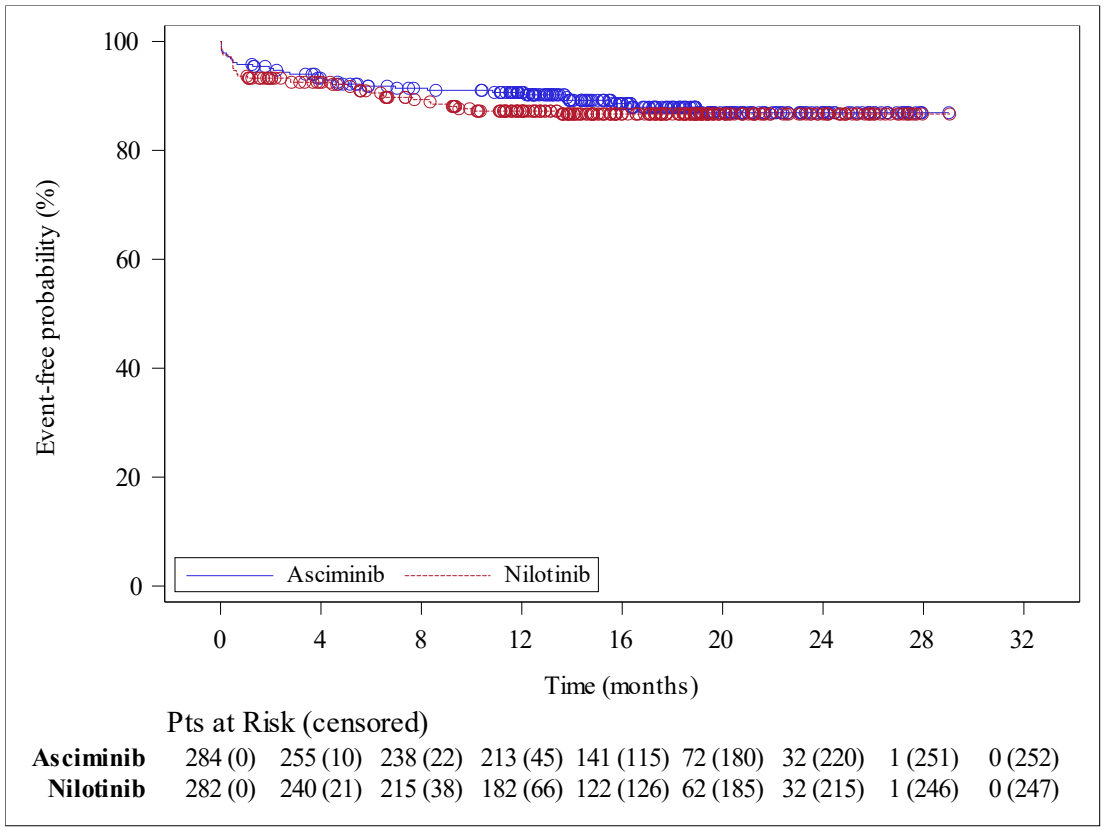
Dyspnoea



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

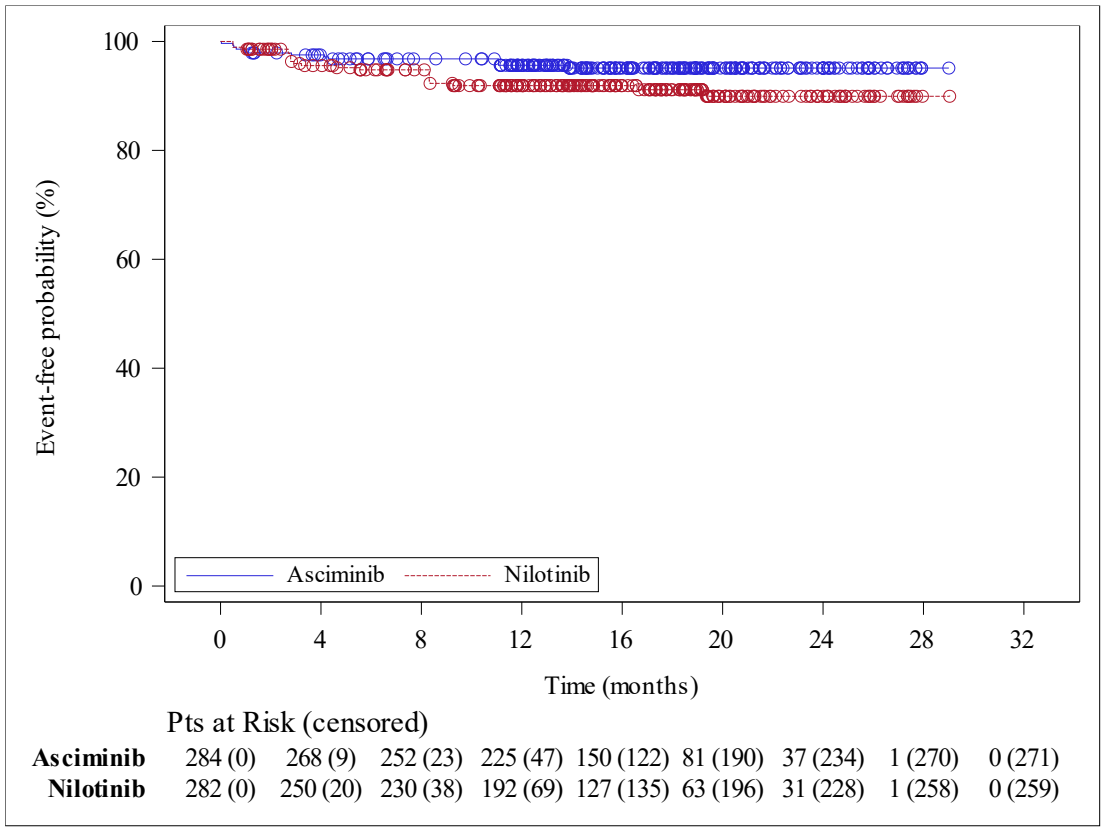
Fatigue



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

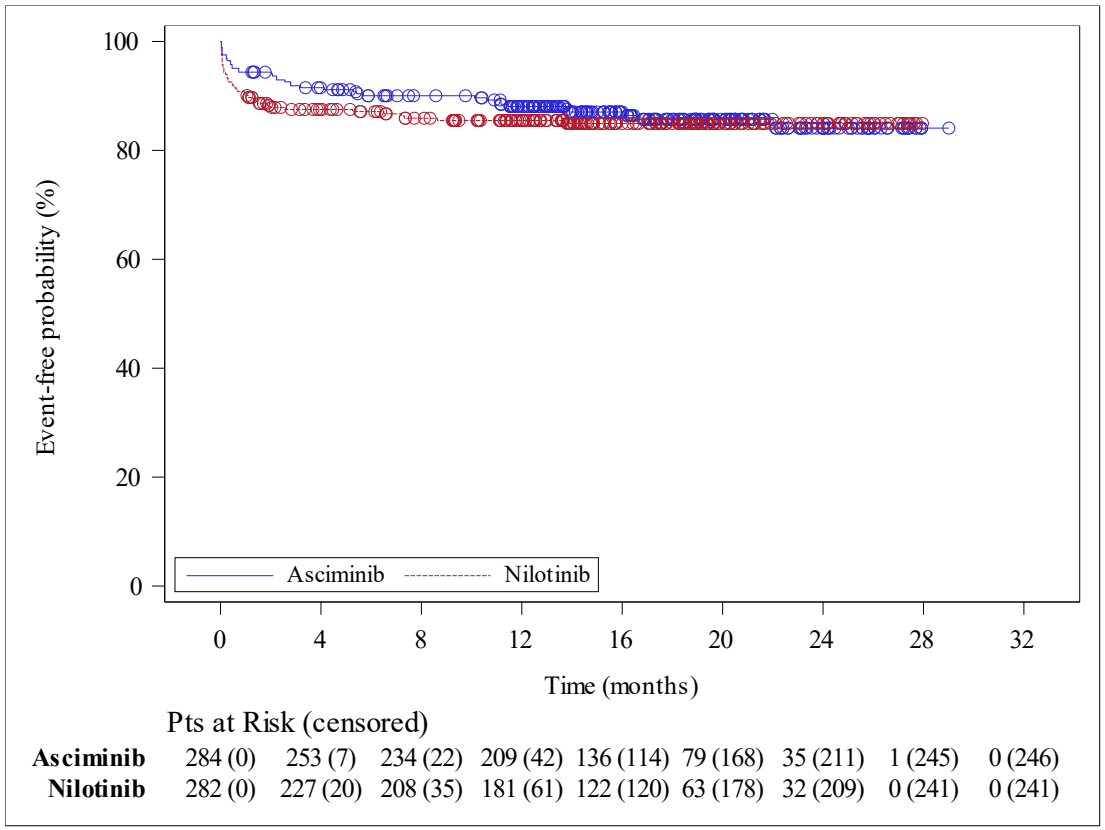
Gamma-glutamyltransferase increased



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

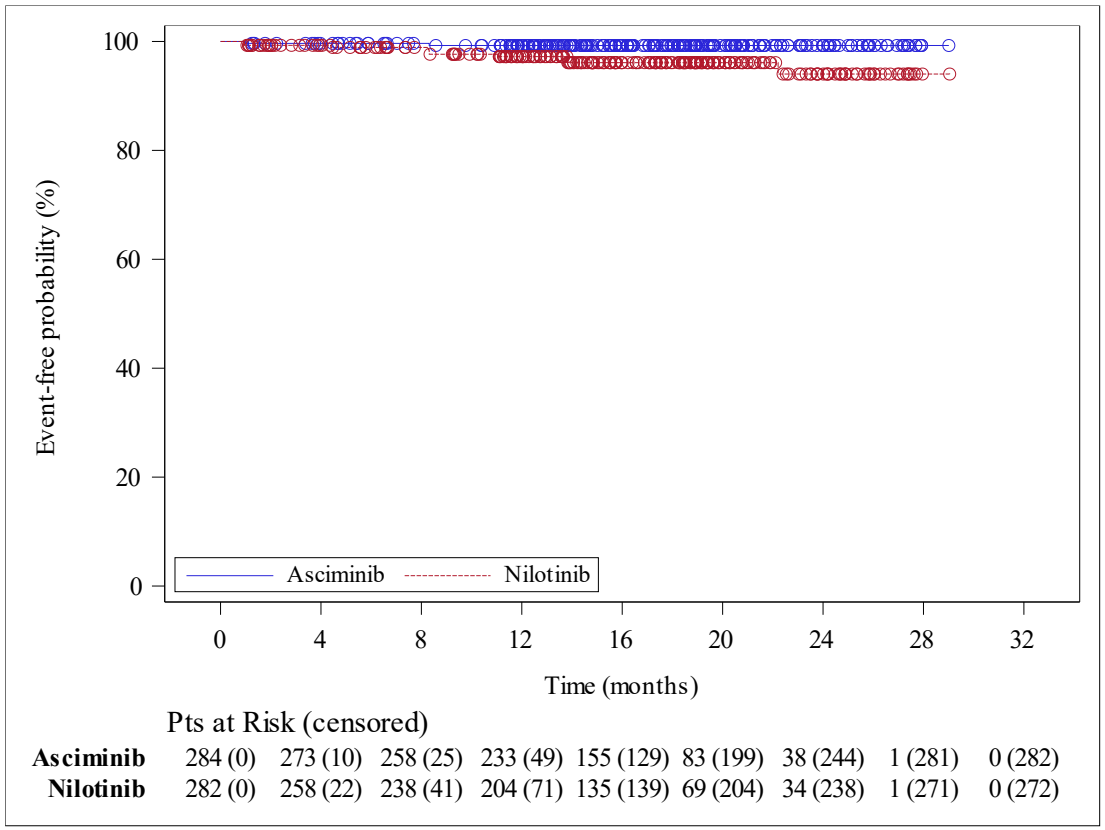
Headache



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

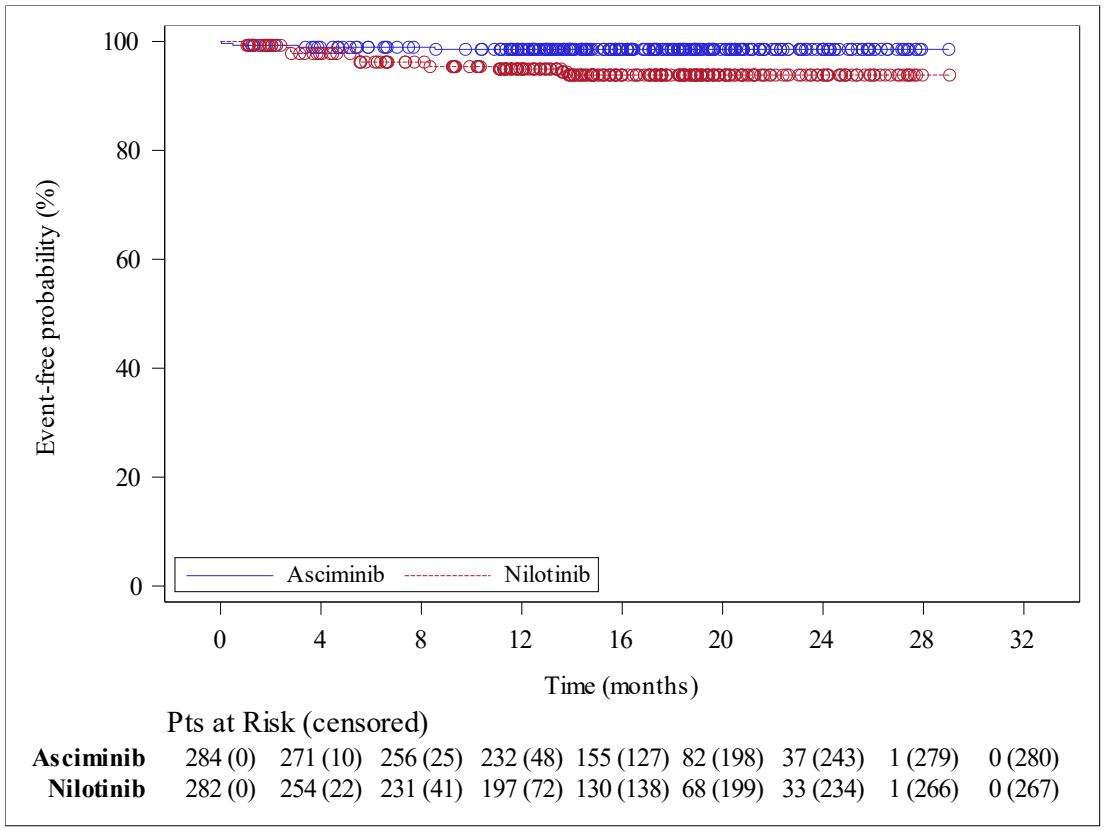
Hyperbilirubinaemia



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

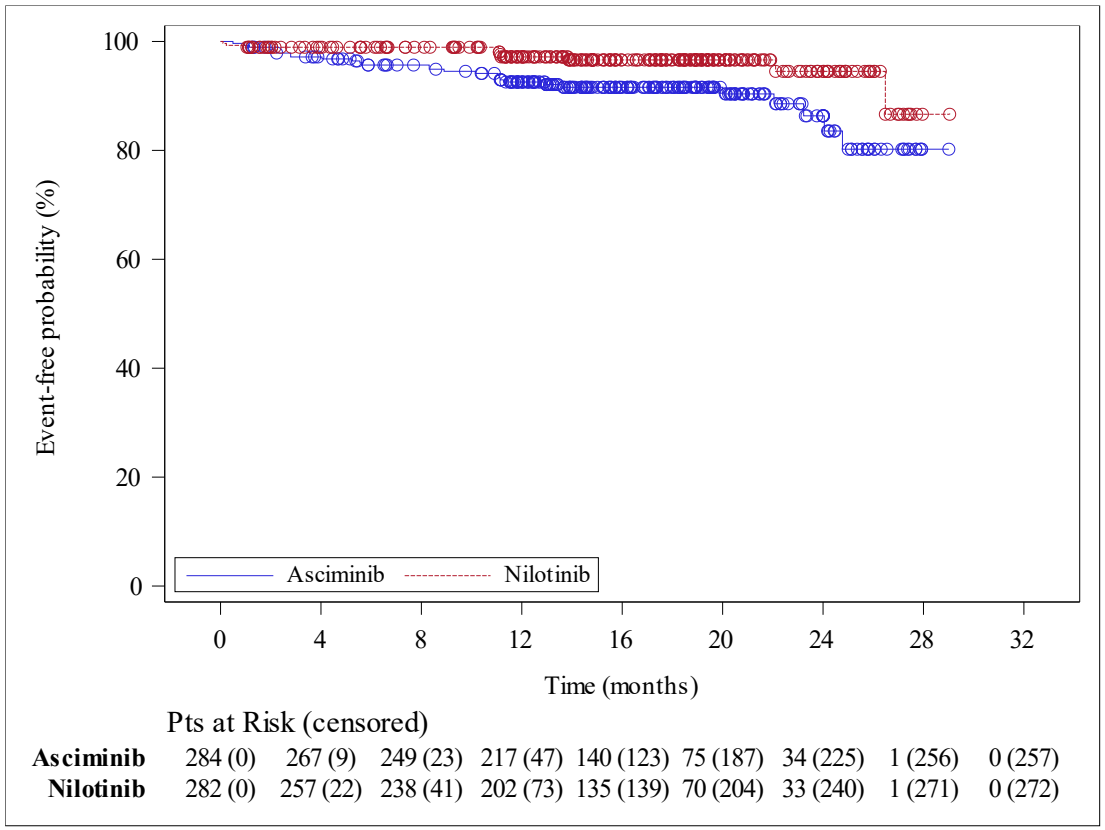
Hypercholesterolaemia



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

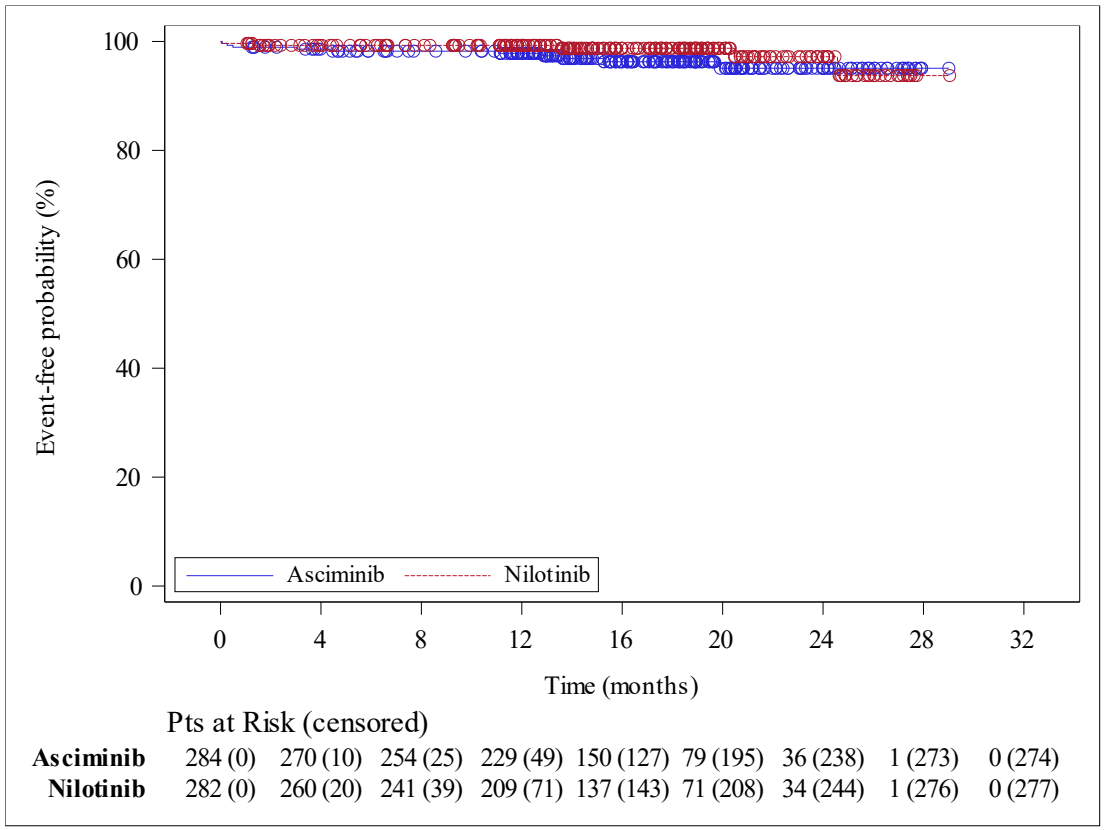
Hypertension



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

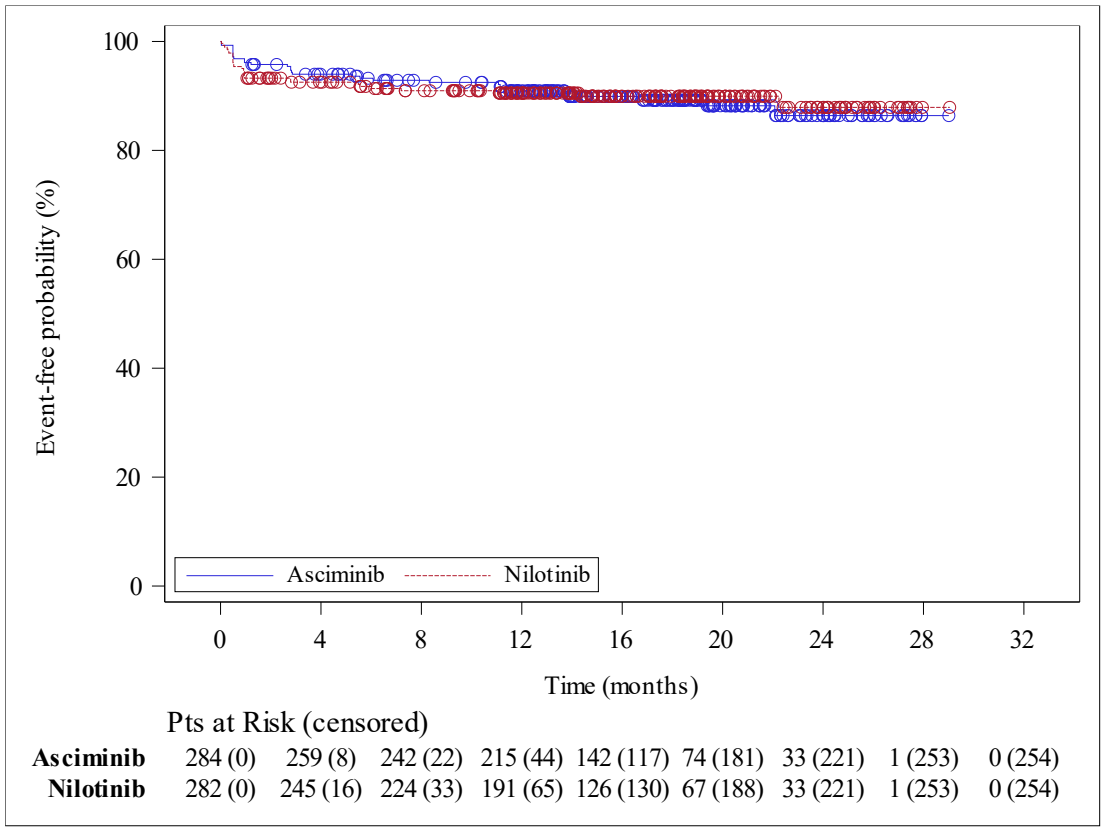
Influenza like illness



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

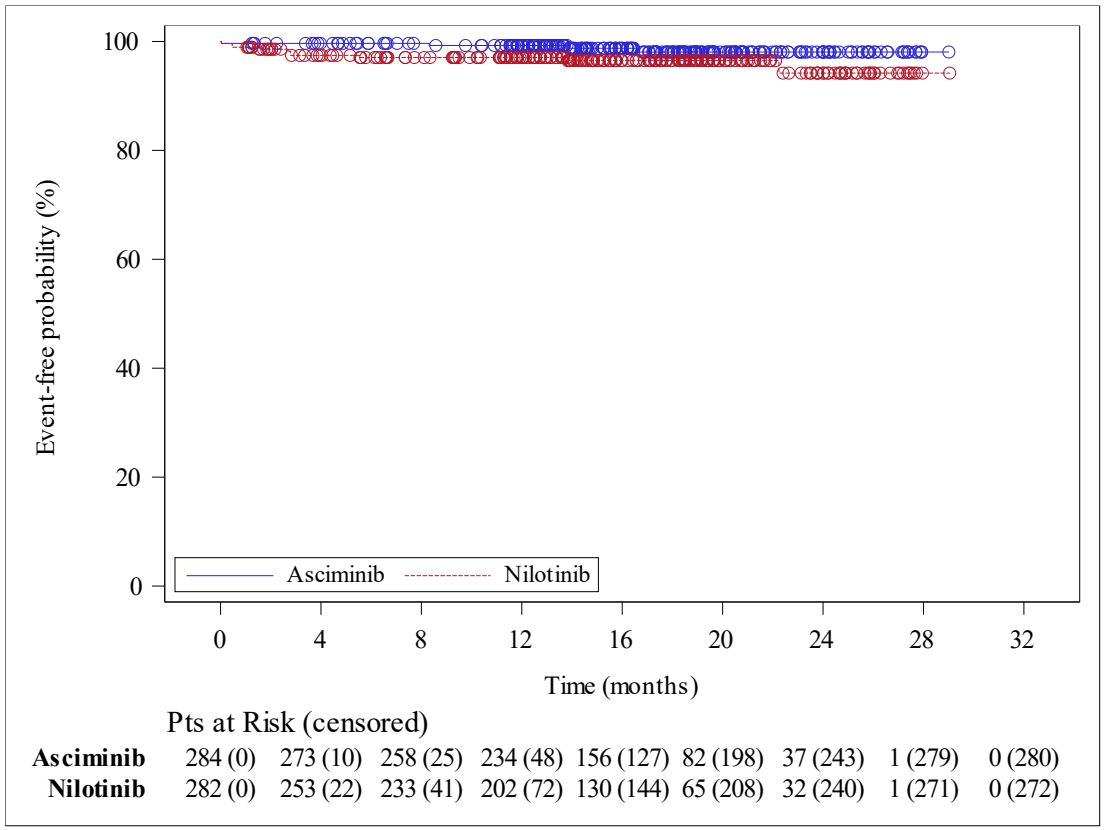
Lipase increased



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

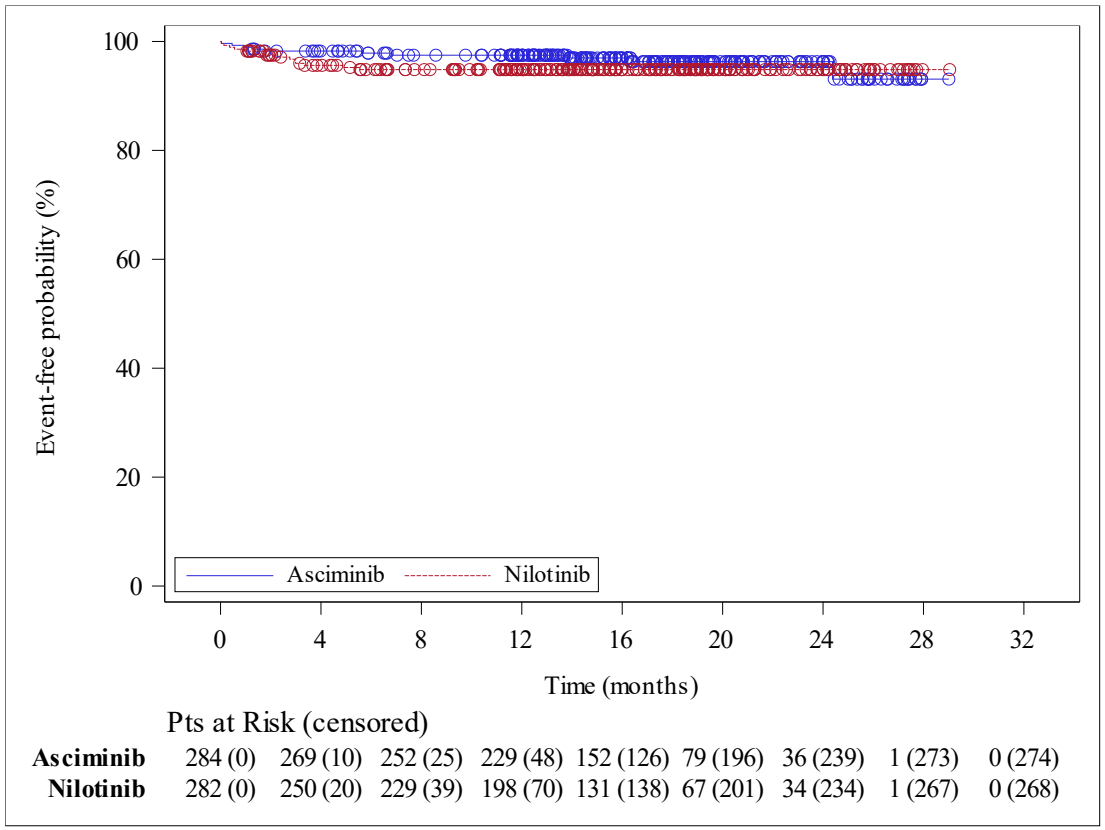
Low density lipoprotein increased



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

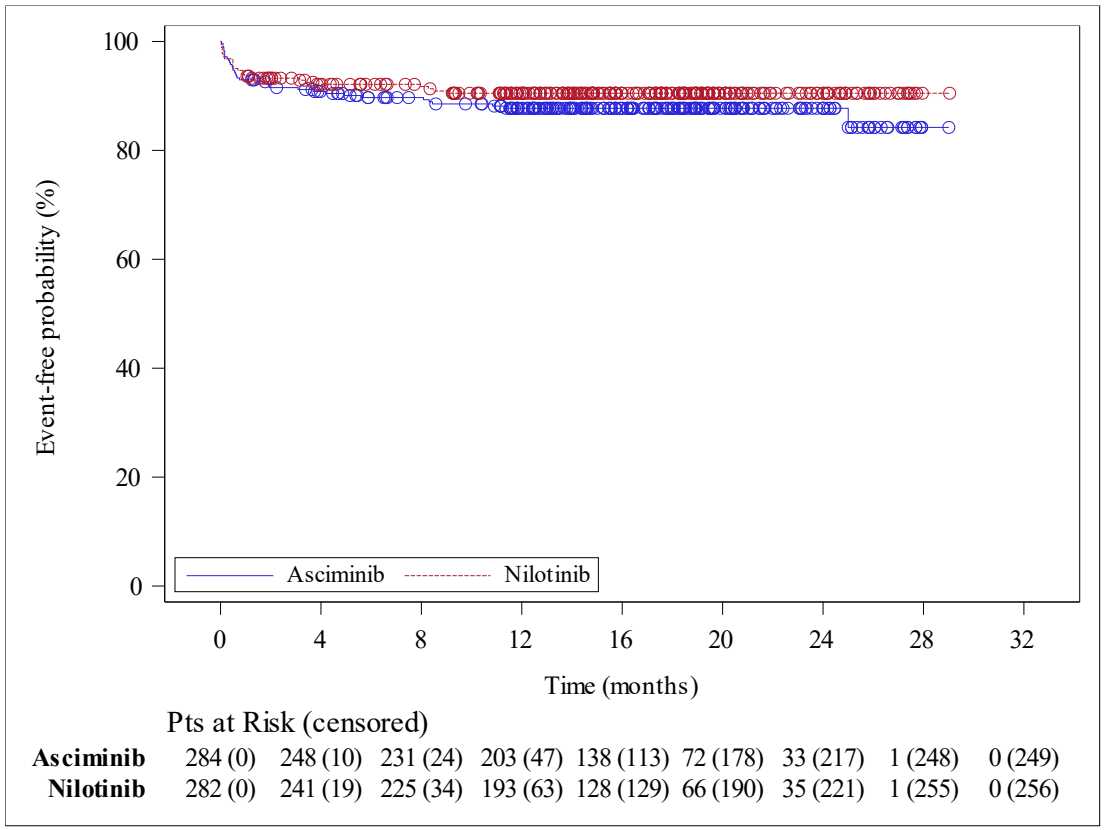
Muscle spasms



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

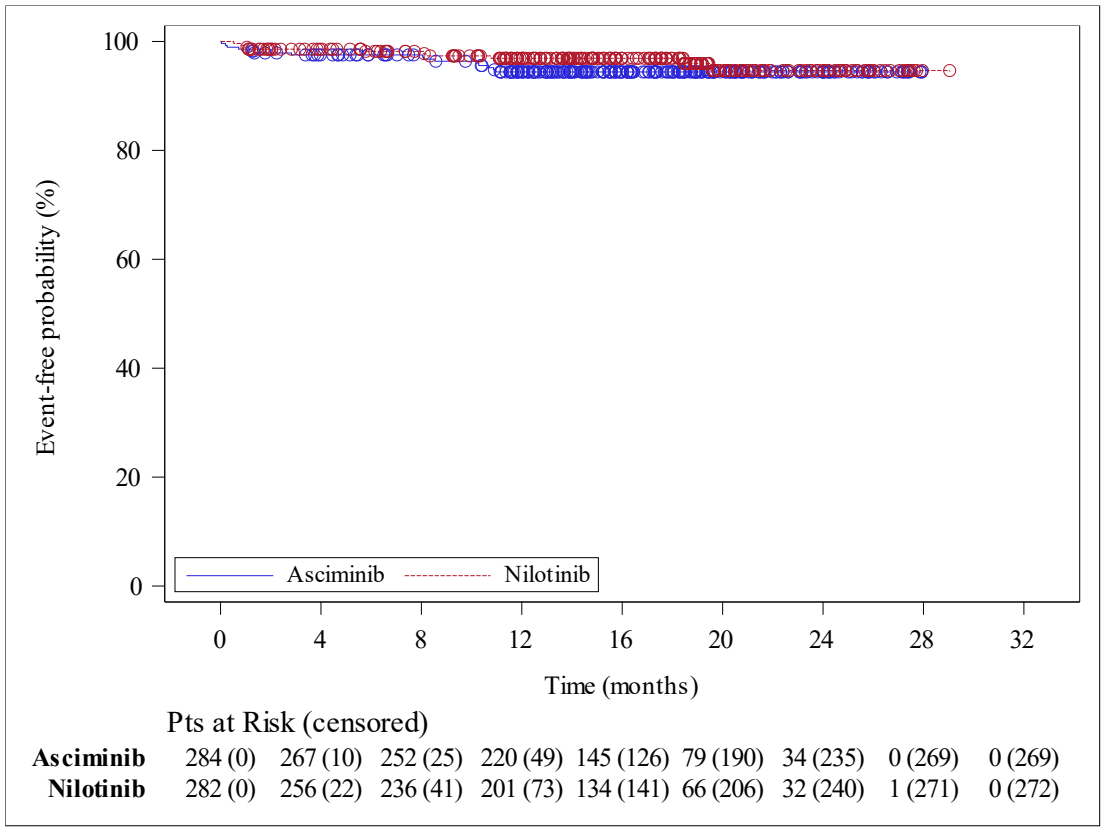
Myalgia



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

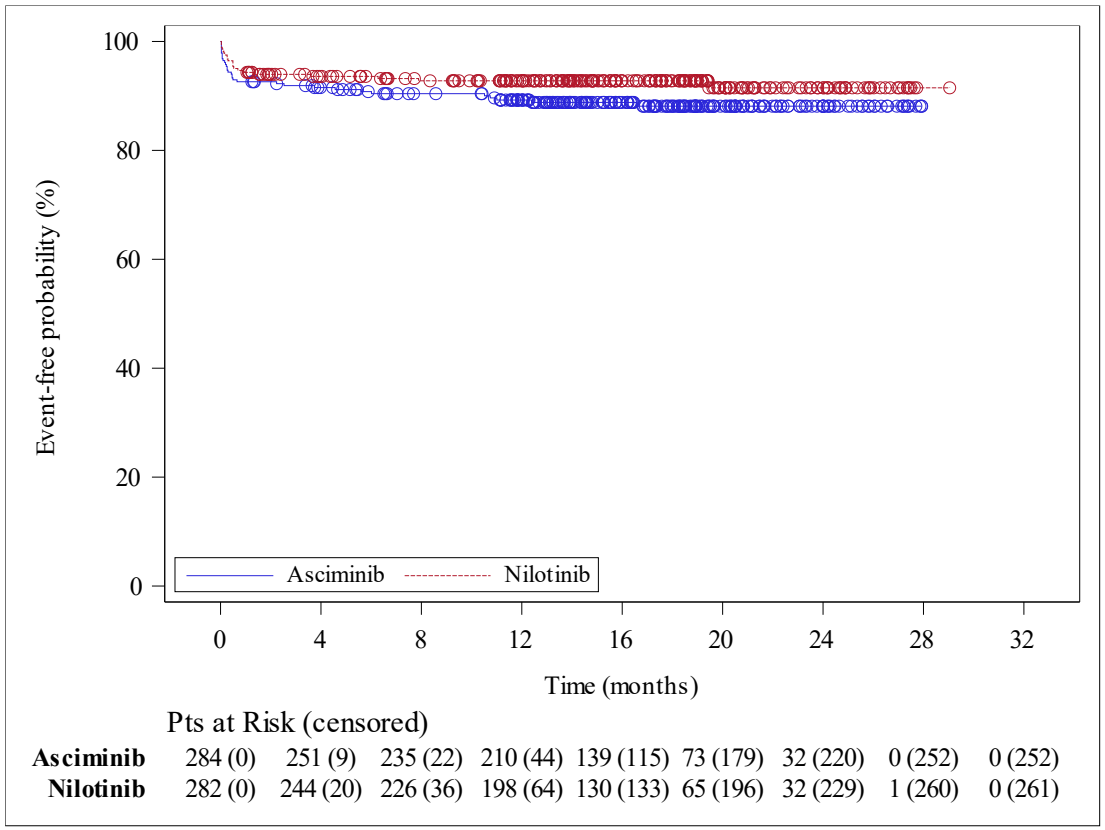
Nasopharyngitis



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

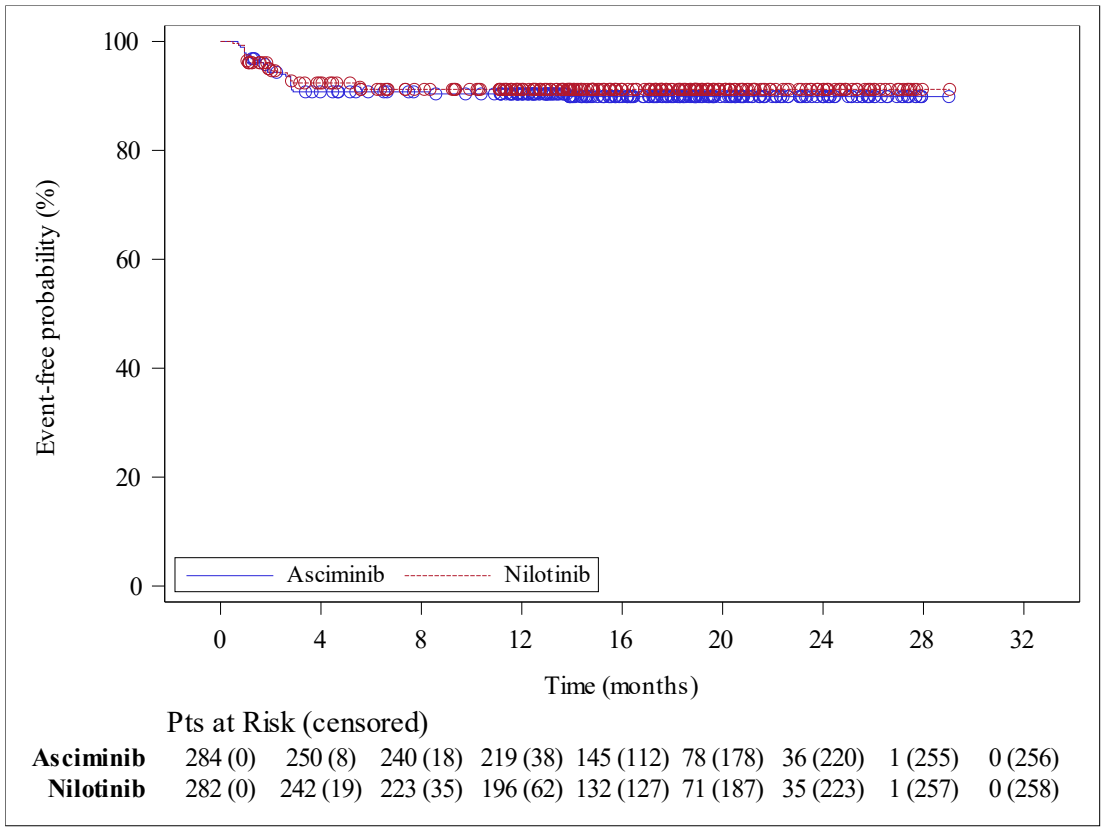
Nausea



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

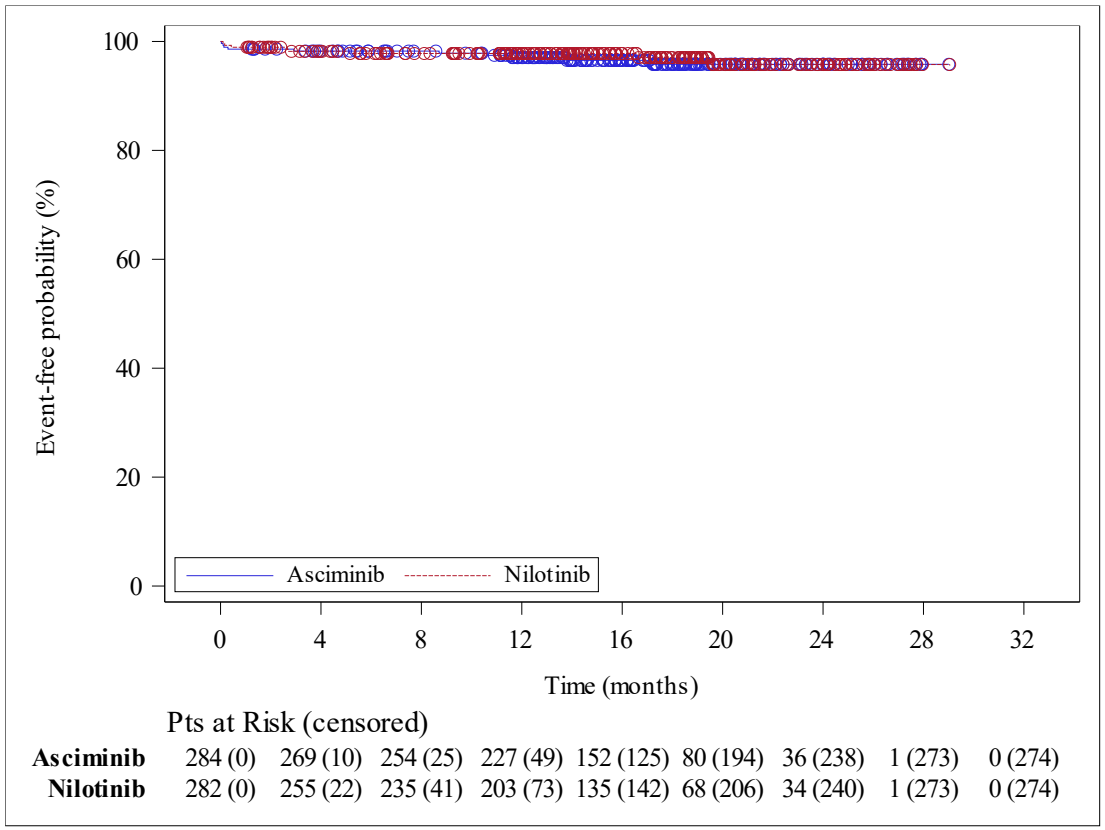
Neutropenia



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

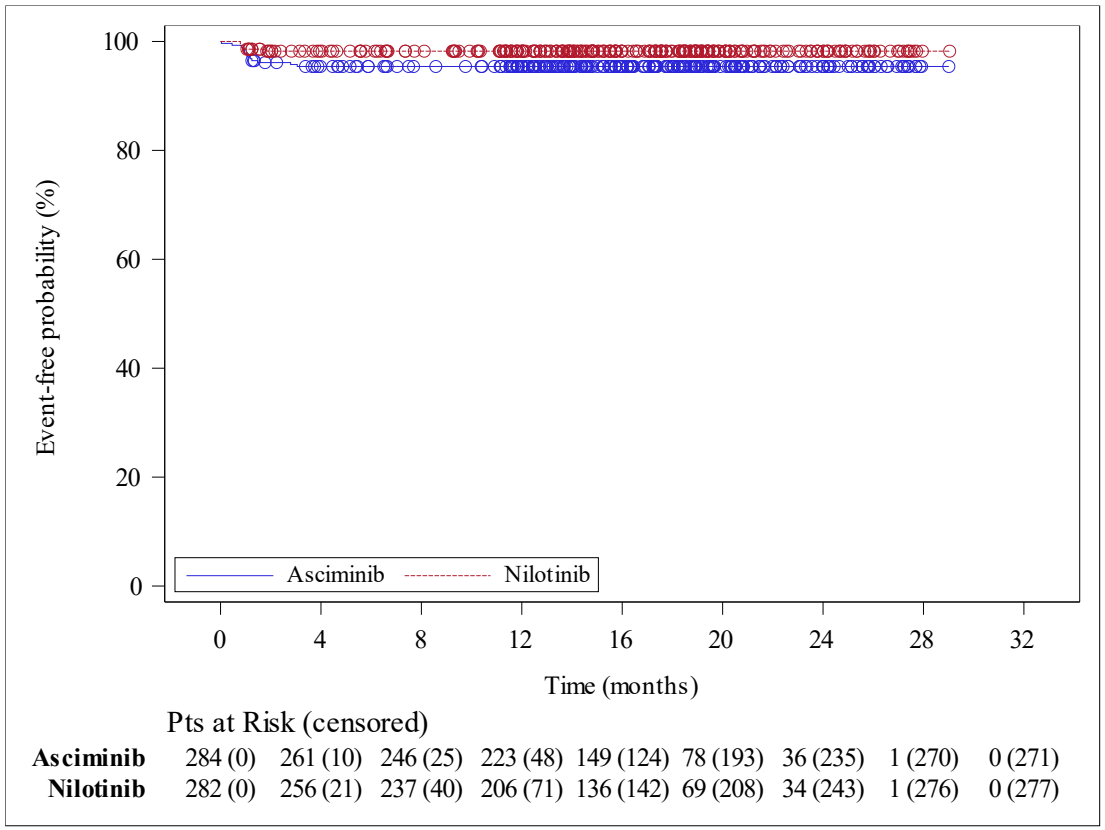
Pain in extremity



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

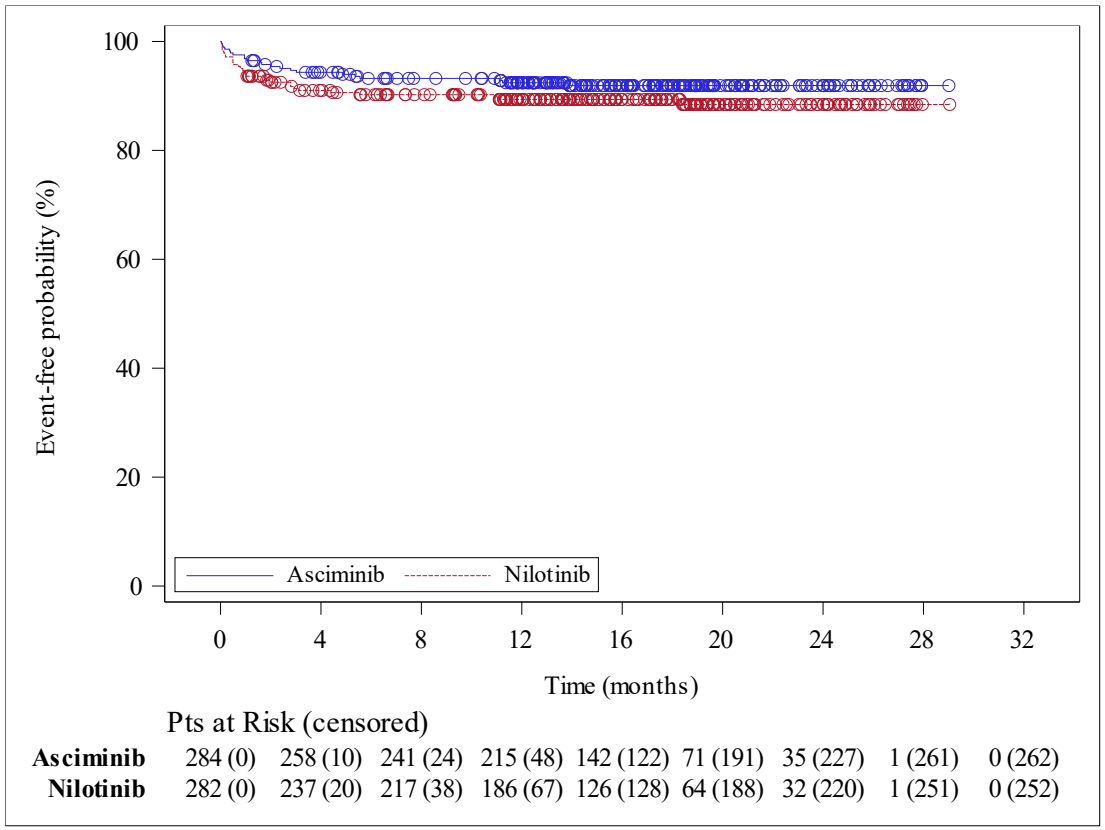
Platelet count decreased



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

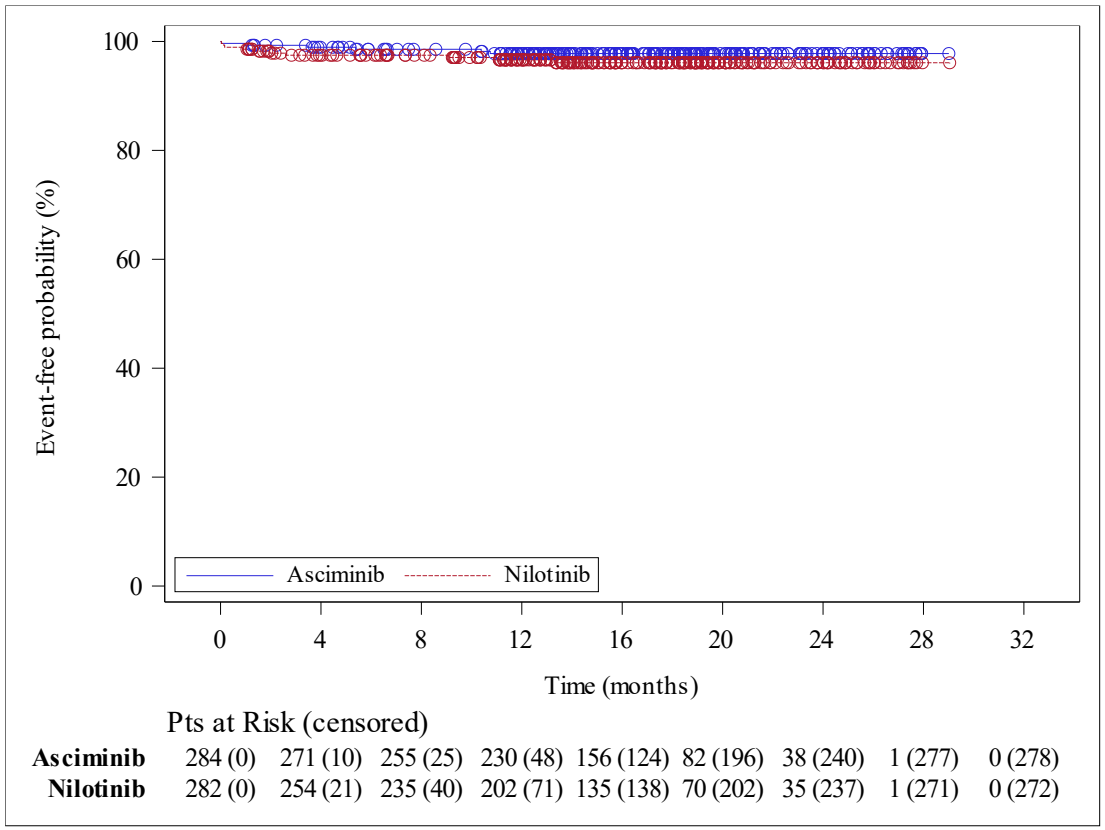
Pruritus



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

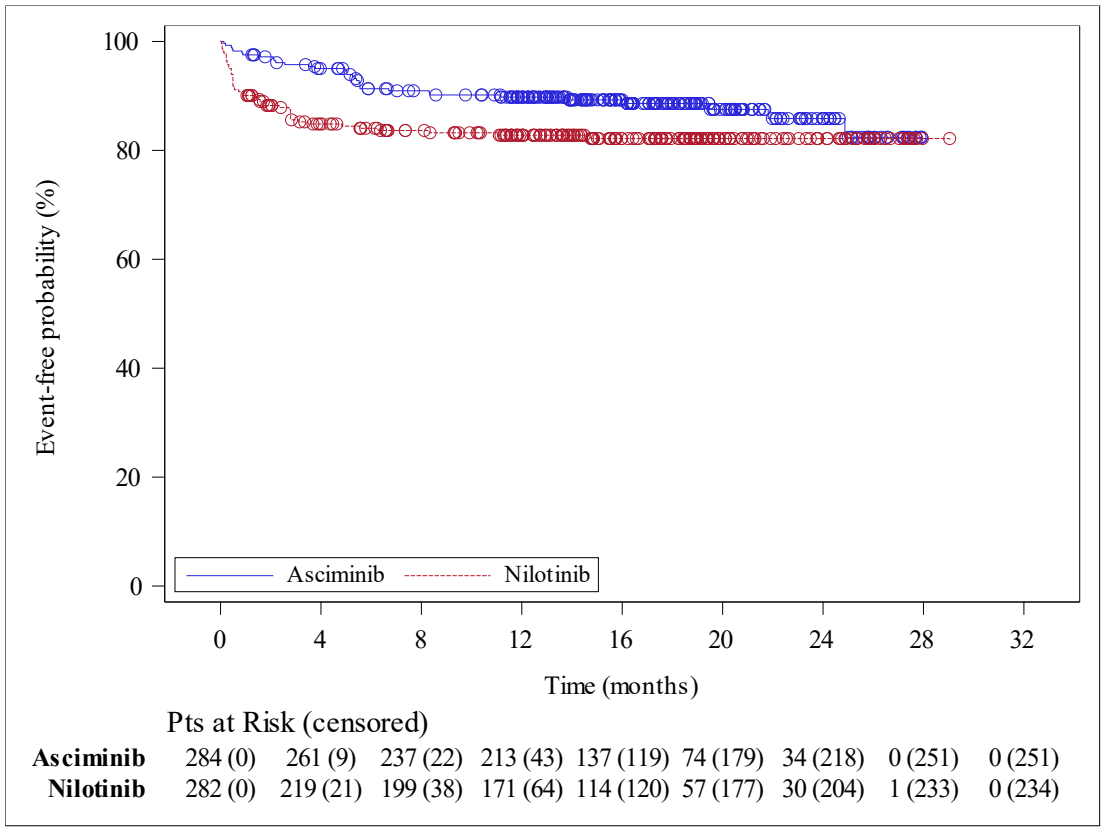
Pyrexia



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

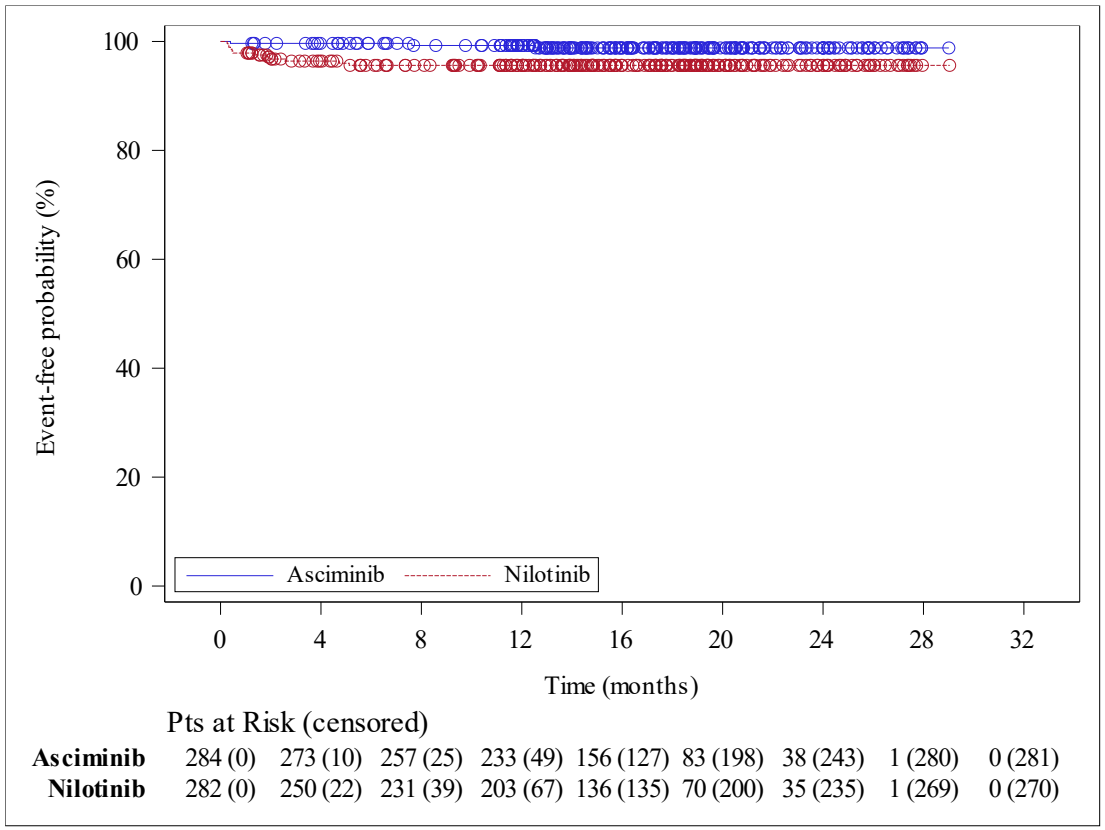
Rash



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

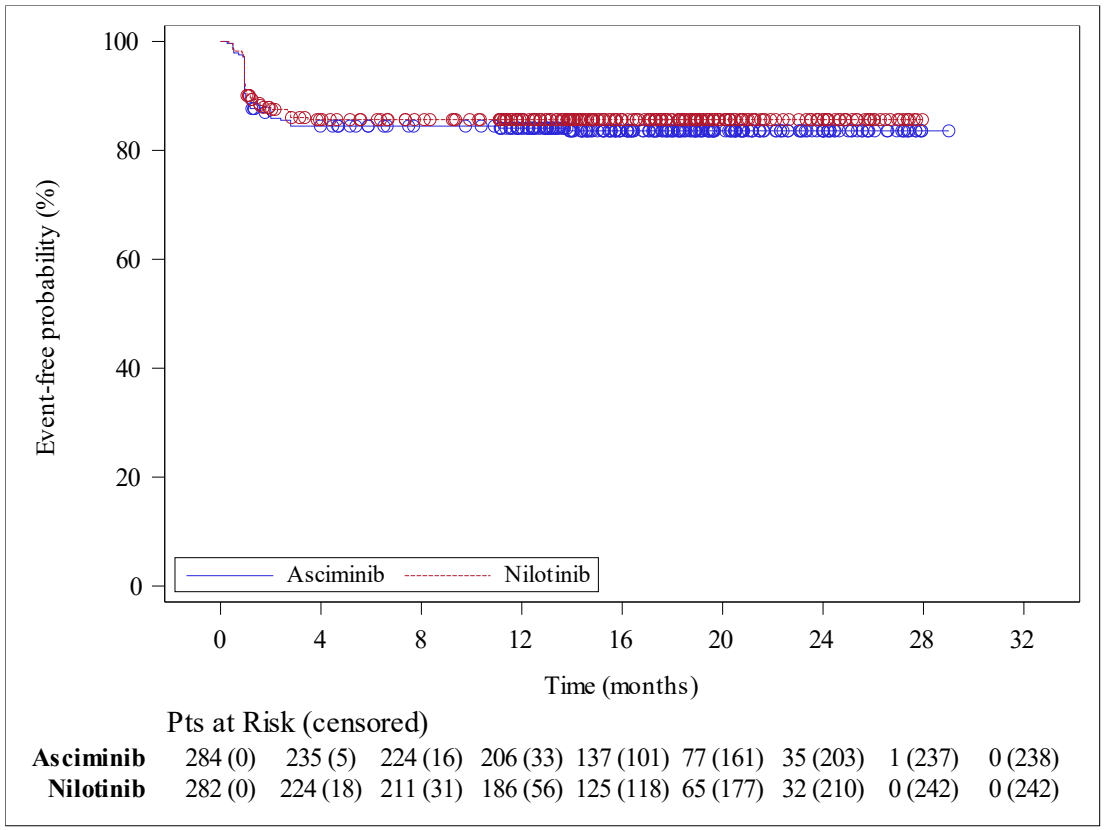
Rash maculo-papular



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

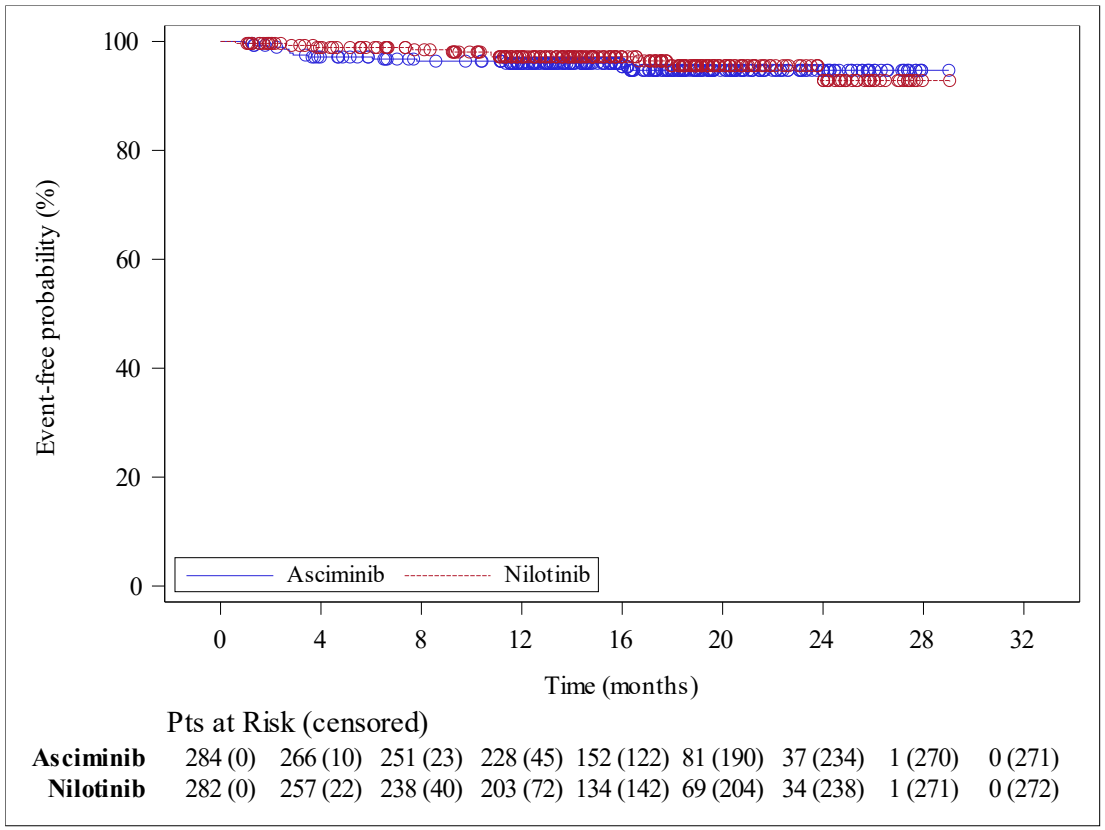
Thrombocytopenia



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

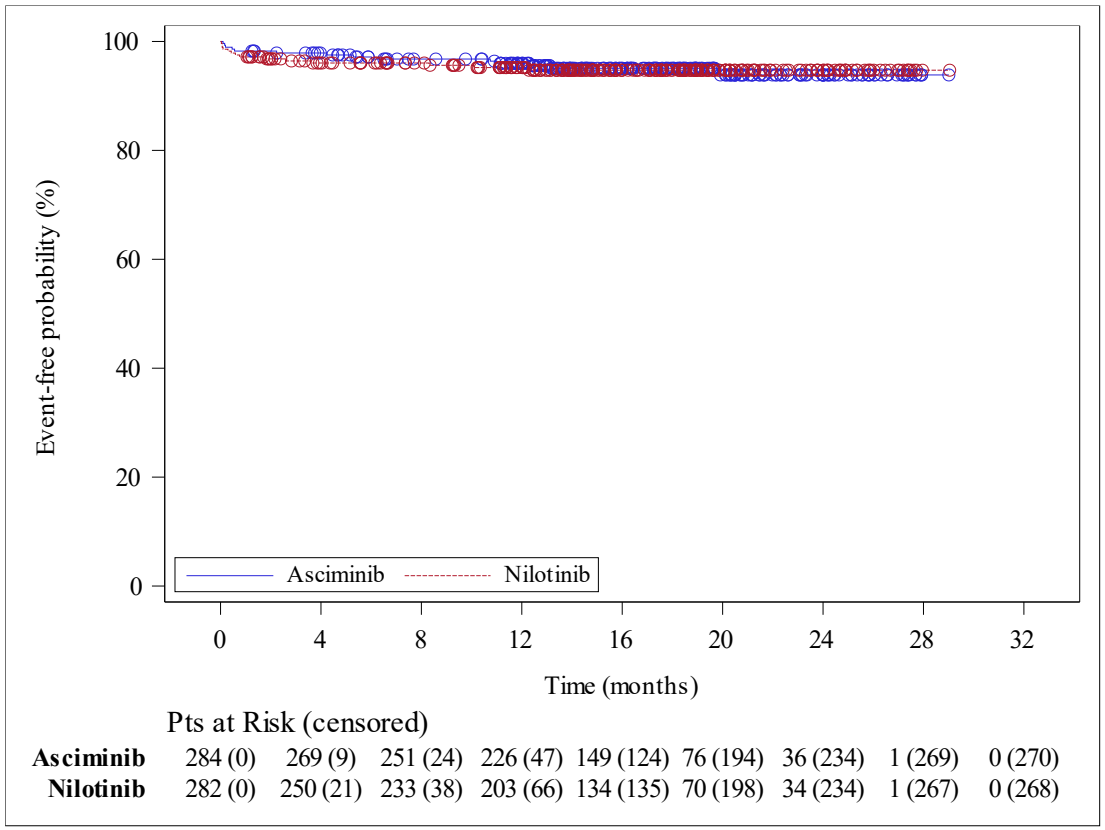
Upper respiratory tract infection



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

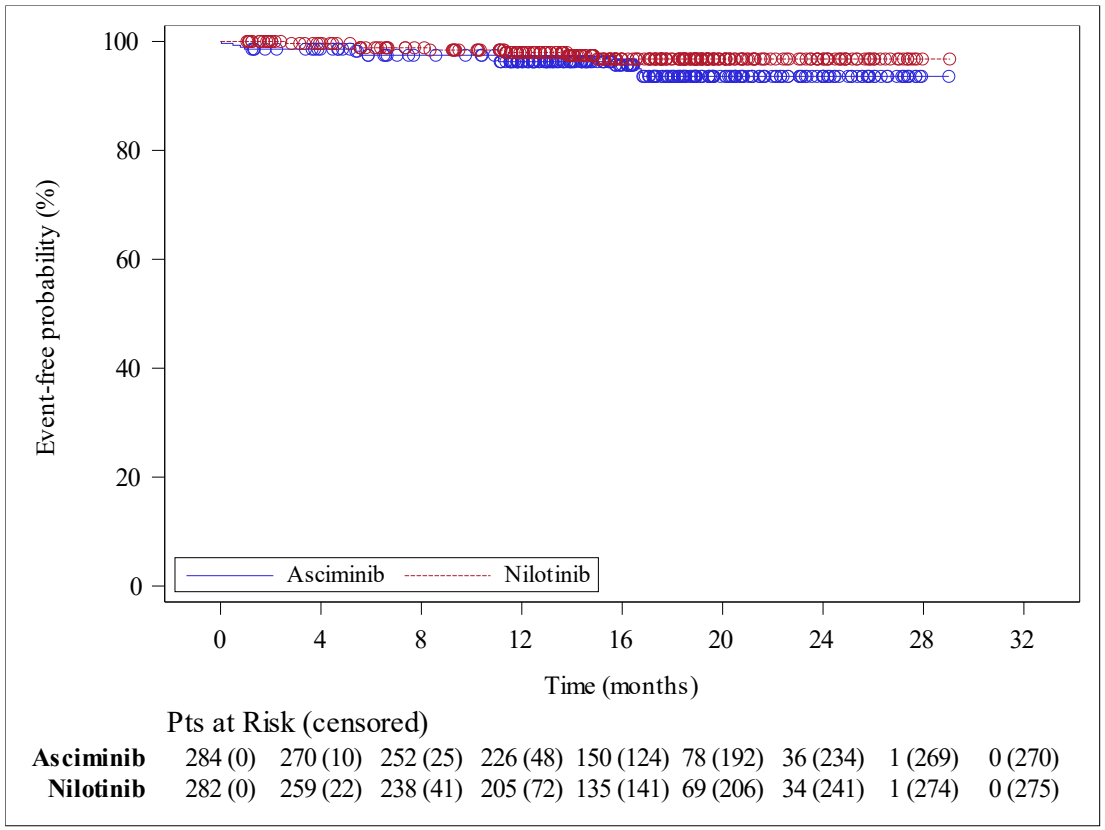
Vomiting



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.3 Any AE by PT: Kaplan-Meier plot (Safety Analysis Set)

Weight increased



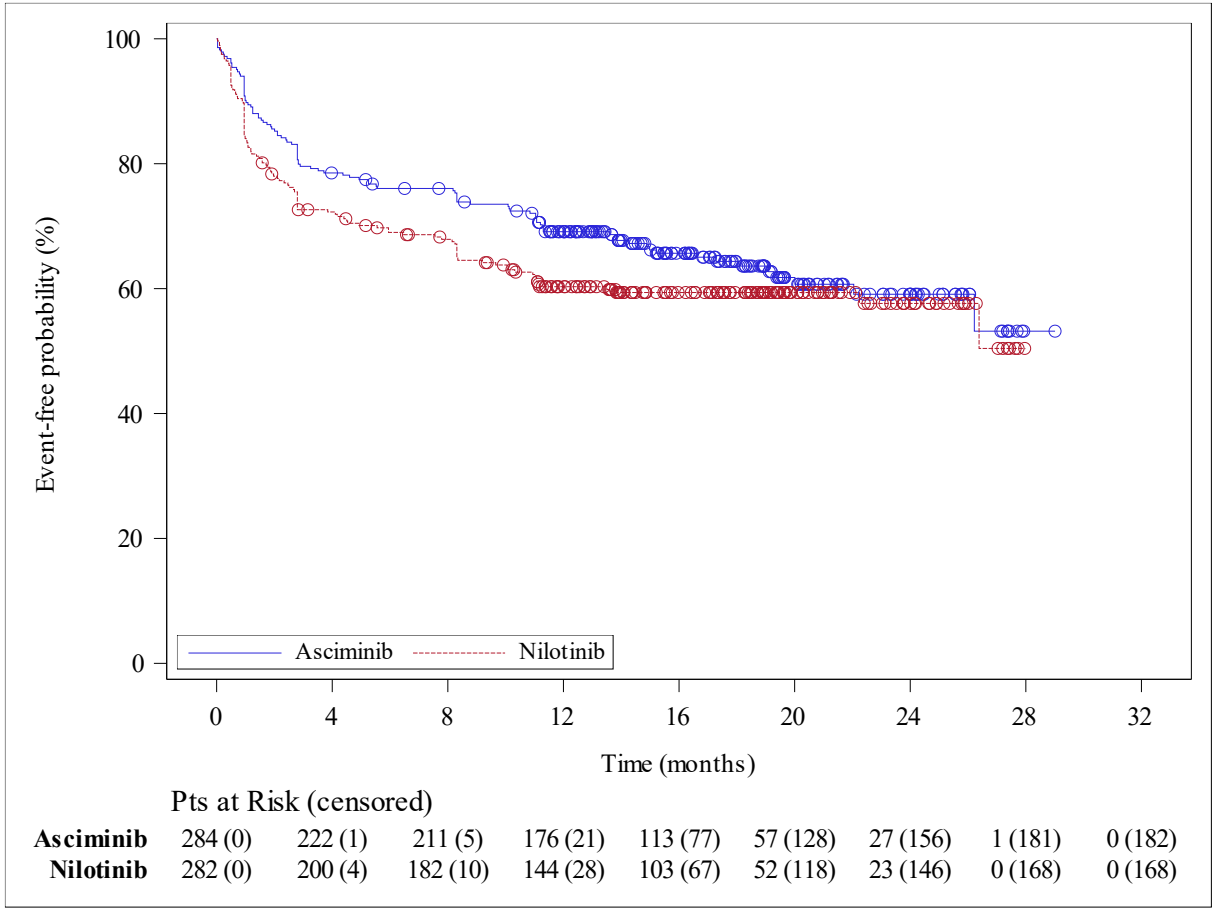
Note: o = Censored observations
Data Cut/15MAY2025

Table 4-1.4 AE with grade >=3: time to first occurrence (Safety Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
N*	284	282	0.81
Number of patients with events, n (%)	102 (35.9)	114 (40.4)	[0.62; 1.07]
			0.136
Percentiles (months) [95% CI]			
25th	8.3 [2.8; 11.3]	2.8 [1.6; 5.6]	
Median	N.E. [26.2; N.E.]	N.E. [26.4; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 4-1.4 AE with grade >=3: Kaplan-Meier plot (Safety Analysis Set)



Note: o = Censored observations
Data Cut/15MAY2025

Table 4-1.5 AE with grade>=3 by SOC: time to first occurrence (Safety Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Blood and lymphatic system disorders			
N*	284	282	1.14
Number of patients with events, n (%)	35 (12.3)	30 (10.6)	[0.70; 1.86]
			0.594
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Infections and infestations			
N*	284	282	1.90
Number of patients with events, n (%)	12 (4.2)	6 (2.1)	[0.71; 5.07]
			0.191
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

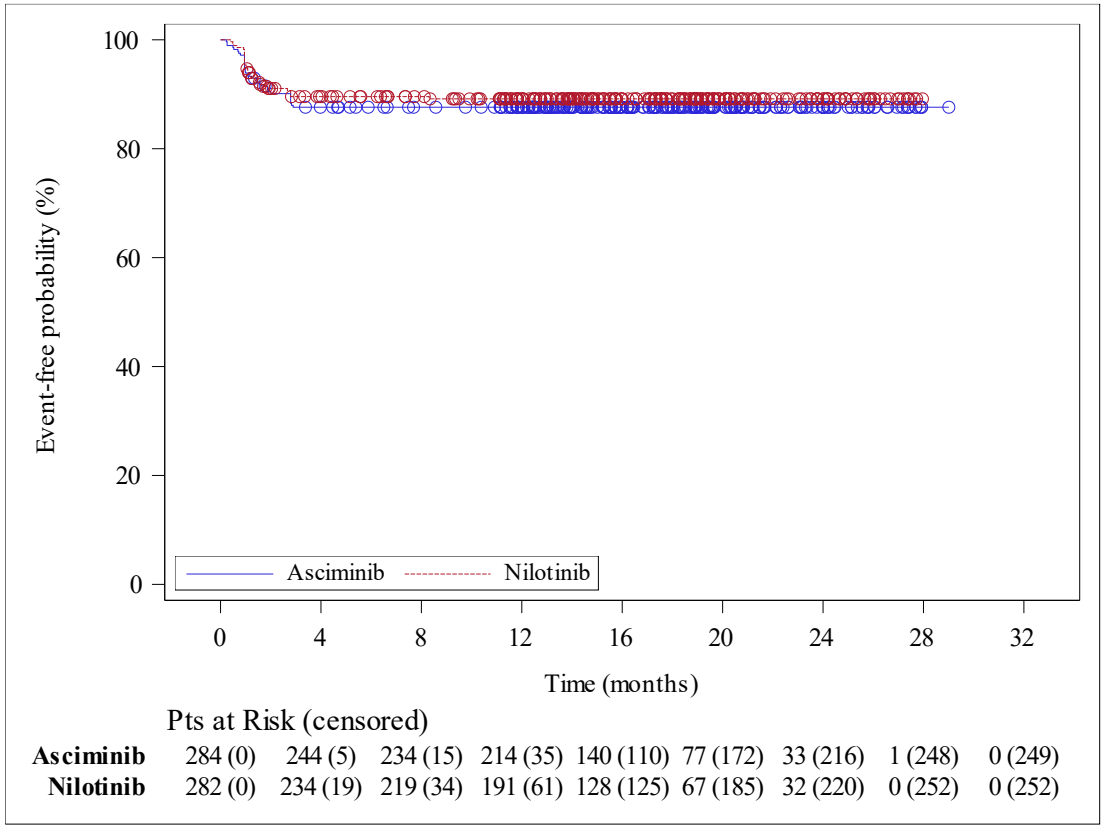
	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Investigations			
N*	284	282	0.40
Number of patients with events, n (%)	21 (7.4)	48 (17.0)	[0.24; 0.68]
			<0.001
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [22.2; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Vascular disorders			
N*	284	282	2.65
Number of patients with events, n (%)	17 (6.0)	6 (2.1)	[1.04; 6.72]
			0.033
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [26.4; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
SOC: System Organ Class
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factor ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 4-1.5 AE with grade>=3 by SOC: Kaplan-Meier plot (Safety Analysis Set)

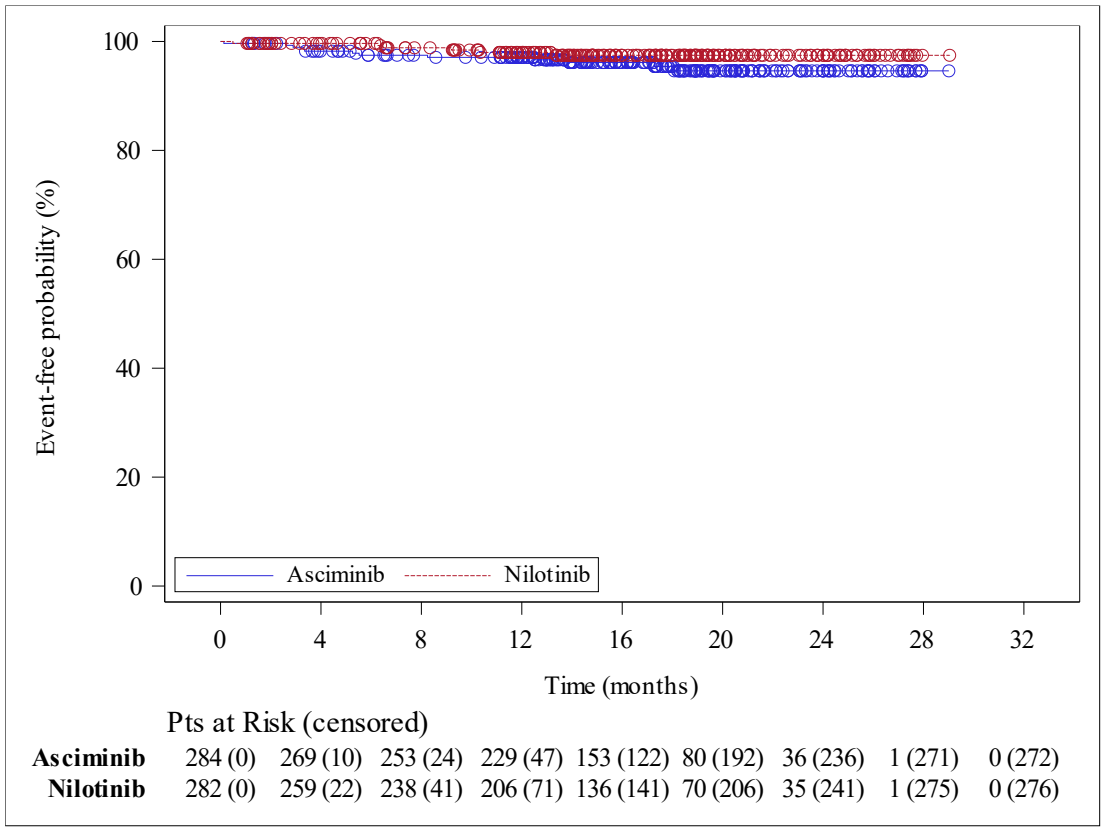
Blood and lymphatic system disorders



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.5 AE with grade>=3 by SOC: Kaplan-Meier plot (Safety Analysis Set)

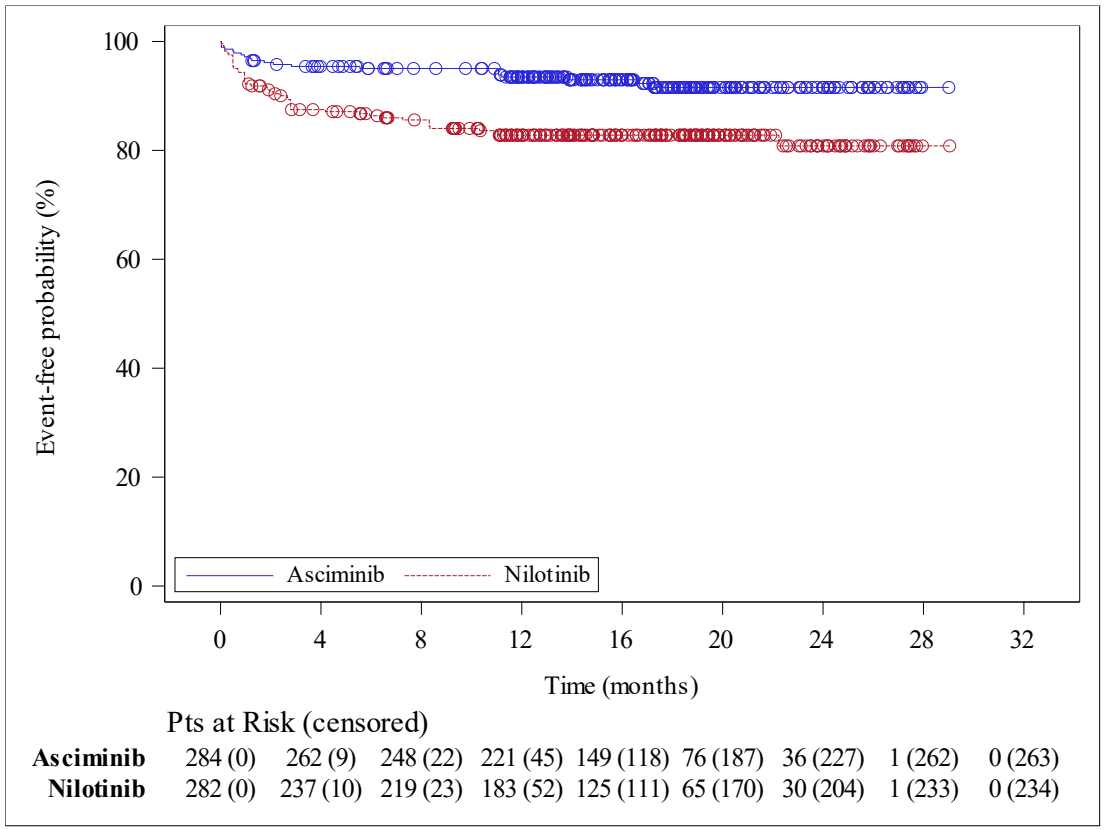
Infections and infestations



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.5 AE with grade>=3 by SOC: Kaplan-Meier plot (Safety Analysis Set)

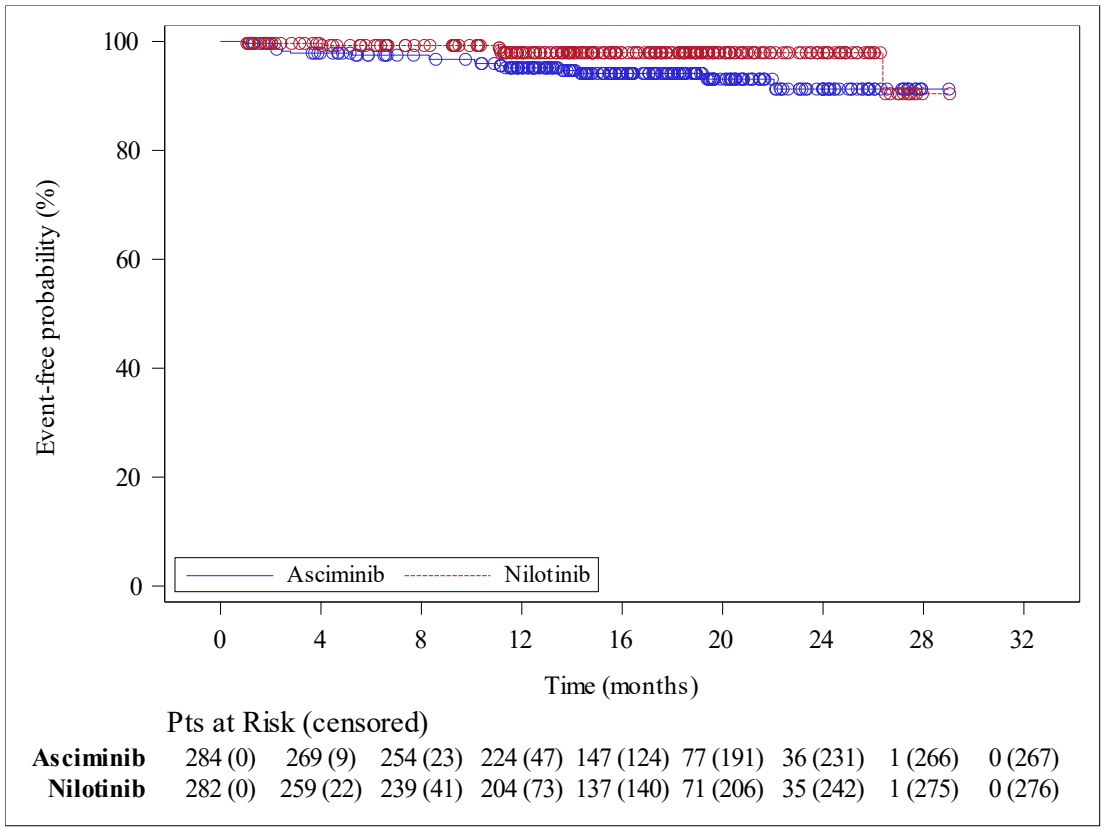
Investigations



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.5 AE with grade>=3 by SOC: Kaplan-Meier plot (Safety Analysis Set)

Vascular disorders



Note: o = Censored observations
Data Cut/15MAY2025

Table 4-1.6 AE with grade>=3 by PT: time to first occurrence (Safety Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Alanine aminotransferase increased			
N*	284	282	0.53
Number of patients with events, n (%)	6 (2.1)	11 (3.9)	[0.20; 1.44]
			0.206
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Anaemia			
N*	284	282	2.66
Number of patients with events, n (%)	11 (3.9)	4 (1.4)	[0.85; 8.37]
			0.081
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

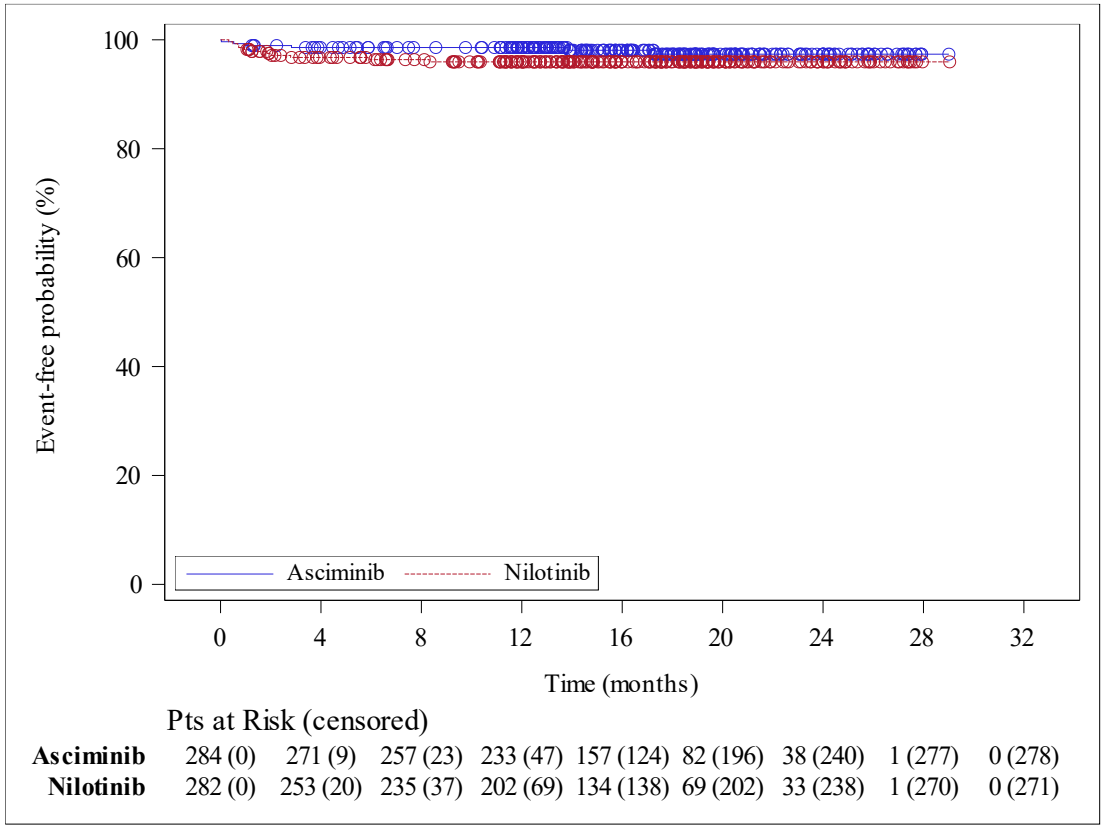
	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Hypertension			
N*	284	282	2.62
Number of patients with events, n (%)	14 (4.9)	5 (1.8)	[0.94; 7.28]
			0.055
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [26.5; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Neutropenia			
N*	284	282	1.12
Number of patients with events, n (%)	19 (6.7)	17 (6.0)	[0.58; 2.15]
			0.743
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Thrombocytopenia			

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
N*	284	282	1.26
Number of patients with events, n (%)	26 (9.2)	20 (7.1)	[0.70; 2.26]
			0.434
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
PT: Preferred Term
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 4-1.6 AE with grade>=3 by PT: Kaplan-Meier plot (Safety Analysis Set)

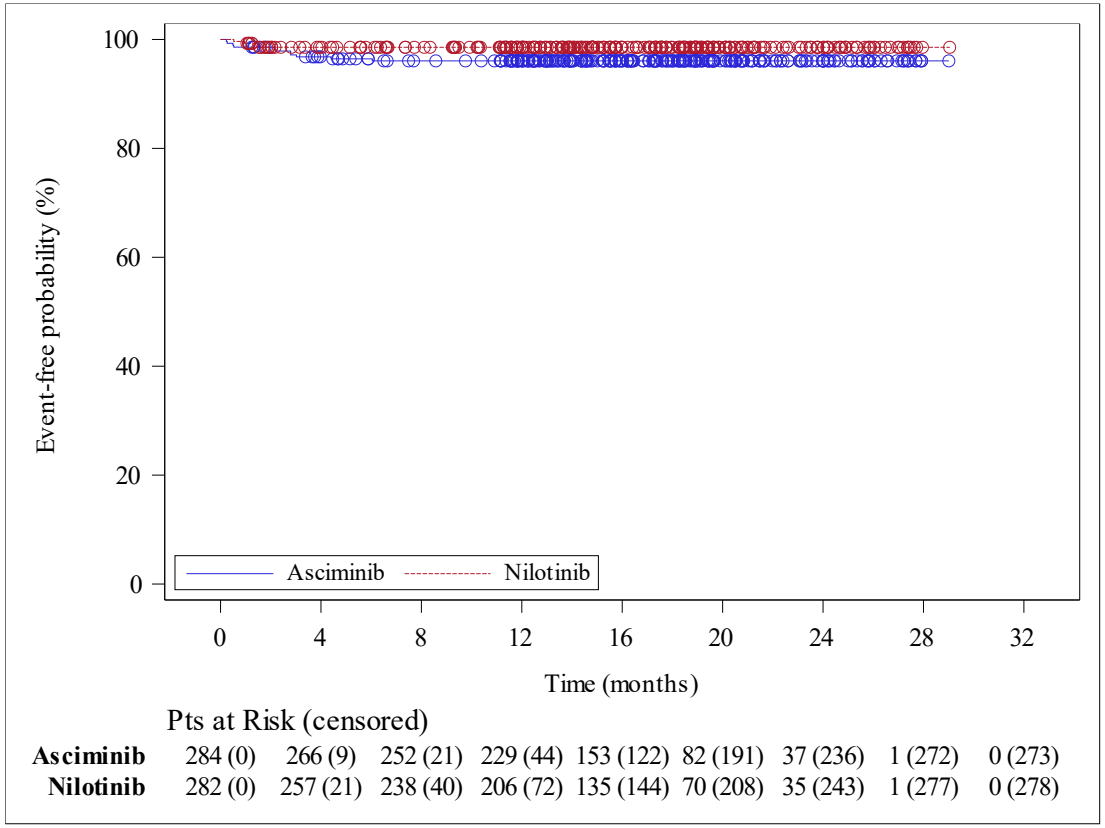
Alanine aminotransferase increased



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.6 AE with grade>=3 by PT: Kaplan-Meier plot (Safety Analysis Set)

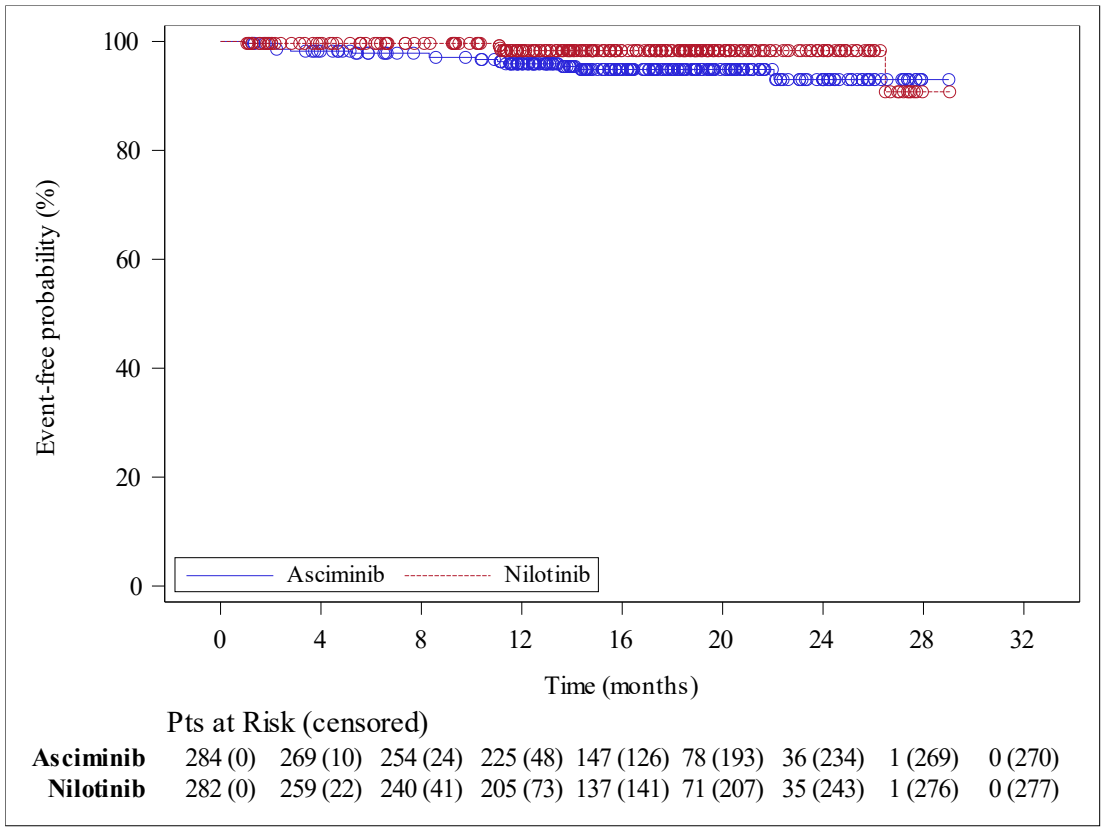
Anaemia



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.6 AE with grade>=3 by PT: Kaplan-Meier plot (Safety Analysis Set)

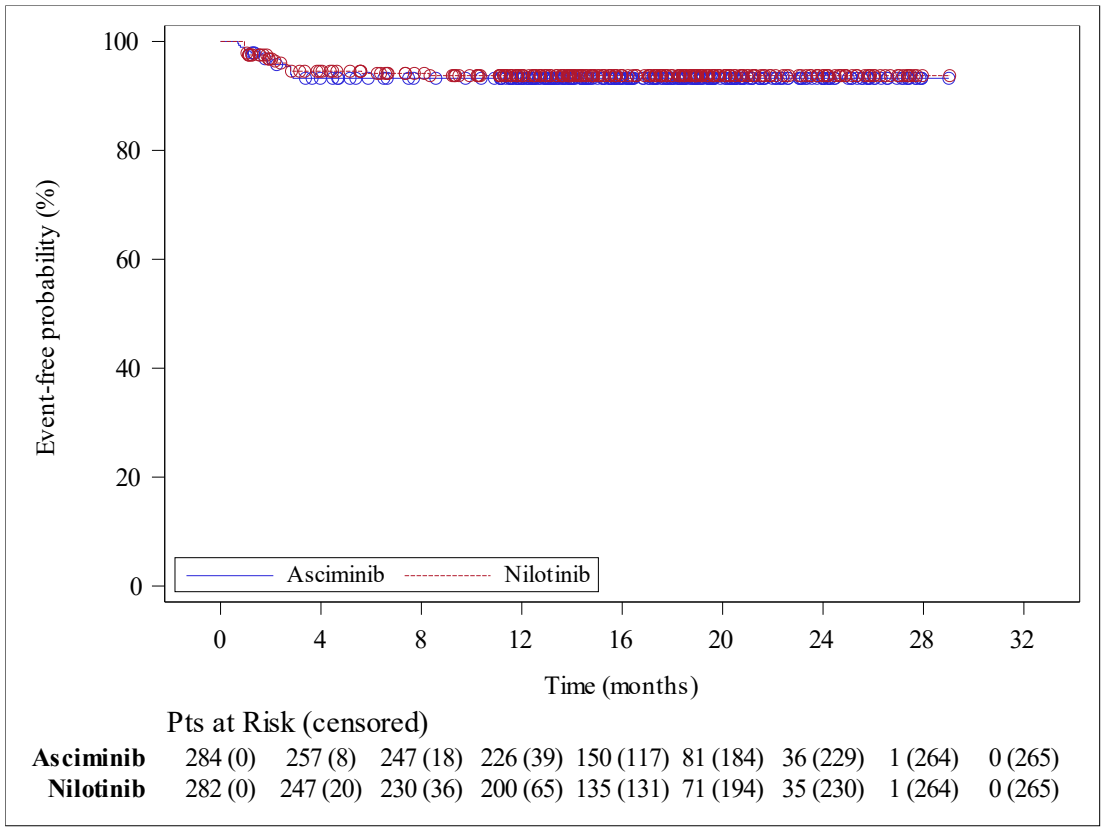
Hypertension



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.6 AE with grade>=3 by PT: Kaplan-Meier plot (Safety Analysis Set)

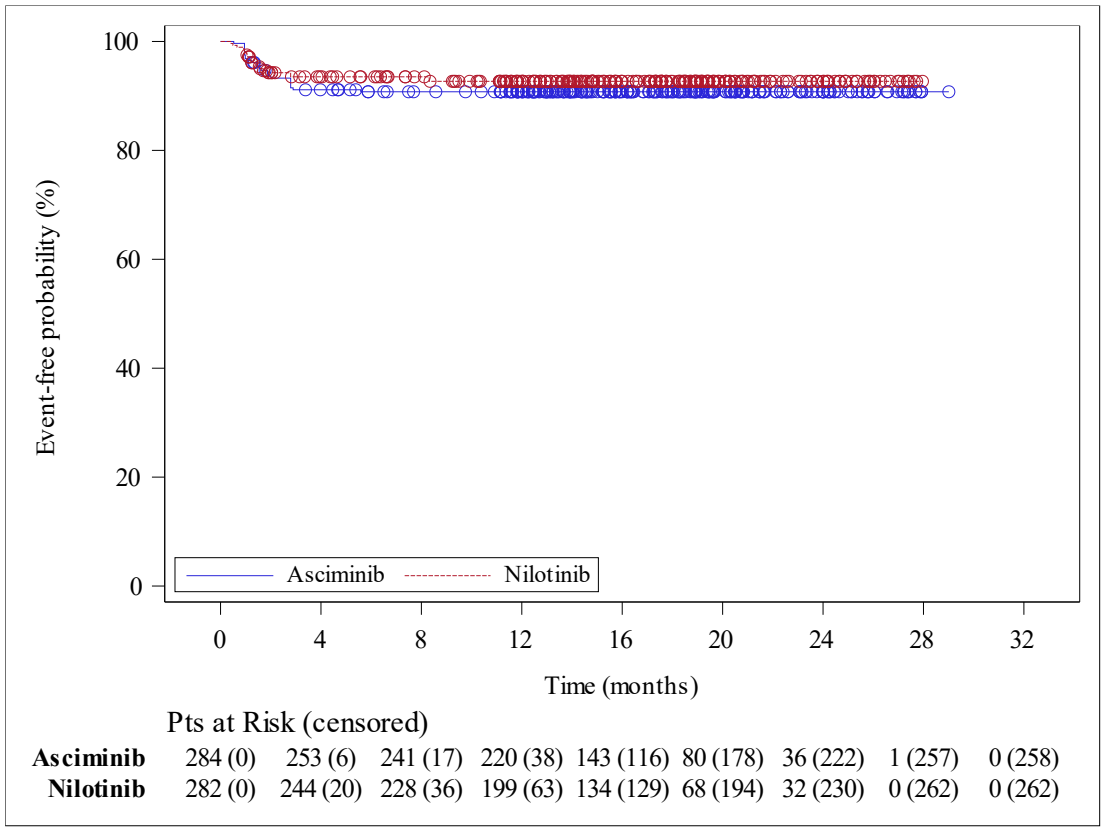
Neutropenia



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.6 AE with grade>=3 by PT: Kaplan-Meier plot (Safety Analysis Set)

Thrombocytopenia



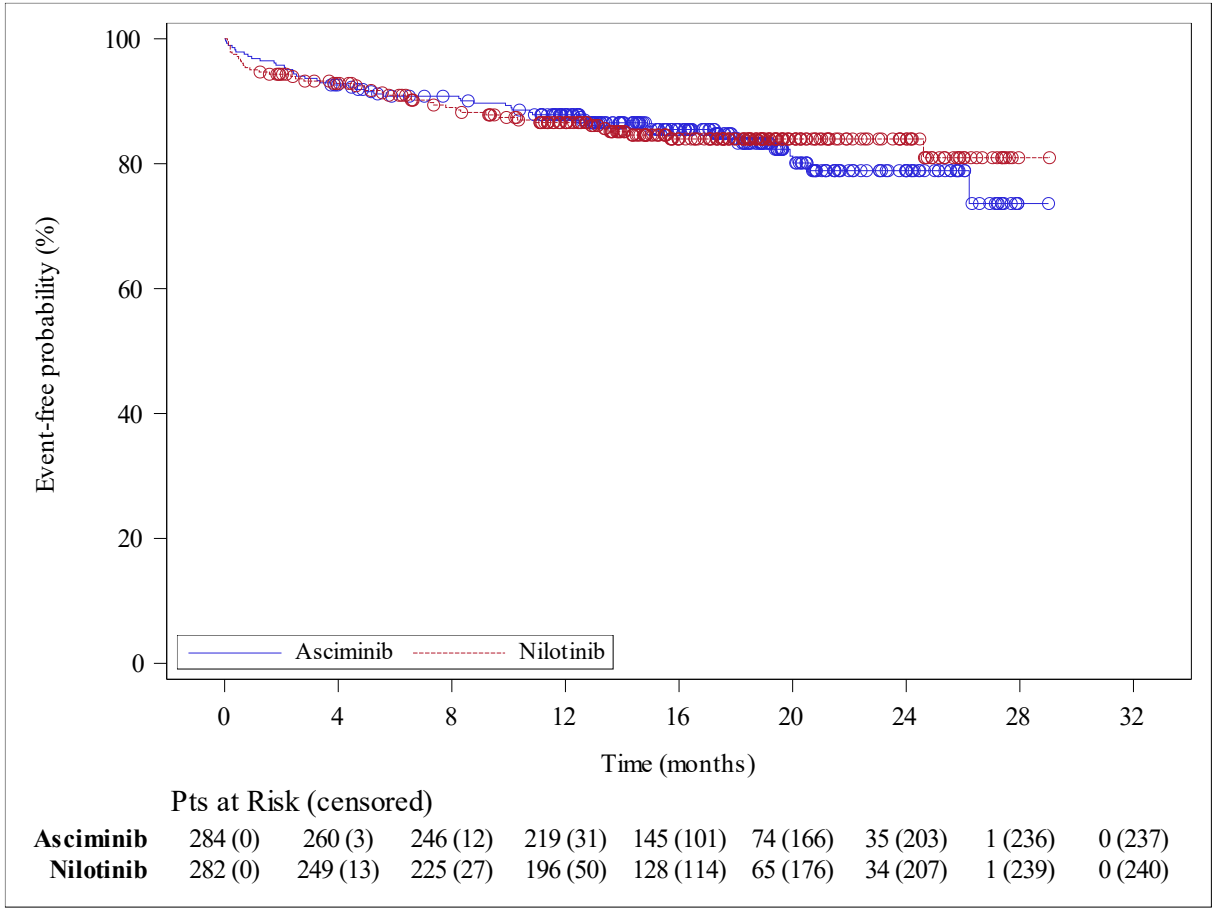
Note: o = Censored observations
Data Cut/15MAY2025

Table 4-1.7 Serious AE: time to first occurrence (Safety Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
N*	284	282	1.06
Number of patients with events, n (%)	47 (16.5)	42 (14.9)	[0.70; 1.61]
			0.773
Percentiles (months) [95% CI]			
25th	26.2 [19.9; N.E.]	N.E. [24.6; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 4-1.7 Serious AE: Kaplan-Meier plot (Safety Analysis Set)



Note: o = Censored observations
Data Cut/15MAY2025

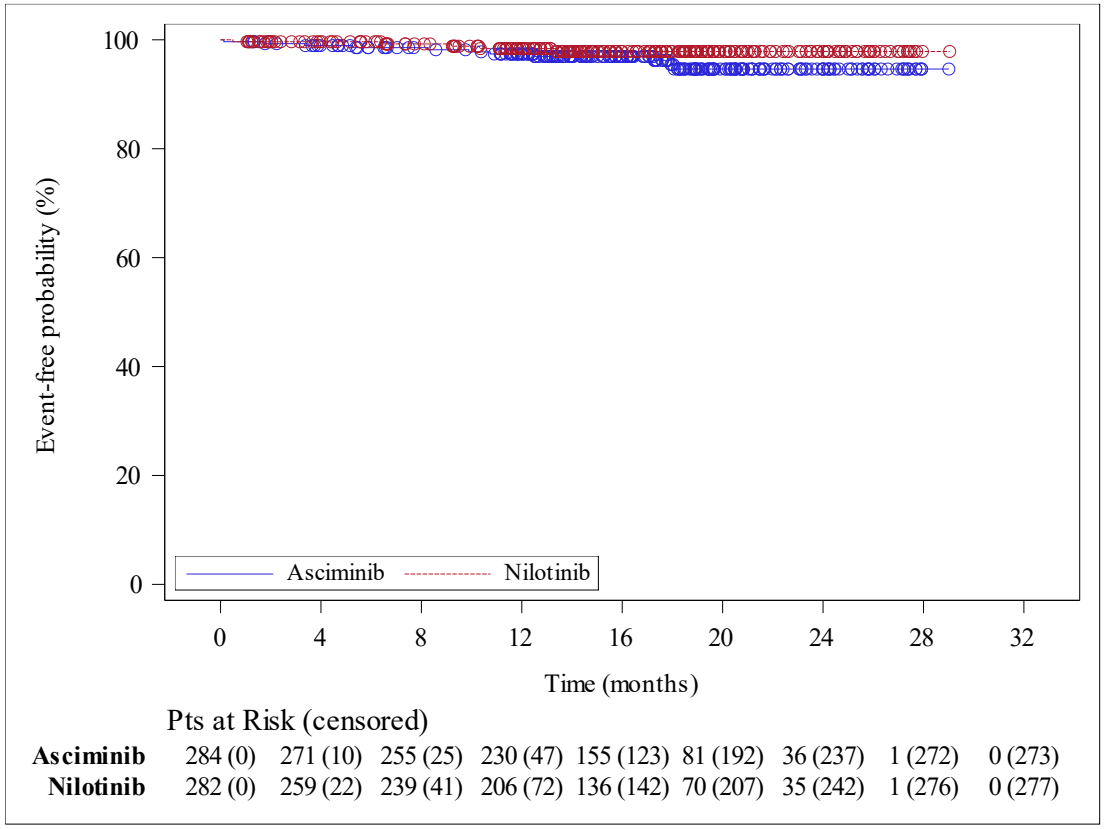
Table 4-1.8 Serious AE by SOC: time to first occurrence (Safety Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Infections and infestations			
N*	284	282	2.09
Number of patients with events, n (%)	11 (3.9)	5 (1.8)	[0.73; 6.01]
			0.162
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
SOC: System Organ Class
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factor ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 4-1.8 Serious AE by SOC: Kaplan-Meier plot (Safety Analysis Set)

Infections and infestations



Note: o = Censored observations
Data Cut/15MAY2025

Table 4-1.9 Serious AE by PT: time to first occurrence (Safety Analysis Set)

No analyses were performed, because there are not enough patients with an event.

.....
Data Cut/15MAY2025

Table 4-1.10 AESI all grades: time to first occurrence (Safety Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Acute pancreatitis (including isolated pancreatic enzyme elevations)			
N*	284	282	0.78
Number of patients with events, n (%)	33 (11.6)	40 (14.2)	[0.49; 1.24]
			0.289
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Acute pancreatitis (clinical events)			
N*	284	282	0.14
Number of patients with events, n (%)	1 (0.4)	7 (2.5)	[0.02; 1.13]
			0.031
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Arterial-occlusive events (AOE)			
N*	284	282	0.61
Number of patients with events, n (%)	7 (2.5)	10 (3.5)	[0.23; 1.61]
			0.318
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [26.4; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Cardiac failure			
N*	284	282	0.91
Number of patients with events, n (%)	1 (0.4)	1 (0.4)	[0.06; 14.59]
			0.949
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Edema and fluid retention			
N*	284	282	0.53
Number of patients with events, n (%)	10 (3.5)	18 (6.4)	[0.24; 1.15]
			0.103
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Gastrointestinal toxicity			
N*	284	282	1.11
Number of patients with events, n (%)	85 (29.9)	77 (27.3)	[0.81; 1.51]
			0.510
Percentiles (months) [95% CI]			
25th	10.2 [3.8; 16.6]	9.4 [3.8; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Hemorrhage			
N*	284	282	0.83
Number of patients with events, n (%)	17 (6.0)	19 (6.7)	[0.43; 1.61]
			0.586
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Hepatotoxicity (clinical events)			
N*	284	282	0.48
Number of patients with events, n (%)	7 (2.5)	14 (5.0)	[0.19; 1.18]
			0.100
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Hepatotoxicity (including laboratory terms)			
N*	284	282	0.35
Number of patients with events, n (%)	35 (12.3)	86 (30.5)	[0.23; 0.51]
			<0.001
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	8.3 [2.8; 11.1]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Hypersensitivity			
N*	284	282	0.54
Number of patients with events, n (%)	50 (17.6)	79 (28.0)	[0.38; 0.77]
			<0.001
Percentiles (months) [95% CI]			
25th	N.E. [21.8; N.E.]	5.6 [2.0; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Ischemic heart and CNS conditions			
N*	284	282	0.59
Number of patients with events, n (%)	11 (3.9)	17 (6.0)	[0.28; 1.27]
			0.174
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Ischemic CNS conditions			
N*	284	282	6.24
Number of patients with events, n (%)	3 (1.1)	0	[0.20; 191.4]
			0.102
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Ischemic heart conditions			
N*	284	282	0.43
Number of patients with events, n (%)	8 (2.8)	17 (6.0)	[0.19; 1.01]
			0.045
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Myelosuppression			
N*	284	282	1.11
Number of patients with events, n (%)	78 (27.5)	69 (24.5)	[0.80; 1.54]
			0.513
Percentiles (months) [95% CI]			
25th	2.8 [1.1; N.E.]	N.E. [1.2; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Myelosuppression (Erythropenia)			
N*	284	282	1.01
Number of patients with events, n (%)	26 (9.2)	25 (8.9)	[0.58; 1.75]
			0.982
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Myelosuppression (Leukopenia)			
N*	284	282	1.24
Number of patients with events, n (%)	44 (15.5)	35 (12.4)	[0.79; 1.93]
			0.341
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Myelosuppression (Thrombocytopenia)			
N*	284	282	1.30
Number of patients with events, n (%)	58 (20.4)	45 (16.0)	[0.88; 1.91]
			0.192
Percentiles (months) [95% CI]			
25th	N.E. [11.1; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Phototoxicity			
N*	284	282	0.99
Number of patients with events, n (%)	2 (0.7)	2 (0.7)	[0.14; 7.02]
			0.991
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

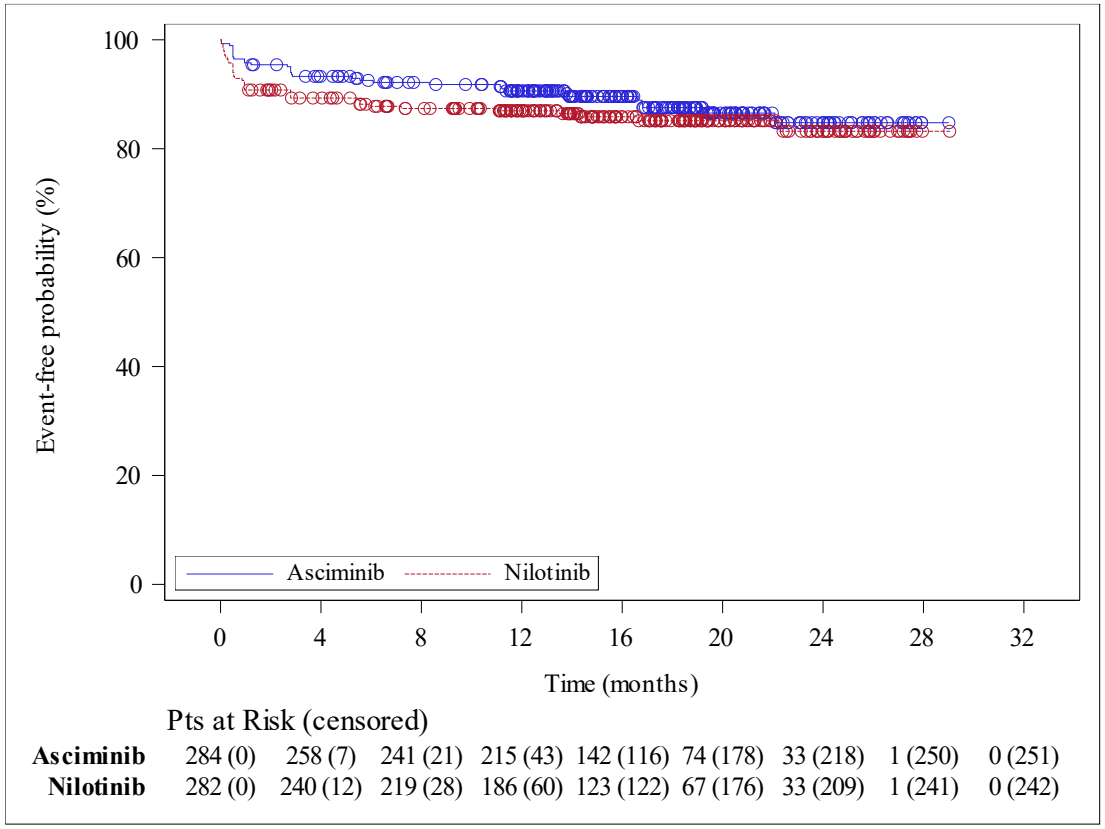
	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
QTc prolongation			
N*	284	282	0.80
Number of patients with events, n (%)	5 (1.8)	6 (2.1)	[0.24; 2.62]
			0.709
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Reproductive toxicity			
N*	284	282	0.24
Number of patients with events, n (%)	1 (0.4)	4 (1.4)	[0.03; 2.18]
			0.171
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 4-1.10 AESI all grades: Kaplan-Meier plot (Safety Analysis Set)

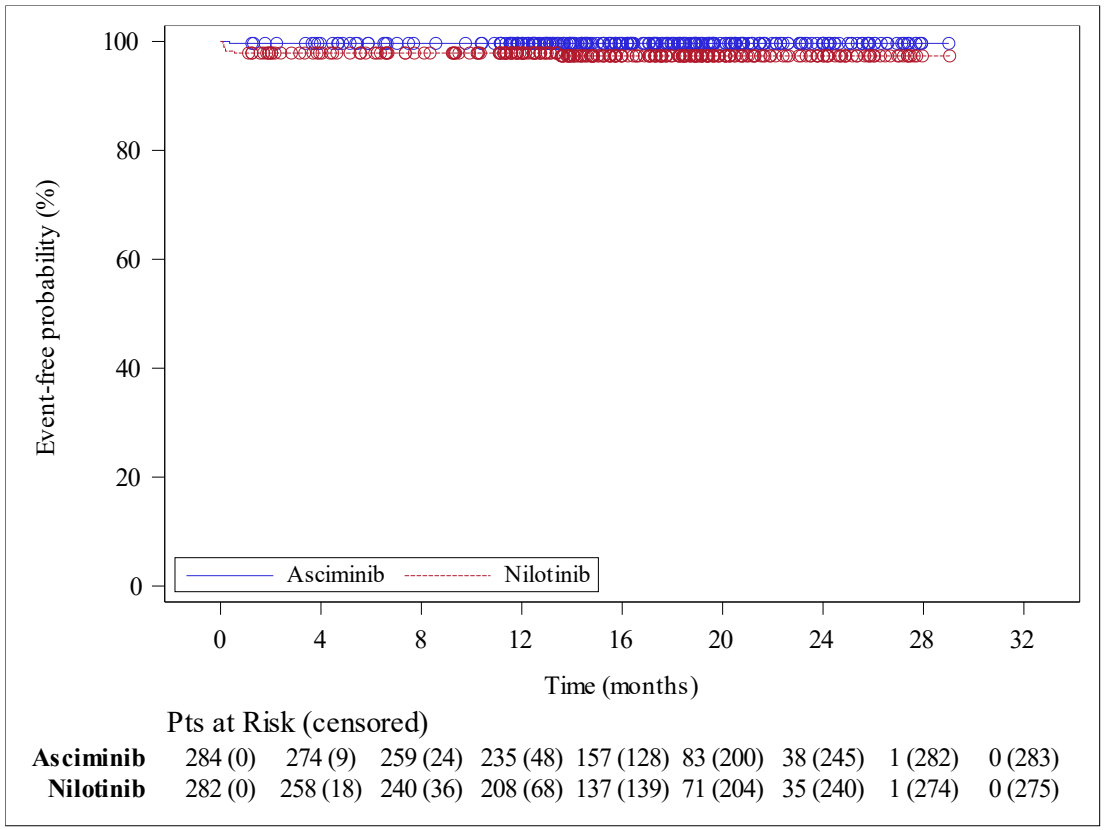
Acute pancreatitis (including isolated pancreatic enzyme elevations)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.10 AESI all grades: Kaplan-Meier plot (Safety Analysis Set)

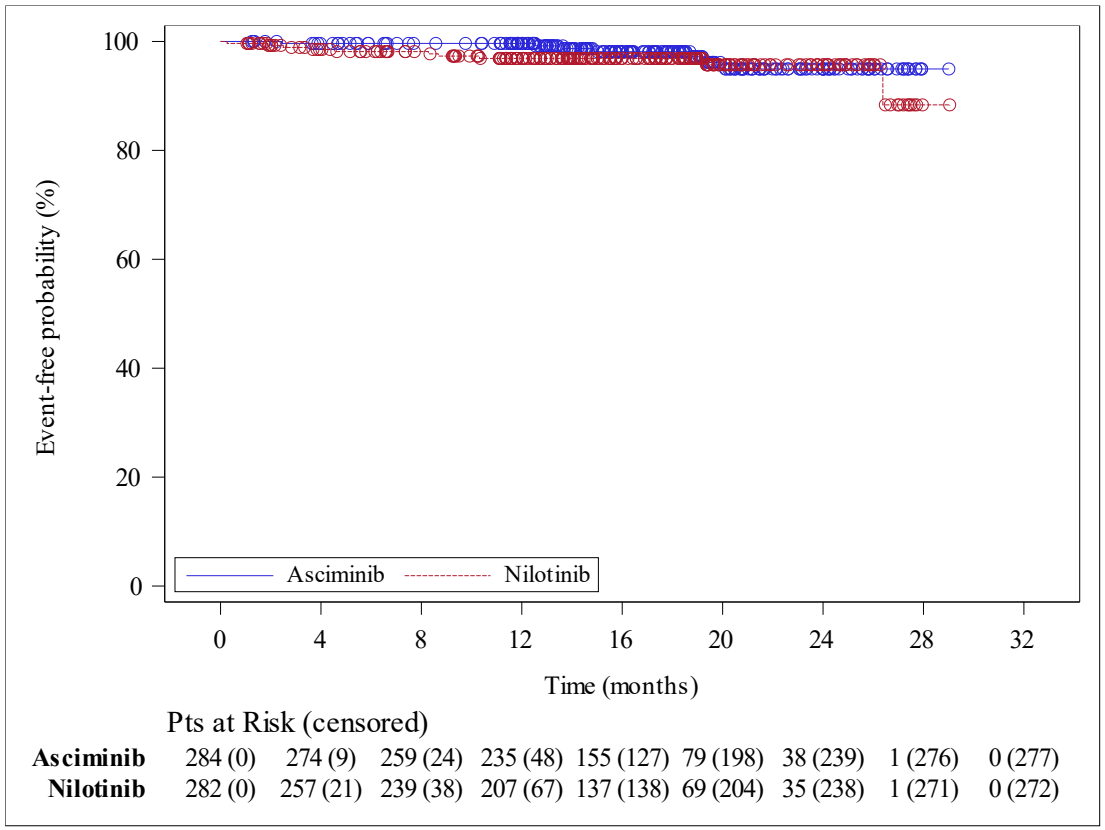
Acute pancreatitis (clinical events)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.10 AESI all grades: Kaplan-Meier plot (Safety Analysis Set)

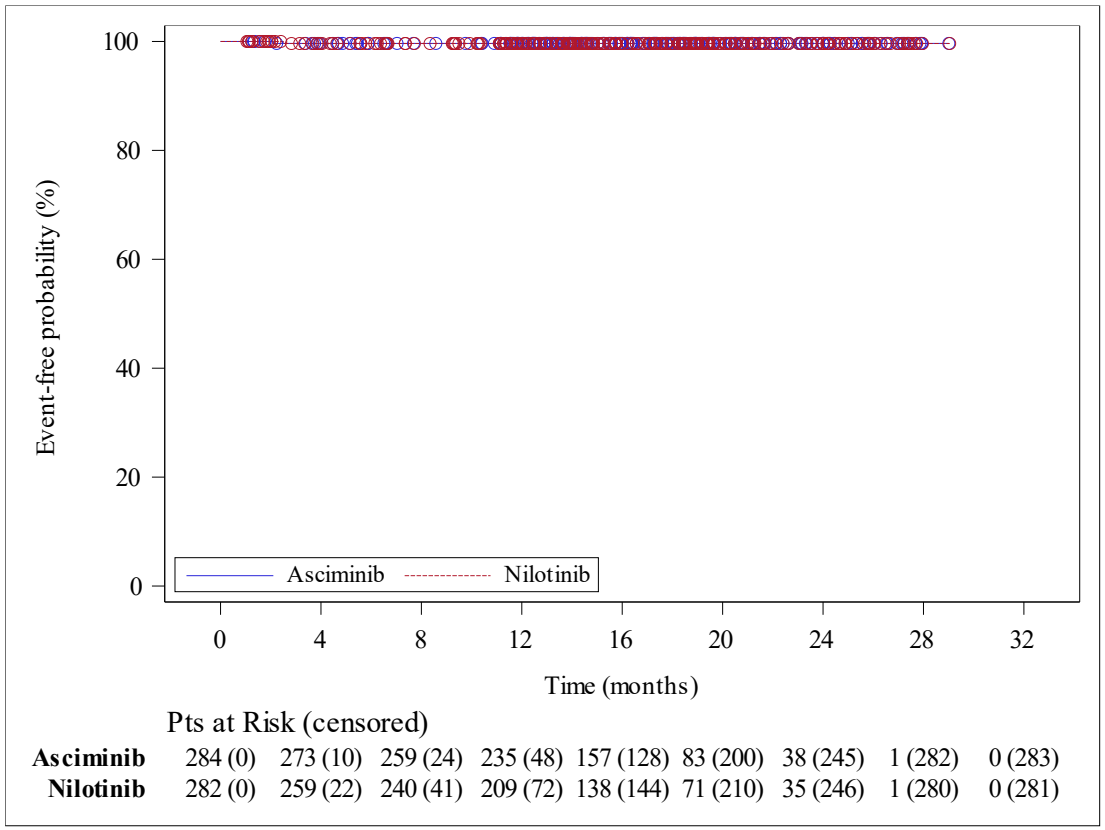
Arterial-occlusive events (AOE)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.10 AESI all grades: Kaplan-Meier plot (Safety Analysis Set)

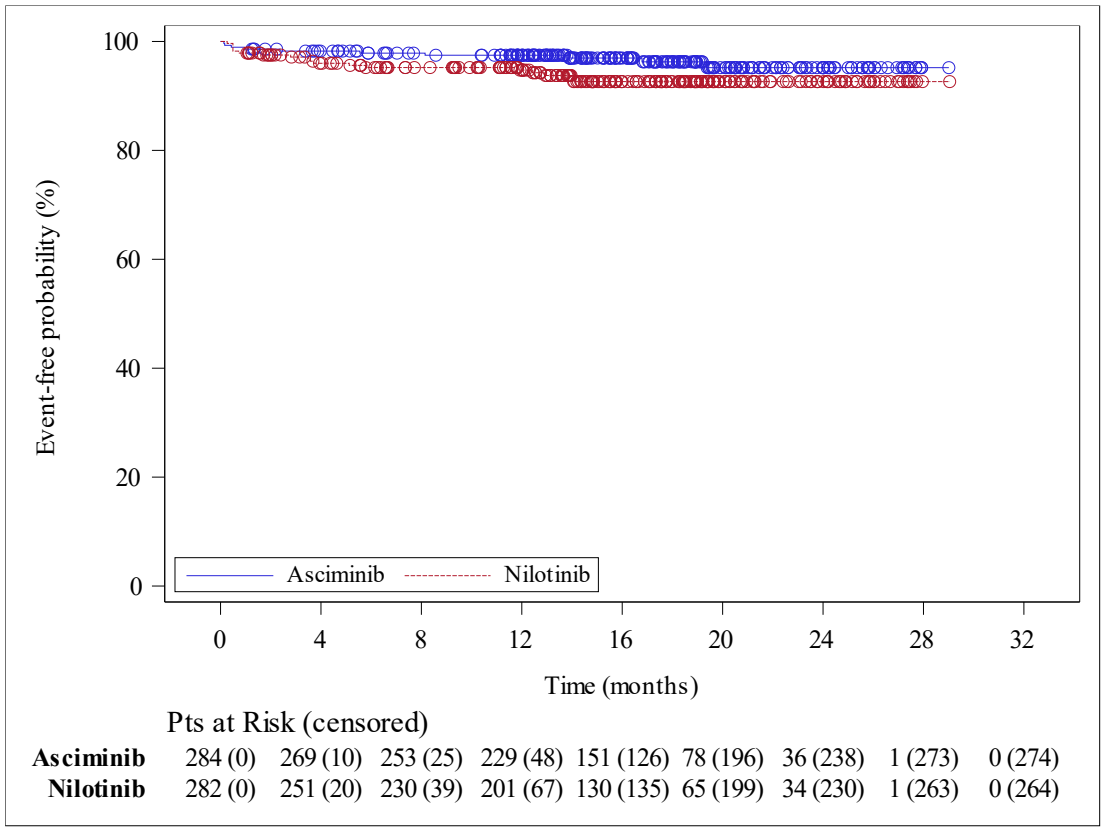
Cardiac failure



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.10 AESI all grades: Kaplan-Meier plot (Safety Analysis Set)

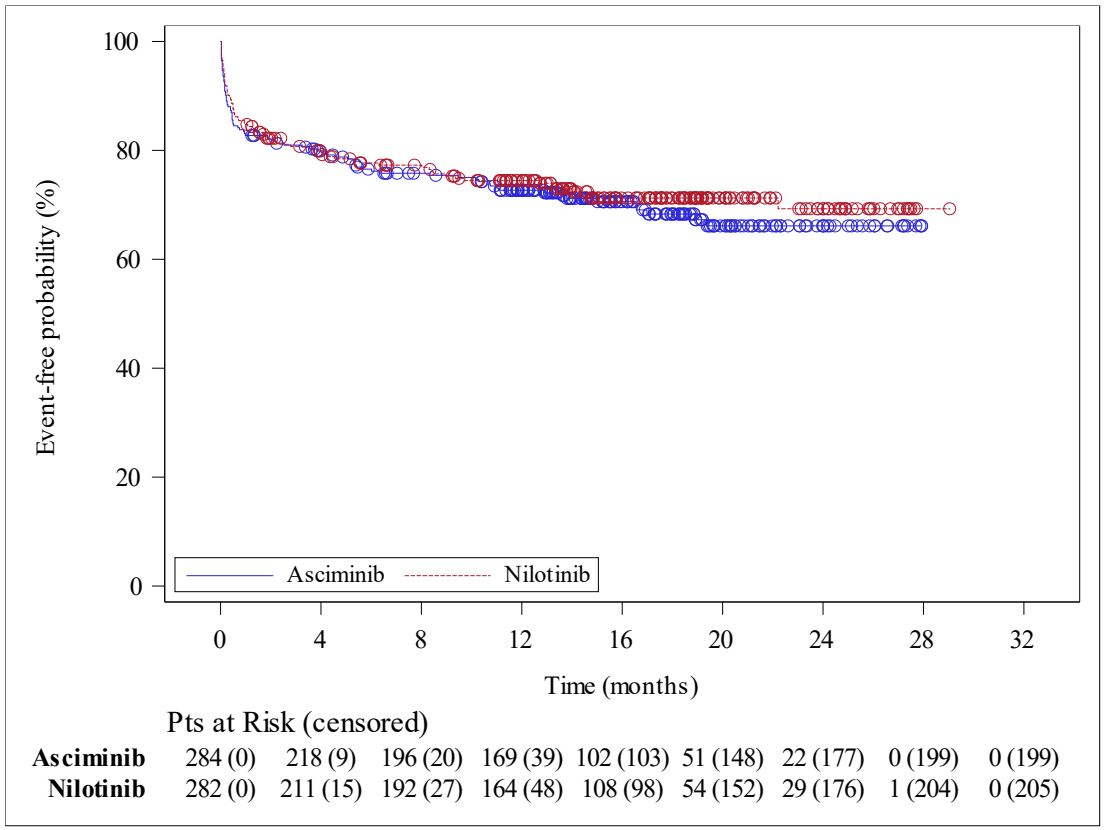
Edema and fluid retention



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.10 AESI all grades: Kaplan-Meier plot (Safety Analysis Set)

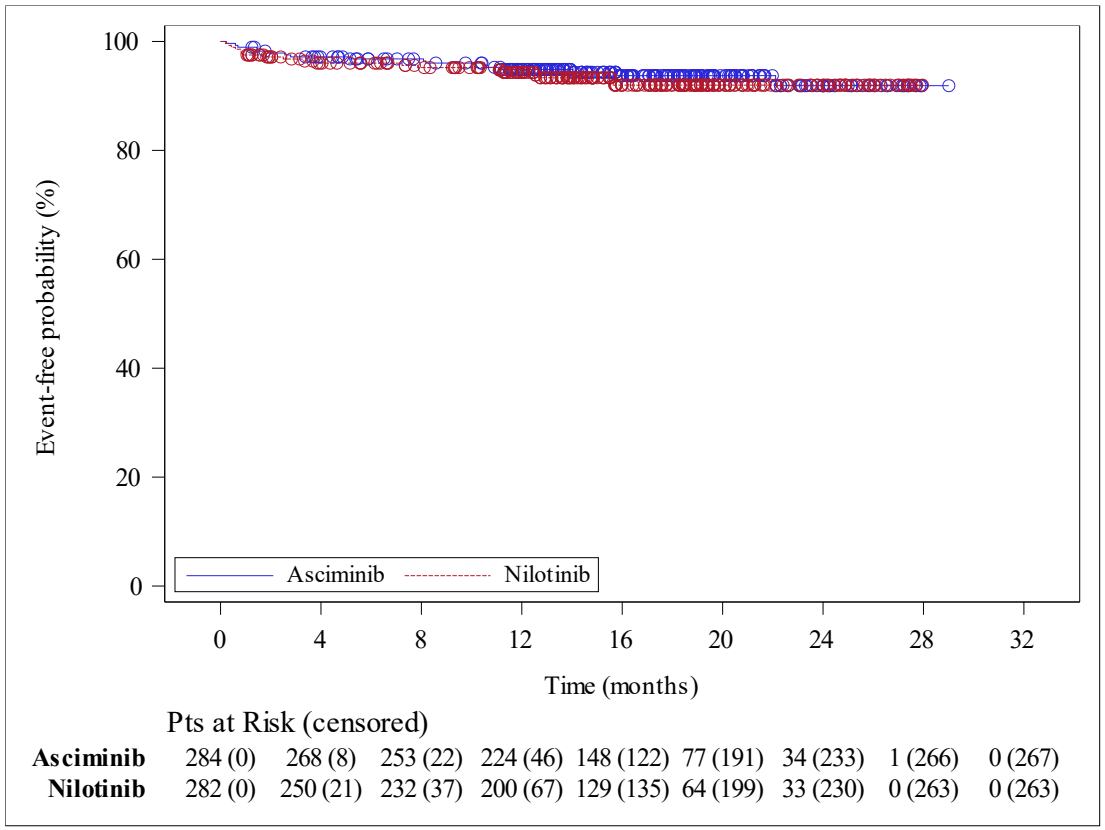
Gastrointestinal toxicity



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.10 AESI all grades: Kaplan-Meier plot (Safety Analysis Set)

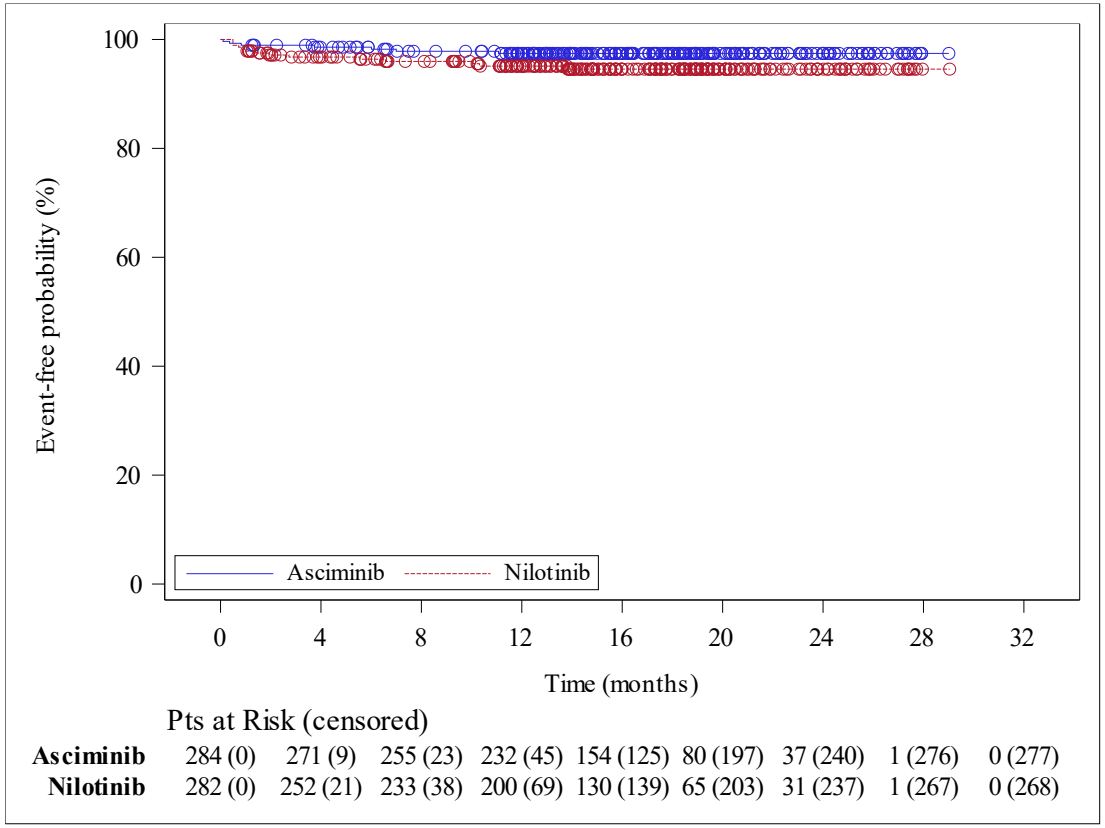
Hemorrhage



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.10 AESI all grades: Kaplan-Meier plot (Safety Analysis Set)

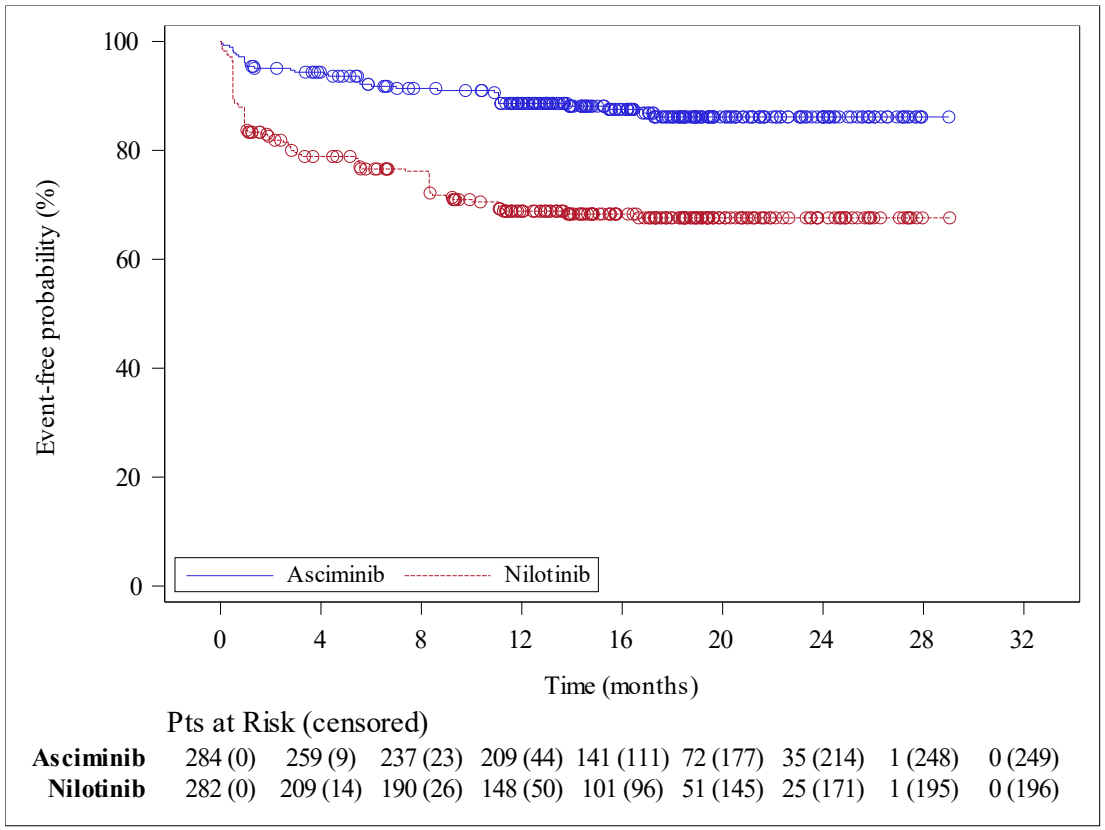
Hepatotoxicity (clinical events)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.10 AESI all grades: Kaplan-Meier plot (Safety Analysis Set)

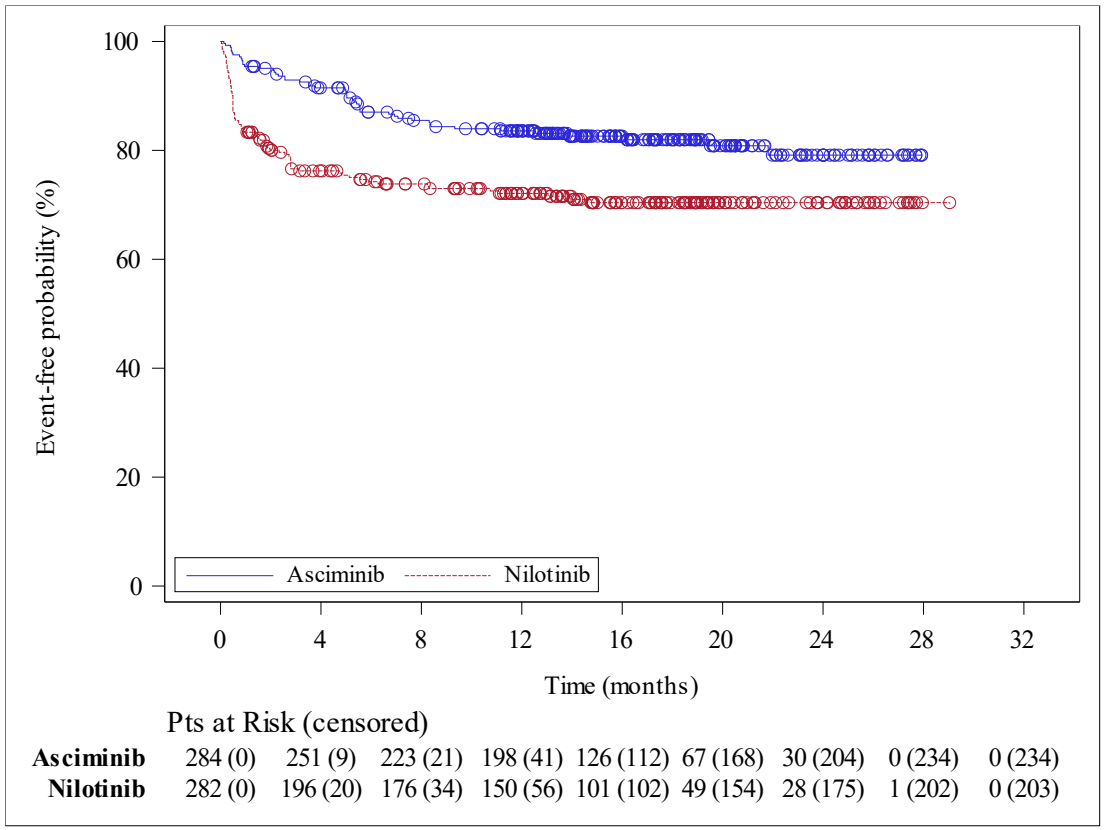
Hepatotoxicity (including laboratory terms)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.10 AESI all grades: Kaplan-Meier plot (Safety Analysis Set)

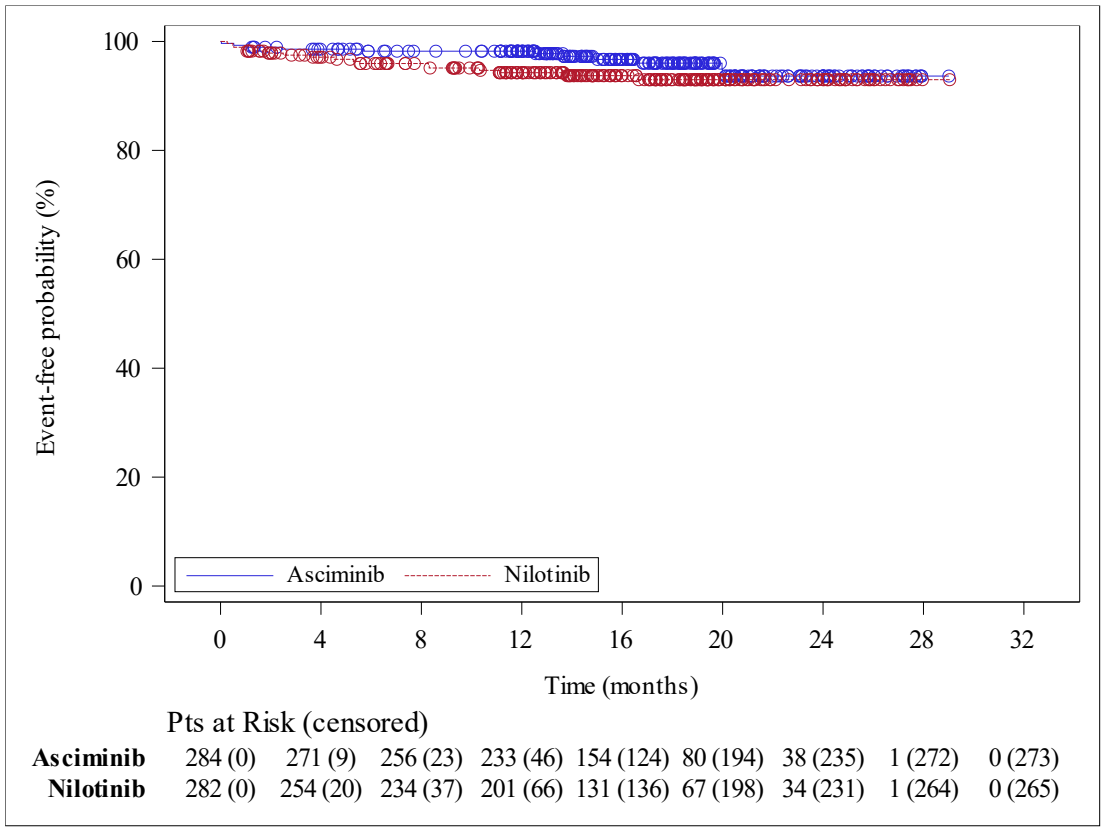
Hypersensitivity



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.10 AESI all grades: Kaplan-Meier plot (Safety Analysis Set)

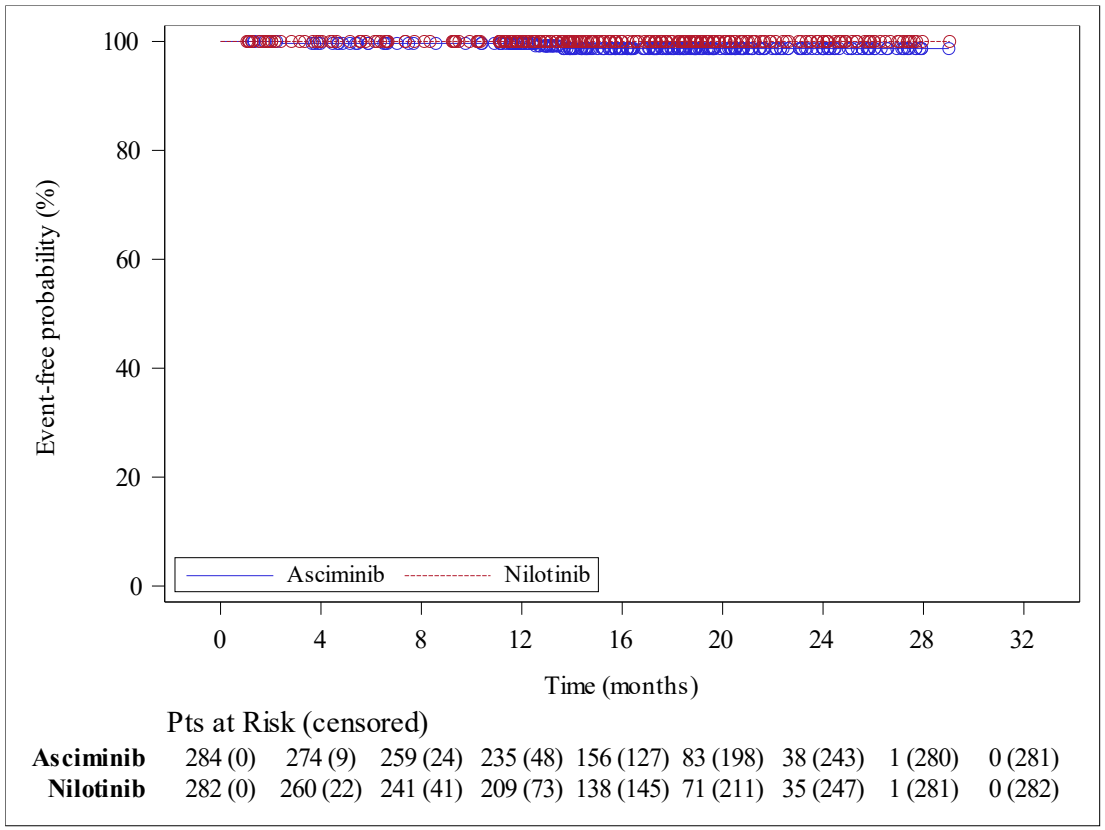
Ischemic heart and CNS conditions



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.10 AESI all grades: Kaplan-Meier plot (Safety Analysis Set)

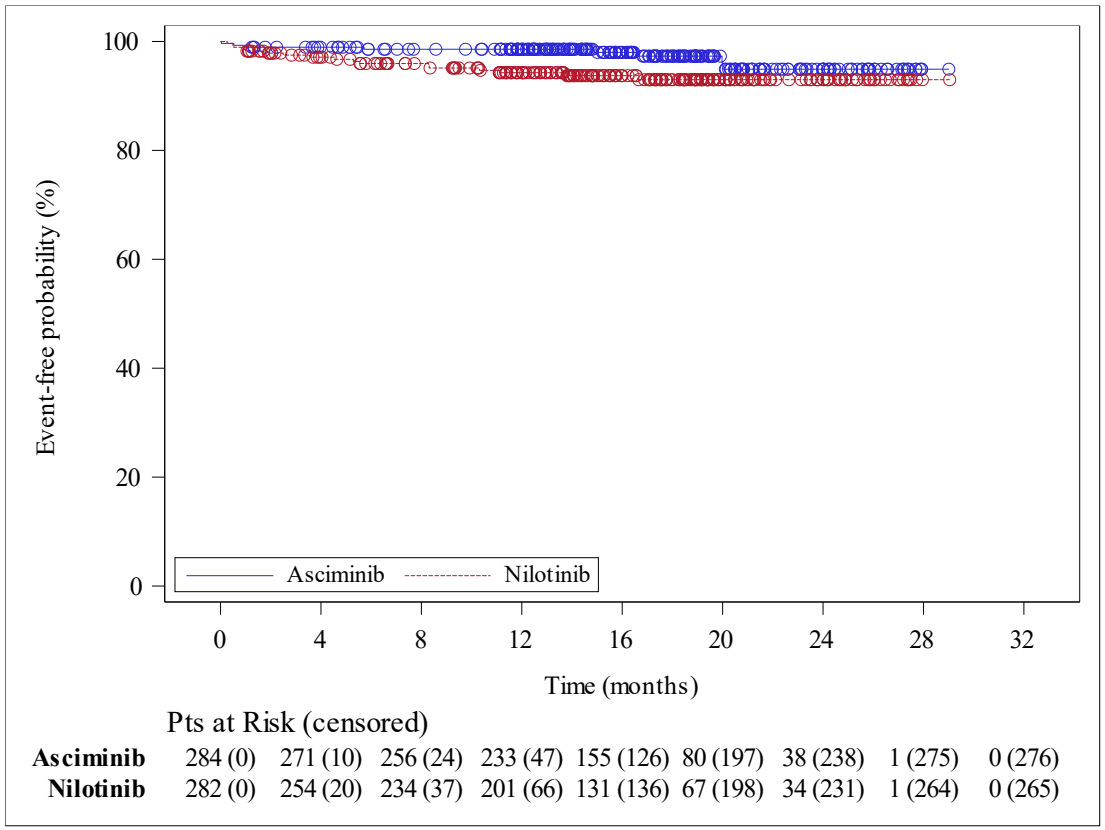
Ischemic CNS conditions



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.10 AESI all grades: Kaplan-Meier plot (Safety Analysis Set)

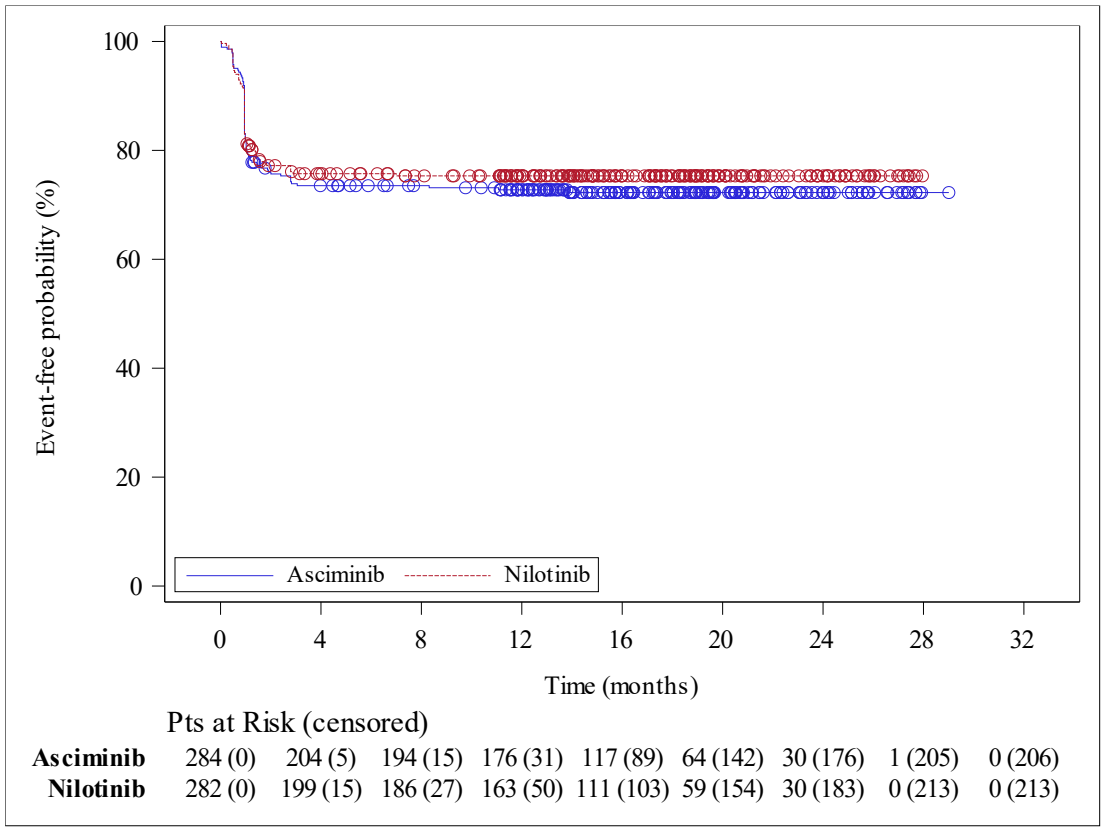
Ischemic heart conditions



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.10 AESI all grades: Kaplan-Meier plot (Safety Analysis Set)

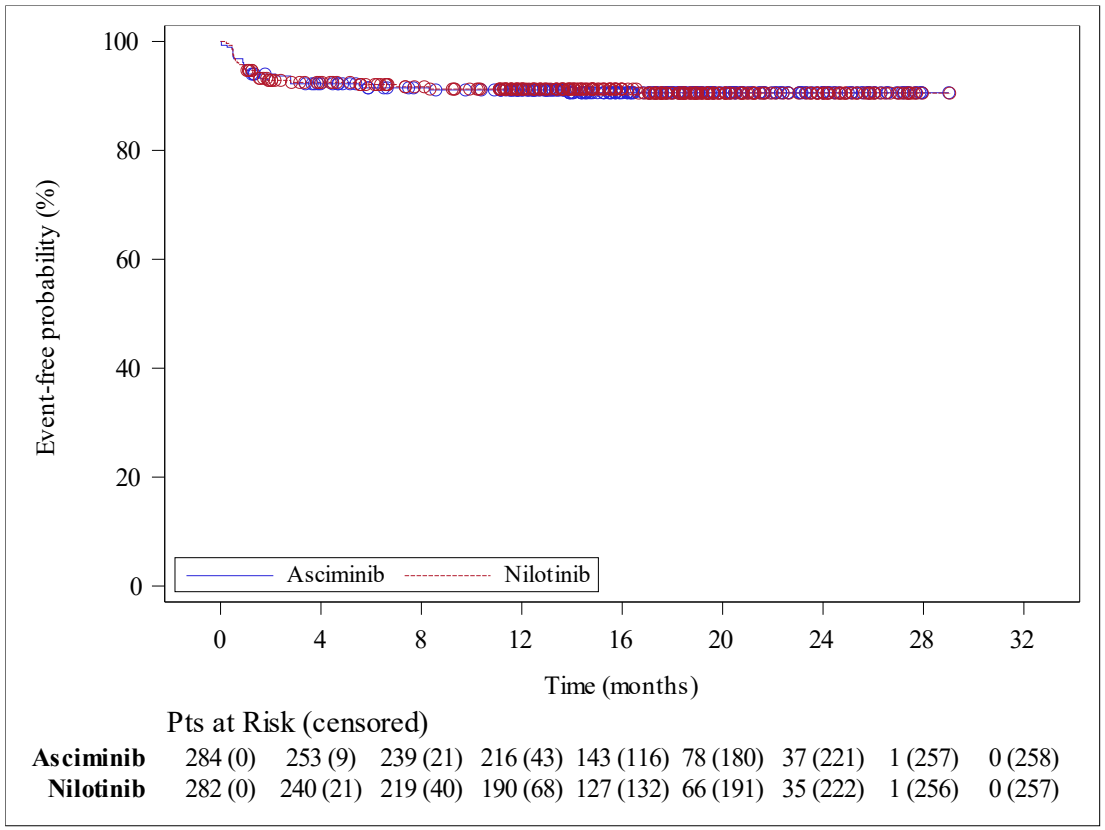
Myelosuppression



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.10 AESI all grades: Kaplan-Meier plot (Safety Analysis Set)

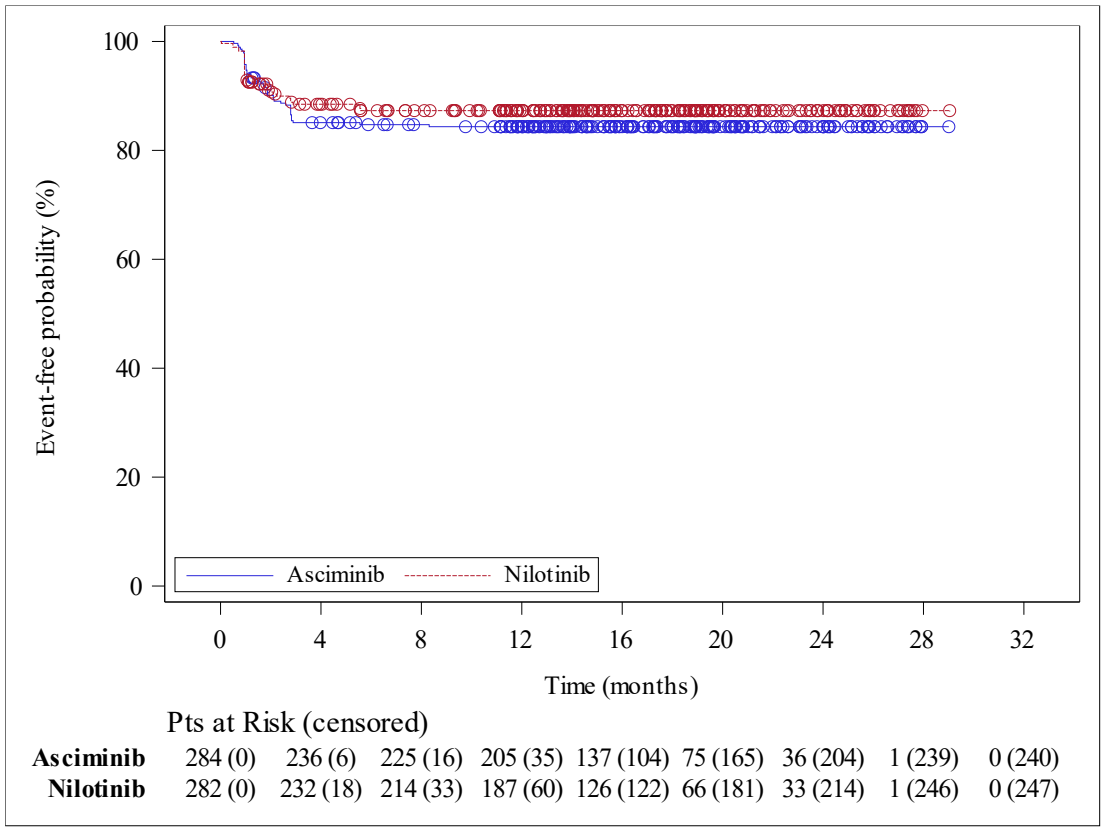
Myelosuppression (Erythropenia)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.10 AESI all grades: Kaplan-Meier plot (Safety Analysis Set)

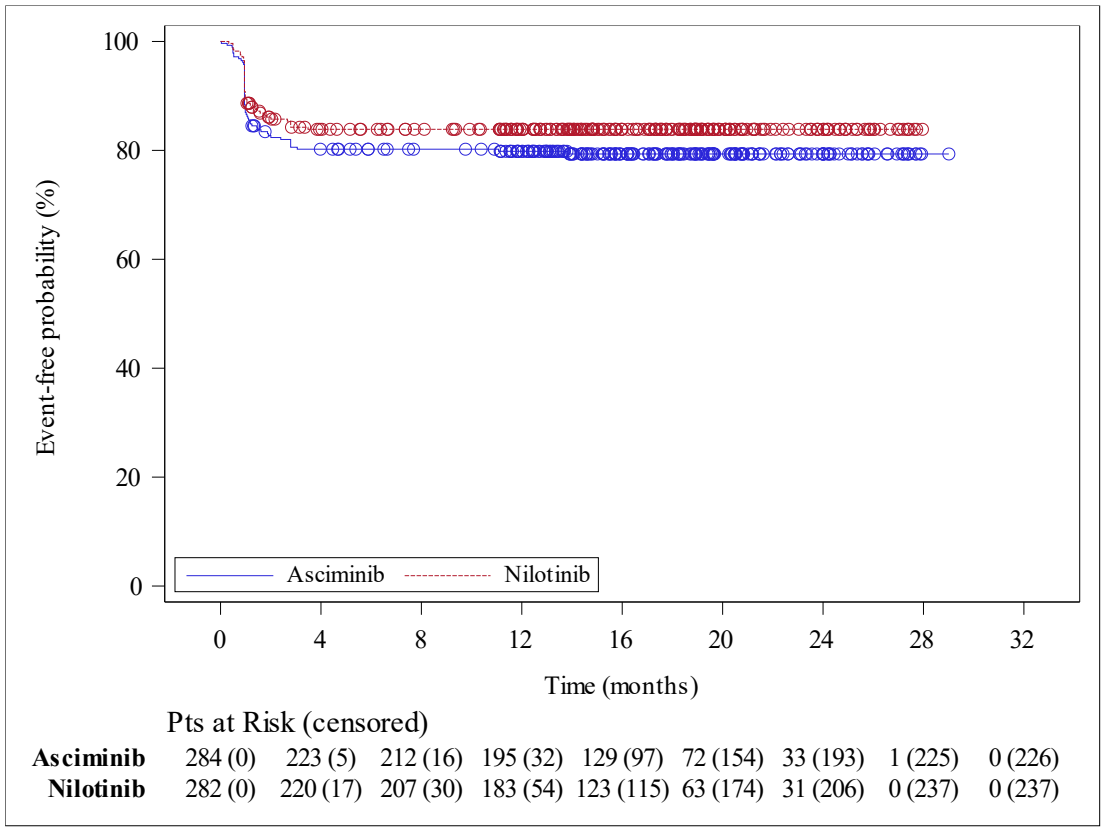
Myelosuppression (Leukopenia)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.10 AESI all grades: Kaplan-Meier plot (Safety Analysis Set)

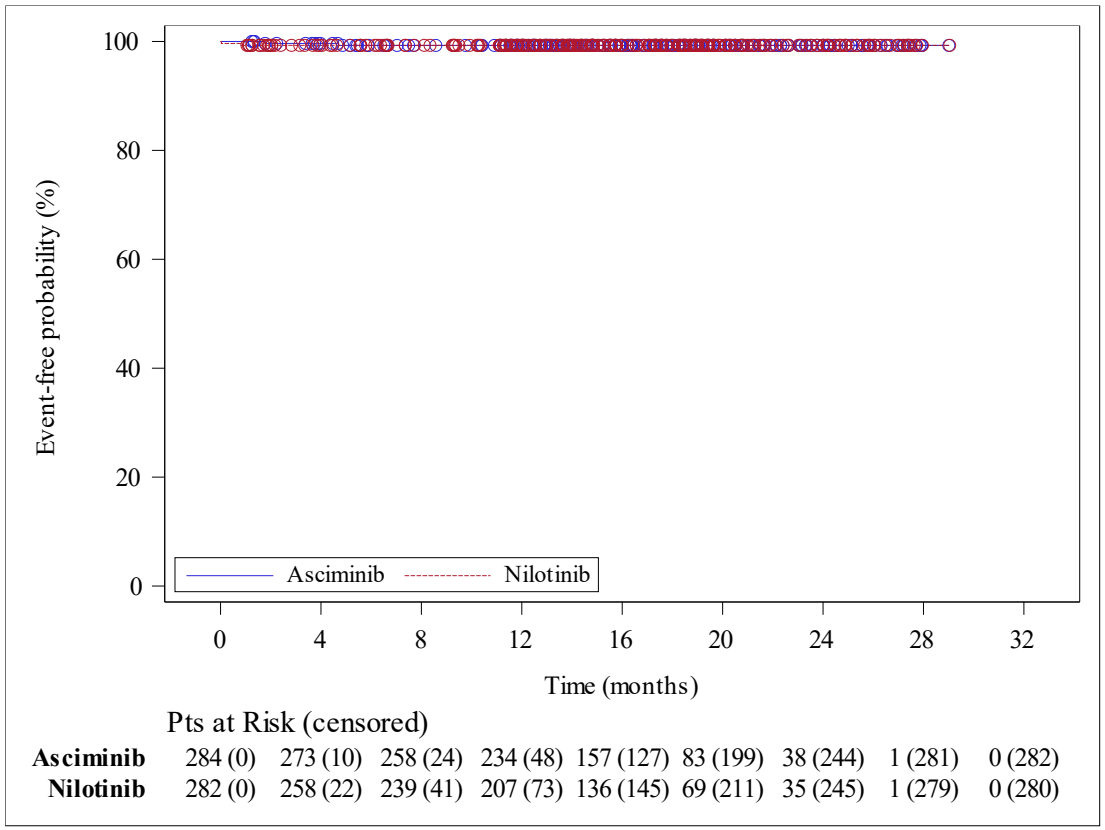
Myelosuppression (Thrombocytopenia)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.10 AESI all grades: Kaplan-Meier plot (Safety Analysis Set)

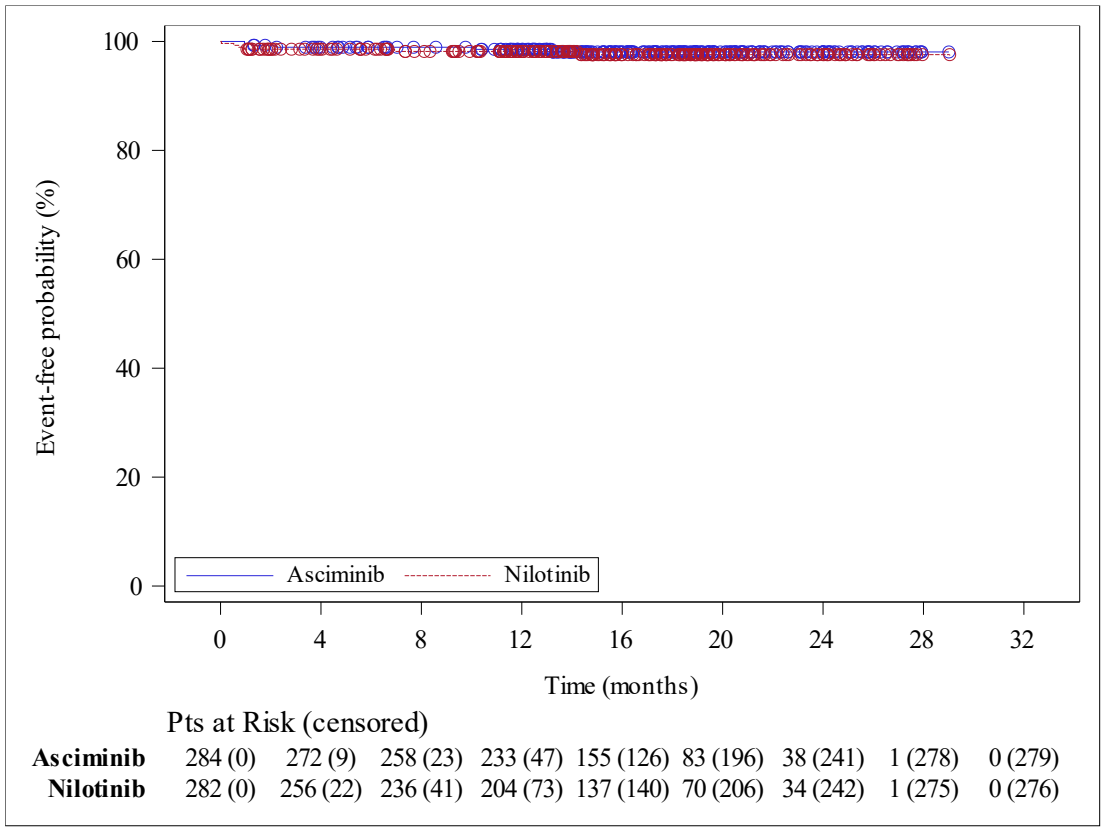
Phototoxicity



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.10 AESI all grades: Kaplan-Meier plot (Safety Analysis Set)

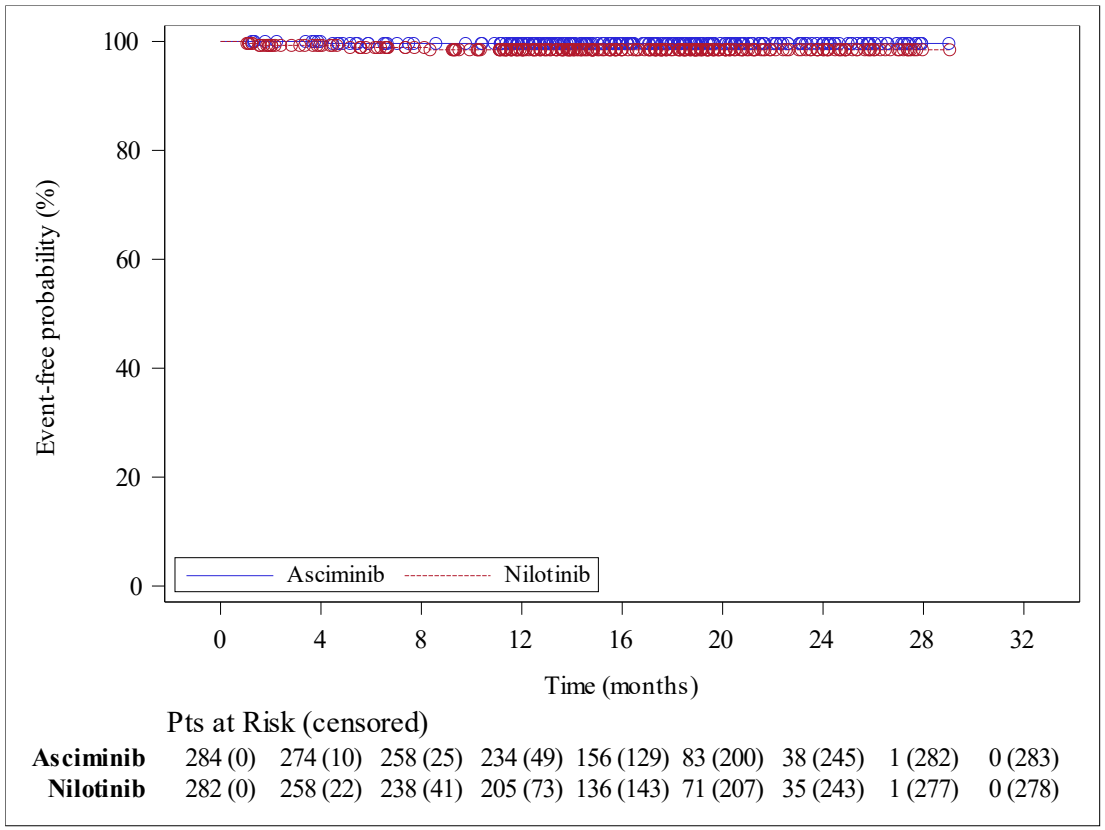
QTc prolongation



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.10 AESI all grades: Kaplan-Meier plot (Safety Analysis Set)

Reproductive toxicity



Note: o = Censored observations
Data Cut/15MAY2025

Table 4-1.11 Grade 1/2 AESI: time to first occurrence (Safety Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Acute pancreatitis (including isolated pancreatic enzyme elevations)			
N*	284	282	0.84
Number of patients with events, n (%)	31 (10.9)	35 (12.4)	[0.52; 1.36]
			0.474
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Acute pancreatitis (clinical events)			
N*	284	282	0.14
Number of patients with events, n (%)	0	3 (1.1)	[0.00; 4.28]
			0.080
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Arterial-occlusive events (AOE)			
N*	284	282	0.59
Number of patients with events, n (%)	4 (1.4)	6 (2.1)	[0.17; 2.11]
			0.416
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Cardiac failure			
N*	284	282	0.28
Number of patients with events, n (%)	0	1 (0.4)	[0.00; 26.00]
			0.277
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Edema and fluid retention			
N*	284	282	0.53
Number of patients with events, n (%)	10 (3.5)	18 (6.4)	[0.24; 1.15]
			0.103
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Gastrointestinal toxicity			
N*	284	282	1.10
Number of patients with events, n (%)	84 (29.6)	77 (27.3)	[0.80; 1.49]
			0.560
Percentiles (months) [95% CI]			
25th	10.2 [3.8; 16.6]	9.4 [3.8; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Hemorrhage			
N*	284	282	0.78
Number of patients with events, n (%)	16 (5.6)	19 (6.7)	[0.40; 1.52]
			0.471
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Hepatotoxicity (clinical events)			
N*	284	282	0.31
Number of patients with events, n (%)	4 (1.4)	12 (4.3)	[0.10; 0.97]
			0.034
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Hepatotoxicity (including laboratory terms)			
N*	284	282	0.35
Number of patients with events, n (%)	34 (12.0)	82 (29.1)	[0.24; 0.53]
			<0.001
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	8.3 [3.2; 13.8]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Hypersensitivity			
N*	284	282	0.53
Number of patients with events, n (%)	49 (17.3)	79 (28.0)	[0.37; 0.76]
			<0.001
Percentiles (months) [95% CI]			
25th	N.E. [21.8; N.E.]	5.6 [2.3; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Ischemic heart and CNS conditions			
N*	284	282	0.54
Number of patients with events, n (%)	7 (2.5)	12 (4.3)	[0.21; 1.38]
			0.195
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Ischemic CNS conditions			
N*	284	282	4.46
Number of patients with events, n (%)	2 (0.7)	0	[0.11; 184.2]
			0.182
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Ischemic heart conditions			
N*	284	282	0.39
Number of patients with events, n (%)	5 (1.8)	12 (4.3)	[0.14; 1.11]
			0.068
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Myelosuppression			
N*	284	282	1.10
Number of patients with events, n (%)	70 (24.6)	62 (22.0)	[0.78; 1.54]
			0.588
Percentiles (months) [95% CI]			
25th	N.E. [1.9; N.E.]	N.E. [1.9; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Myelosuppression (Erythropenia)			
N*	284	282	0.84
Number of patients with events, n (%)	20 (7.0)	23 (8.2)	[0.46; 1.52]
			0.555
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Myelosuppression (Leukopenia)			
N*	284	282	1.19
Number of patients with events, n (%)	32 (11.3)	26 (9.2)	[0.71; 2.00]
			0.508
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Myelosuppression (Thrombocytopenia)			
N*	284	282	1.26
Number of patients with events, n (%)	53 (18.7)	42 (14.9)	[0.84; 1.89]
			0.261
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Phototoxicity			
N*	284	282	0.99
Number of patients with events, n (%)	2 (0.7)	2 (0.7)	[0.14; 7.02]
			0.991
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

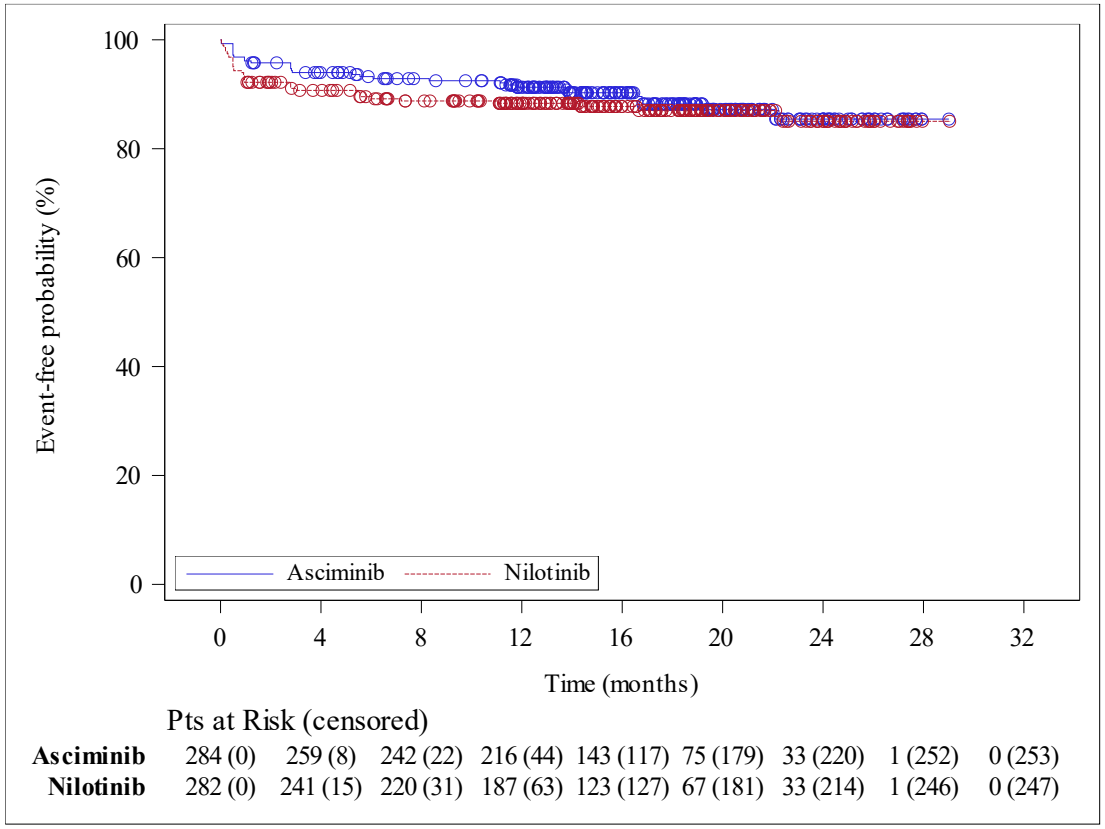
	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
QTc prolongation			
N*	284	282	0.95
Number of patients with events, n (%)	4 (1.4)	4 (1.4)	[0.24; 3.81]
			0.946
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Reproductive toxicity			
N*	284	282	0.24
Number of patients with events, n (%)	1 (0.4)	4 (1.4)	[0.03; 2.18]
			0.171
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 4-1.11 Grade 1/2 AESI: Kaplan-Meier plot (Safety Analysis Set)

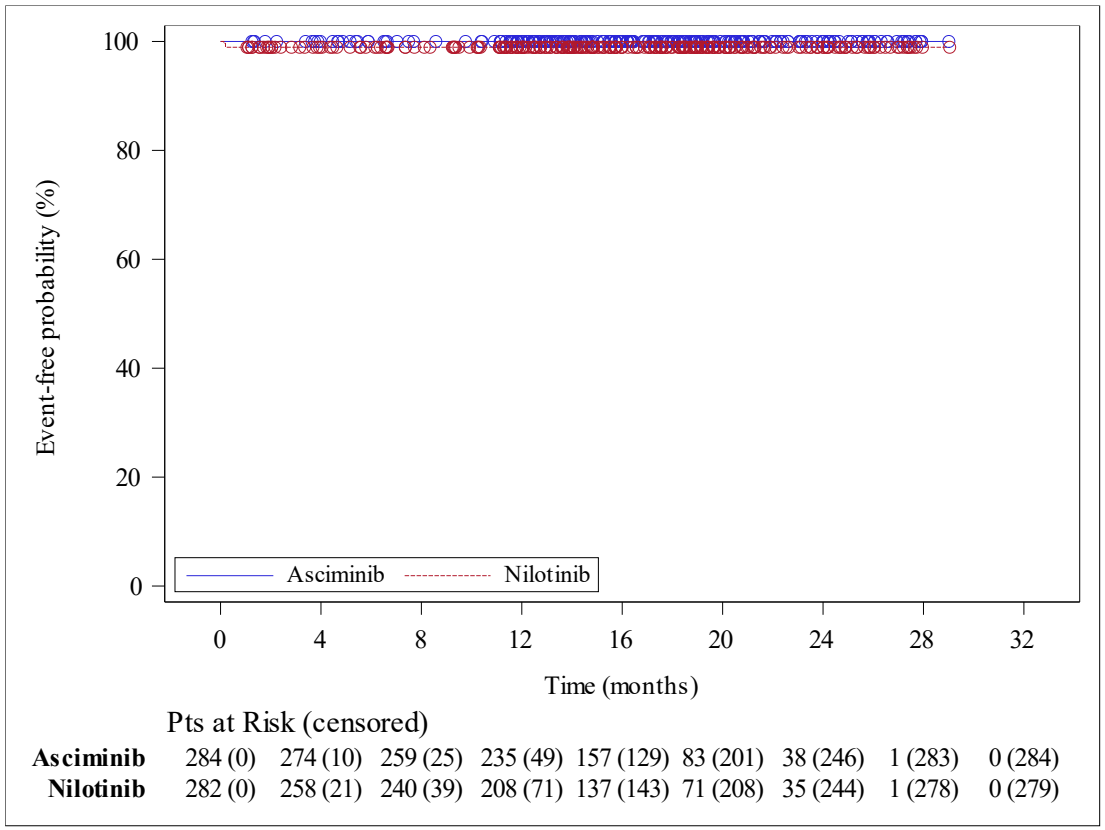
Acute pancreatitis (including isolated pancreatic enzyme elevations)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.11 Grade 1/2 AESI: Kaplan-Meier plot (Safety Analysis Set)

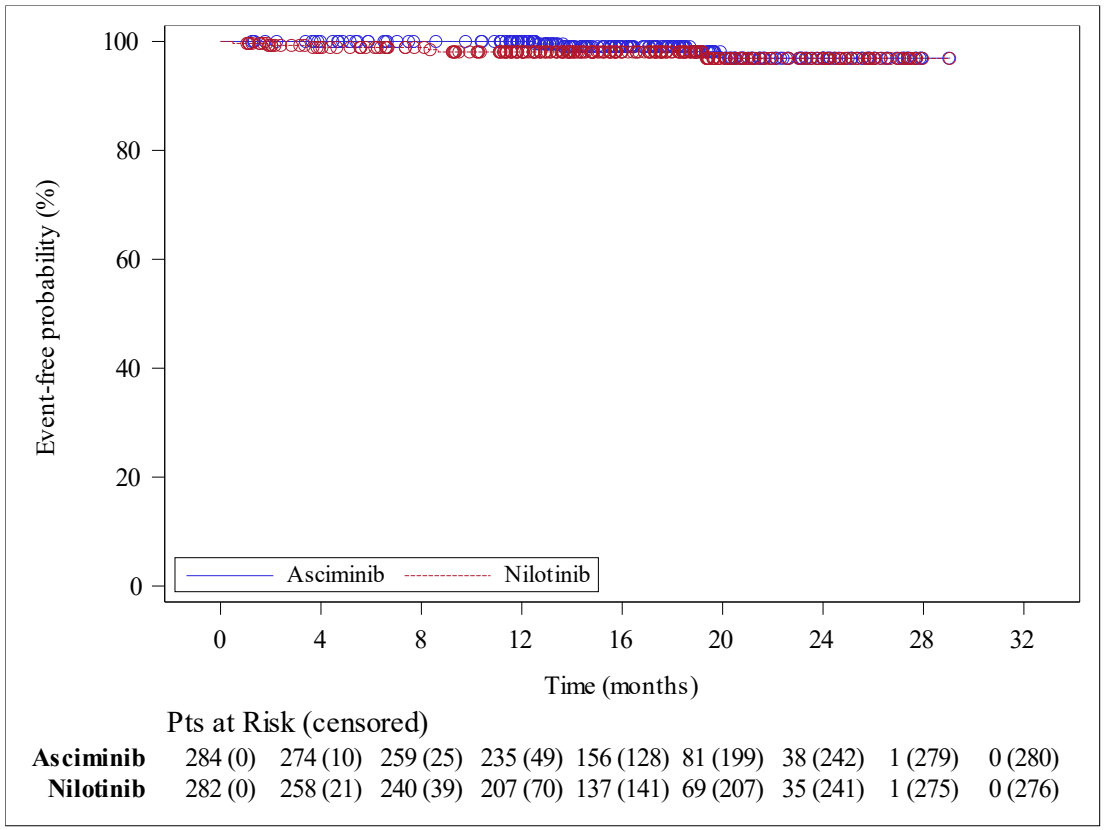
Acute pancreatitis (clinical events)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.11 Grade 1/2 AESI: Kaplan-Meier plot (Safety Analysis Set)

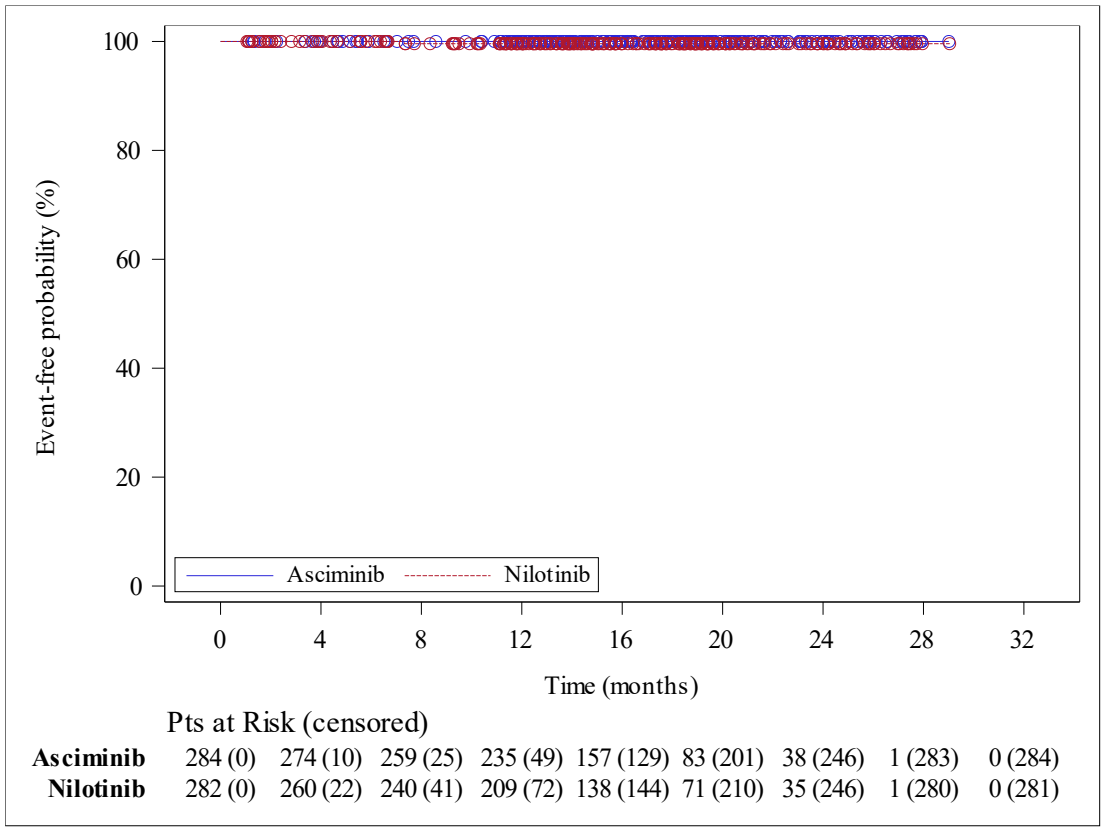
Arterial-occlusive events (AOE)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.11 Grade 1/2 AESI: Kaplan-Meier plot (Safety Analysis Set)

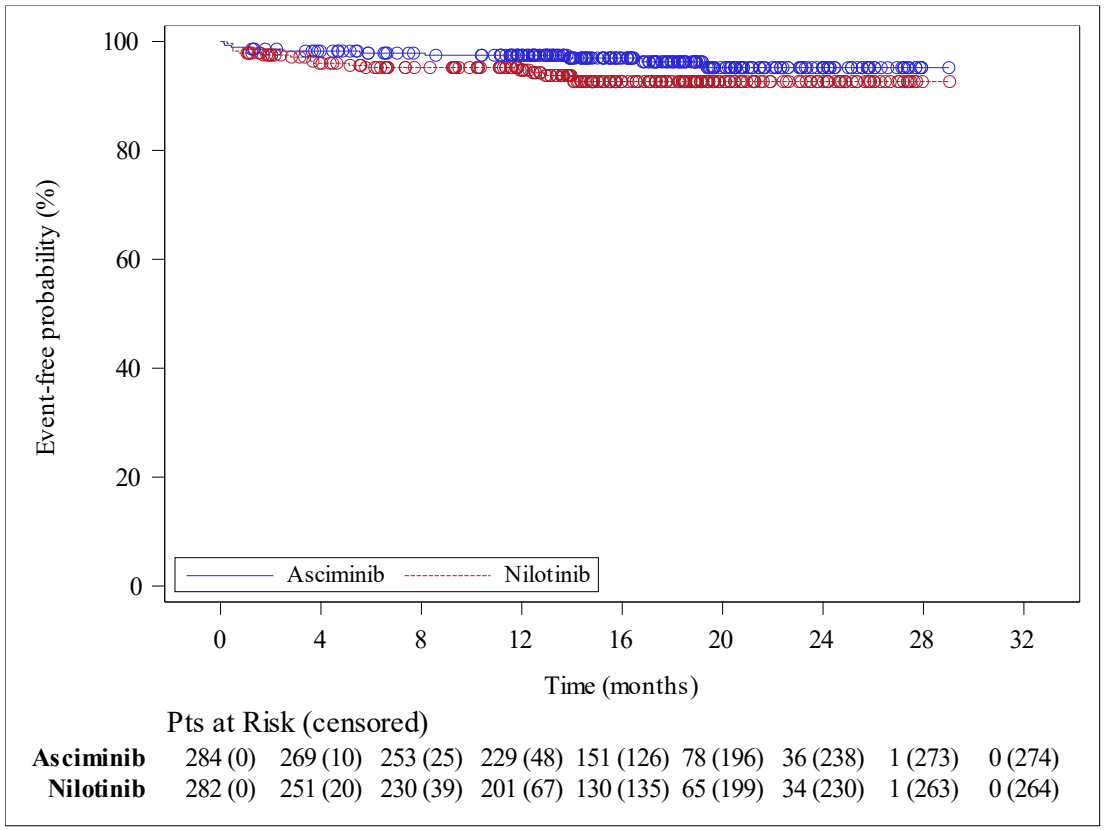
Cardiac failure



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.11 Grade 1/2 AESI: Kaplan-Meier plot (Safety Analysis Set)

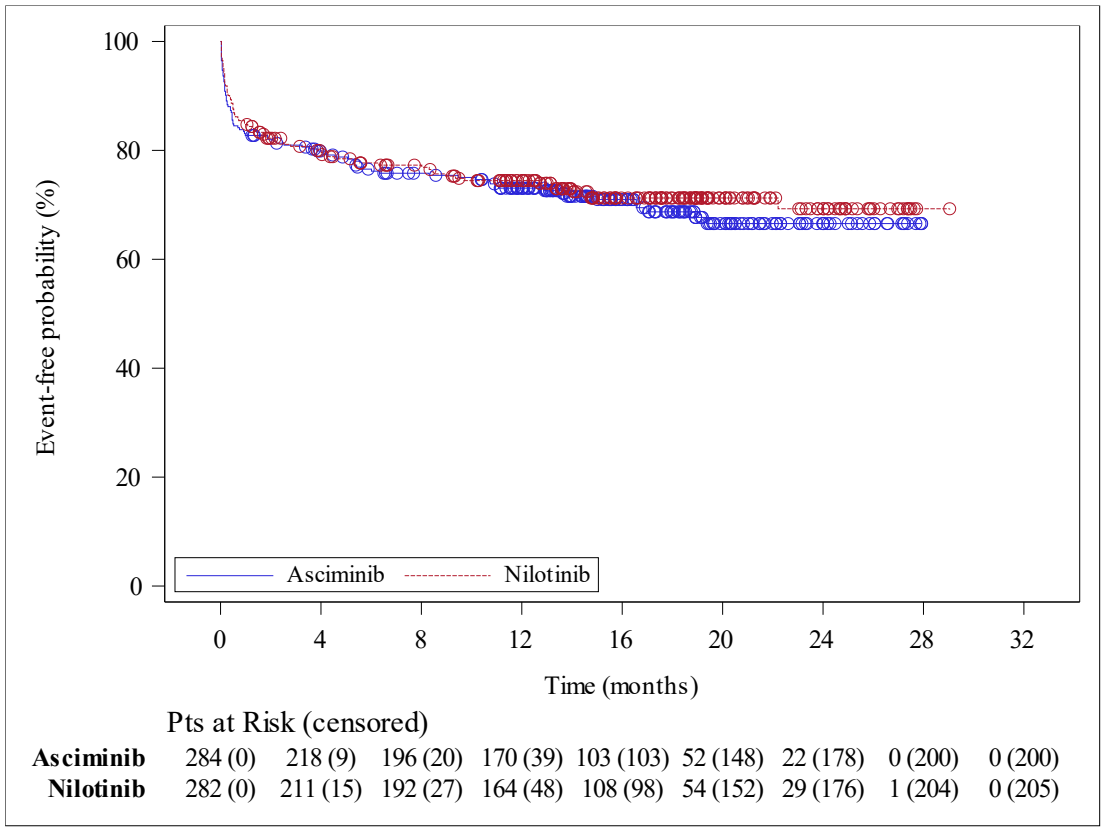
Edema and fluid retention



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.11 Grade 1/2 AESI: Kaplan-Meier plot (Safety Analysis Set)

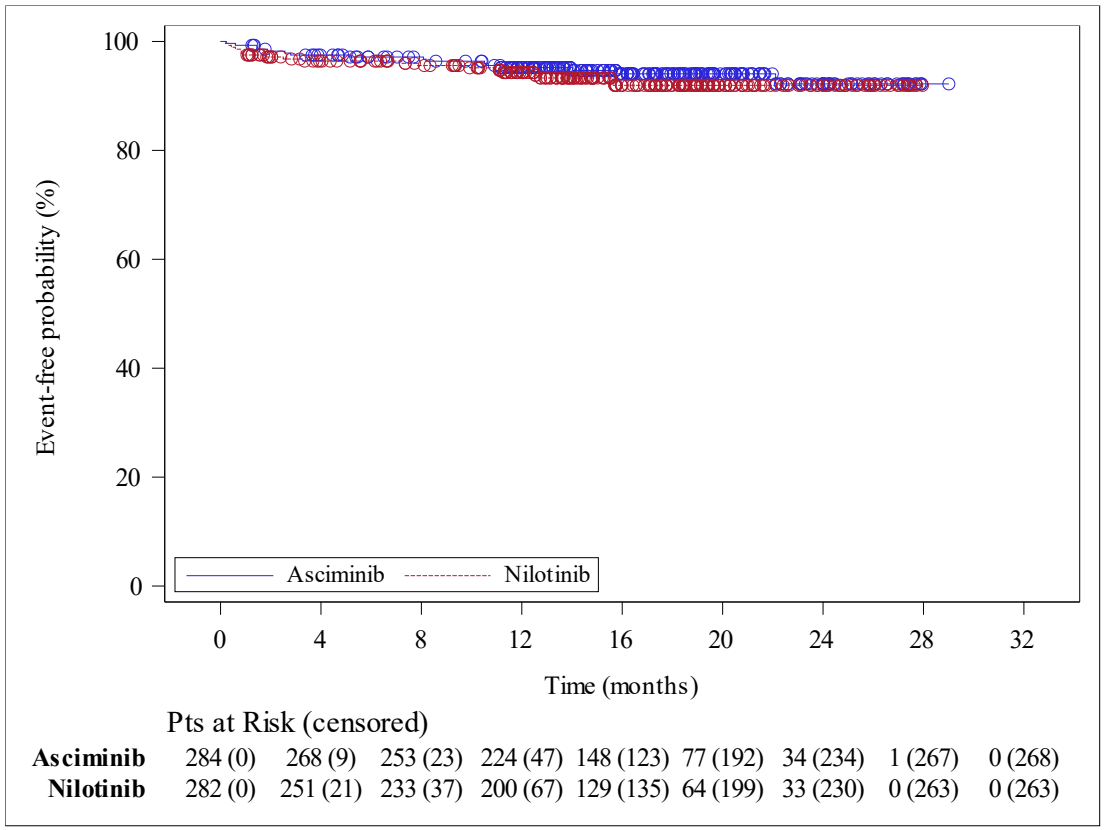
Gastrointestinal toxicity



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.11 Grade 1/2 AESI: Kaplan-Meier plot (Safety Analysis Set)

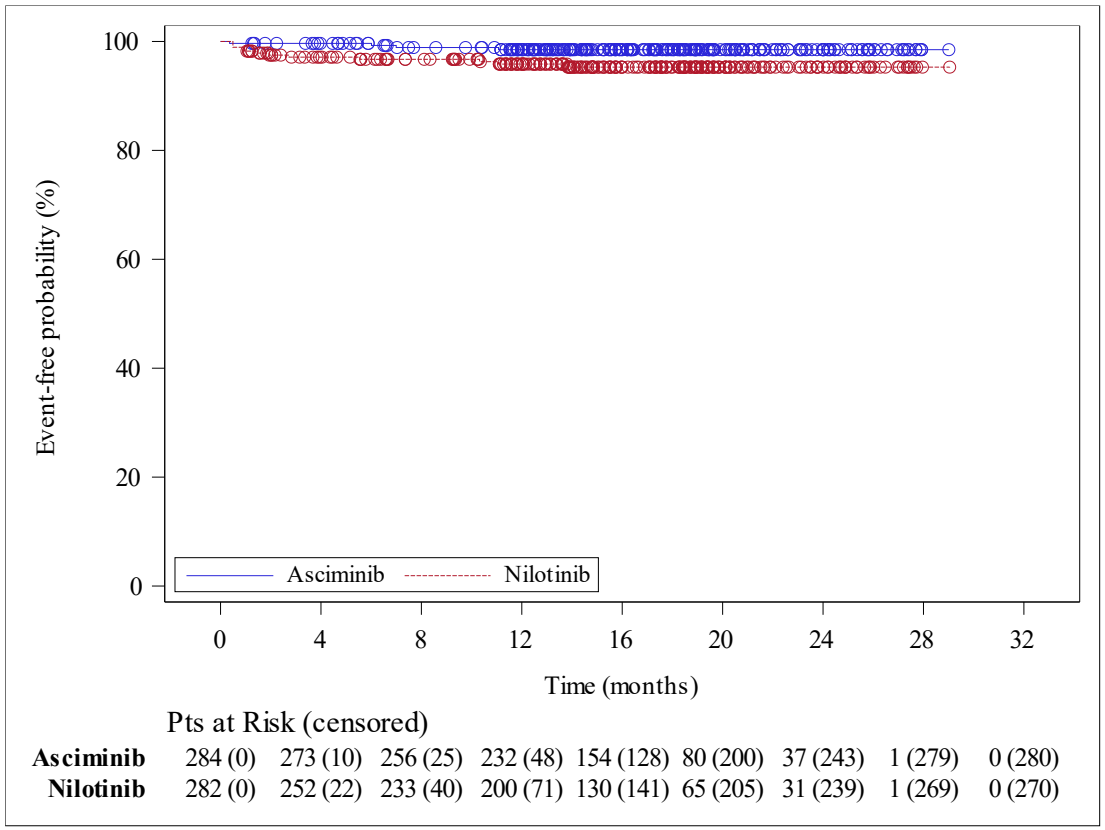
Hemorrhage



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.11 Grade 1/2 AESI: Kaplan-Meier plot (Safety Analysis Set)

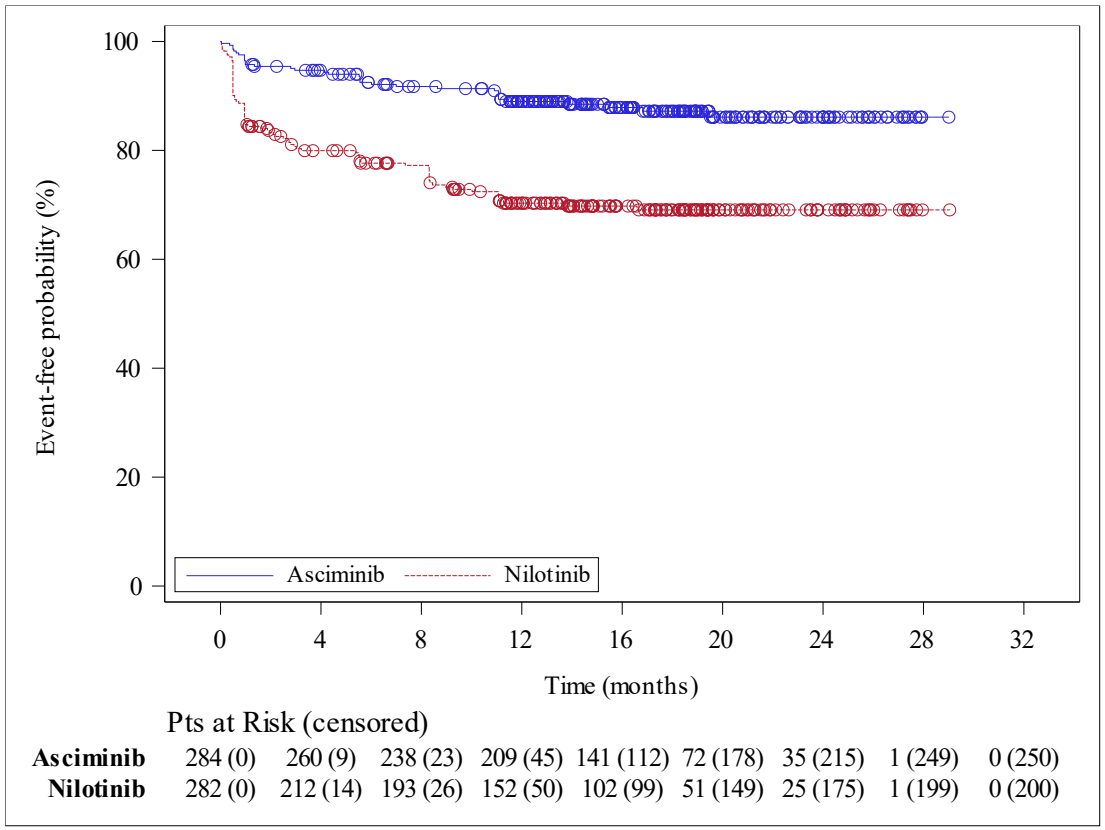
Hepatotoxicity (clinical events)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.11 Grade 1/2 AESI: Kaplan-Meier plot (Safety Analysis Set)

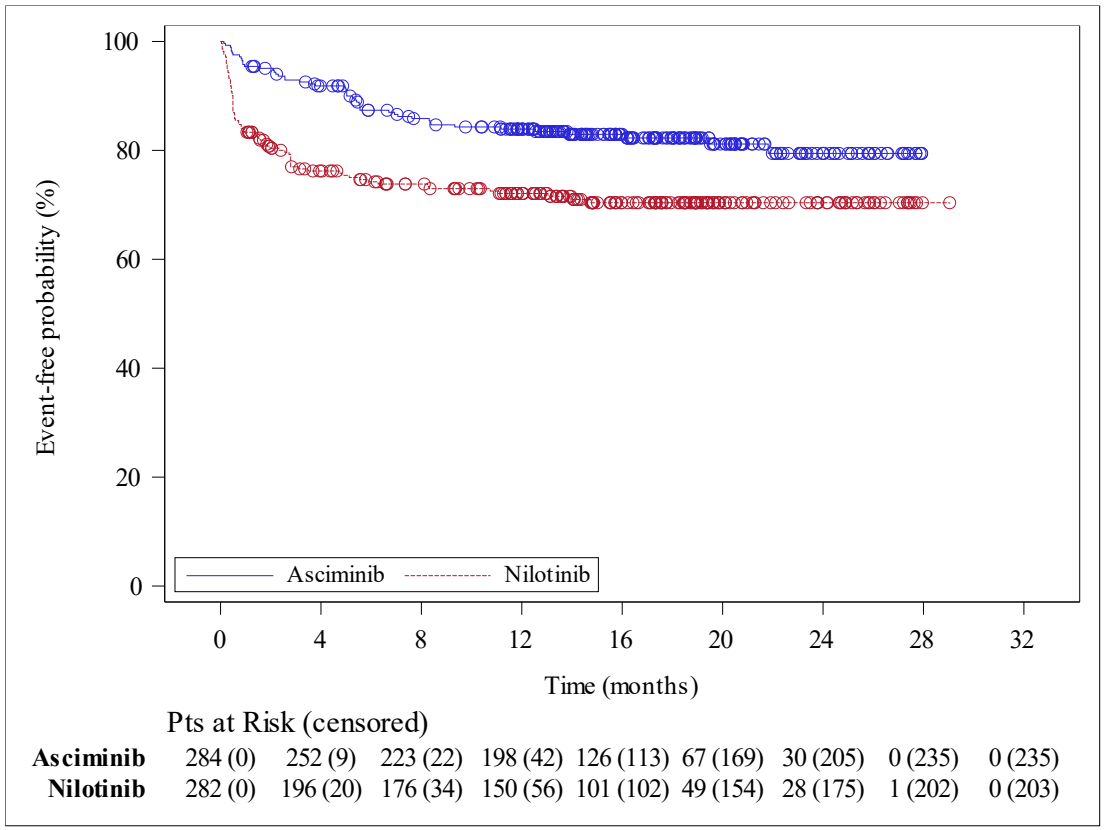
Hepatotoxicity (including laboratory terms)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.11 Grade 1/2 AESI: Kaplan-Meier plot (Safety Analysis Set)

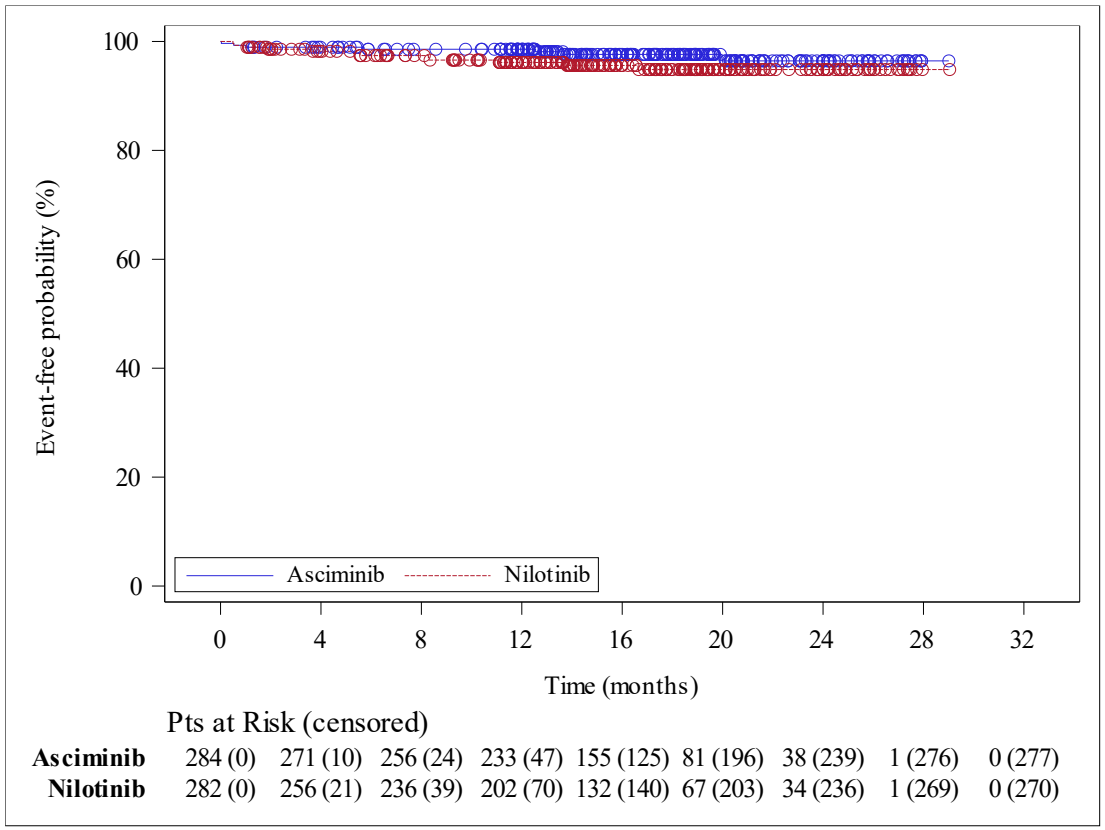
Hypersensitivity



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.11 Grade 1/2 AESI: Kaplan-Meier plot (Safety Analysis Set)

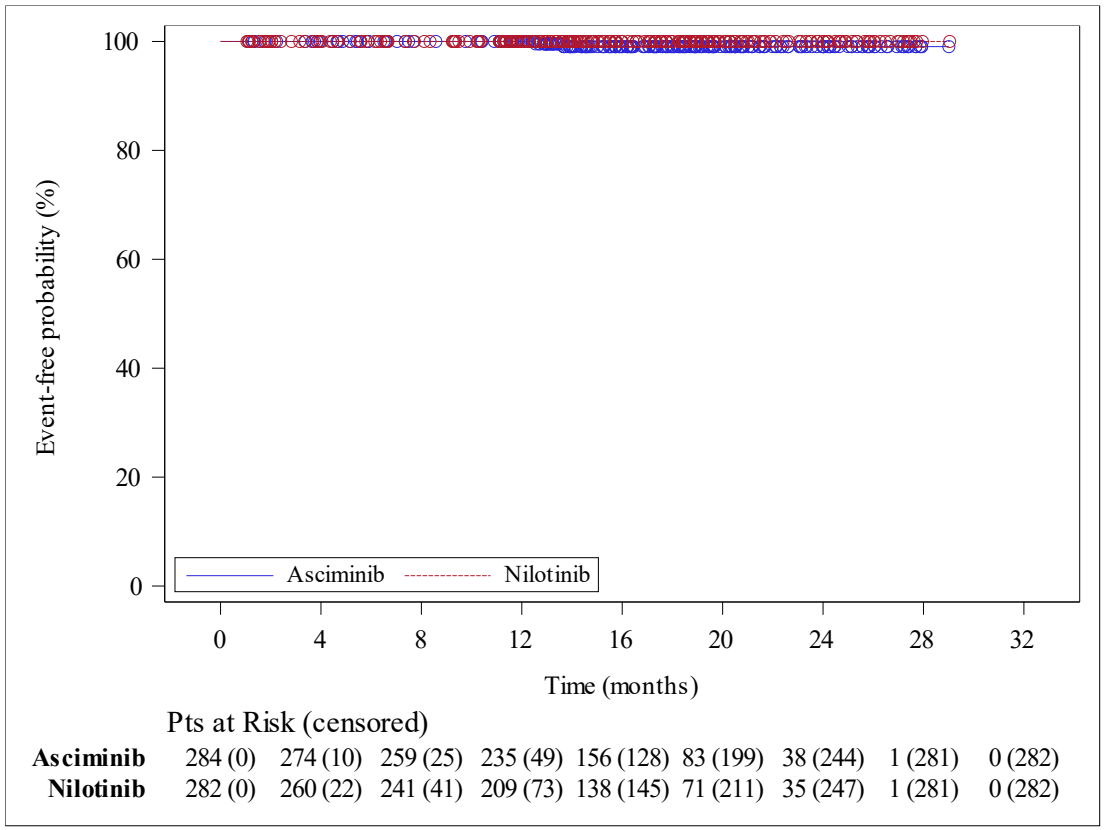
Ischemic heart and CNS conditions



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.11 Grade 1/2 AESI: Kaplan-Meier plot (Safety Analysis Set)

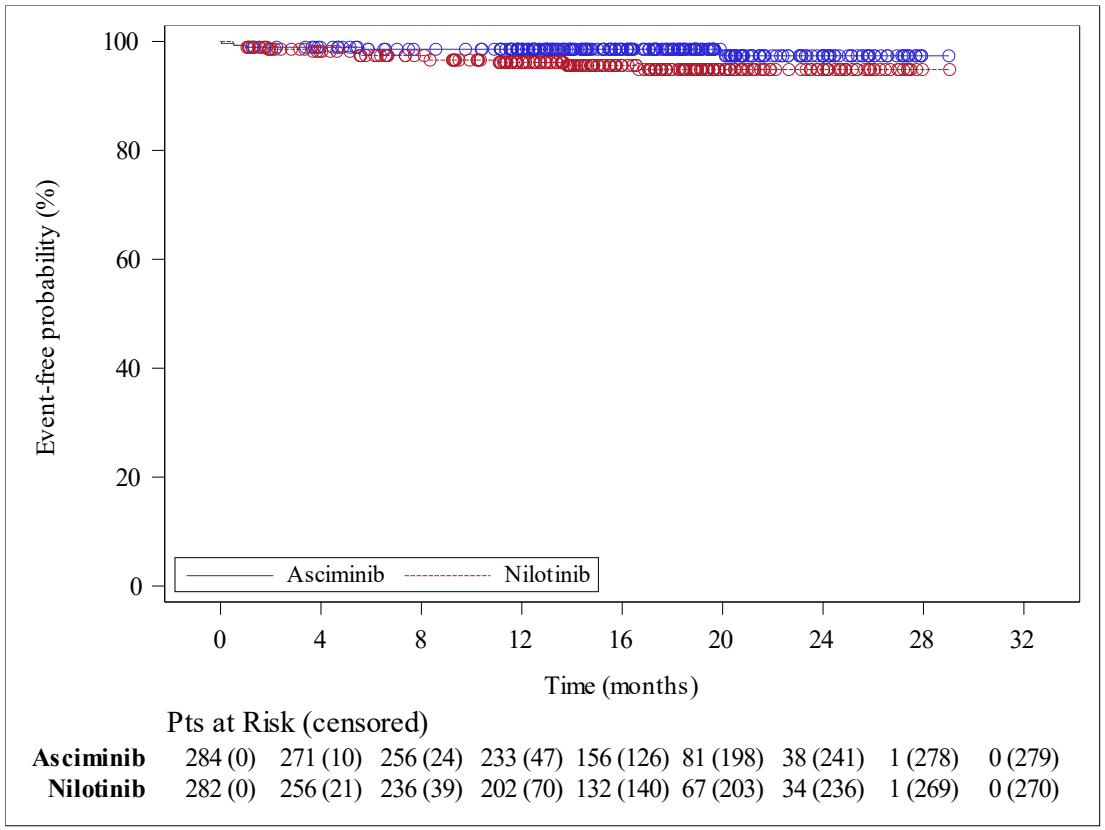
Ischemic CNS conditions



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.11 Grade 1/2 AESI: Kaplan-Meier plot (Safety Analysis Set)

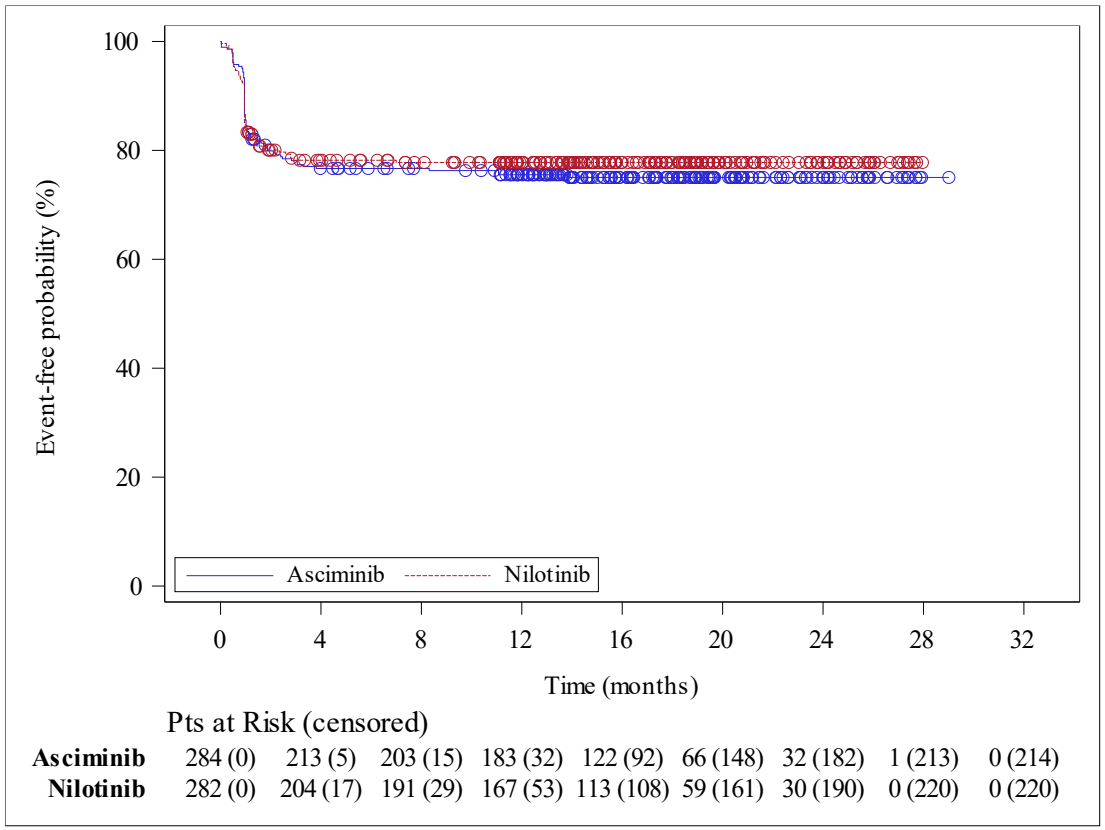
Ischemic heart conditions



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.11 Grade 1/2 AESI: Kaplan-Meier plot (Safety Analysis Set)

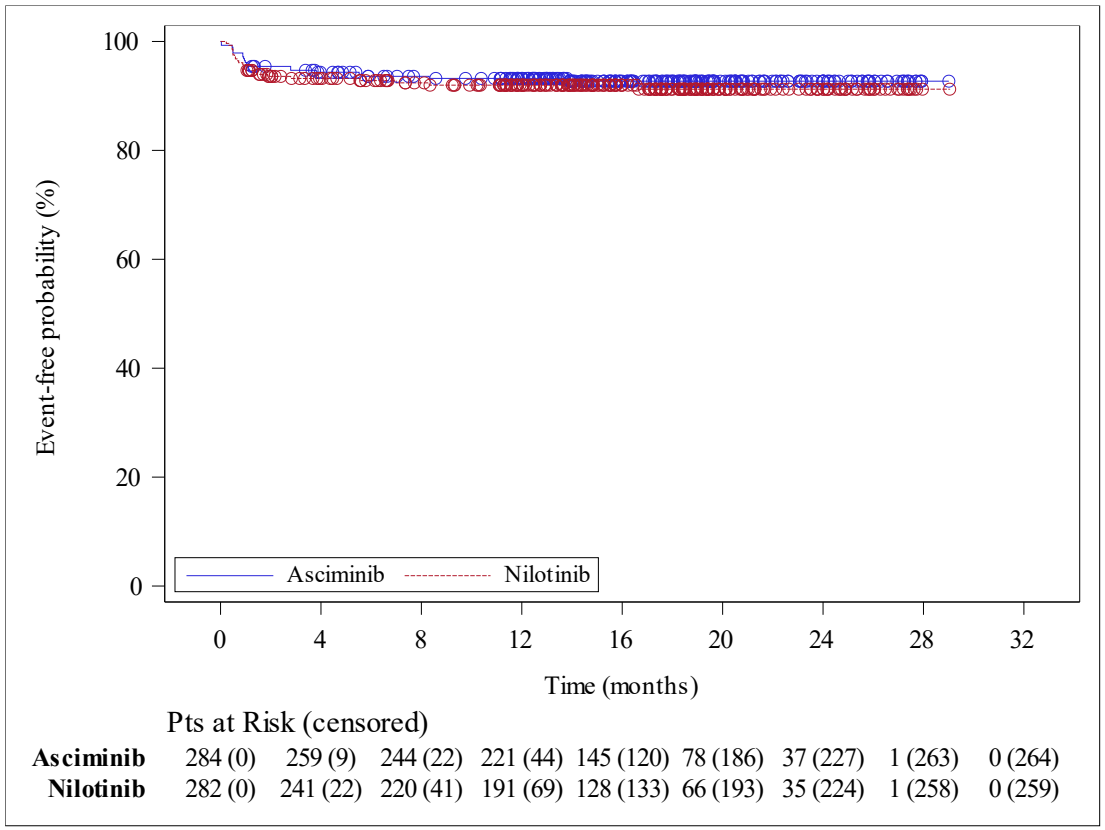
Myelosuppression



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.11 Grade 1/2 AESI: Kaplan-Meier plot (Safety Analysis Set)

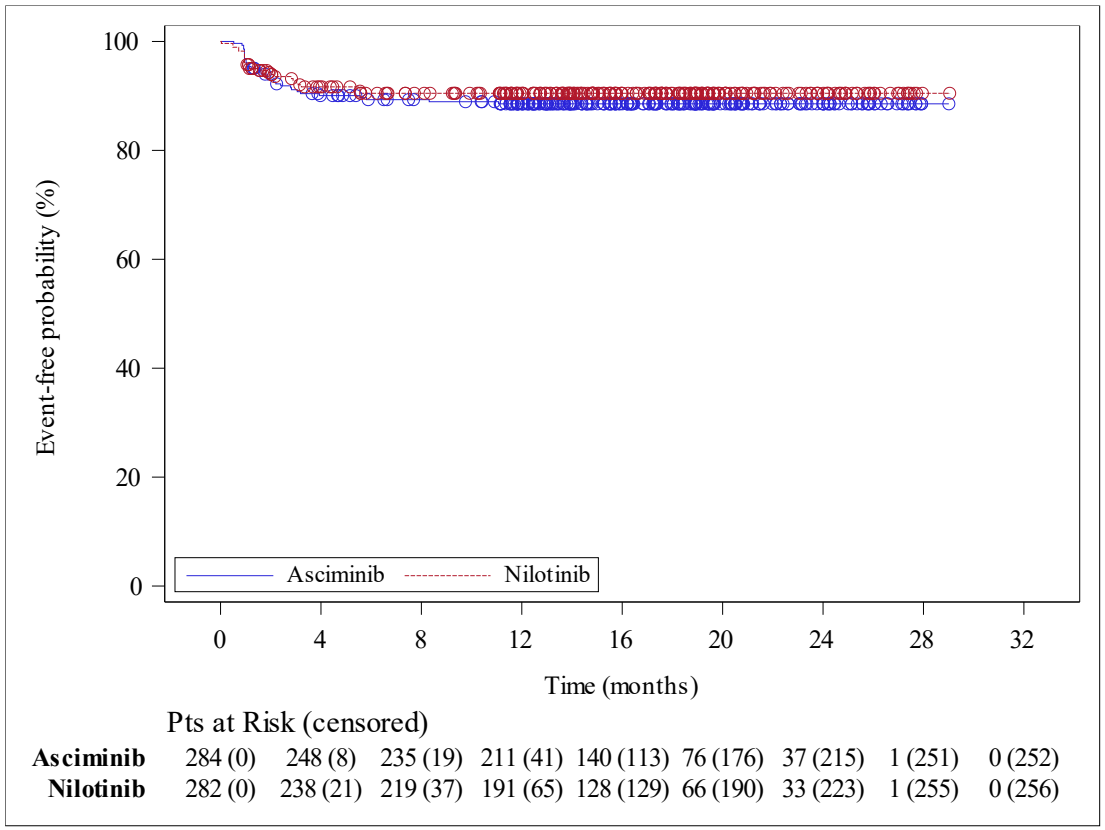
Myelosuppression (Erythropenia)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.11 Grade 1/2 AESI: Kaplan-Meier plot (Safety Analysis Set)

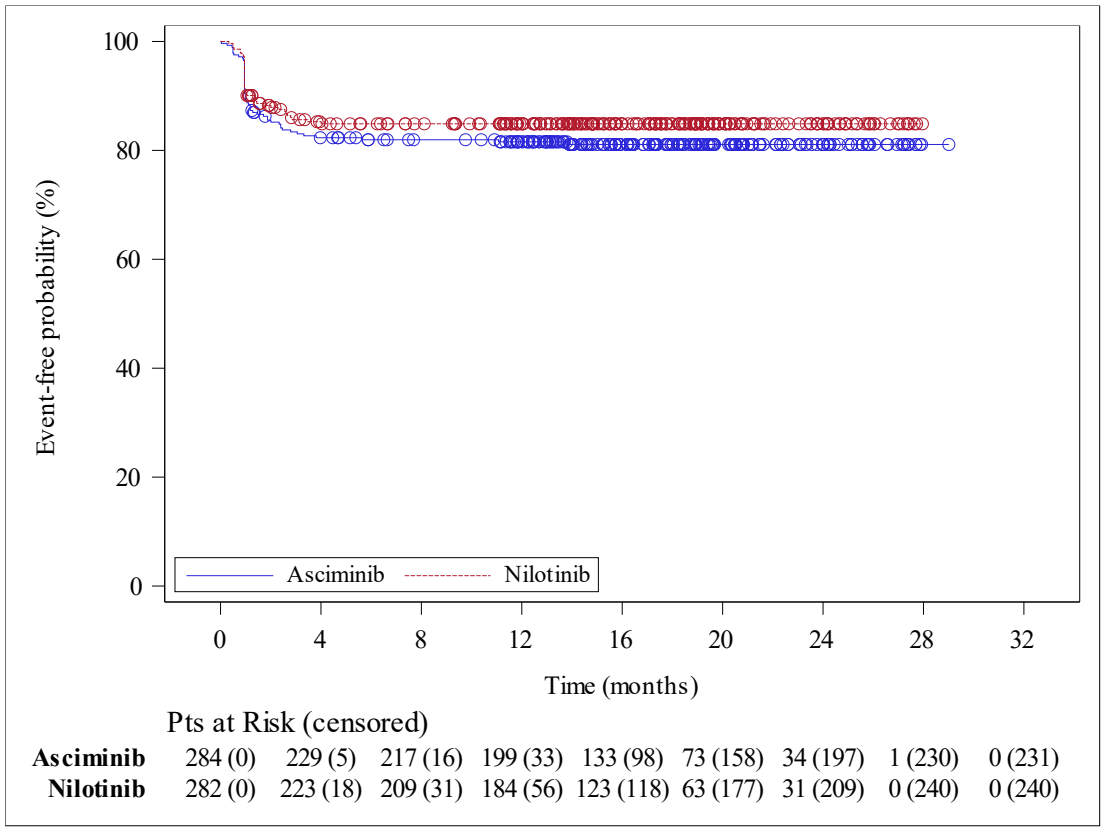
Myelosuppression (Leukopenia)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.11 Grade 1/2 AESI: Kaplan-Meier plot (Safety Analysis Set)

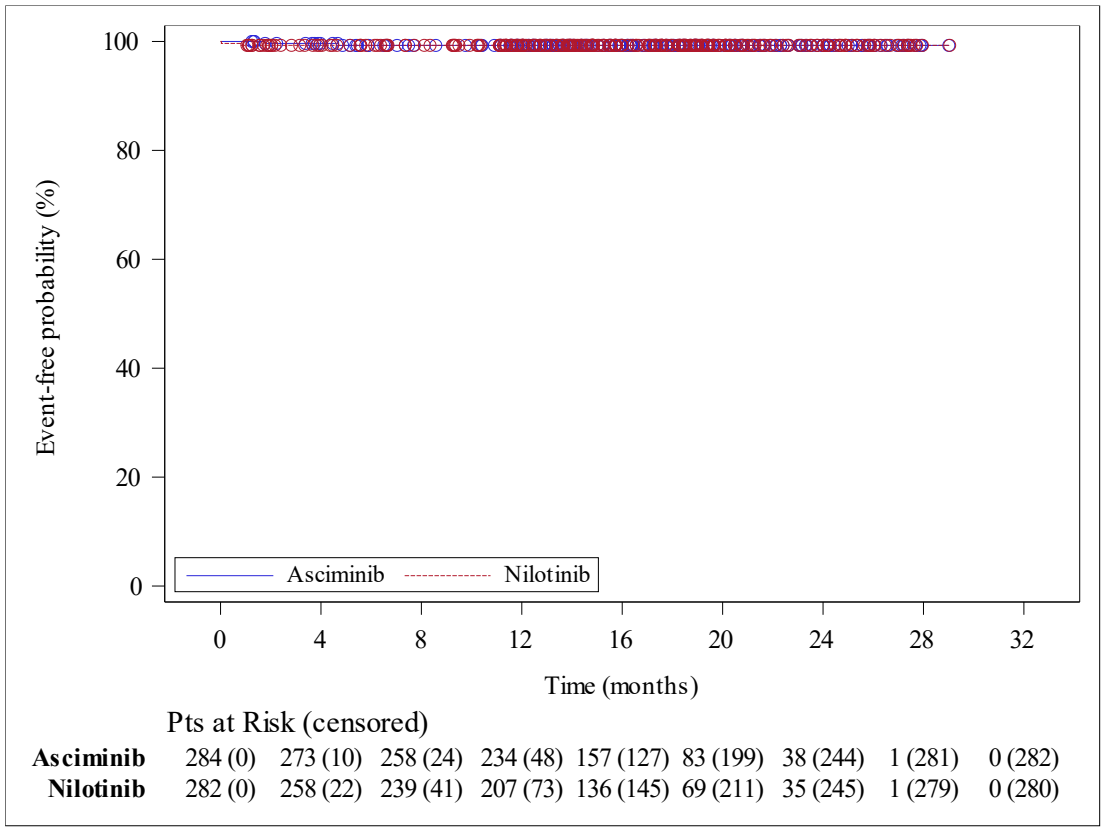
Myelosuppression (Thrombocytopenia)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.11 Grade 1/2 AESI: Kaplan-Meier plot (Safety Analysis Set)

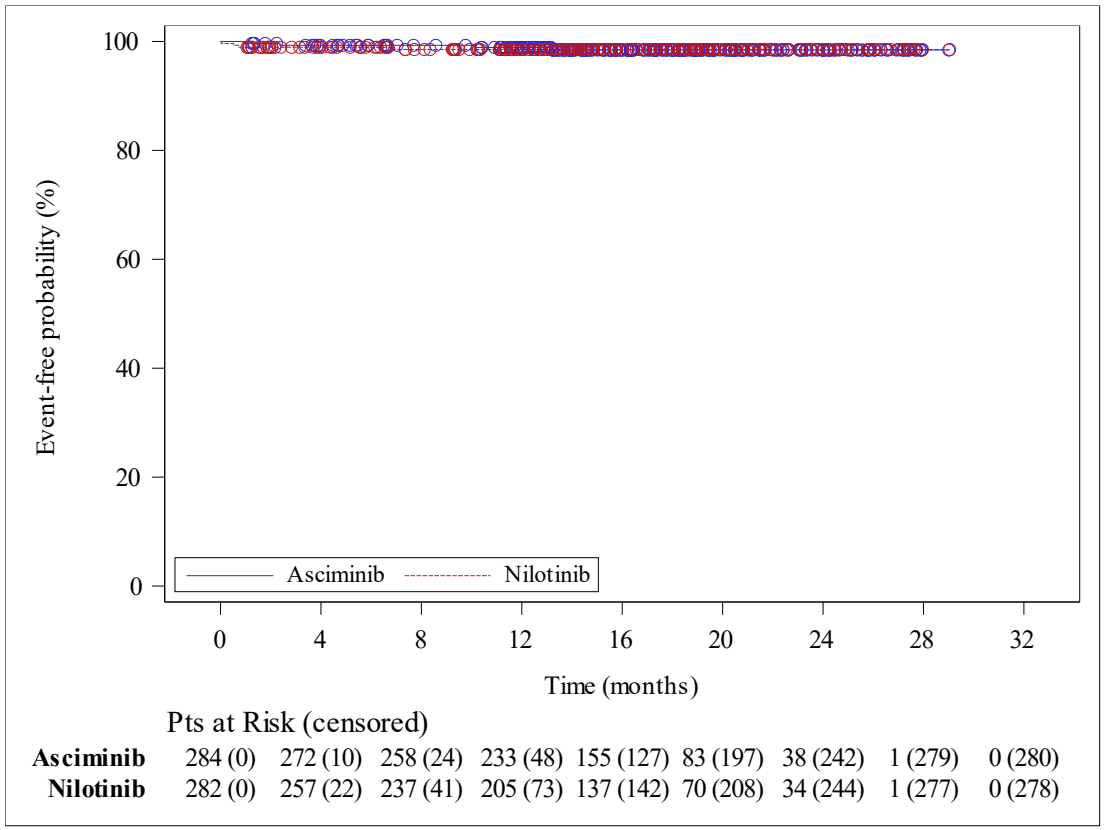
Phototoxicity



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.11 Grade 1/2 AESI: Kaplan-Meier plot (Safety Analysis Set)

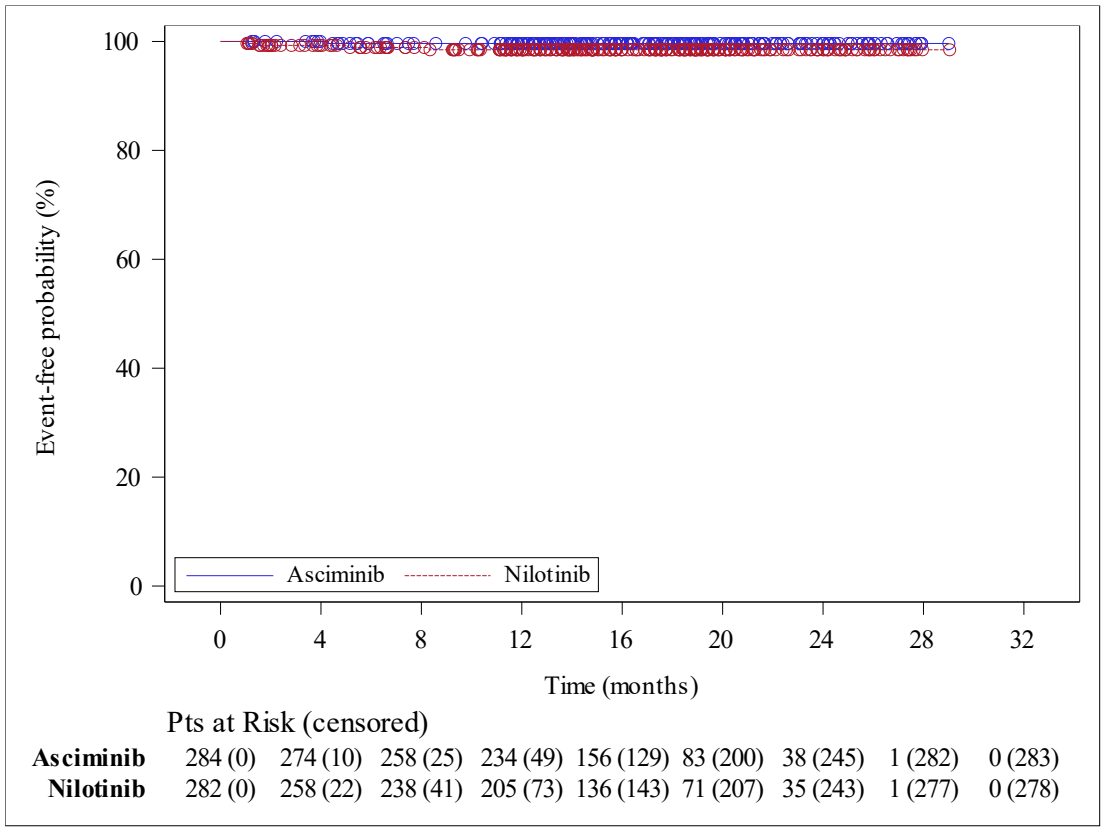
QTc prolongation



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.11 Grade 1/2 AESI: Kaplan-Meier plot (Safety Analysis Set)

Reproductive toxicity



Note: o = Censored observations
Data Cut/15MAY2025

Table 4-1.12 Grade >=3 AESI: time to first occurrence (Safety Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Acute pancreatitis (including isolated pancreatic enzyme elevations)			
N*	284	282	0.27
Number of patients with events, n (%)	4 (1.4)	14 (5.0)	[0.09; 0.82]
			0.014
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Acute pancreatitis (clinical events)			
N*	284	282	0.25
Number of patients with events, n (%)	1 (0.4)	4 (1.4)	[0.03; 2.20]
			0.174
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Arterial-occlusive events (AOE)			
N*	284	282	0.58
Number of patients with events, n (%)	4 (1.4)	6 (2.1)	[0.16; 2.06]
			0.396
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [26.4; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Cardiac failure			
N*	284	282	0.91
Number of patients with events, n (%)	1 (0.4)	1 (0.4)	[0.06; 14.59]
			0.949
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Gastrointestinal toxicity			
N*	284	282	0.30
Number of patients with events, n (%)	1 (0.4)	3 (1.1)	[0.03; 2.91]
			0.272
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Hemorrhage			
N*	284	282	0.98
Number of patients with events, n (%)	1 (0.4)	1 (0.4)	[0.06; 15.63]
			0.987
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Hepatotoxicity (clinical events)			
N*	284	282	0.99
Number of patients with events, n (%)	3 (1.1)	3 (1.1)	[0.20; 4.88]
			0.986
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Hepatotoxicity (including laboratory terms)			
N*	284	282	0.26
Number of patients with events, n (%)	8 (2.8)	29 (10.3)	[0.12; 0.56]
			<0.001
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Hypersensitivity			
N*	284	282	0.32
Number of patients with events, n (%)	1 (0.4)	3 (1.1)	[0.03; 3.12]
			0.305
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Ischemic heart and CNS conditions			
N*	284	282	0.65
Number of patients with events, n (%)	5 (1.8)	7 (2.5)	[0.21; 2.04]
			0.456
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Ischemic CNS conditions			
N*	284	282	2.80
Number of patients with events, n (%)	1 (0.4)	0	[0.03; 273.4]
			0.345
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Ischemic heart conditions			
N*	284	282	0.52
Number of patients with events, n (%)	4 (1.4)	7 (2.5)	[0.15; 1.78]
			0.288
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Myelosuppression			
N*	284	282	1.18
Number of patients with events, n (%)	41 (14.4)	34 (12.1)	[0.75; 1.86]
			0.470
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Myelosuppression (Erythropenia)			
N*	284	282	2.91
Number of patients with events, n (%)	12 (4.2)	4 (1.4)	[0.94; 9.03]
			0.053
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Myelosuppression (Leukopenia)			
N*	284	282	1.14
Number of patients with events, n (%)	23 (8.1)	20 (7.1)	[0.62; 2.07]
			0.669
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Myelosuppression (Thrombocytopenia)			
N*	284	282	1.36
Number of patients with events, n (%)	29 (10.2)	21 (7.4)	[0.78; 2.39]
			0.279
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

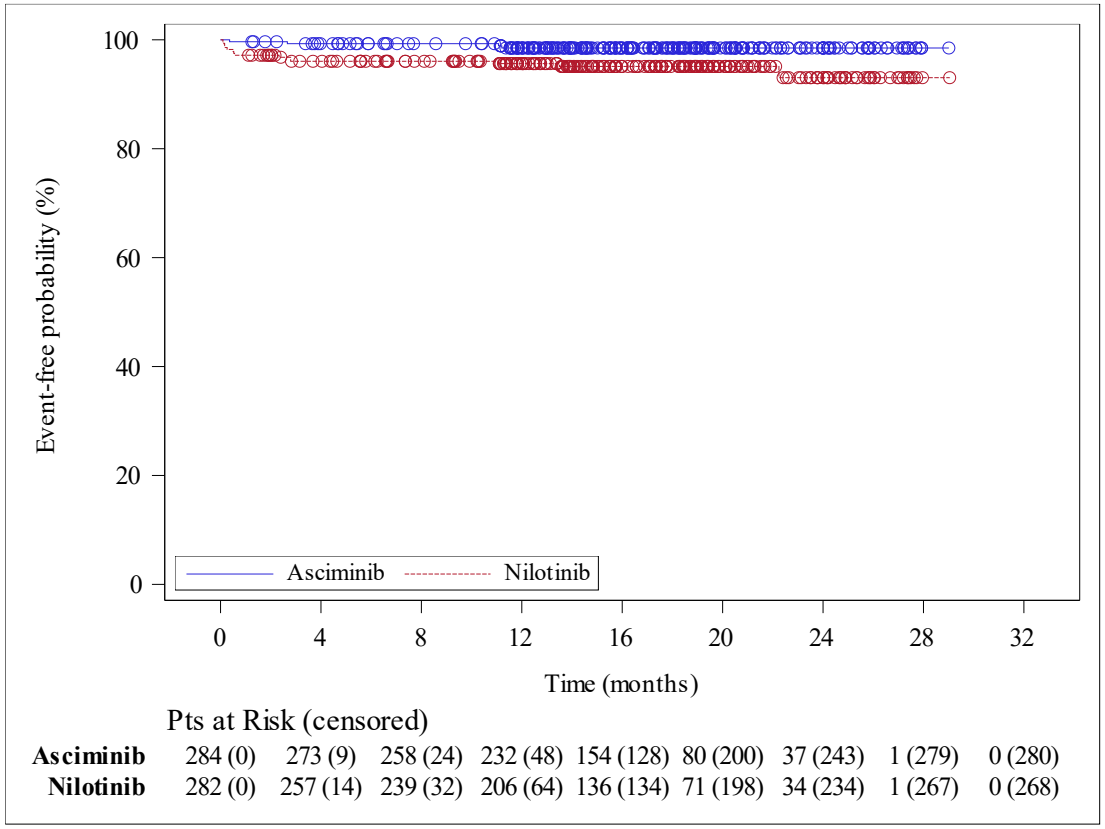
	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
QTc prolongation			
N*	284	282	0.96
Number of patients with events, n (%)	2 (0.7)	2 (0.7)	[0.14; 6.83]
			0.968
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Reproductive toxicity			
N*	284	282	2.90
Number of patients with events, n (%)	1 (0.4)	0	[0.03; 267.7]
			0.325
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 4-1.12 Grade >=3 AESI: Kaplan-Meier plot (Safety Analysis Set)

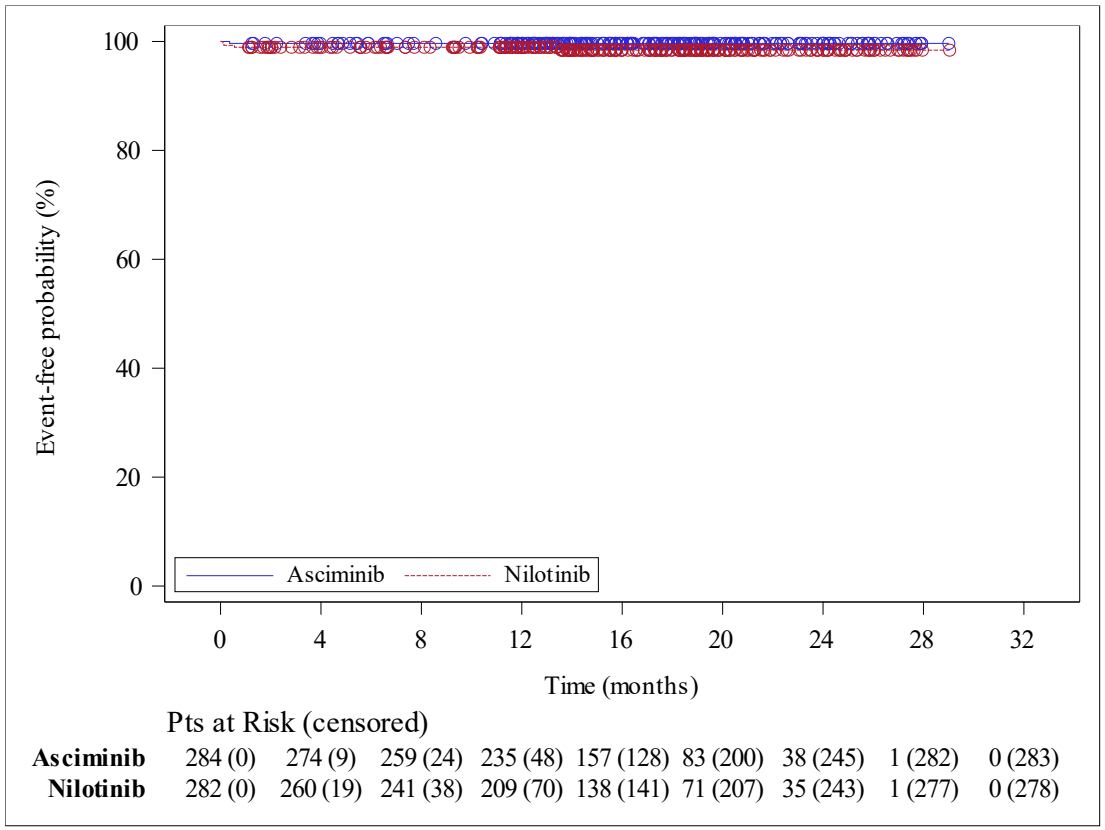
Acute pancreatitis (including isolated pancreatic enzyme elevations)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.12 Grade >=3 AESI: Kaplan-Meier plot (Safety Analysis Set)

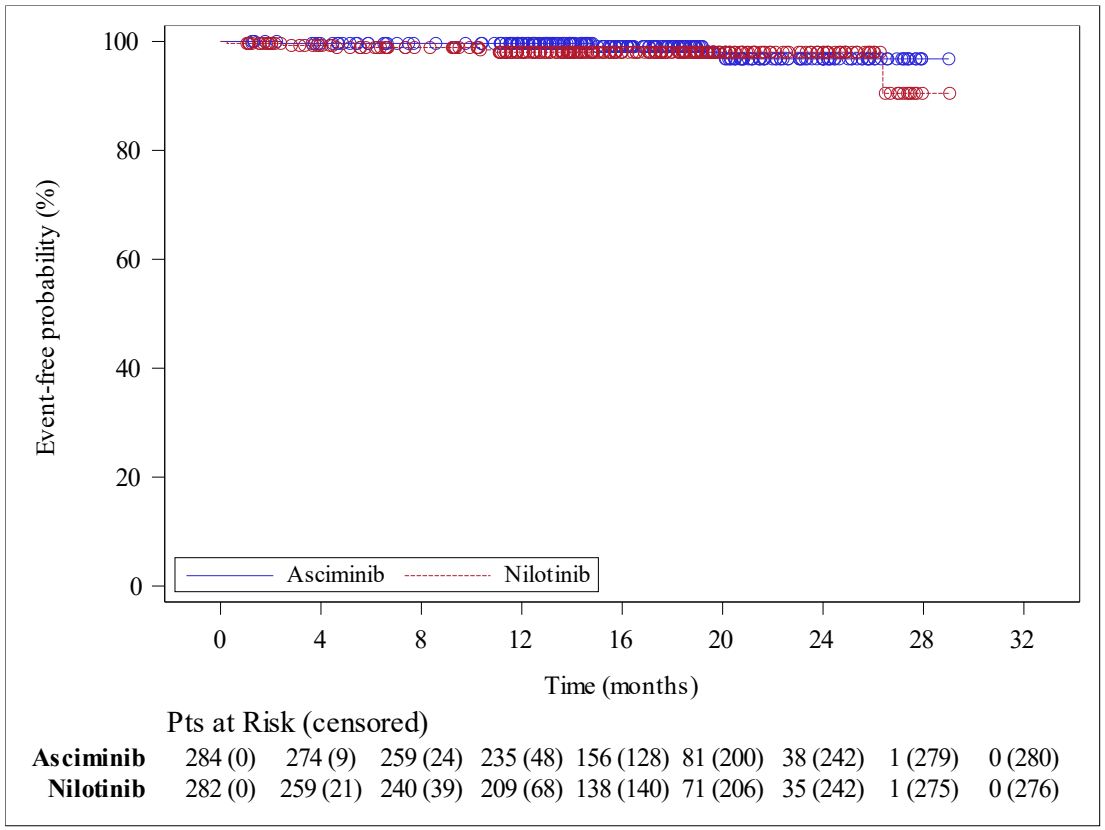
Acute pancreatitis (clinical events)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.12 Grade >=3 AESI: Kaplan-Meier plot (Safety Analysis Set)

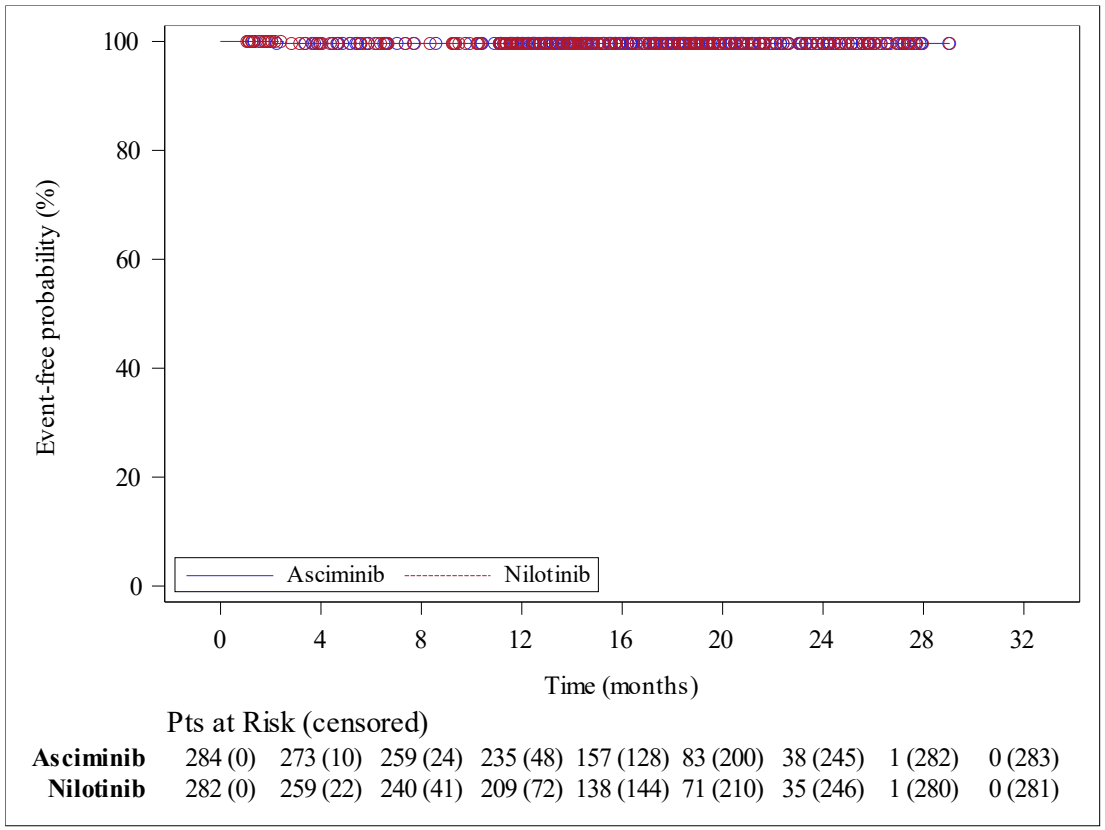
Arterial-occlusive events (AOE)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.12 Grade >=3 AESI: Kaplan-Meier plot (Safety Analysis Set)

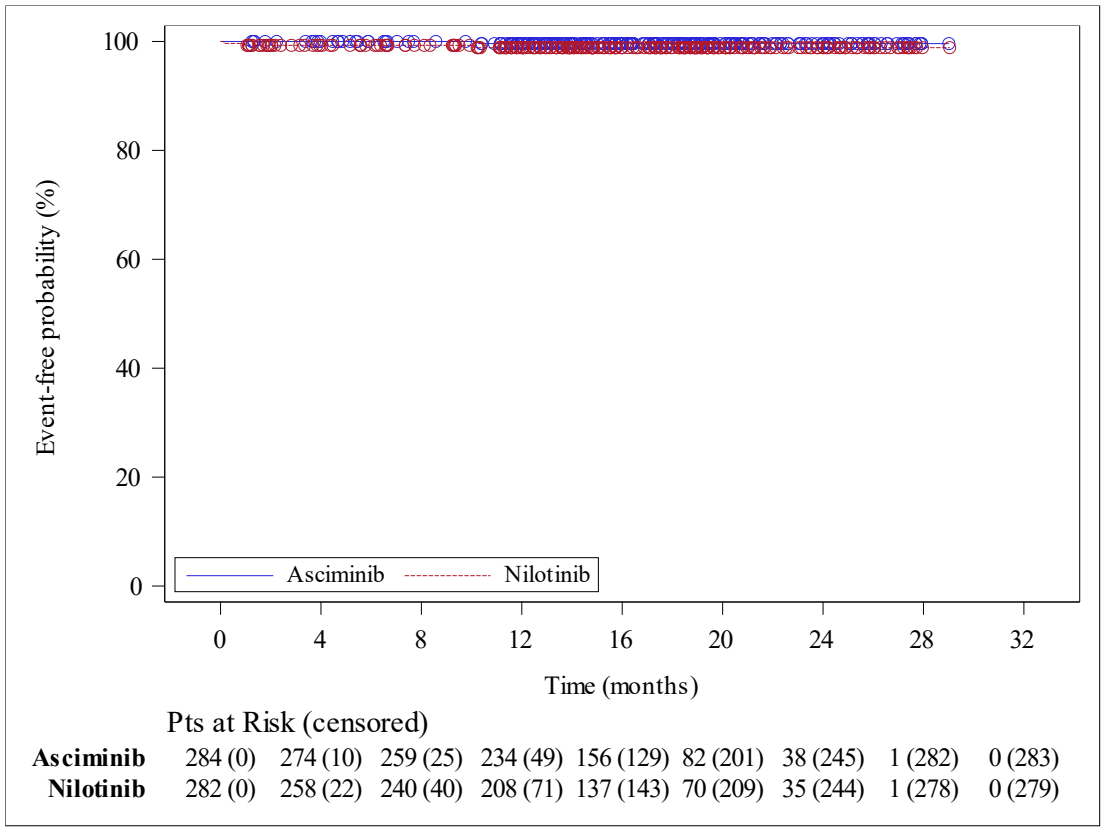
Cardiac failure



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.12 Grade >=3 AESI: Kaplan-Meier plot (Safety Analysis Set)

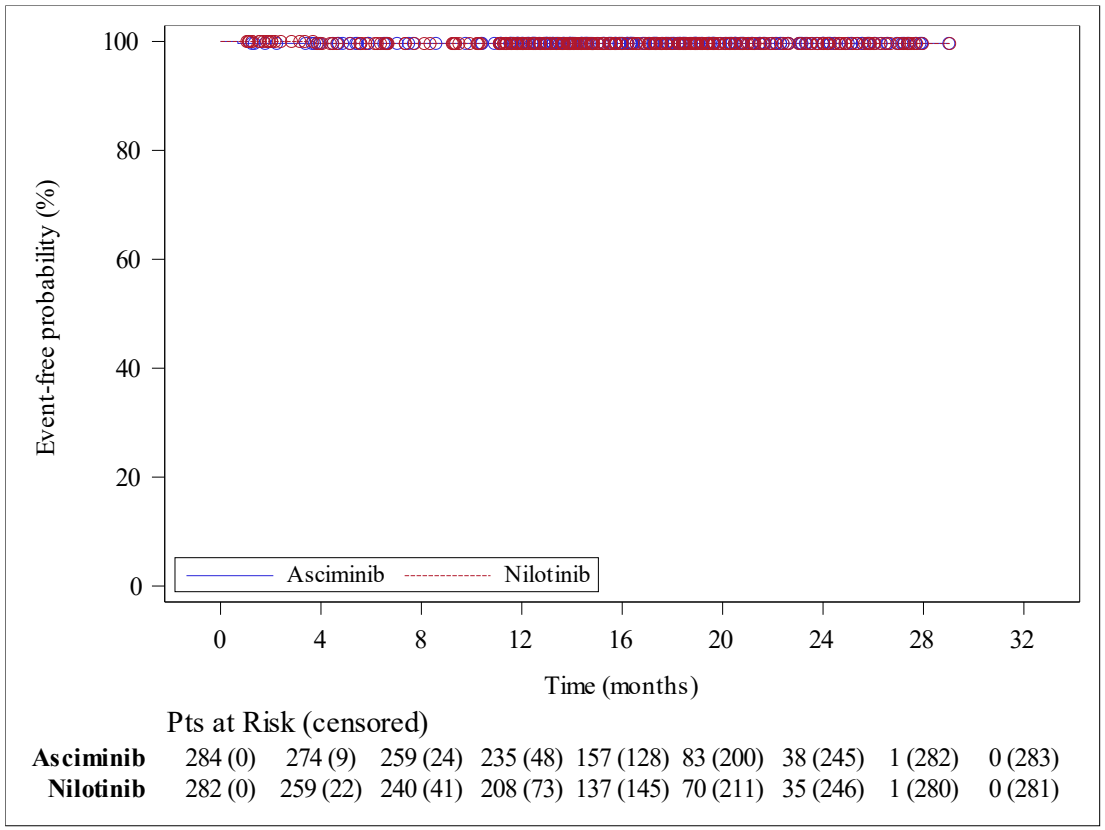
Gastrointestinal toxicity



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.12 Grade >=3 AESI: Kaplan-Meier plot (Safety Analysis Set)

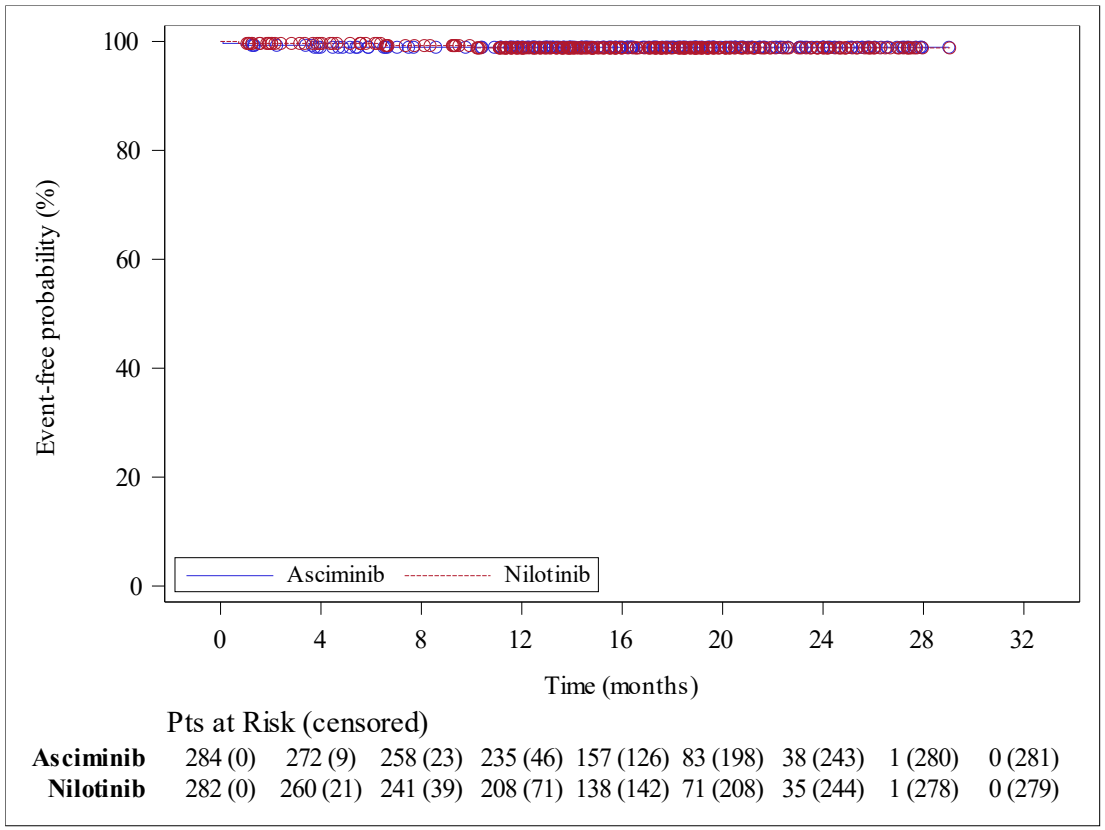
Hemorrhage



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.12 Grade >=3 AESI: Kaplan-Meier plot (Safety Analysis Set)

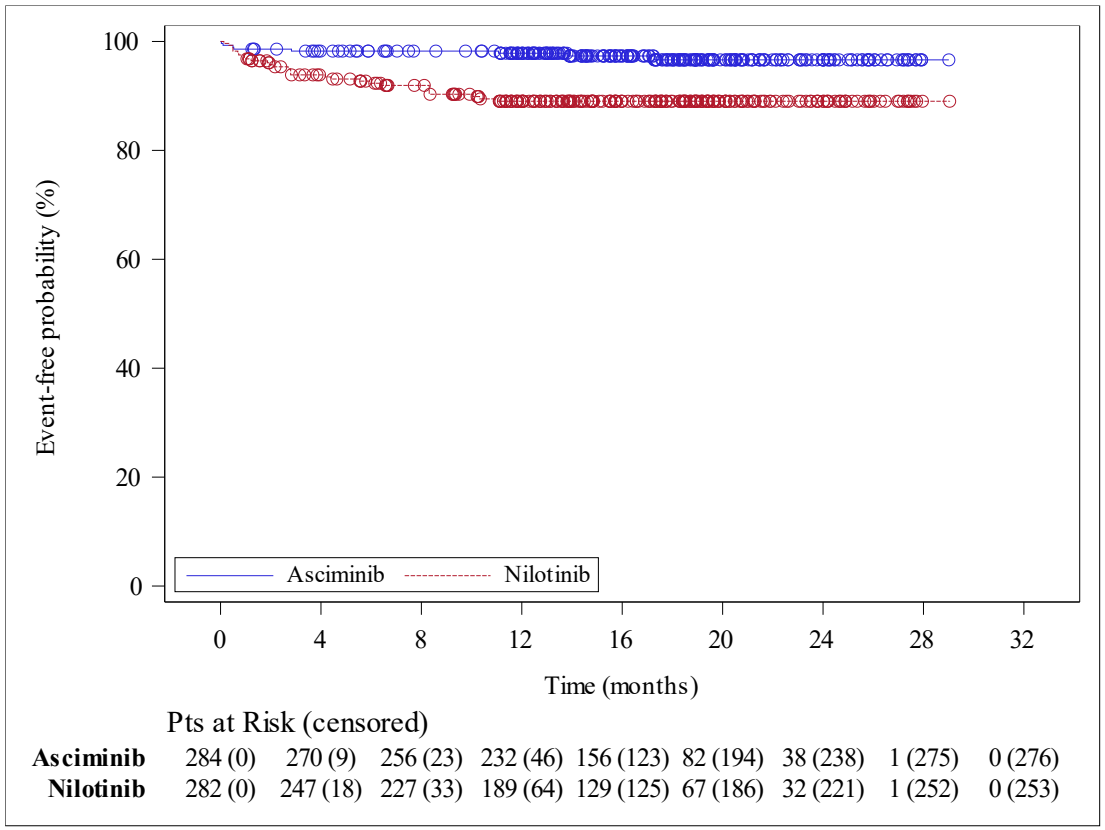
Hepatotoxicity (clinical events)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.12 Grade >=3 AESI: Kaplan-Meier plot (Safety Analysis Set)

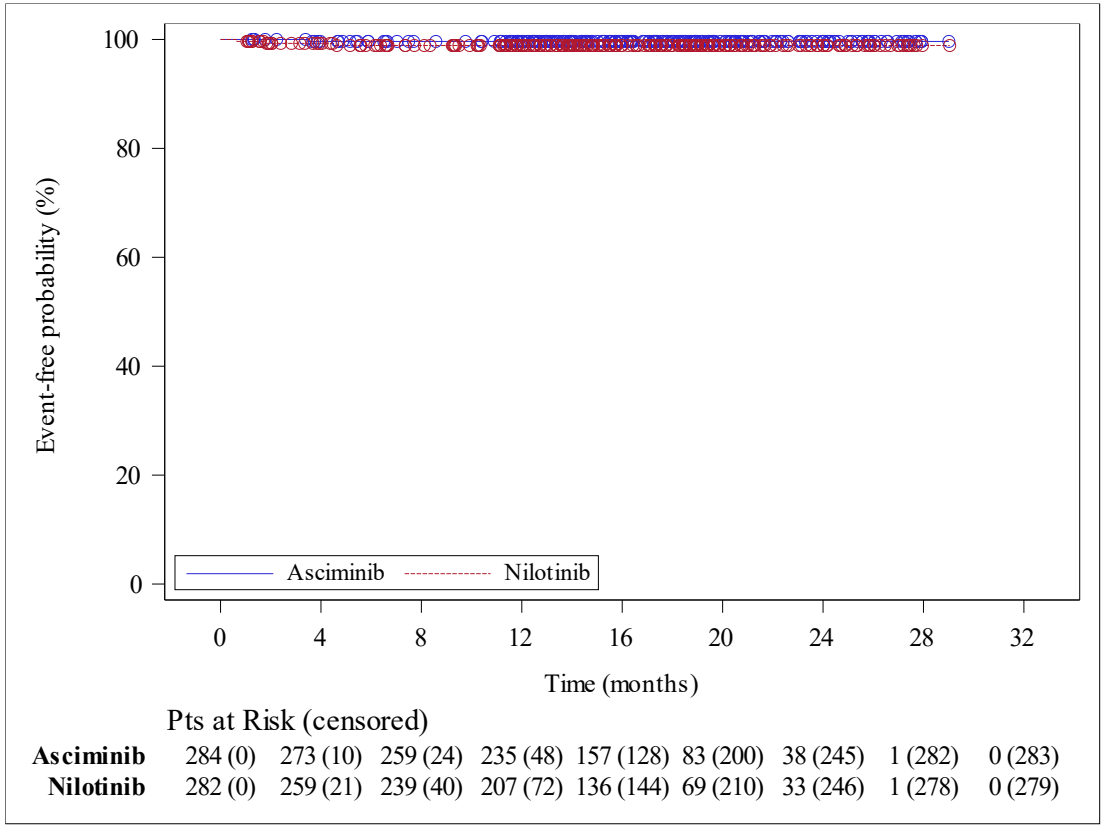
Hepatotoxicity (including laboratory terms)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.12 Grade >=3 AESI: Kaplan-Meier plot (Safety Analysis Set)

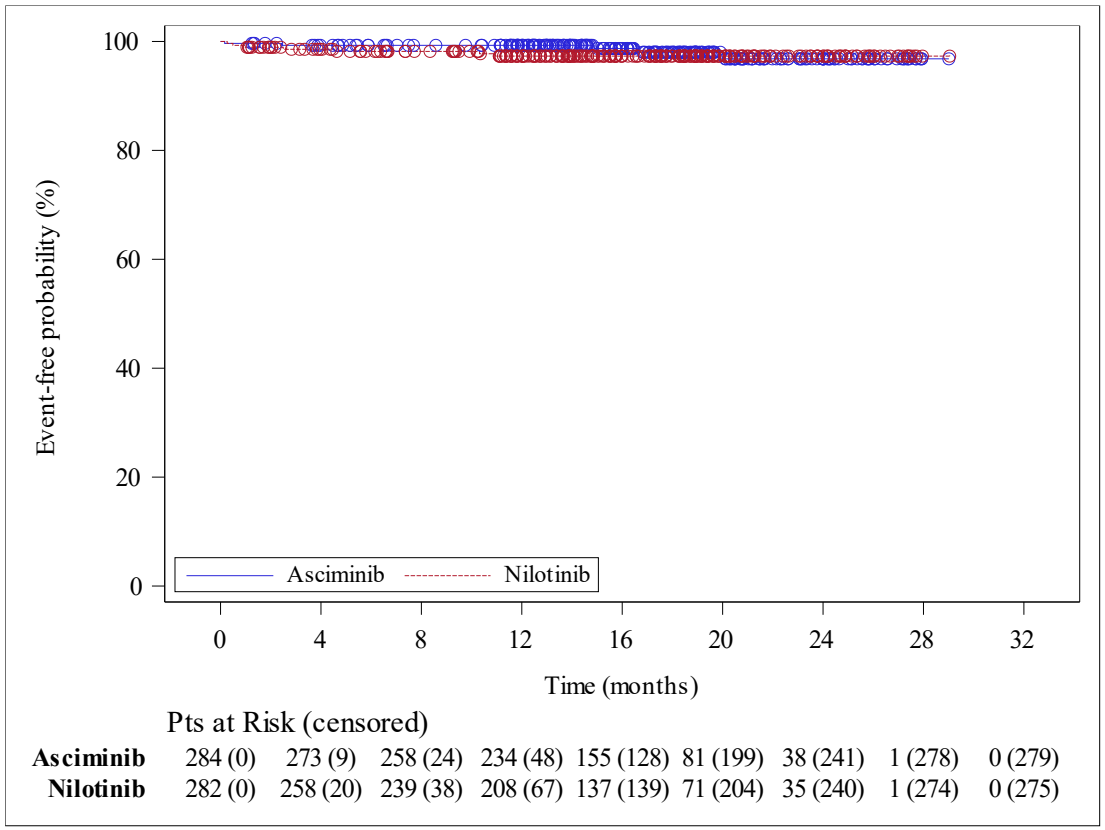
Hypersensitivity



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.12 Grade >=3 AESI: Kaplan-Meier plot (Safety Analysis Set)

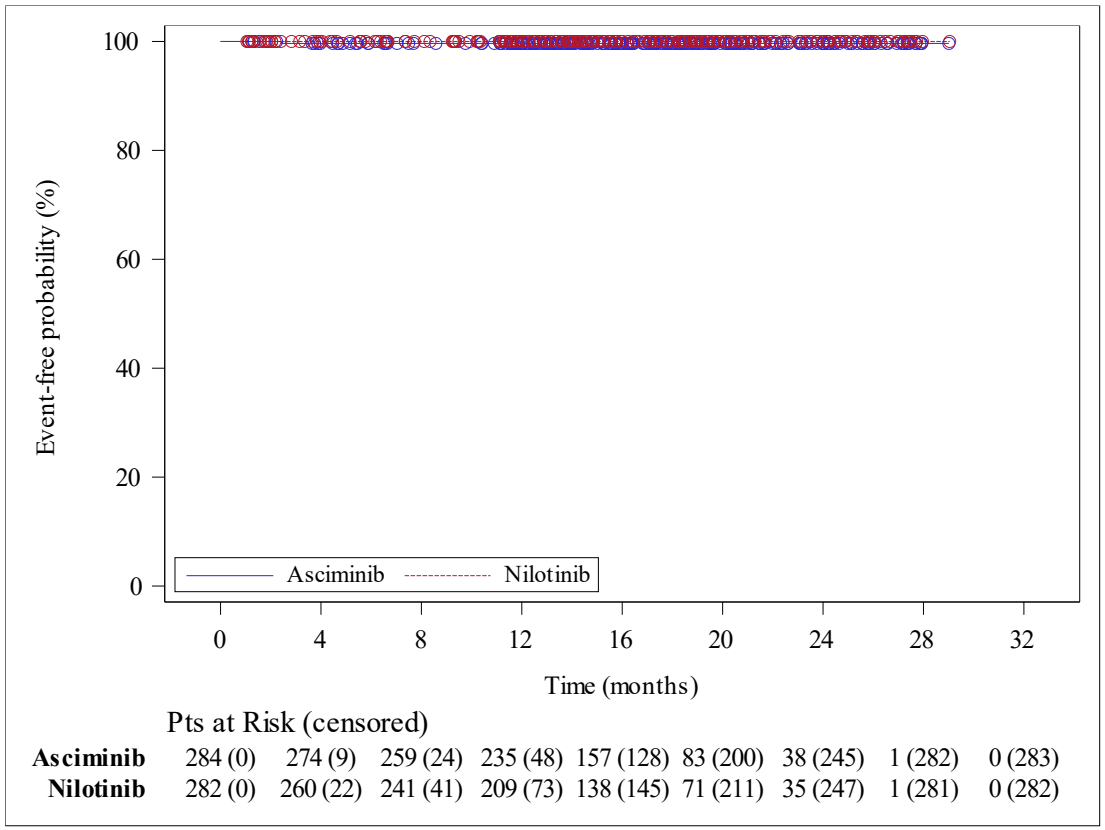
Ischemic heart and CNS conditions



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.12 Grade >=3 AESI: Kaplan-Meier plot (Safety Analysis Set)

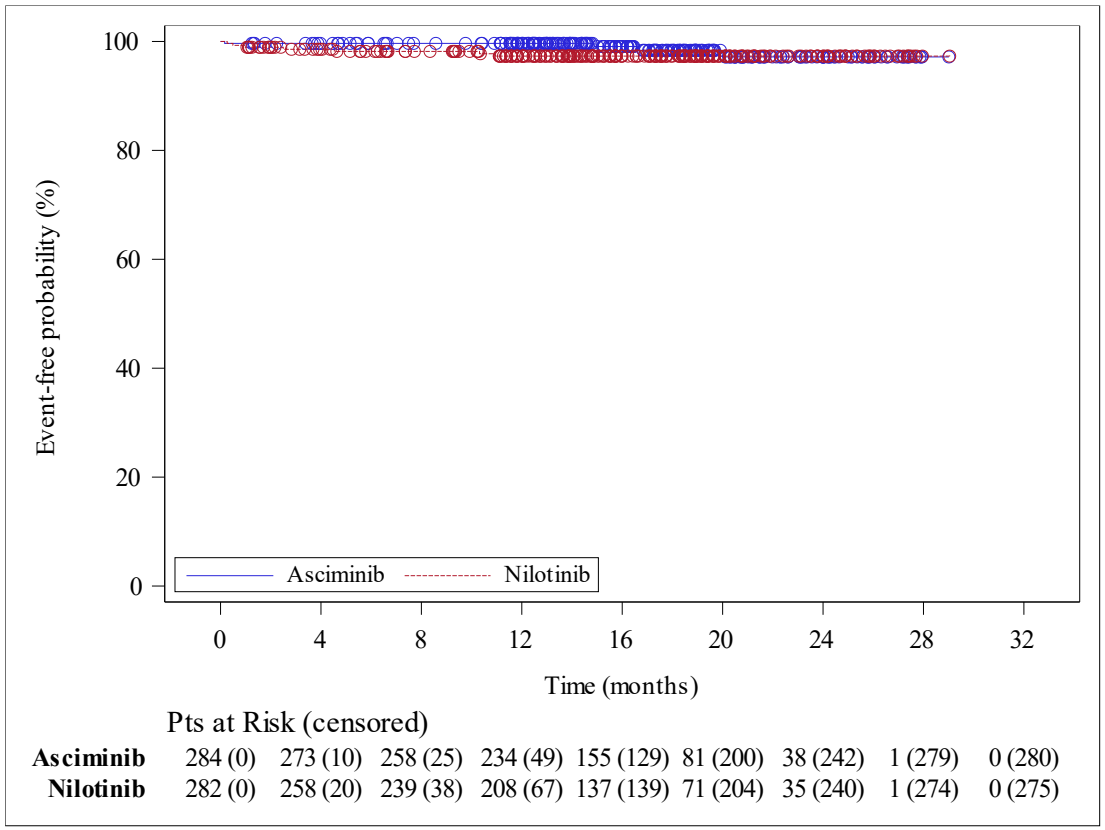
Ischemic CNS conditions



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.12 Grade >=3 AESI: Kaplan-Meier plot (Safety Analysis Set)

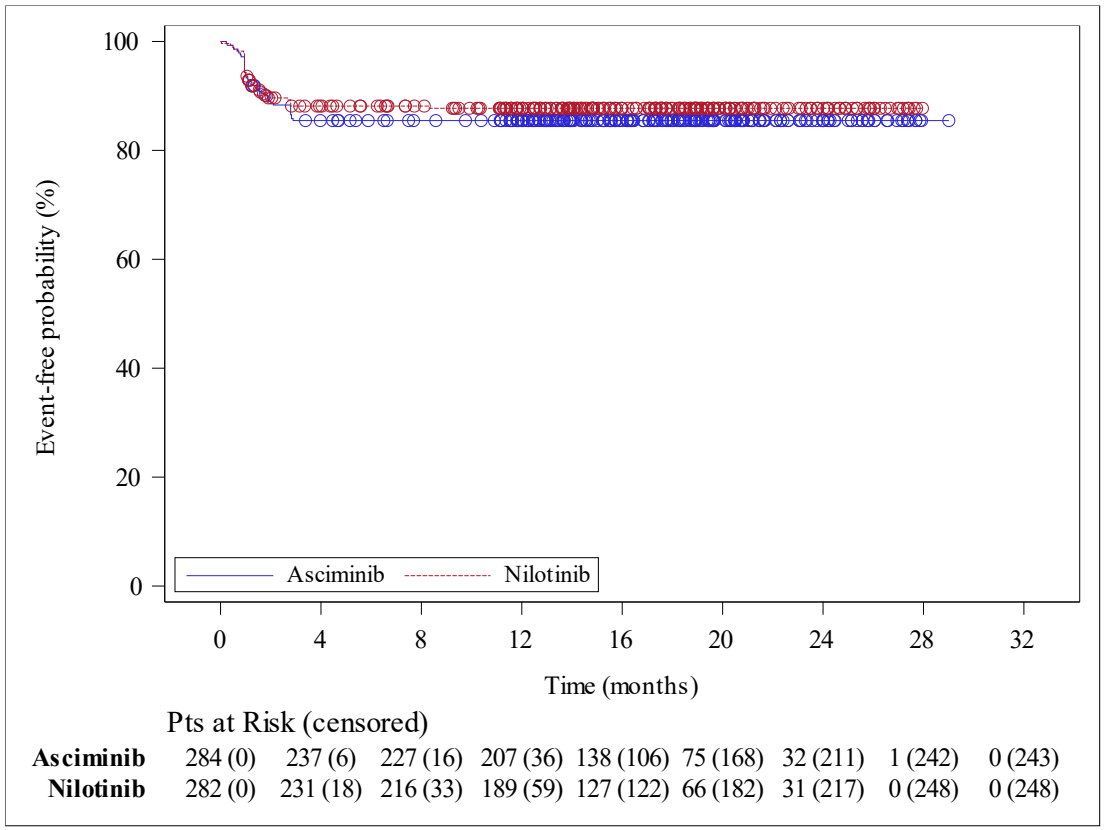
Ischemic heart conditions



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.12 Grade >=3 AESI: Kaplan-Meier plot (Safety Analysis Set)

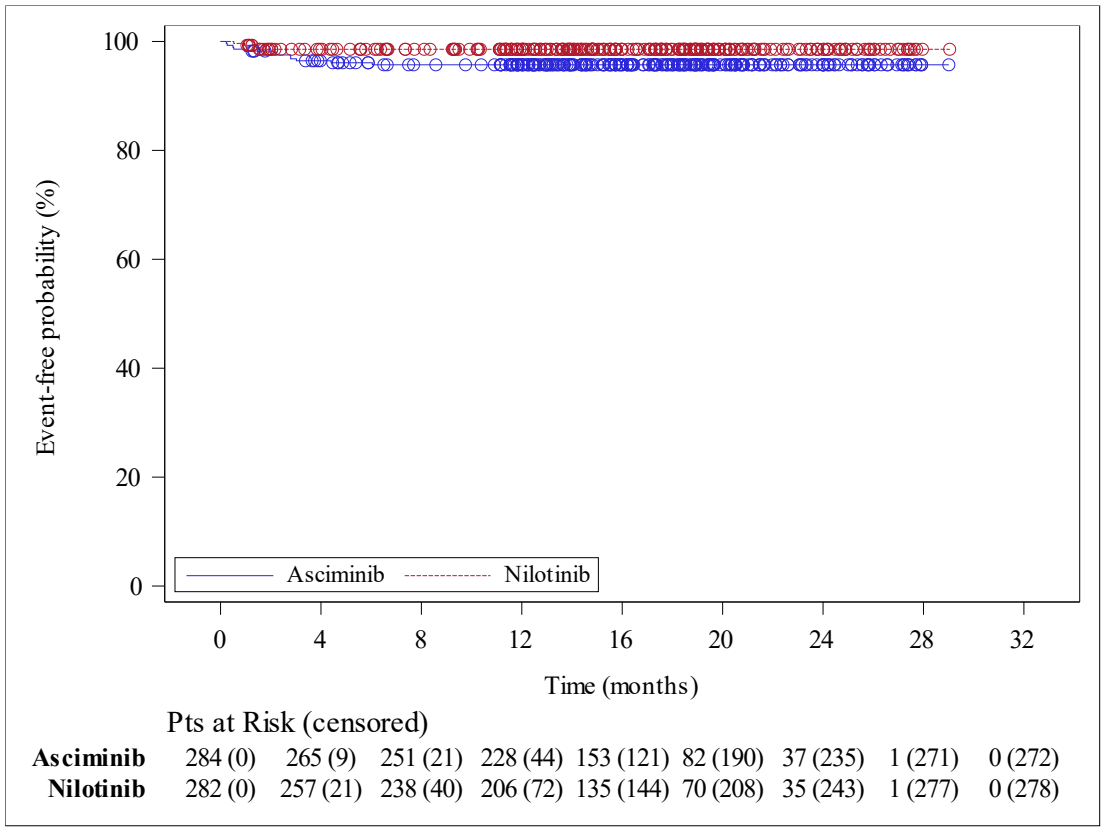
Myelosuppression



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.12 Grade >=3 AESI: Kaplan-Meier plot (Safety Analysis Set)

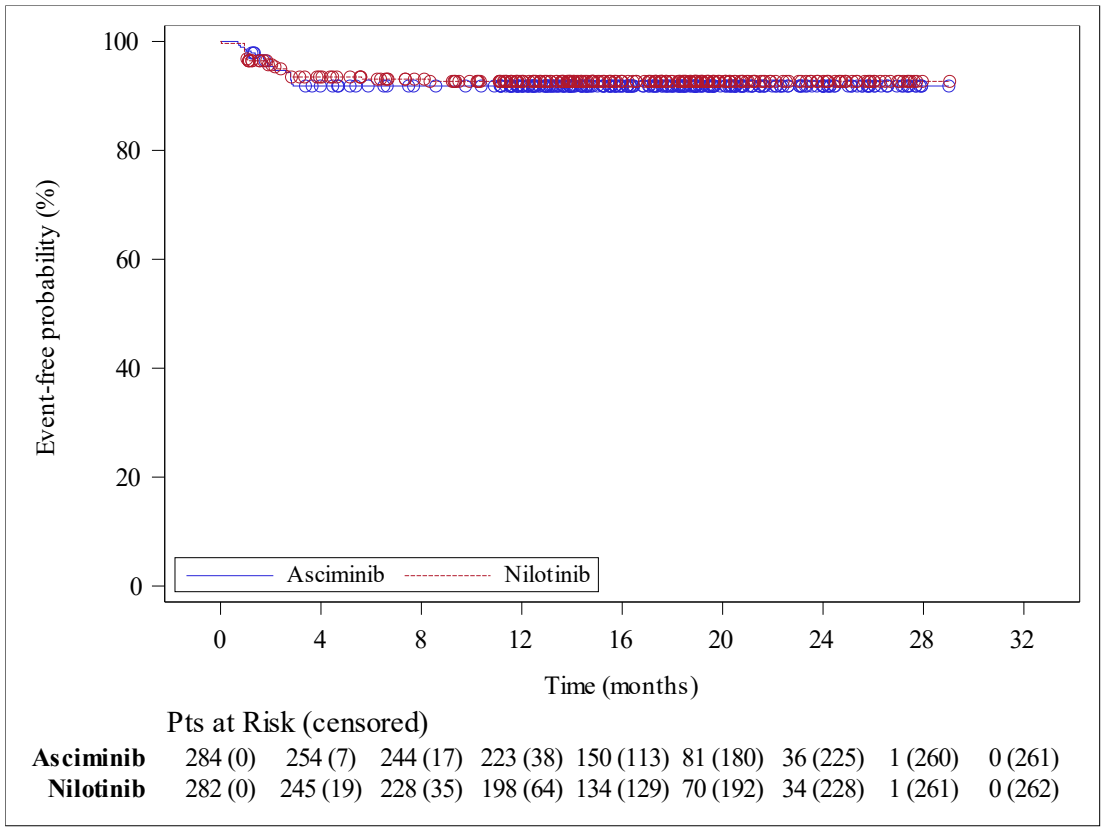
Myelosuppression (Erythropenia)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.12 Grade >=3 AESI: Kaplan-Meier plot (Safety Analysis Set)

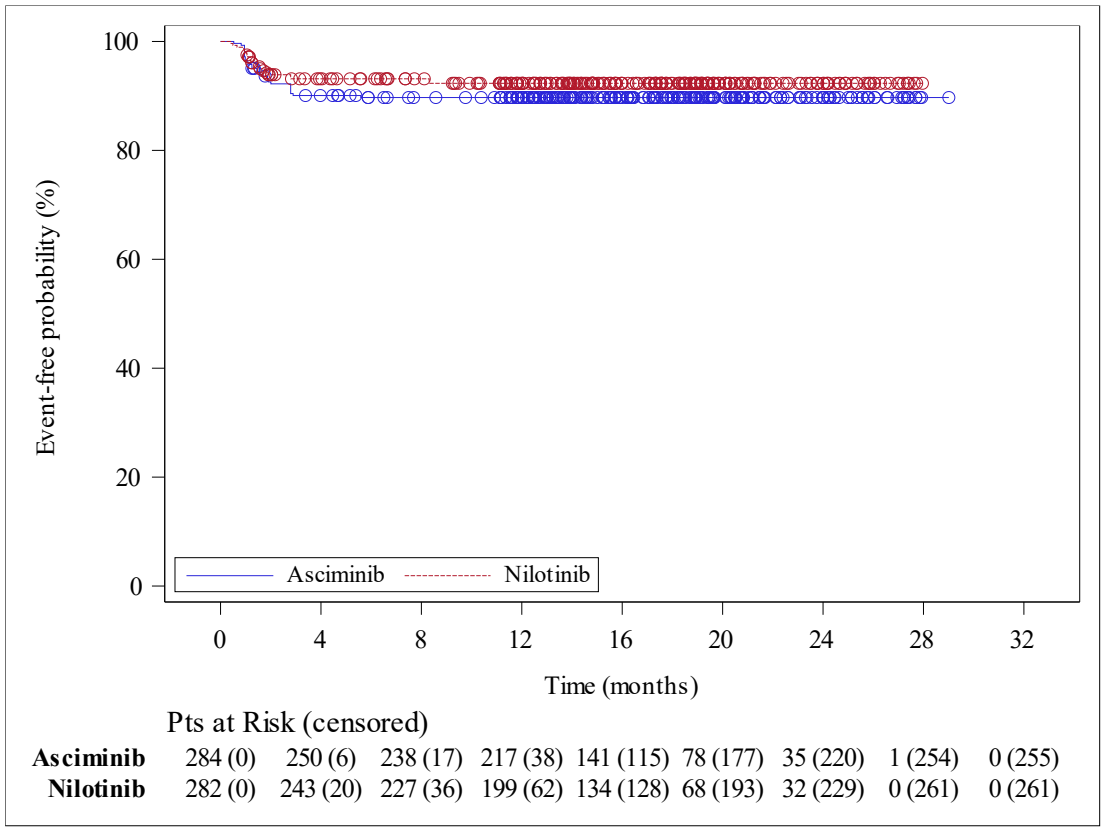
Myelosuppression (Leukopenia)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.12 Grade >=3 AESI: Kaplan-Meier plot (Safety Analysis Set)

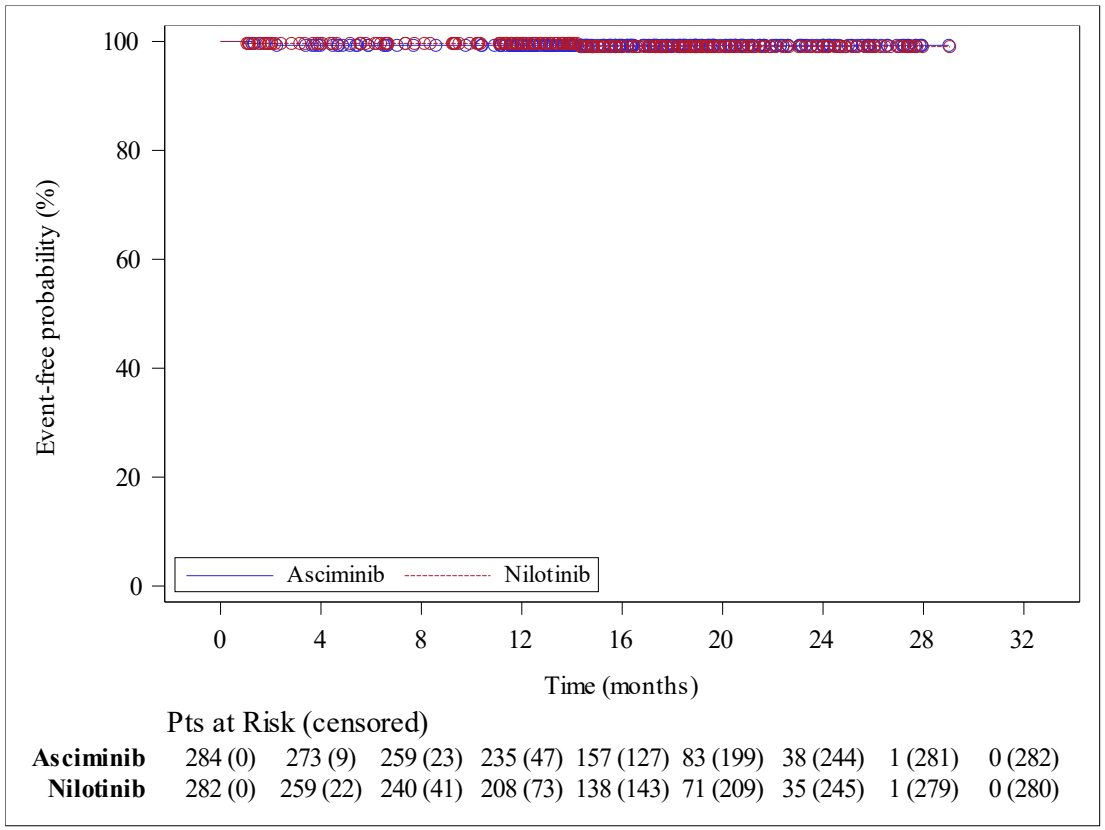
Myelosuppression (Thrombocytopenia)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.12 Grade >=3 AESI: Kaplan-Meier plot (Safety Analysis Set)

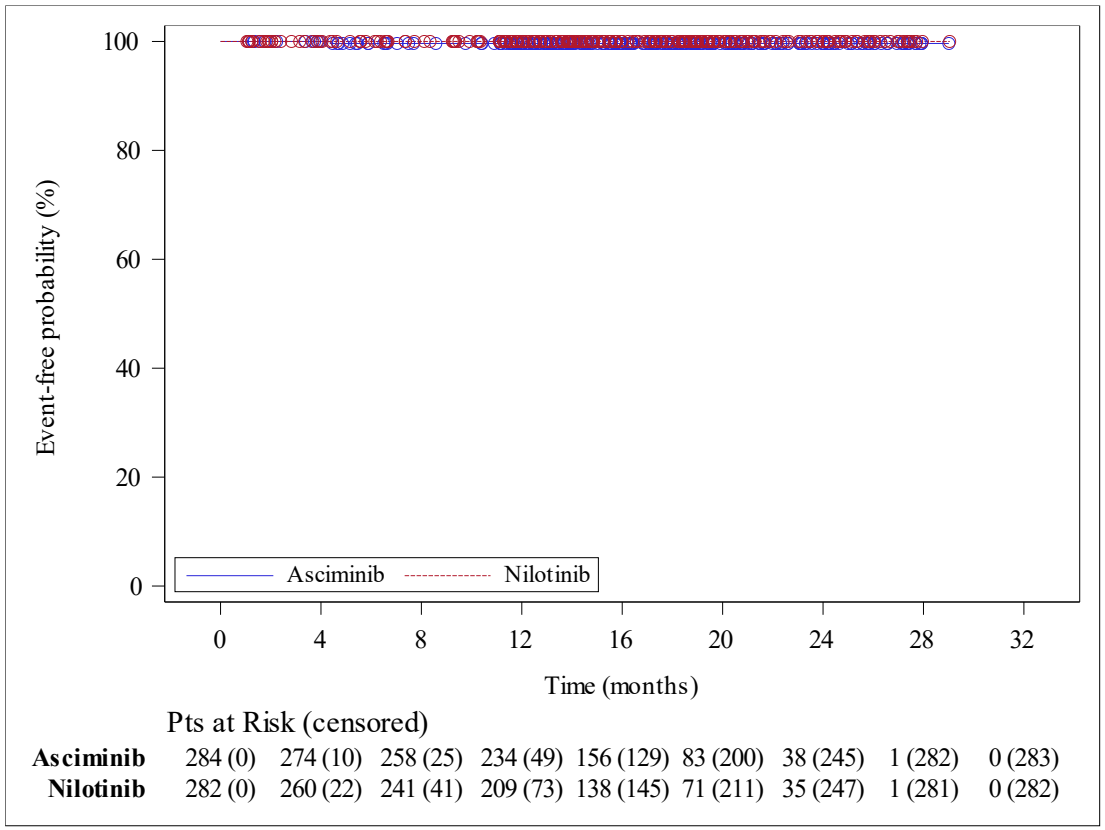
QTc prolongation



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.12 Grade >=3 AESI: Kaplan-Meier plot (Safety Analysis Set)

Reproductive toxicity



Note: o = Censored observations
Data Cut/15MAY2025

Table 4-1.13 Serious AESI: time to first occurrence (Safety Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Acute pancreatitis (including isolated pancreatic enzyme elevations)			
N*	284	282	0.28
Number of patients with events, n (%)	2 (0.7)	7 (2.5)	[0.06; 1.33]
			0.086
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Acute pancreatitis (clinical events)			
N*	284	282	0.16
Number of patients with events, n (%)	1 (0.4)	6 (2.1)	[0.02; 1.36]
			0.055
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Arterial-occlusive events (AOE)			
N*	284	282	1.35
Number of patients with events, n (%)	6 (2.1)	4 (1.4)	[0.38; 4.79]
			0.640
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Cardiac failure			
N*	284	282	0.91
Number of patients with events, n (%)	1 (0.4)	1 (0.4)	[0.06; 14.59]
			0.949
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Gastrointestinal toxicity			
N*	284	282	1.79
Number of patients with events, n (%)	2 (0.7)	1 (0.4)	[0.16; 19.82]
			0.629
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Hemorrhage			
N*	284	282	0.48
Number of patients with events, n (%)	1 (0.4)	2 (0.7)	[0.04; 5.25]
			0.535
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Hepatotoxicity (clinical events)			
N*	284	282	0.66
Number of patients with events, n (%)	2 (0.7)	3 (1.1)	[0.11; 3.95]
			0.646
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Hepatotoxicity (including laboratory terms)			
N*	284	282	0.40
Number of patients with events, n (%)	2 (0.7)	5 (1.8)	[0.08; 2.05]
			0.253
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Ischemic heart and CNS conditions			
N*	284	282	1.12
Number of patients with events, n (%)	5 (1.8)	4 (1.4)	[0.30; 4.19]
			0.862
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Ischemic CNS conditions			
N*	284	282	4.60
Number of patients with events, n (%)	2 (0.7)	0	[0.11; 189.7]
			0.175
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Ischemic heart conditions			
N*	284	282	0.67
Number of patients with events, n (%)	3 (1.1)	4 (1.4)	[0.15; 2.99]
			0.597
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Myelosuppression			
N*	284	282	0.94
Number of patients with events, n (%)	5 (1.8)	5 (1.8)	[0.27; 3.24]
			0.920
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Myelosuppression (Leukopenia)			
N*	284	282	4.70
Number of patients with events, n (%)	2 (0.7)	0	[0.11; 193.9]
			0.170
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Myelosuppression (Thrombocytopenia)			
N*	284	282	0.56
Number of patients with events, n (%)	3 (1.1)	5 (1.8)	[0.13; 2.36]
			0.425
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

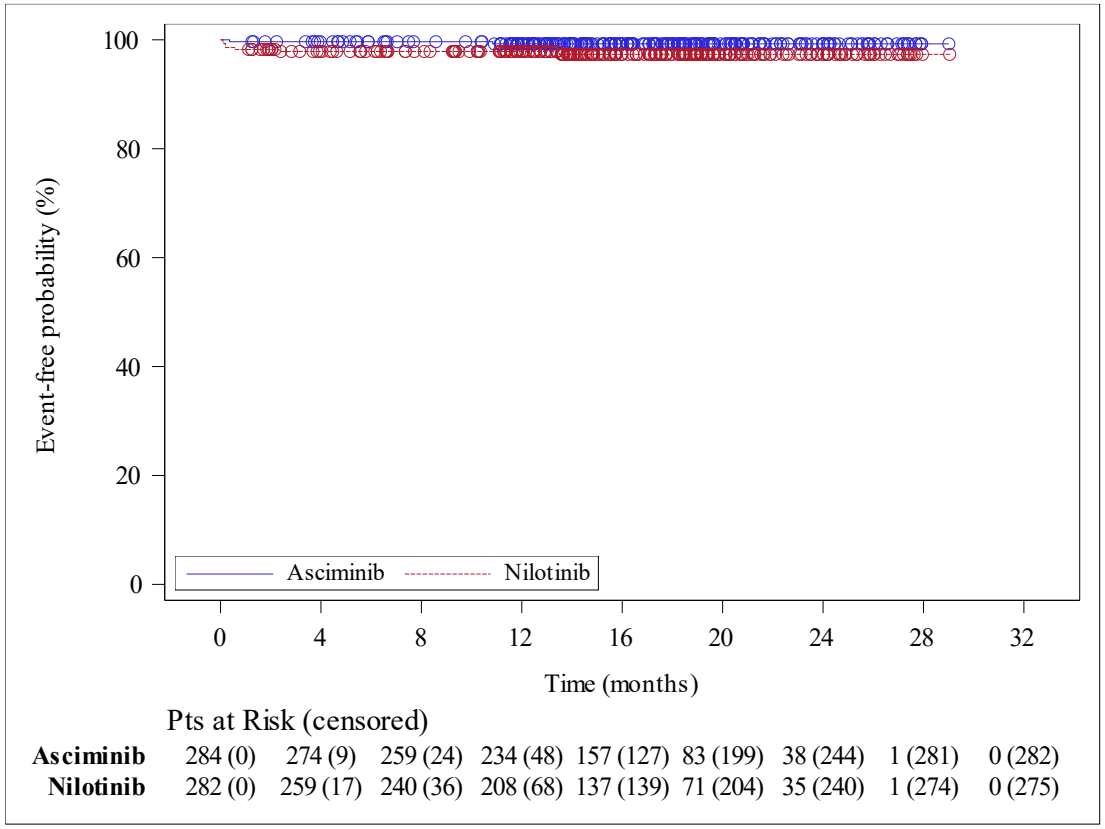
	Treatment groups		Comparison
	Asciminib (N = 284)	Nilotinib (N = 282)	HR [95% CI] p-value
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
QTc prolongation			
N*	284	282	0.97
Number of patients with events, n (%)	1 (0.4)	1 (0.4)	[0.06; 15.51]
			0.983
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Reproductive toxicity			
N*	284	282	2.90
Number of patients with events, n (%)	1 (0.4)	0	[0.03; 267.7]
			0.325
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 4-1.13 Serious AESI: Kaplan-Meier plot (Safety Analysis Set)

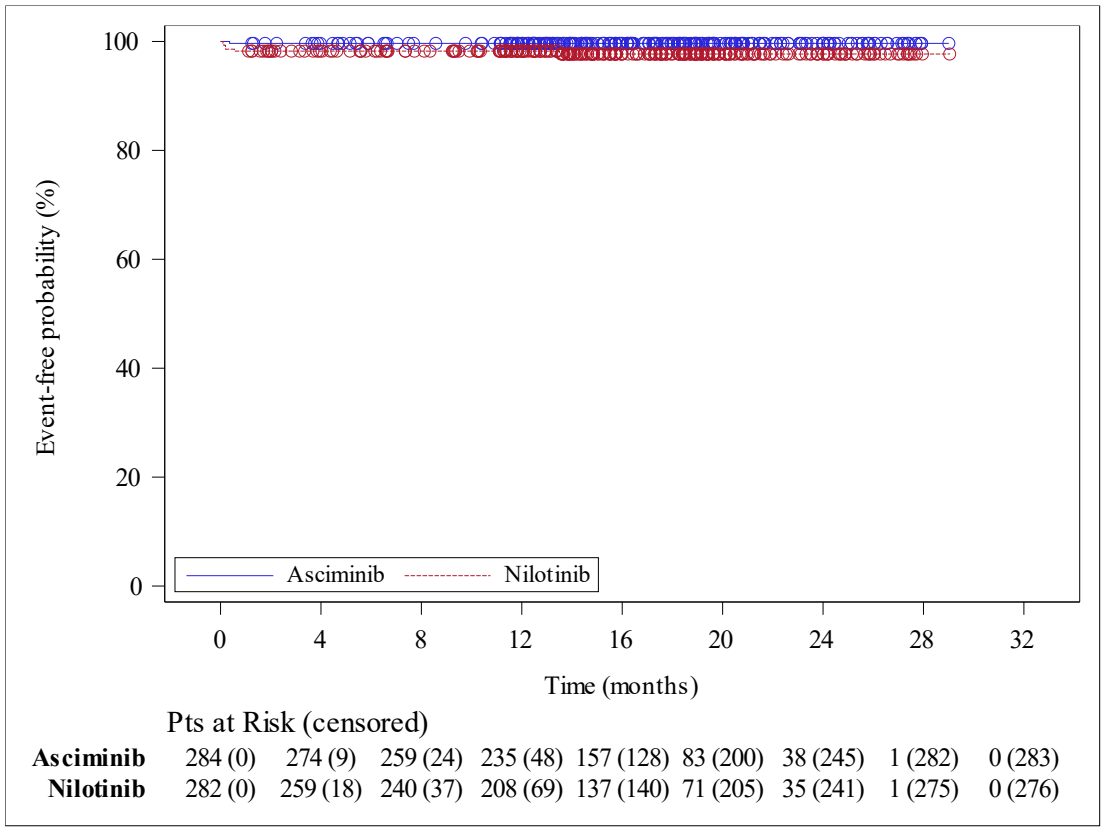
Acute pancreatitis (including isolated pancreatic enzyme elevations)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.13 Serious AESI: Kaplan-Meier plot (Safety Analysis Set)

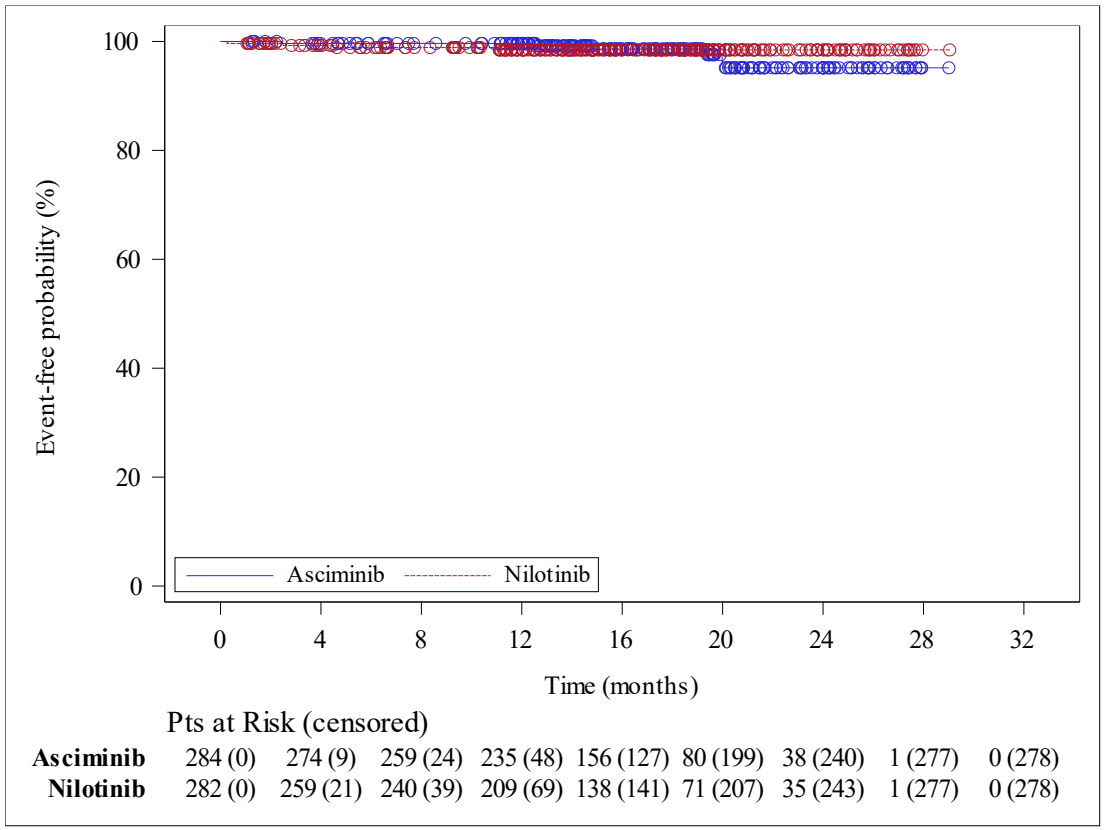
Acute pancreatitis (clinical events)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.13 Serious AESI: Kaplan-Meier plot (Safety Analysis Set)

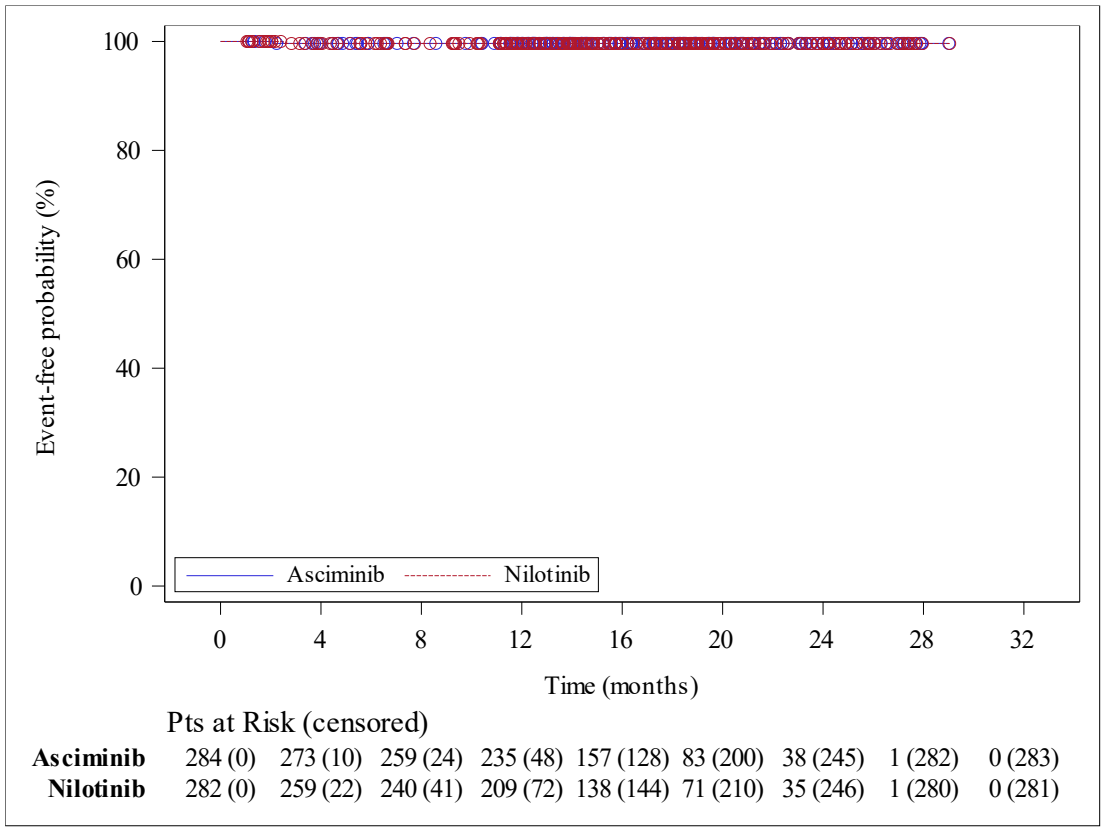
Arterial-occlusive events (AOE)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.13 Serious AESI: Kaplan-Meier plot (Safety Analysis Set)

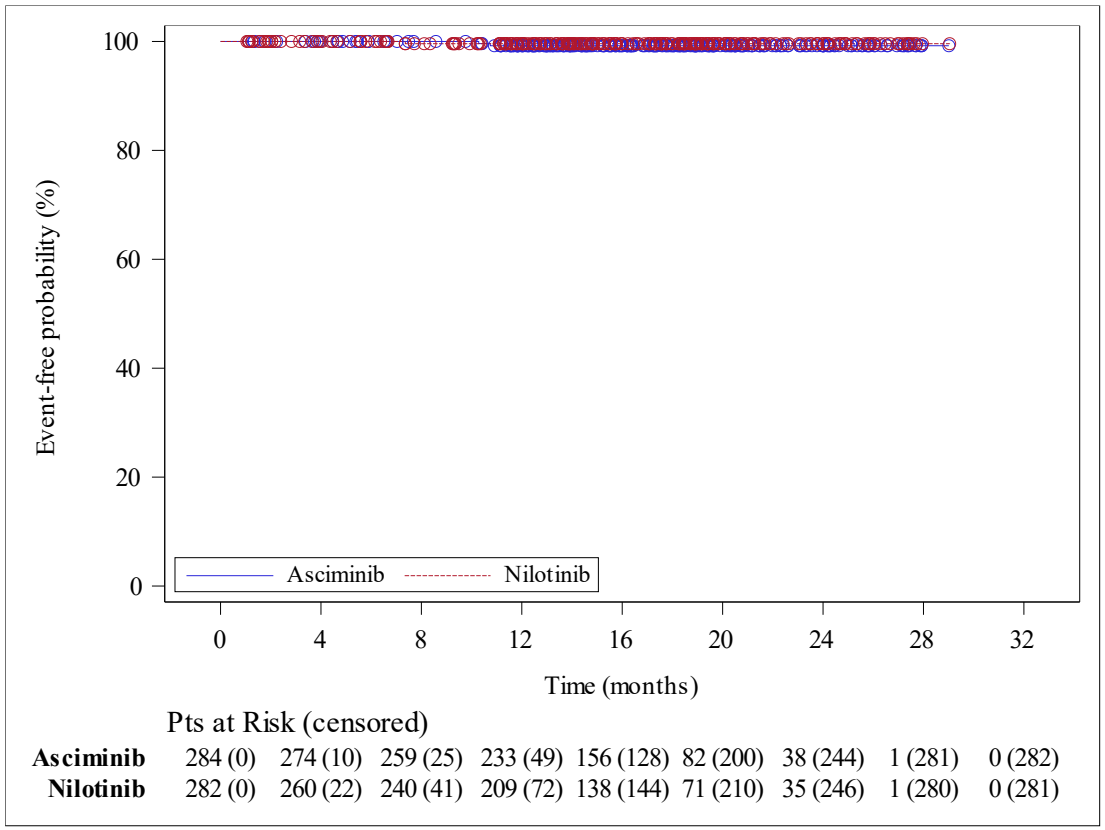
Cardiac failure



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.13 Serious AESI: Kaplan-Meier plot (Safety Analysis Set)

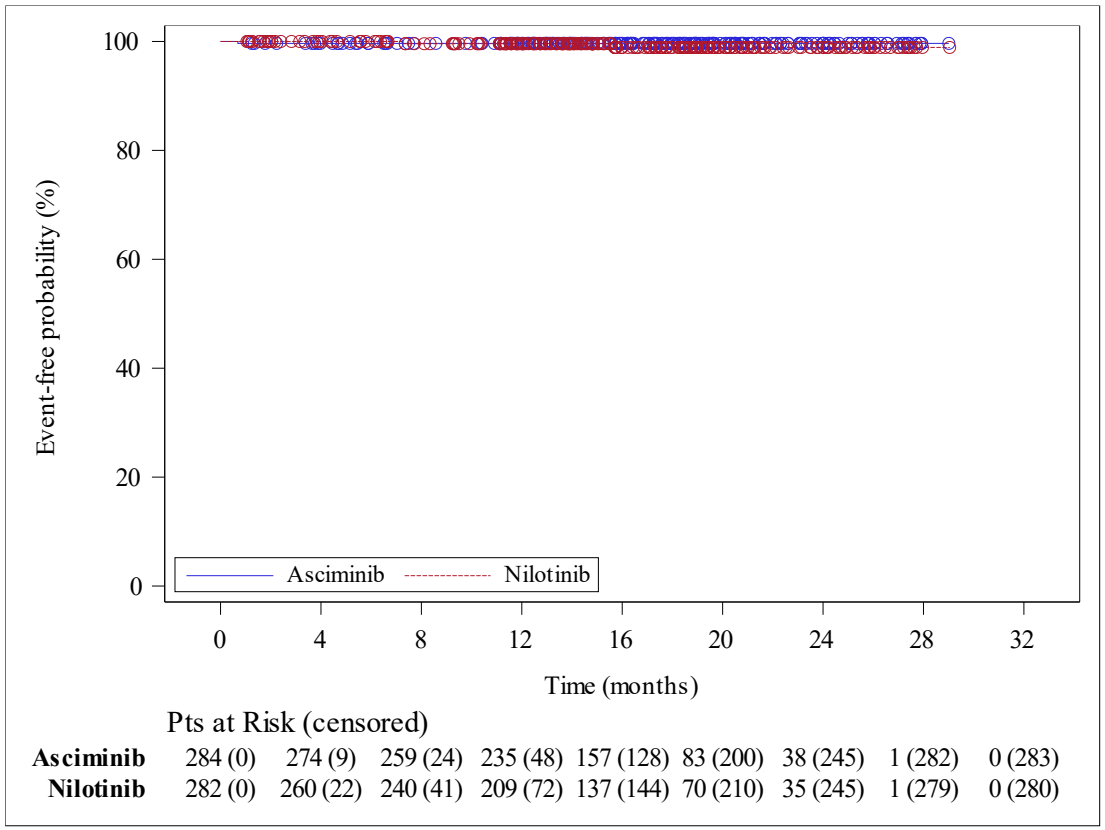
Gastrointestinal toxicity



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.13 Serious AESI: Kaplan-Meier plot (Safety Analysis Set)

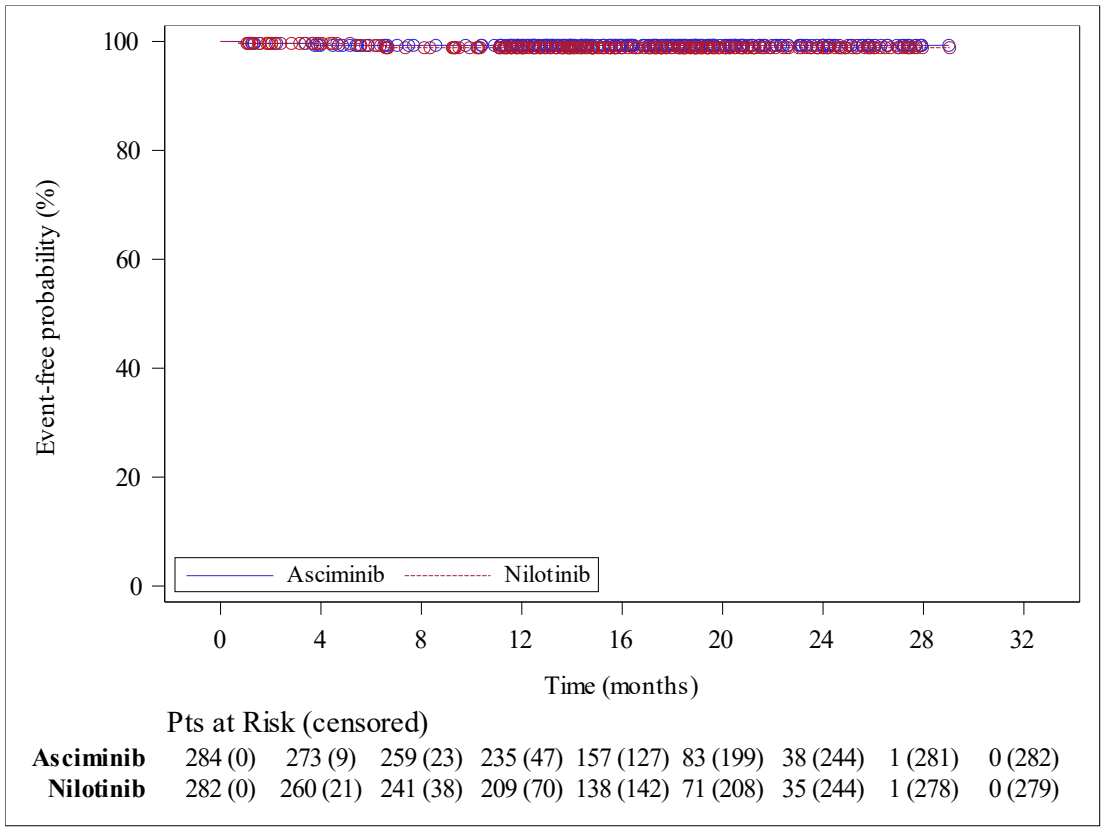
Hemorrhage



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.13 Serious AESI: Kaplan-Meier plot (Safety Analysis Set)

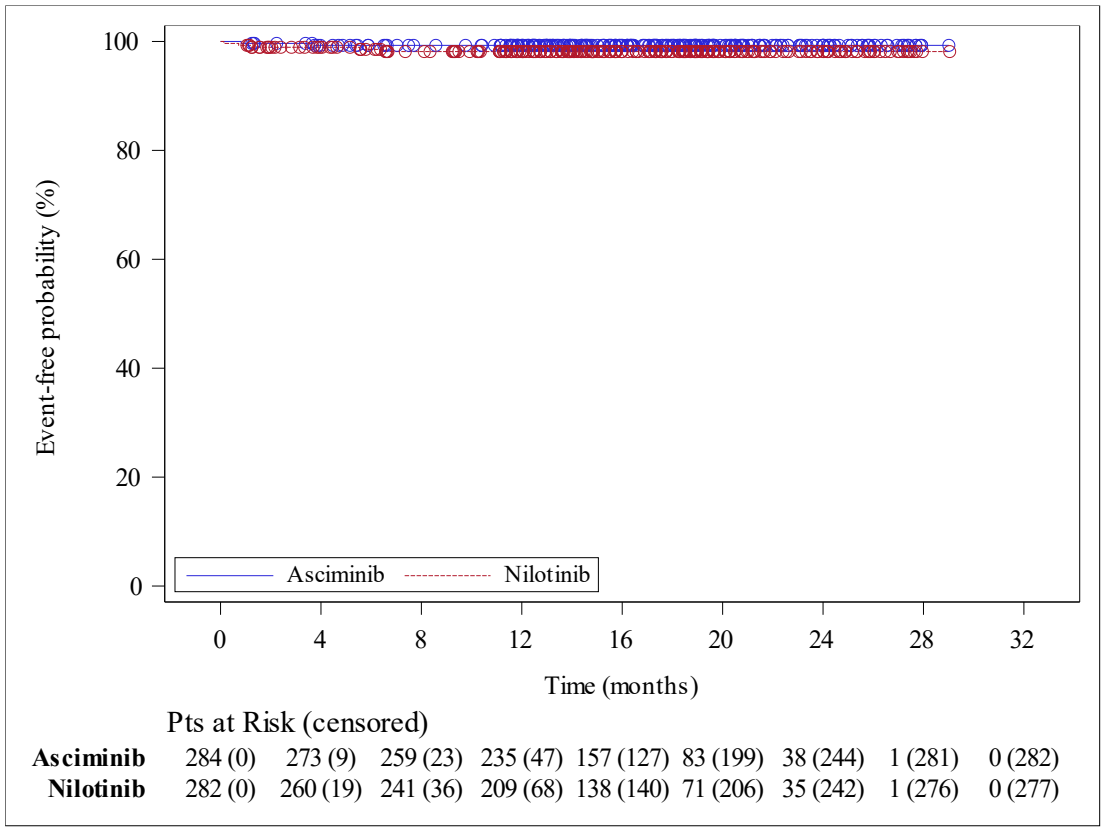
Hepatotoxicity (clinical events)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.13 Serious AESI: Kaplan-Meier plot (Safety Analysis Set)

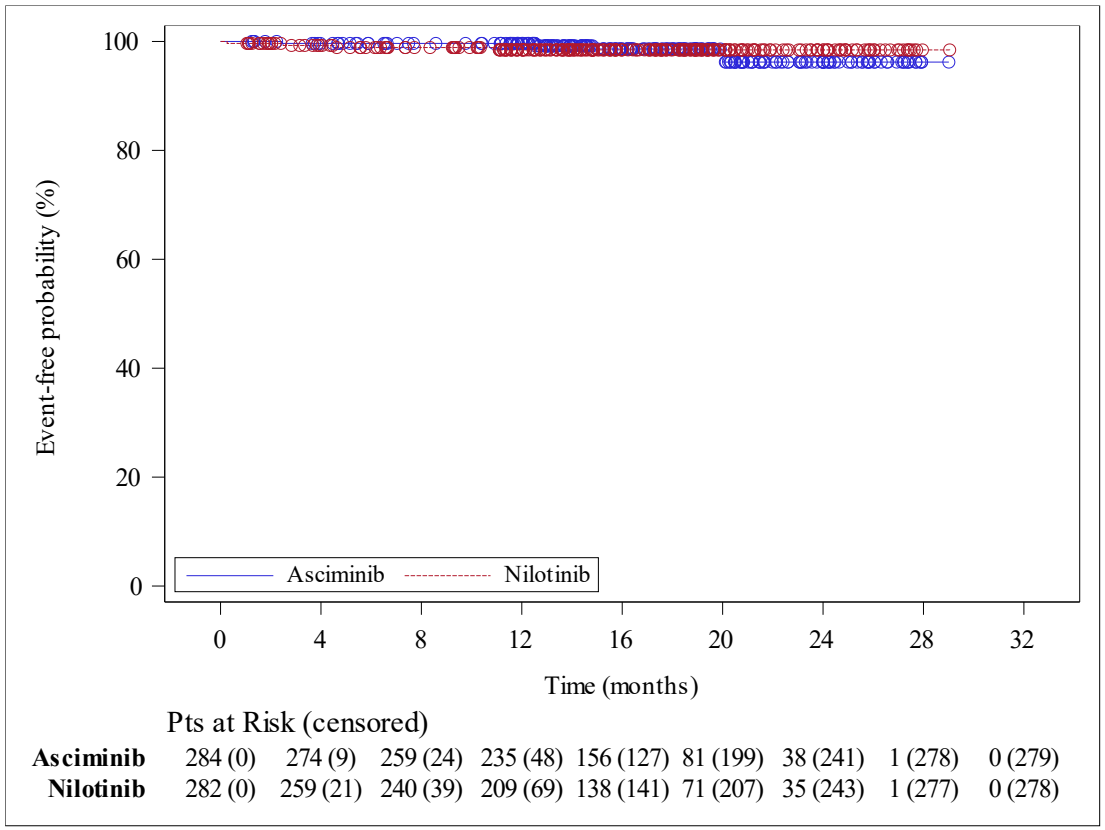
Hepatotoxicity (including laboratory terms)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.13 Serious AESI: Kaplan-Meier plot (Safety Analysis Set)

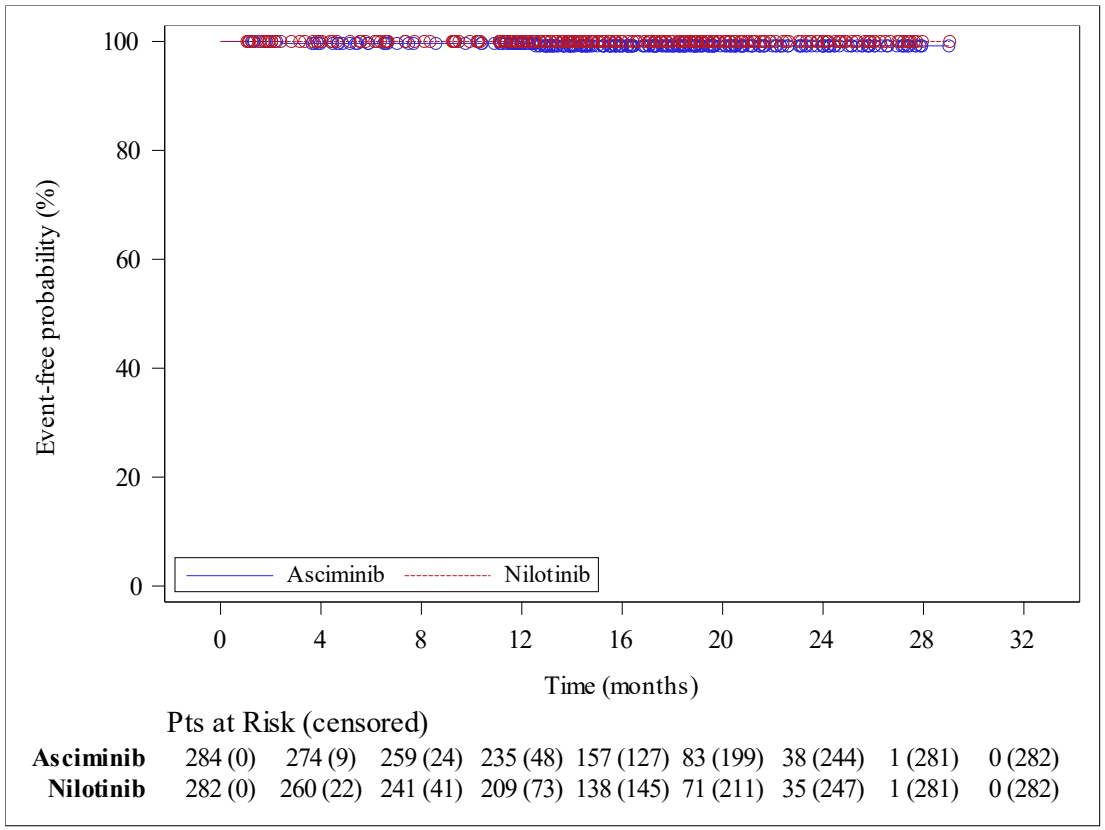
Ischemic heart and CNS conditions



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.13 Serious AESI: Kaplan-Meier plot (Safety Analysis Set)

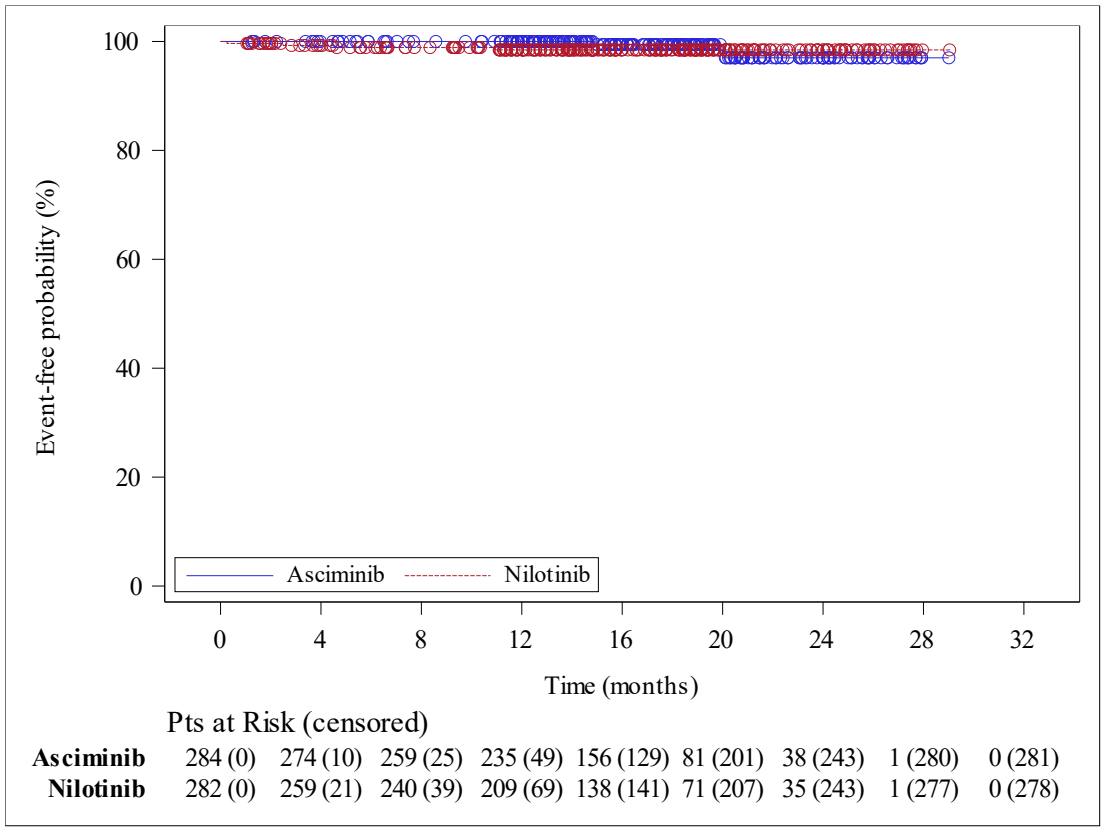
Ischemic CNS conditions



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.13 Serious AESI: Kaplan-Meier plot (Safety Analysis Set)

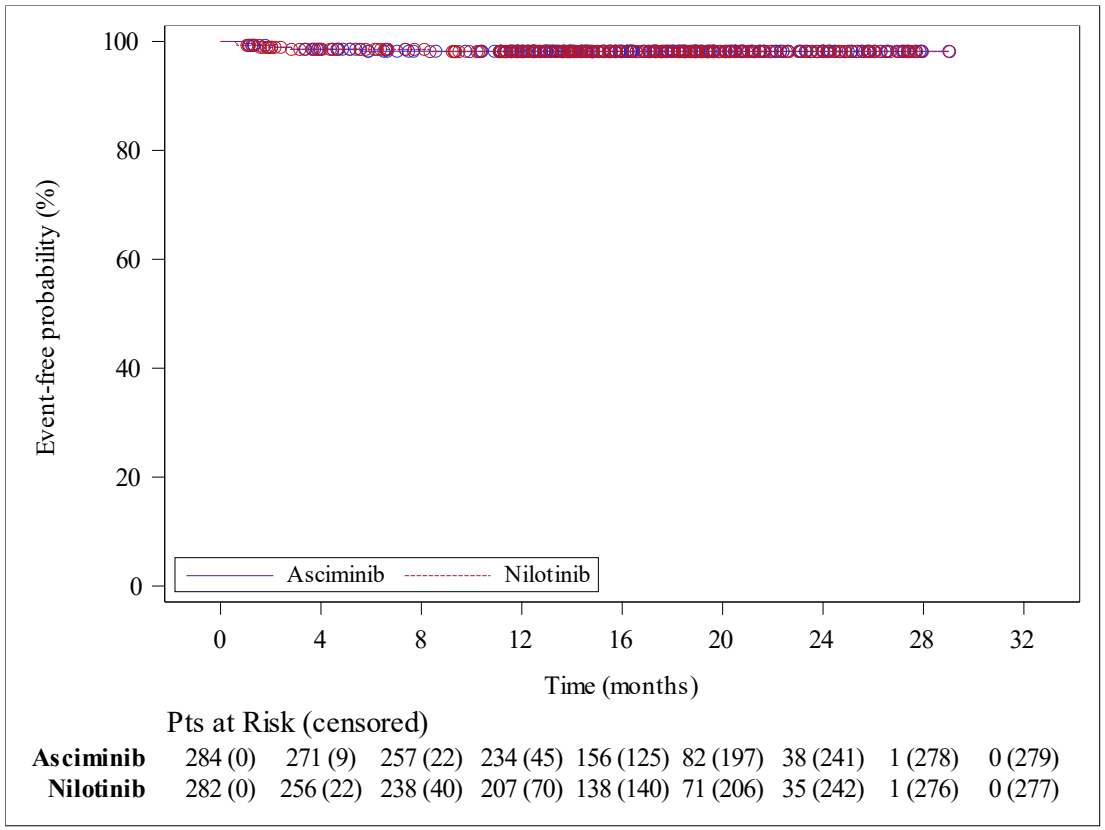
Ischemic heart conditions



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.13 Serious AESI: Kaplan-Meier plot (Safety Analysis Set)

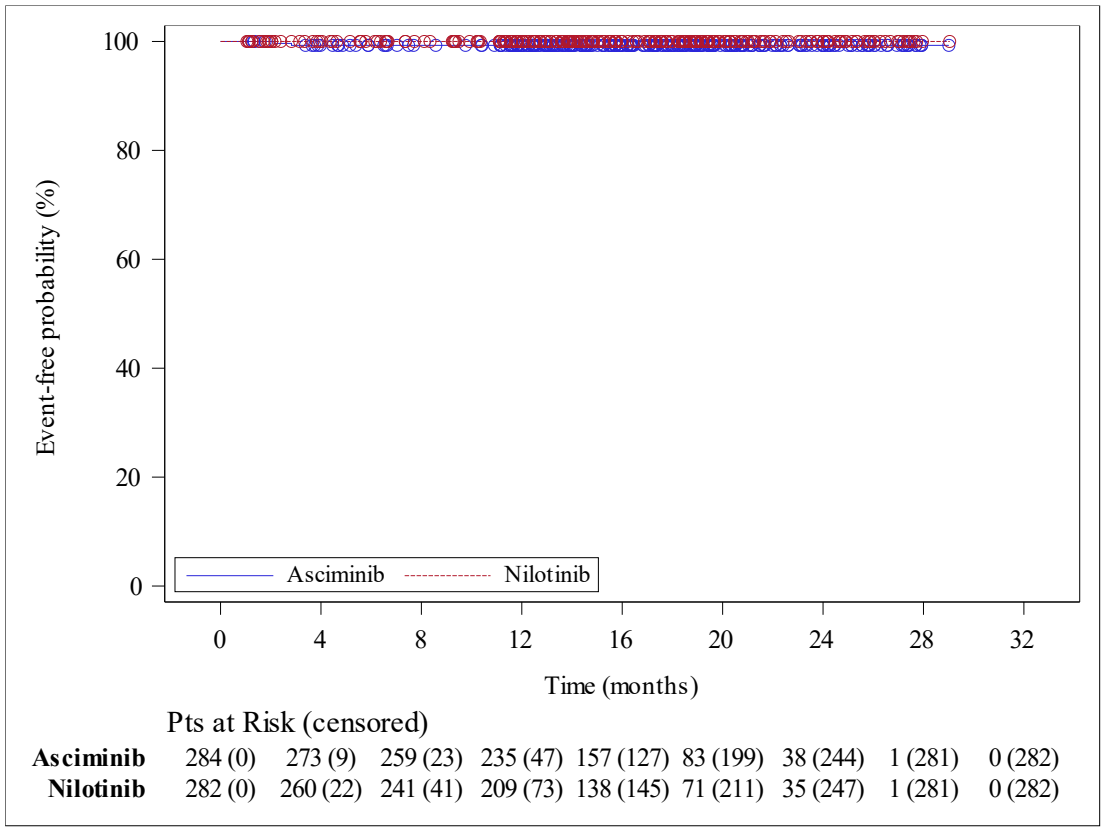
Myelosuppression



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.13 Serious AESI: Kaplan-Meier plot (Safety Analysis Set)

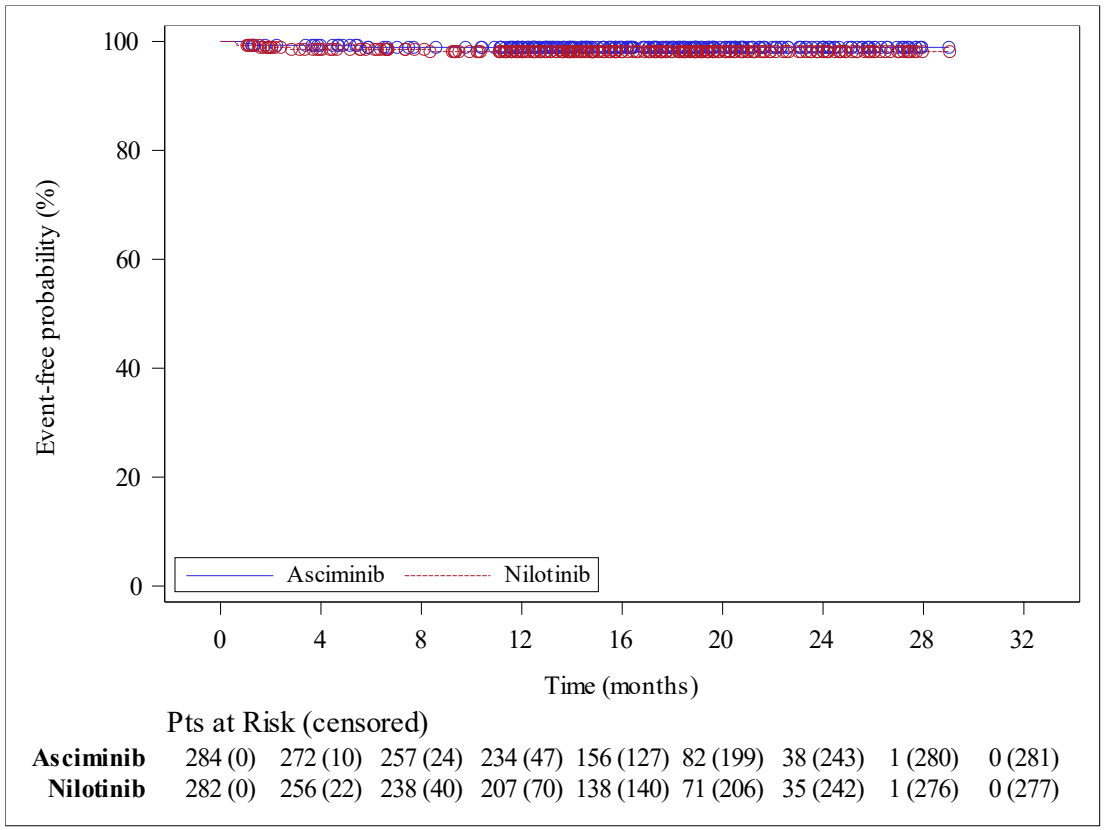
Myelosuppression (Leukopenia)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.13 Serious AESI: Kaplan-Meier plot (Safety Analysis Set)

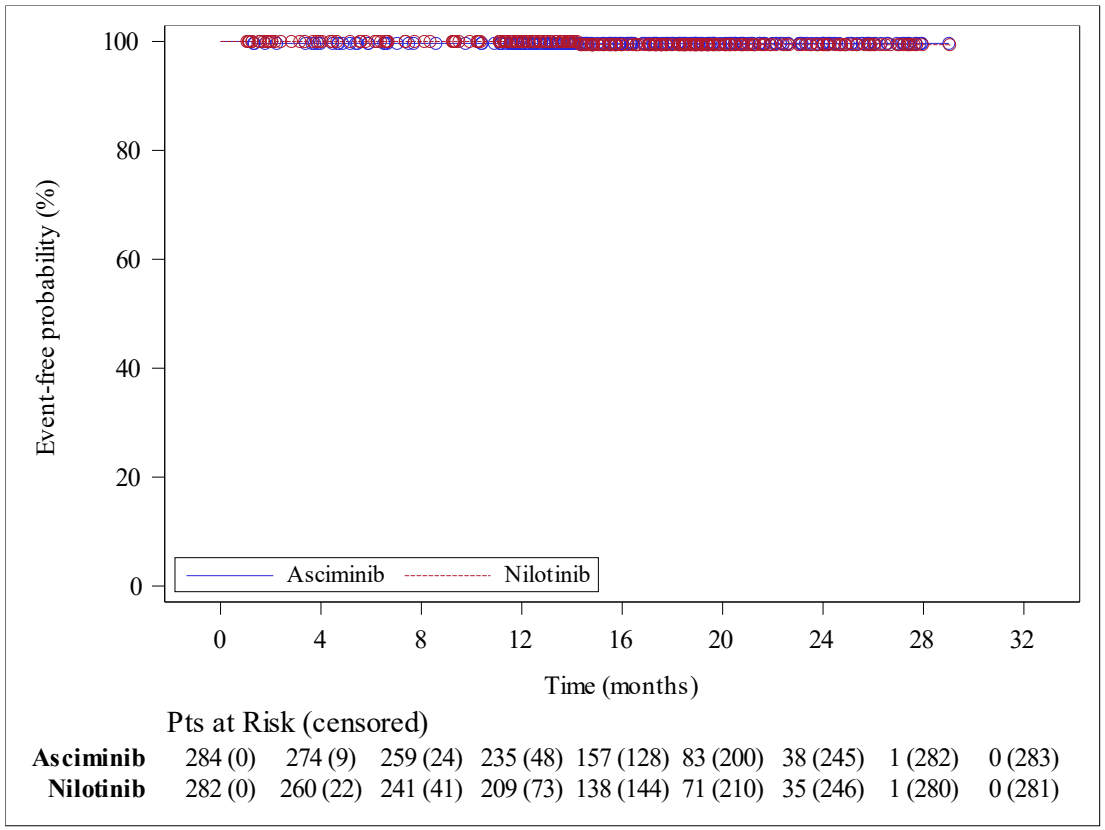
Myelosuppression (Thrombocytopenia)



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.13 Serious AESI: Kaplan-Meier plot (Safety Analysis Set)

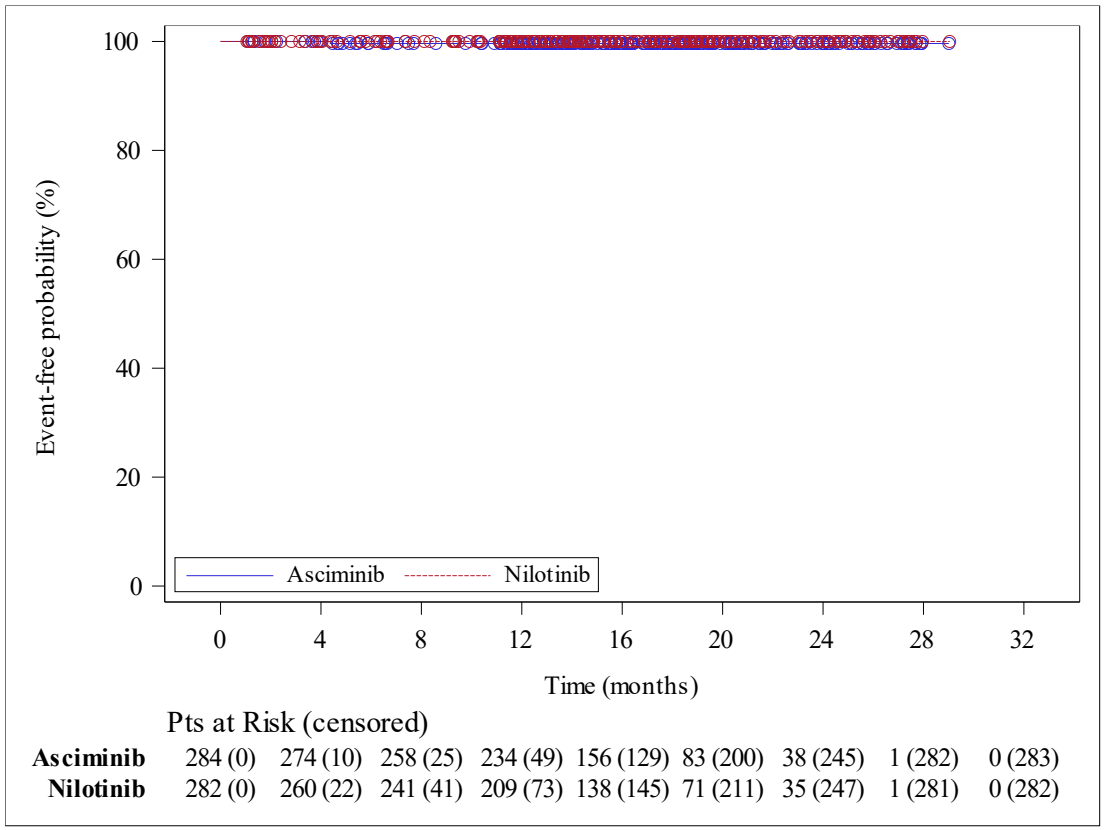
QTc prolongation



Note: o = Censored observations
Data Cut/15MAY2025

Figure 4-1.13 Serious AESI: Kaplan-Meier plot (Safety Analysis Set)

Reproductive toxicity



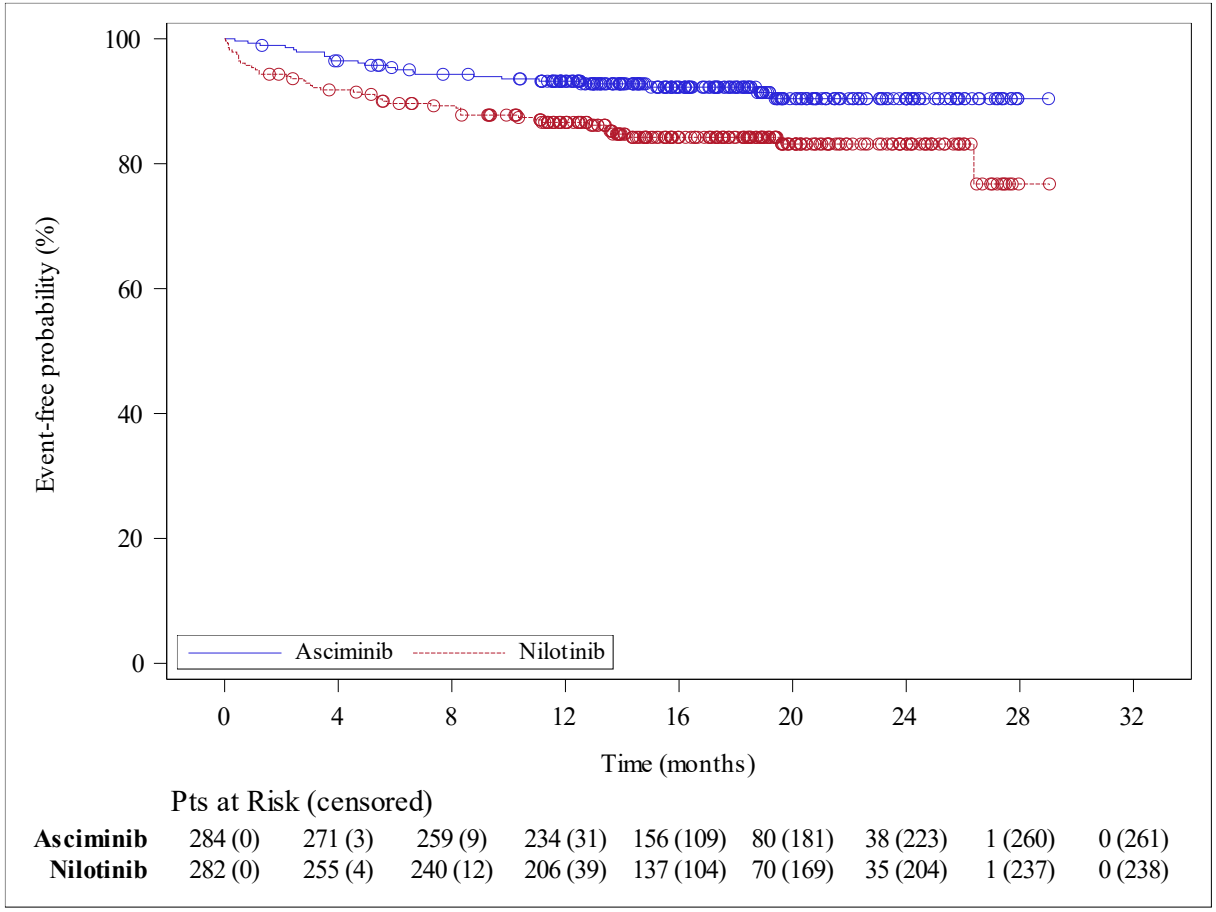
Note: o = Censored observations
Data Cut/15MAY2025

Table 4-1.14 AE leading to discontinuation of treatment: time to first occurrence (Safety Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
N*	284	282	0.48
Number of patients with events, n (%)	23 (8.1)	44 (15.6)	[0.29; 0.80]
			0.004
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [26.4; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 4-1.14 AE leading to discontinuation of treatment: Kaplan-Meier plot (Safety Analysis Set)



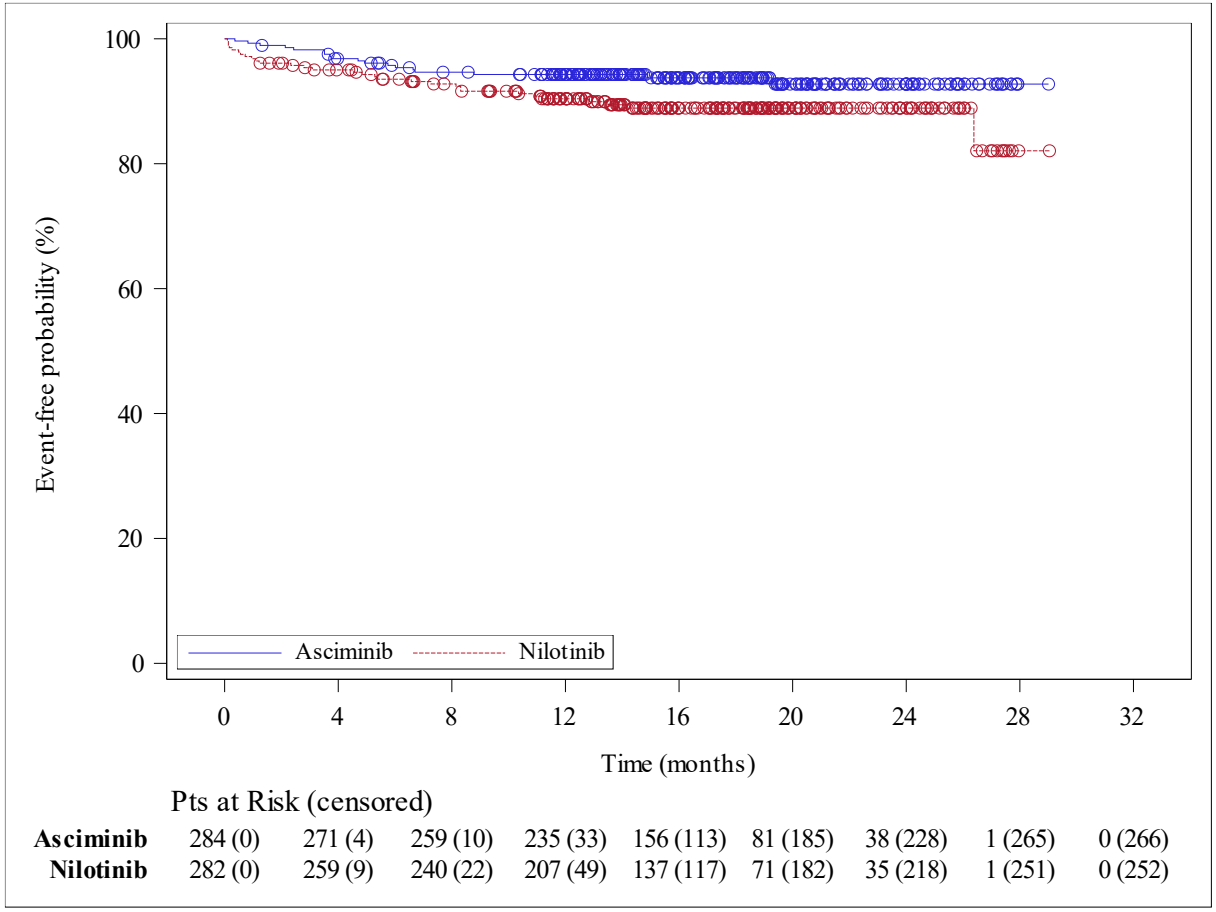
Note: o = Censored observations
Data Cut/15MAY2025

Table 4-1.15 Severe AE leading to discontinuation of treatment: time to first occurrence (Safety Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
N*	284	282	0.56
Number of patients with events, n (%)	18 (6.3)	30 (10.6)	[0.31; 1.00]
			0.046
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [26.4; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 4-1.15 Severe AE leading to discontinuation of treatment: Kaplan-Meier plot (Safety Analysis Set)



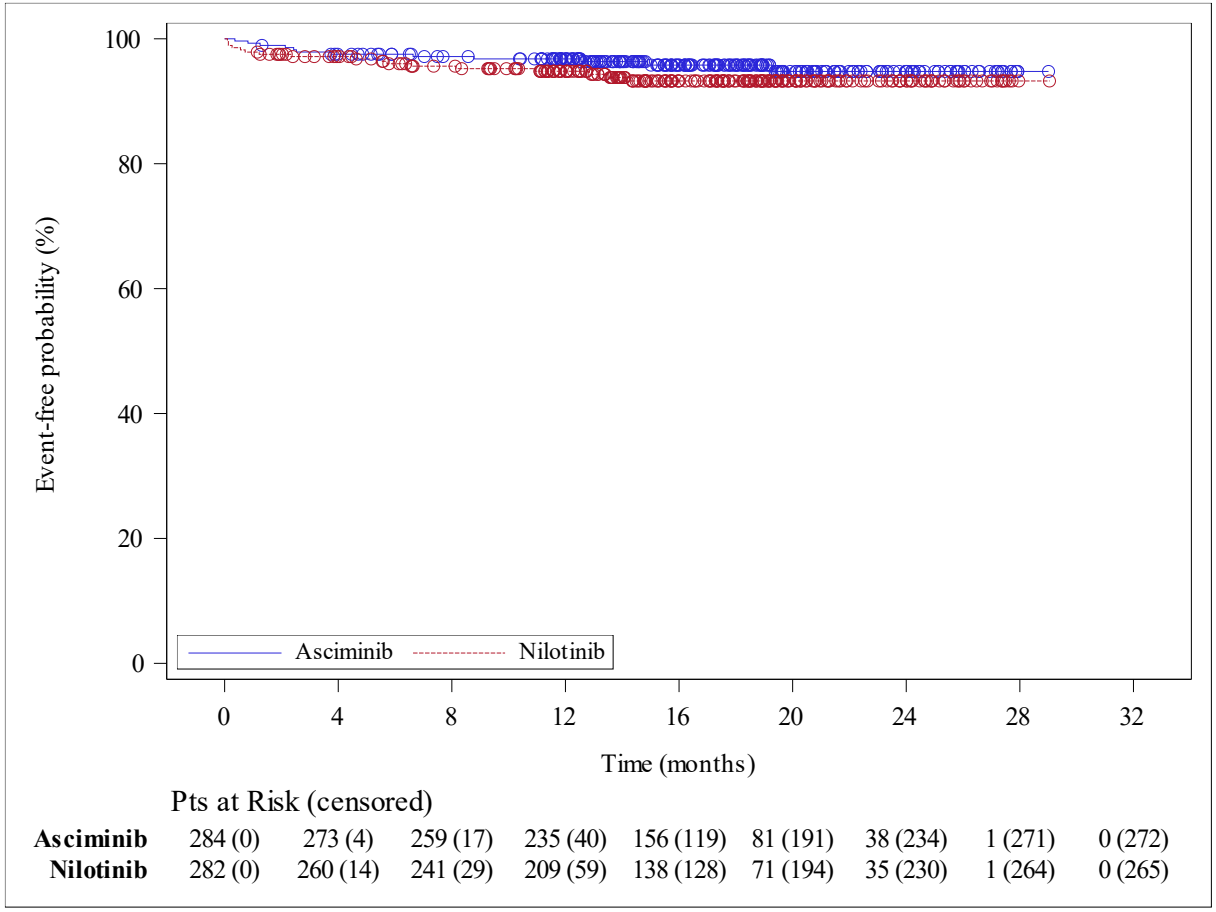
Note: o = Censored observations
Data Cut/15MAY2025

Table 4-1.16 SAE leading to discontinuation of treatment: time to first occurrence (Safety Analysis Set)

	Treatment groups		Comparison
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**HR [95% CI] p-value**
N*	284	282	0.67
Number of patients with events, n (%)	12 (4.2)	17 (6.0)	[0.32; 1.41]
			0.290
Percentiles (months) [95% CI]			
25th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
Median	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	
75th	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]	

HR: Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients with event
.....
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification factors ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified logrank test with stratification factors ELTS Score (IRT).
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 4-1.16 SAE leading to discontinuation of treatment: Kaplan-Meier plot (Safety Analysis Set)



Note: o = Censored observations
Data Cut/15MAY2025

Table 4-2.1 Time to first any AE: Time to event analysis by subgroups (Safety Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.674)							
Low	150/171 (87.7)	0.5 [0.5; 0.9]	162/172 (94.2)	0.5 [0.3; 0.5]	0.74	[0.59; 0.93]	0.009
Intermediate	64/75 (85.3)	0.9 [0.4; 1.4]	62/73 (84.9)	0.5 [0.3; 1.0]	0.90	[0.63; 1.28]	0.595
High	35/38 (92.1)	1.0 [0.5; 1.2]	33/37 (89.2)	0.5 [0.3; 0.6]	0.78	[0.48; 1.26]	0.319
Sex							
(Interaction test: p = 0.902)							
Female	97/107 (90.7)	0.5 [0.3; 0.7]	119/124 (96.0)	0.5 [0.3; 0.5]	0.76	[0.58; 1.00]	0.062
Male	152/177 (85.9)	1.0 [0.6; 1.1]	138/158 (87.3)	0.5 [0.4; 0.6]	0.81	[0.64; 1.02]	0.082
Race							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.235)							
Asian	35/40 (87.5)	1.7 [0.6; 3.0]	42/45 (93.3)	0.5 [0.2; 0.5]	0.52	[0.32; 0.84]	0.006
White	198/227 (87.2)	0.6 [0.5; 1.0]	194/216 (89.8)	0.5 [0.5; 0.6]	0.85	[0.70; 1.04]	0.127
Other	16/17 (94.1)	0.5 [0.1; 1.0]	21/21 (100.0)	0.3 [0.1; 0.5]	0.66	[0.32; 1.37]	0.298
Age groups							
(Interaction test: p = 0.925)							
18 - < 65 years	208/237 (87.8)	0.6 [0.5; 1.0]	223/246 (90.7)	0.5 [0.4; 0.5]	0.79	[0.66; 0.96]	0.019
65 - < 75 years	32/38 (84.2)	0.9 [0.3; 2.1]	22/24 (91.7)	0.5 [0.1; 1.0]	0.70	[0.40; 1.22]	0.228
>= 75 years	9/9 (100.0)	1.0 [0.0; 10.1]	12/12 (100.0)	0.2 [0.1; 2.8]	0.76	[0.30; 1.97]	0.592
Geographic region							
(Interaction test: p = 0.796)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Europe excluding Germany	118/138 (85.5)	0.7 [0.5; 1.0]	124/140 (88.6)	0.5 [0.5; 0.9]	0.83	[0.64; 1.07]	0.160
Germany	62/72 (86.1)	0.8 [0.5; 1.1]	48/53 (90.6)	0.5 [0.2; 0.5]	0.77	[0.52; 1.13]	0.196
Others	69/74 (93.2)	0.6 [0.4; 1.0]	85/89 (95.5)	0.4 [0.3; 0.5]	0.71	[0.51; 0.99]	0.039

N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
If there are not at least 10 patients in every subgroup or not at least 10 events in at least one subgroup, no subgroup analyses were performed for the corresponding attribute.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variable ELTS Score (IRT) and covariate treatment arm.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variable ELTS Score (IRT).
For the subgroups of Stratification factor: ELTS based on IRT randomisation data no stratification variable was used.
The reference group in the stratified Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Table 4-2.2 Time to first any AE by SOC: Time to event analysis by subgroups (Safety Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Hepatobiliary disorders							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.701)							
Low	8/171 (4.7)	N.E. [N.E.; N.E.]	16/172 (9.3)	N.E. [N.E.; N.E.]	0.47	[0.20; 1.11]	0.079
Intermediate	2/75 (2.7)	N.E. [N.E.; N.E.]	5/73 (6.8)	N.E. [N.E.; N.E.]	0.35	[0.07; 1.79]	0.185
High	1/38 (2.6)	N.E. [N.E.; N.E.]	5/37 (13.5)	N.E. [N.E.; N.E.]	0.18	[0.02; 1.56]	0.081
Sex							
(Interaction test: p = 0.531)							
Female	5/107 (4.7)	N.E. [N.E.; N.E.]	16/124 (12.9)	N.E. [N.E.; N.E.]	0.33	[0.12; 0.89]	0.021
Male	6/177 (3.4)	N.E. [N.E.; N.E.]	10/158 (6.3)	N.E. [N.E.; N.E.]	0.52	[0.19; 1.45]	0.204

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Race							
(Interaction test: p = 0.622)							
Asian	3/40 (7.5)	N.E. [N.E.; N.E.]	12/45 (26.7)	N.E. [N.E.; N.E.]	0.27	[0.08; 0.97]	0.031
White	8/227 (3.5)	N.E. [N.E.; N.E.]	13/216 (6.0)	N.E. [N.E.; N.E.]	0.55	[0.23; 1.33]	0.180
Other	0/17	N.E. [N.E.; N.E.]	1/21 (4.8)	N.E. [N.E.; N.E.]	0.31	[0.00; 28.42]	0.298
Age groups							
(Interaction test: p = 0.880)							
18 - < 65 years	9/237 (3.8)	N.E. [N.E.; N.E.]	23/246 (9.3)	N.E. [N.E.; N.E.]	0.38	[0.18; 0.83]	0.012
65 - < 75 years	1/38 (2.6)	N.E. [N.E.; N.E.]	1/24 (4.2)	N.E. [N.E.; N.E.]	0.66	[0.04; 11.22]	0.773
>= 75 years	1/9 (11.1)	N.E. [10.9; N.E.]	2/12 (16.7)	N.E. [10.3; N.E.]	0.63	[0.06; 6.98]	0.700
Geographic region							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.225)							
Europe excluding Germany	7/138 (5.1)	N.E. [N.E.; N.E.]	8/140 (5.7)	N.E. [N.E.; N.E.]	0.80	[0.29; 2.23]	0.676
Germany	1/72 (1.4)	N.E. [N.E.; N.E.]	4/53 (7.5)	N.E. [N.E.; N.E.]	0.18	[0.02; 1.68]	0.094
Others	3/74 (4.1)	N.E. [N.E.; N.E.]	14/89 (15.7)	N.E. [N.E.; N.E.]	0.26	[0.07; 0.91]	0.023
Injury, poisoning and procedural complications							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.969)							
Low	11/171 (6.4)	N.E. [N.E.; N.E.]	6/172 (3.5)	N.E. [N.E.; N.E.]	1.83	[0.67; 4.94]	0.229
Intermediate	3/75 (4.0)	N.E. [N.E.; N.E.]	0/73	N.E. [N.E.; N.E.]	6.07	[0.20; 185.88]	0.107
High	5/38 (13.2)	N.E. [21.3; N.E.]	2/37 (5.4)	N.E. [N.E.; N.E.]	2.33	[0.45; 12.03]	0.298

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Sex							
(Interaction test: p = 0.585)							
Female	6/107 (5.6)	N.E. [N.E.; N.E.]	2/124 (1.6)	N.E. [N.E.; N.E.]	3.22	[0.65; 15.98]	0.130
Male	13/177 (7.3)	N.E. [N.E.; N.E.]	6/158 (3.8)	N.E. [N.E.; N.E.]	1.92	[0.73; 5.05]	0.179
Race							
(Interaction test: p = 0.606)							
Asian	1/40 (2.5)	N.E. [N.E.; N.E.]	2/45 (4.4)	N.E. [N.E.; N.E.]	0.73	[0.07; 8.06]	0.796
White	15/227 (6.6)	N.E. [N.E.; N.E.]	6/216 (2.8)	N.E. [N.E.; N.E.]	2.27	[0.88; 5.87]	0.081
Other	3/17 (17.6)	N.E. [14.0; N.E.]	0/21	N.E. [N.E.; N.E.]	9.03	[0.28; 295.73]	0.056
Age groups							
(Interaction test: p = 0.997)							
18 - < 65 years	14/237	N.E. [N.E.; N.E.]	7/246	N.E. [N.E.; N.E.]	2.00	[0.81; 4.95]	0.128

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(5.9)		(2.8)				
65 - < 75 years	4/38	N.E. [N.E.; N.E.]	1/24	N.E. [N.E.; N.E.]	1.87	[0.21; 16.91]	0.570
	(10.5)		(4.2)				
>= 75 years	1/9	N.E. [11.1; N.E.]	0/12	N.E. [N.E.; N.E.]	2.99	[0.03; 275.43]	0.317
	(11.1)						
Geographic region							
(Interaction test: p = 0.971)							
Europe excluding Germany	5/138	N.E. [N.E.; N.E.]	3/140	N.E. [N.E.; N.E.]	1.57	[0.37; 6.58]	0.537
	(3.6)		(2.1)				
Germany	7/72	N.E. [N.E.; N.E.]	0/53	N.E. [N.E.; N.E.]	8.63	[0.40; 184.59]	0.045
	(9.7)						
Others	7/74	N.E. [N.E.; N.E.]	5/89	N.E. [N.E.; N.E.]	1.93	[0.61; 6.15]	0.258
	(9.5)		(5.6)				
Investigations							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.673)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Low	58/171 (33.9)	N.E. [N.E.; N.E.]	73/172 (42.4)	N.E. [14.3; N.E.]	0.73	[0.51; 1.03]	0.066
Intermediate	26/75 (34.7)	N.E. [16.6; N.E.]	30/73 (41.1)	N.E. [8.3; N.E.]	0.75	[0.45; 1.28]	0.299
High	12/38 (31.6)	N.E. [11.1; N.E.]	18/37 (48.6)	22.1 [1.0; N.E.]	0.53	[0.26; 1.10]	0.088
Sex							
(Interaction test: p = 0.011)							
Female	29/107 (27.1)	N.E. [N.E.; N.E.]	58/124 (46.8)	N.E. [7.8; N.E.]	0.44	[0.28; 0.70]	<0.001
Male	67/177 (37.9)	N.E. [22.1; N.E.]	63/158 (39.9)	N.E. [22.1; N.E.]	0.94	[0.66; 1.32]	0.715
Race							
(Interaction test: p = 0.927)							
Asian	16/40 (40.0)	N.E. [11.1; N.E.]	21/45 (46.7)	N.E. [2.6; N.E.]	0.73	[0.38; 1.42]	0.360
White	73/227	N.E. [N.E.; N.E.]	91/216	N.E. [14.9; N.E.]	0.70	[0.51; 0.95]	0.022

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(32.2)		(42.1)				
Other	7/17	N.E. [1.1; N.E.]	9/21	N.E. [0.5; N.E.]	0.83	[0.30; 2.28]	0.733
	(41.2)		(42.9)				
Age groups							
(Interaction test: p = 0.175)							
18 - < 65 years	83/237	N.E. [N.E.; N.E.]	100/246	N.E. [N.E.; N.E.]	0.79	[0.59; 1.05]	0.104
	(35.0)		(40.7)				
65 - < 75 years	11/38	N.E. [N.E.; N.E.]	12/24	8.5 [2.8; N.E.]	0.41	[0.17; 0.97]	0.040
	(28.9)		(50.0)				
>= 75 years	2/9	N.E. [0.5; N.E.]	9/12	4.2 [0.5; 22.1]	0.26	[0.06; 1.24]	0.065
	(22.2)		(75.0)				
Geographic region							
(Interaction test: p = 0.653)							
Europe excluding Germany	40/138	N.E. [N.E.; N.E.]	48/140	N.E. [22.1; N.E.]	0.79	[0.52; 1.20]	0.272
	(29.0)		(34.3)				
Germany	27/72	N.E. [13.8; N.E.]	28/53	5.6 [2.8; N.E.]	0.62	[0.36; 1.06]	0.082
	(37.5)		(52.8)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Others	29/74 (39.2)	N.E. [13.7; N.E.]	45/89 (50.6)	11.1 [5.5; N.E.]	0.67	[0.42; 1.07]	0.091
Skin and subcutaneous tissue disorders							
Stratification factor: ELTS based on randomization data from IRT (Interaction test: p = 0.551)							
Low	55/171 (32.2)	N.E. [N.E.; N.E.]	81/172 (47.1)	N.E. [6.2; N.E.]	0.56	[0.40; 0.80]	<0.001
Intermediate	24/75 (32.0)	N.E. [19.5; N.E.]	33/73 (45.2)	18.4 [2.8; N.E.]	0.56	[0.33; 0.95]	0.030
High	9/38 (23.7)	N.E. [N.E.; N.E.]	18/37 (48.6)	17.1 [0.8; N.E.]	0.37	[0.17; 0.82]	0.011
Sex (Interaction test: p = 0.825)							
Female	43/107 (40.2)	N.E. [13.8; N.E.]	70/124 (56.5)	3.6 [2.1; N.E.]	0.52	[0.36; 0.76]	<0.001
Male	45/177	N.E. [N.E.; N.E.]	62/158	N.E. [18.4; N.E.]	0.56	[0.38; 0.83]	0.003

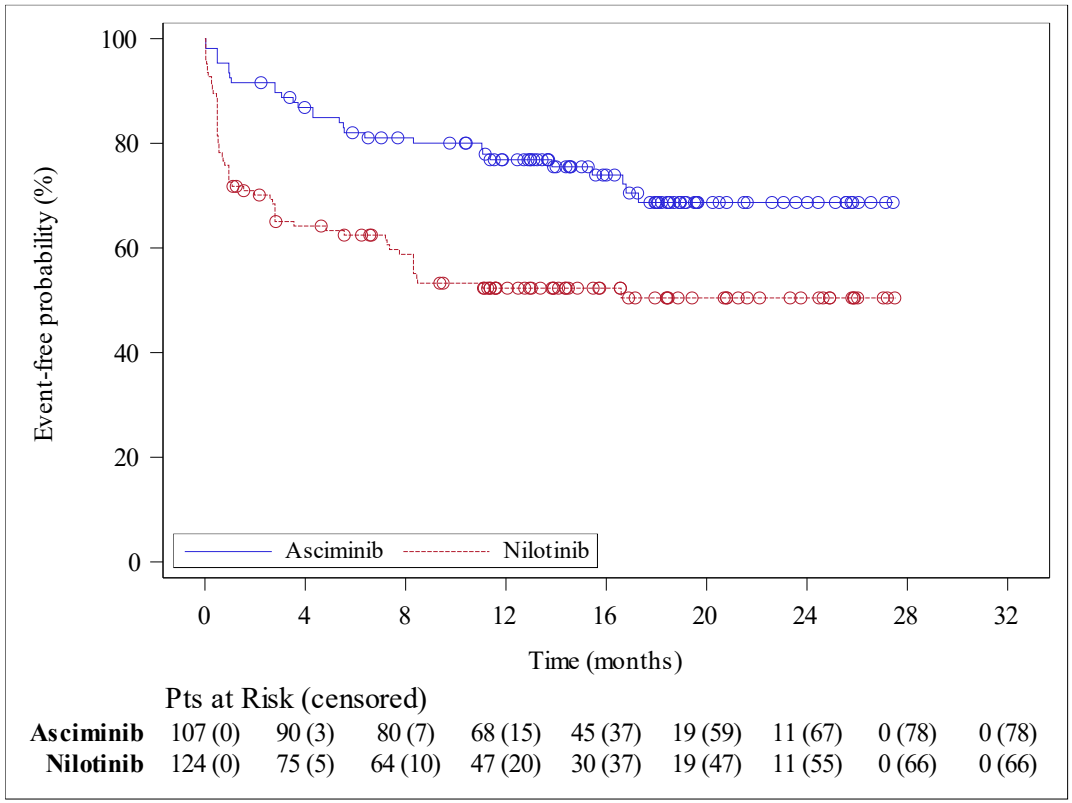
	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(25.4)		(39.2)				
Race							
(Interaction test: p = 0.422)							
Asian	10/40	N.E. [N.E.; N.E.]	21/45	14.8 [2.8; N.E.]	0.40	[0.18; 0.85]	0.015
	(25.0)		(46.7)				
White	71/227	N.E. [N.E.; N.E.]	102/216	18.4 [6.2; N.E.]	0.53	[0.39; 0.72]	<0.001
	(31.3)		(47.2)				
Other	7/17	N.E. [1.0; N.E.]	9/21	N.E. [0.7; N.E.]	1.03	[0.38; 2.80]	0.960
	(41.2)		(42.9)				
Age groups							
(Interaction test: p = 0.688)							
18 - < 65 years	71/237	N.E. [N.E.; N.E.]	112/246	N.E. [8.5; N.E.]	0.54	[0.40; 0.73]	<0.001
	(30.0)		(45.5)				
65 - < 75 years	15/38	N.E. [8.3; N.E.]	13/24	17.1 [0.6; N.E.]	0.48	[0.23; 1.03]	0.056
	(39.5)		(54.2)				
>= 75 years	2/9	N.E. [0.5; N.E.]	7/12	3.5 [0.3; N.E.]	0.30	[0.06; 1.49]	0.123
	(22.2)		(58.3)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = 0.228)							
Europe excluding Germany	34/138 (24.6)	N.E. [N.E.; N.E.]	67/140 (47.9)	17.1 [6.2; N.E.]	0.42	[0.27; 0.63]	<0.001
Germany	28/72 (38.9)	N.E. [13.8; N.E.]	24/53 (45.3)	N.E. [1.7; N.E.]	0.72	[0.41; 1.25]	0.230
Others	26/74 (35.1)	N.E. [13.8; N.E.]	41/89 (46.1)	N.E. [3.1; N.E.]	0.62	[0.38; 1.02]	0.058

N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
SOC: System Organ Class
.....
If there are not at least 10 patients in every subgroup or not at least 10 events in at least one subgroup, no subgroup analyses were performed for the corresponding attribute.
Results on AEs differentiated by SOC or PT are only reported if the given result is statistically significant for the total population.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variable ELTS Score (IRT) and covariate treatment arm.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variable ELTS Score (IRT).
For the subgroups of Stratification factor: ELTS based on IRT randomisation data no stratification variable was used.
The reference group in the stratified Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 4-2.2 Time to first any AE by SOC: Time to event analysis by subgroups: Kaplan-Meier plot by subgroups (Safety Analysis Set)

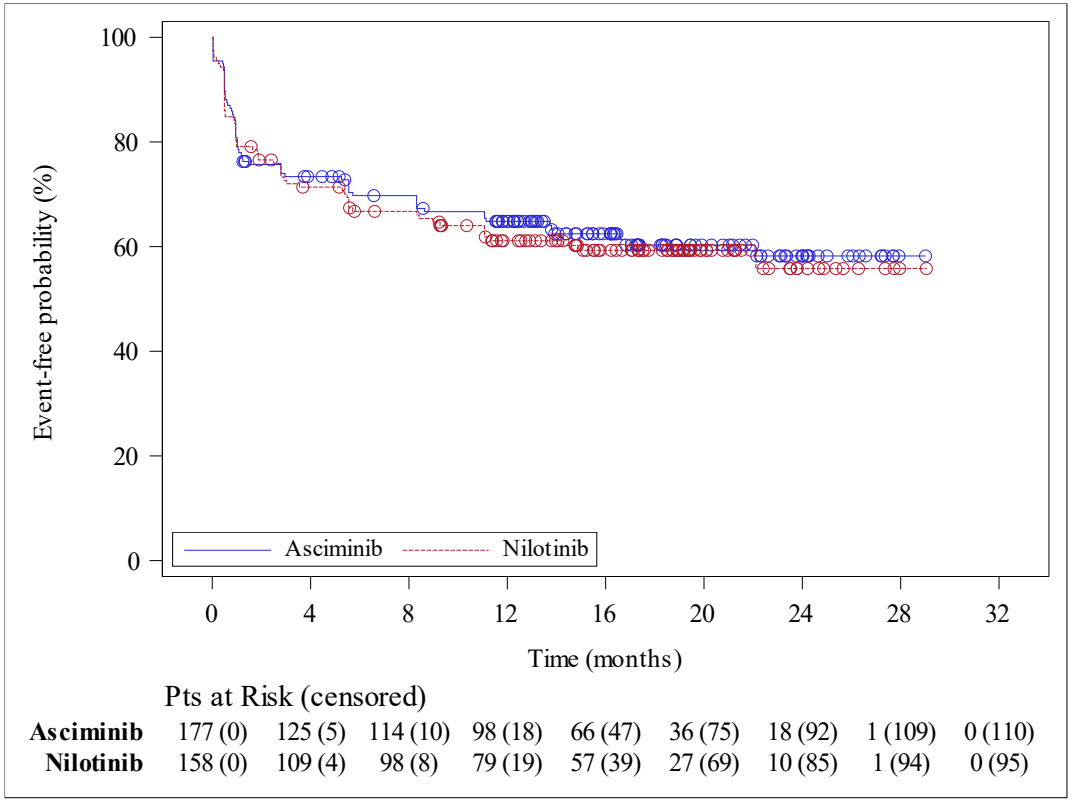
Investigations: Sex: Female



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/15MAY2025

Figure 4-2.2 Time to first any AE by SOC: Time to event analysis by subgroups: Kaplan-Meier plot by subgroups (Safety Analysis Set)

Investigations: Sex: Male



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/15MAY2025

Table 4-2.3 Time to first any AE by PT: Time to event analysis by subgroups (Safety Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Alanine aminotransferase increased							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.267)							
Low	13/171 (7.6)	N.E. [N.E.; N.E.]	27/172 (15.7)	N.E. [N.E.; N.E.]	0.44	[0.23; 0.86]	0.013
Intermediate	1/75 (1.3)	N.E. [N.E.; N.E.]	11/73 (15.1)	N.E. [N.E.; N.E.]	0.08	[0.01; 0.61]	0.002
High	1/38 (2.6)	N.E. [N.E.; N.E.]	4/37 (10.8)	N.E. [N.E.; N.E.]	0.23	[0.03; 2.05]	0.151
Sex							
(Interaction test: p = 0.761)							
Female	7/107 (6.5)	N.E. [N.E.; N.E.]	20/124 (16.1)	N.E. [N.E.; N.E.]	0.36	[0.15; 0.85]	0.015
Male	8/177	N.E. [N.E.; N.E.]	22/158	N.E. [N.E.; N.E.]	0.30	[0.13; 0.68]	0.002

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(4.5)		(13.9)				
Race							
(Interaction test: p = 0.881)							
Asian	2/40	N.E. [N.E.; N.E.]	4/45	N.E. [N.E.; N.E.]	0.62	[0.11; 3.38]	0.574
	(5.0)		(8.9)				
White	13/227	N.E. [N.E.; N.E.]	34/216	N.E. [N.E.; N.E.]	0.33	[0.17; 0.63]	<0.001
	(5.7)		(15.7)				
Other	0/17	N.E. [N.E.; N.E.]	4/21	N.E. [N.E.; N.E.]	0.14	[0.00; 3.90]	0.080
			(19.0)				
Age groups							
(Interaction test: p = 1.000)							
18 - < 65 years	13/237	N.E. [N.E.; N.E.]	38/246	N.E. [N.E.; N.E.]	0.33	[0.17; 0.62]	<0.001
	(5.5)		(15.4)				
65 - < 75 years	2/38	N.E. [N.E.; N.E.]	3/24	N.E. [N.E.; N.E.]	0.19	[0.03; 1.27]	0.067
	(5.3)		(12.5)				
>= 75 years	0/9	N.E. [N.E.; N.E.]	1/12	N.E. [11.3; N.E.]	0.53	[0.01; 51.67]	0.439
			(8.3)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = 0.843)							
Europe excluding Germany	7/138 (5.1)	N.E. [N.E.; N.E.]	20/140 (14.3)	N.E. [N.E.; N.E.]	0.33	[0.14; 0.78]	0.008
Germany	6/72 (8.3)	N.E. [N.E.; N.E.]	11/53 (20.8)	N.E. [N.E.; N.E.]	0.31	[0.11; 0.84]	0.015
Others	2/74 (2.7)	N.E. [N.E.; N.E.]	11/89 (12.4)	N.E. [N.E.; N.E.]	0.21	[0.05; 0.95]	0.026
Alopecia							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.219)							
Low	5/171 (2.9)	N.E. [N.E.; N.E.]	23/172 (13.4)	N.E. [N.E.; N.E.]	0.20	[0.08; 0.54]	<0.001
Intermediate	4/75 (5.3)	N.E. [N.E.; N.E.]	4/73 (5.5)	N.E. [N.E.; N.E.]	0.94	[0.23; 3.75]	0.928
High	1/38	N.E. [N.E.; N.E.]	3/37	N.E. [N.E.; N.E.]	0.31	[0.03; 3.03]	0.290

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(2.6)		(8.1)				
Sex							
(Interaction test: p = 0.070)							
Female	5/107	N.E. [N.E.; N.E.]	25/124	N.E. [N.E.; N.E.]	0.21	[0.08; 0.54]	<0.001
	(4.7)		(20.2)				
Male	5/177	N.E. [N.E.; N.E.]	5/158	N.E. [N.E.; N.E.]	0.88	[0.25; 3.04]	0.841
	(2.8)		(3.2)				
Race							
(Interaction test: p = 0.879)							
Asian	1/40	N.E. [N.E.; N.E.]	2/45	N.E. [N.E.; N.E.]	0.65	[0.06; 7.18]	0.724
	(2.5)		(4.4)				
White	9/227	N.E. [N.E.; N.E.]	27/216	N.E. [N.E.; N.E.]	0.30	[0.14; 0.64]	<0.001
	(4.0)		(12.5)				
Other	0/17	N.E. [N.E.; N.E.]	1/21	N.E. [N.E.; N.E.]	0.28	[0.00; 26.04]	0.277
			(4.8)				
Age groups							
(Interaction test: p = 0.953)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
18 - < 65 years	9/237 (3.8)	N.E. [N.E.; N.E.]	26/246 (10.6)	N.E. [N.E.; N.E.]	0.34	[0.16; 0.73]	0.004
65 - < 75 years	1/38 (2.6)	N.E. [N.E.; N.E.]	1/24 (4.2)	N.E. [N.E.; N.E.]	0.53	[0.03; 8.49]	0.649
>= 75 years	0/9	N.E. [N.E.; N.E.]	3/12 (25.0)	N.E. [1.6; N.E.]	0.18	[0.01; 5.51]	0.123
Geographic region (Interaction test: p = 0.049)							
Europe excluding Germany	2/138 (1.4)	N.E. [N.E.; N.E.]	20/140 (14.3)	N.E. [N.E.; N.E.]	0.09	[0.02; 0.40]	<0.001
Germany	6/72 (8.3)	N.E. [N.E.; N.E.]	4/53 (7.5)	N.E. [N.E.; N.E.]	1.10	[0.31; 3.94]	0.883
Others	2/74 (2.7)	N.E. [N.E.; N.E.]	6/89 (6.7)	N.E. [N.E.; N.E.]	0.42	[0.08; 2.08]	0.271
Aspartate aminotransferase increased							
Stratification factor: ELTS based on randomization data from IRT							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.536)							
Low	10/171 (5.8)	N.E. [N.E.; N.E.]	20/172 (11.6)	N.E. [N.E.; N.E.]	0.47	[0.22; 1.01]	0.047
Intermediate	1/75 (1.3)	N.E. [N.E.; N.E.]	5/73 (6.8)	N.E. [N.E.; N.E.]	0.18	[0.02; 1.53]	0.076
High	2/38 (5.3)	N.E. [N.E.; N.E.]	2/37 (5.4)	N.E. [N.E.; N.E.]	0.95	[0.13; 6.74]	0.958
Sex							
(Interaction test: p = 0.258)							
Female	5/107 (4.7)	N.E. [N.E.; N.E.]	17/124 (13.7)	N.E. [N.E.; N.E.]	0.31	[0.11; 0.84]	0.015
Male	8/177 (4.5)	N.E. [N.E.; N.E.]	10/158 (6.3)	N.E. [N.E.; N.E.]	0.69	[0.27; 1.75]	0.431
Race							
(Interaction test: p = 0.856)							
Asian	1/40 (2.5)	N.E. [N.E.; N.E.]	4/45 (8.9)	N.E. [N.E.; N.E.]	0.32	[0.04; 2.87]	0.282

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
White	11/227 (4.8)	N.E. [N.E.; N.E.]	20/216 (9.3)	N.E. [N.E.; N.E.]	0.49	[0.24; 1.03]	0.056
Other	1/17 (5.9)	N.E. [N.E.; N.E.]	3/21 (14.3)	N.E. [N.E.; N.E.]	0.35	[0.04; 3.47]	0.349
Age groups (Interaction test: p = 0.954)							
18 - < 65 years	11/237 (4.6)	N.E. [N.E.; N.E.]	24/246 (9.8)	N.E. [N.E.; N.E.]	0.45	[0.22; 0.92]	0.025
65 - < 75 years	2/38 (5.3)	N.E. [N.E.; N.E.]	3/24 (12.5)	N.E. [N.E.; N.E.]	0.19	[0.03; 1.27]	0.060
>= 75 years	0/9	N.E. [N.E.; N.E.]	0/12	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.
Geographic region (Interaction test: p = 0.639)							
Europe excluding Germany	6/138 (4.3)	N.E. [N.E.; N.E.]	10/140 (7.1)	N.E. [N.E.; N.E.]	0.60	[0.22; 1.65]	0.317
Germany	5/72	N.E. [N.E.; N.E.]	9/53	N.E. [N.E.; N.E.]	0.32	[0.11; 0.96]	0.032

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(6.9)		(17.0)				
Others	2/74	N.E. [N.E.; N.E.]	8/89	N.E. [N.E.; N.E.]	0.31	[0.07; 1.49]	0.125
	(2.7)		(9.0)				
Blood bilirubin increased							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.968)							
Low	4/171	N.E. [N.E.; N.E.]	27/172	N.E. [N.E.; N.E.]	0.14	[0.05; 0.39]	<0.001
	(2.3)		(15.7)				
Intermediate	1/75	N.E. [N.E.; N.E.]	5/73	N.E. [N.E.; N.E.]	0.18	[0.02; 1.52]	0.075
	(1.3)		(6.8)				
High	1/38	N.E. [N.E.; N.E.]	7/37	N.E. [N.E.; N.E.]	0.13	[0.02; 1.05]	0.023
	(2.6)		(18.9)				
Sex							
(Interaction test: p = 0.515)							
Female	3/107	N.E. [N.E.; N.E.]	16/124	N.E. [N.E.; N.E.]	0.19	[0.06; 0.67]	0.004
	(2.8)		(12.9)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Male	3/177 (1.7)	N.E. [N.E.; N.E.]	23/158 (14.6)	N.E. [N.E.; N.E.]	0.11	[0.03; 0.37]	<0.001
Race (Interaction test: p = 1.000)							
Asian	0/40	N.E. [N.E.; N.E.]	7/45 (15.6)	N.E. [N.E.; N.E.]	0.08	[0.00; 1.61]	0.013
White	6/227 (2.6)	N.E. [N.E.; N.E.]	29/216 (13.4)	N.E. [N.E.; N.E.]	0.18	[0.07; 0.43]	<0.001
Other	0/17	N.E. [N.E.; N.E.]	3/21 (14.3)	N.E. [N.E.; N.E.]	0.16	[0.00; 5.17]	0.105
Age groups (Interaction test: p = 0.517)							
18 - < 65 years	5/237 (2.1)	N.E. [N.E.; N.E.]	34/246 (13.8)	N.E. [N.E.; N.E.]	0.14	[0.06; 0.36]	<0.001
65 - < 75 years	0/38	N.E. [N.E.; N.E.]	3/24 (12.5)	N.E. [N.E.; N.E.]	0.07	[0.00; 2.30]	0.016
>= 75 years	1/9	N.E. [0.5; N.E.]	2/12	N.E. [0.5; N.E.]	0.54	[0.05; 5.95]	0.589

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(11.1)		(16.7)				
Geographic region							
(Interaction test: p = 0.235)							
Europe excluding Germany	4/138	N.E. [N.E.; N.E.]	13/140	N.E. [N.E.; N.E.]	0.31	[0.10; 0.94]	0.028
	(2.9)		(9.3)				
Germany	1/72	N.E. [N.E.; N.E.]	13/53	N.E. [N.E.; N.E.]	0.05	[0.01; 0.36]	<0.001
	(1.4)		(24.5)				
Others	1/74	N.E. [N.E.; N.E.]	13/89	N.E. [N.E.; N.E.]	0.10	[0.01; 0.73]	0.005
	(1.4)		(14.6)				
Bone pain							
Race							
(Interaction test: p = 0.462)							
Asian	1/40	N.E. [N.E.; N.E.]	1/45	N.E. [N.E.; N.E.]	1.28	[0.08; 20.46]	0.861
	(2.5)		(2.2)				
White	10/227	N.E. [N.E.; N.E.]	1/216	N.E. [N.E.; N.E.]	9.69	[1.24; 75.71]	0.008
	(4.4)		(0.5)				
Other	0/17	N.E. [N.E.; N.E.]	0/21	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Age groups							
(Interaction test: p = 1.000)							
18 - < 65 years	10/237 (4.2)	N.E. [N.E.; N.E.]	2/246 (0.8)	N.E. [N.E.; N.E.]	5.22	[1.14; 23.83]	0.017
65 - < 75 years	1/38 (2.6)	N.E. [N.E.; N.E.]	0/24	N.E. [N.E.; N.E.]	1.96	[0.02; 191.12]	0.429
>= 75 years	0/9	N.E. [N.E.; N.E.]	0/12	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.
Constipation							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.867)							
Low	7/171 (4.1)	N.E. [N.E.; N.E.]	13/172 (7.6)	N.E. [N.E.; N.E.]	0.52	[0.21; 1.30]	0.153
Intermediate	2/75 (2.7)	N.E. [N.E.; N.E.]	5/73 (6.8)	N.E. [N.E.; N.E.]	0.37	[0.07; 1.89]	0.210

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
High	1/38 (2.6)	N.E. [21.8; N.E.]	3/37 (8.1)	N.E. [N.E.; N.E.]	0.32	[0.03; 3.06]	0.295
Sex							
(Interaction test: p = 0.175)							
Female	3/107 (2.8)	N.E. [N.E.; N.E.]	13/124 (10.5)	N.E. [N.E.; N.E.]	0.24	[0.07; 0.84]	0.016
Male	7/177 (4.0)	N.E. [N.E.; N.E.]	8/158 (5.1)	N.E. [N.E.; N.E.]	0.76	[0.28; 2.09]	0.594
Race							
(Interaction test: p = 0.989)							
Asian	1/40 (2.5)	N.E. [N.E.; N.E.]	2/45 (4.4)	N.E. [N.E.; N.E.]	0.58	[0.05; 6.44]	0.657
White	9/227 (4.0)	N.E. [N.E.; N.E.]	17/216 (7.9)	N.E. [N.E.; N.E.]	0.49	[0.22; 1.09]	0.073
Other	0/17	N.E. [N.E.; N.E.]	2/21 (9.5)	N.E. [N.E.; N.E.]	0.61	[0.01; 26.03]	0.421
Age groups							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.899)							
18 - < 65 years	8/237 (3.4)	N.E. [N.E.; N.E.]	18/246 (7.3)	N.E. [N.E.; N.E.]	0.44	[0.19; 1.02]	0.050
65 - < 75 years	1/38 (2.6)	N.E. [N.E.; N.E.]	1/24 (4.2)	N.E. [N.E.; N.E.]	0.65	[0.04; 10.32]	0.755
>= 75 years	1/9 (11.1)	N.E. [18.9; N.E.]	2/12 (16.7)	N.E. [0.3; N.E.]	1.55	[0.09; 25.33]	0.757
Geographic region							
(Interaction test: p = 0.611)							
Europe excluding Germany	4/138 (2.9)	N.E. [N.E.; N.E.]	9/140 (6.4)	N.E. [N.E.; N.E.]	0.42	[0.13; 1.39]	0.145
Germany	3/72 (4.2)	N.E. [N.E.; N.E.]	2/53 (3.8)	N.E. [N.E.; N.E.]	1.18	[0.19; 7.15]	0.858
Others	3/74 (4.1)	N.E. [N.E.; N.E.]	10/89 (11.2)	N.E. [N.E.; N.E.]	0.37	[0.10; 1.36]	0.121
Hyperbilirubinaemia							
Age groups							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 1.000)							
18 - < 65 years	2/237 (0.8)	N.E. [N.E.; N.E.]	9/246 (3.7)	N.E. [N.E.; N.E.]	0.22	[0.05; 1.01]	0.032
65 - < 75 years	0/38	N.E. [N.E.; N.E.]	0/24	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.
>= 75 years	0/9	N.E. [N.E.; N.E.]	1/12 (8.3)	N.E. [N.E.; N.E.]	0.39	[0.00; 37.18]	0.361
Hypercholesterolaemia							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.542)							
Low	2/171 (1.2)	N.E. [N.E.; N.E.]	12/172 (7.0)	N.E. [N.E.; N.E.]	0.16	[0.04; 0.72]	0.006
Intermediate	2/75 (2.7)	N.E. [N.E.; N.E.]	3/73 (4.1)	N.E. [N.E.; N.E.]	0.58	[0.10; 3.46]	0.546
High	0/38	N.E. [N.E.; N.E.]	0/37	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Sex							
(Interaction test: p = 0.190)							
Female	2/107 (1.9)	N.E. [N.E.; N.E.]	13/124 (10.5)	N.E. [N.E.; N.E.]	0.16	[0.04; 0.73]	0.007
Male	2/177 (1.1)	N.E. [N.E.; N.E.]	2/158 (1.3)	N.E. [N.E.; N.E.]	0.87	[0.12; 6.16]	0.887
Race							
(Interaction test: p = 1.000)							
Asian	0/40	N.E. [N.E.; N.E.]	1/45 (2.2)	N.E. [N.E.; N.E.]	0.46	[0.00; 44.32]	0.403
White	4/227 (1.8)	N.E. [N.E.; N.E.]	14/216 (6.5)	N.E. [N.E.; N.E.]	0.26	[0.09; 0.79]	0.011
Other	0/17	N.E. [N.E.; N.E.]	0/21	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.
Age groups							
(Interaction test: p = 1.000)							
18 - < 65 years	4/237	N.E. [N.E.; N.E.]	15/246	N.E. [N.E.; N.E.]	0.27	[0.09; 0.80]	0.012

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(1.7)		(6.1)				
65 - < 75 years	0/38	N.E. [N.E.; N.E.]	0/24	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.
>= 75 years	0/9	N.E. [N.E.; N.E.]	0/12	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.
Geographic region							
(Interaction test: p = 0.459)							
Europe excluding Germany	2/138	N.E. [N.E.; N.E.]	11/140	N.E. [N.E.; N.E.]	0.17	[0.04; 0.77]	0.009
	(1.4)		(7.9)				
Germany	0/72	N.E. [N.E.; N.E.]	1/53	N.E. [N.E.; N.E.]	0.17	[0.00; 16.29]	0.168
			(1.9)				
Others	2/74	N.E. [N.E.; N.E.]	3/89	N.E. [N.E.; N.E.]	0.79	[0.13; 4.80]	0.801
	(2.7)		(3.4)				
Hypertension							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.373)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Low	12/171 (7.0)	N.E. [N.E.; N.E.]	6/172 (3.5)	N.E. [N.E.; N.E.]	1.91	[0.72; 5.09]	0.188
Intermediate	12/75 (16.0)	N.E. [24.0; N.E.]	2/73 (2.7)	N.E. [26.5; N.E.]	5.80	[1.30; 25.92]	0.009
High	3/38 (7.9)	N.E. [N.E.; N.E.]	2/37 (5.4)	N.E. [N.E.; N.E.]	1.41	[0.24; 8.43]	0.707
Sex							
(Interaction test: p = 0.735)							
Female	8/107 (7.5)	N.E. [N.E.; N.E.]	3/124 (2.4)	N.E. [N.E.; N.E.]	2.97	[0.79; 11.22]	0.091
Male	19/177 (10.7)	N.E. [N.E.; N.E.]	7/158 (4.4)	N.E. [26.5; N.E.]	2.30	[0.97; 5.48]	0.053
Race							
(Interaction test: p = 0.540)							
Asian	1/40 (2.5)	N.E. [N.E.; N.E.]	2/45 (4.4)	N.E. [N.E.; N.E.]	0.56	[0.05; 6.23]	0.630
White	24/227	N.E. [N.E.; N.E.]	8/216	N.E. [N.E.; N.E.]	2.64	[1.19; 5.89]	0.013

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(10.6)		(3.7)				
Other	2/17	N.E. [N.E.; N.E.]	0/21	N.E. [N.E.; N.E.]	4.33	[0.11; 178.67]	0.188
	(11.8)						
Age groups							
(Interaction test: p = 0.401)							
18 - < 65 years	18/237	N.E. [N.E.; N.E.]	6/246	N.E. [N.E.; N.E.]	2.99	[1.19; 7.55]	0.015
	(7.6)		(2.4)				
65 - < 75 years	6/38	N.E. [N.E.; N.E.]	3/24	26.5 [22.1; N.E.]	1.50	[0.30; 7.48]	0.620
	(15.8)		(12.5)				
>= 75 years	3/9	N.E. [1.0; N.E.]	1/12	N.E. [N.E.; N.E.]	3.58	[0.37; 34.48]	0.239
	(33.3)		(8.3)				
Geographic region							
(Interaction test: p = 0.719)							
Europe excluding Germany	14/138	N.E. [N.E.; N.E.]	6/140	N.E. [N.E.; N.E.]	2.07	[0.79; 5.39]	0.130
	(10.1)		(4.3)				
Germany	6/72	N.E. [N.E.; N.E.]	2/53	N.E. [26.5; N.E.]	2.54	[0.48; 13.41]	0.259
	(8.3)		(3.8)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Others	7/74 (9.5)	N.E. [23.2; N.E.]	2/89 (2.2)	N.E. [N.E.; N.E.]	4.42	[0.91; 21.38]	0.044
Rash							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.556)							
Low	20/171 (11.7)	N.E. [N.E.; N.E.]	31/172 (18.0)	N.E. [N.E.; N.E.]	0.59	[0.34; 1.04]	0.065
Intermediate	10/75 (13.3)	N.E. [24.9; N.E.]	10/73 (13.7)	N.E. [N.E.; N.E.]	0.87	[0.36; 2.09]	0.751
High	3/38 (7.9)	N.E. [N.E.; N.E.]	7/37 (18.9)	N.E. [N.E.; N.E.]	0.37	[0.10; 1.43]	0.134
Sex							
(Interaction test: p = 0.141)							
Female	14/107 (13.1)	N.E. [N.E.; N.E.]	30/124 (24.2)	N.E. [N.E.; N.E.]	0.45	[0.24; 0.85]	0.011
Male	19/177	N.E. [N.E.; N.E.]	18/158	N.E. [N.E.; N.E.]	0.89	[0.47; 1.70]	0.729

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(10.7)		(11.4)				
Race							
(Interaction test: p = 0.619)							
Asian	4/40	N.E. [N.E.; N.E.]	10/45	N.E. [N.E.; N.E.]	0.38	[0.12; 1.21]	0.089
	(10.0)		(22.2)				
White	28/227	N.E. [N.E.; N.E.]	35/216	N.E. [N.E.; N.E.]	0.70	[0.42; 1.15]	0.155
	(12.3)		(16.2)				
Other	1/17	N.E. [N.E.; N.E.]	3/21	N.E. [N.E.; N.E.]	0.39	[0.04; 3.85]	0.403
	(5.9)		(14.3)				
Age groups							
(Interaction test: p = 0.255)							
18 - < 65 years	30/237	N.E. [N.E.; N.E.]	42/246	N.E. [N.E.; N.E.]	0.68	[0.42; 1.08]	0.100
	(12.7)		(17.1)				
65 - < 75 years	2/38	N.E. [N.E.; N.E.]	6/24	N.E. [3.1; N.E.]	0.16	[0.03; 0.78]	0.010
	(5.3)		(25.0)				
>= 75 years	1/9	N.E. [0.5; N.E.]	0/12	N.E. [N.E.; N.E.]	3.71	[0.04; 338.14]	0.264
	(11.1)						

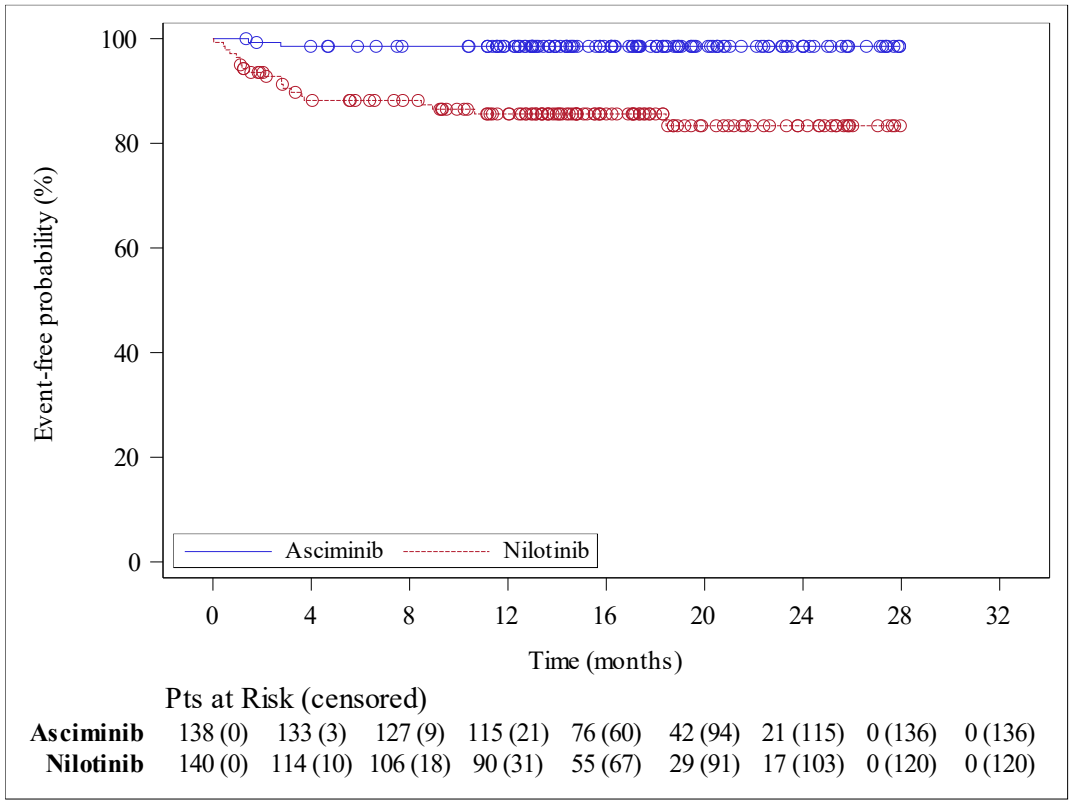
	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = 0.857)							
Europe excluding Germany	12/138 (8.7)	N.E. [N.E.; N.E.]	19/140 (13.6)	N.E. [N.E.; N.E.]	0.61	[0.30; 1.25]	0.174
Germany	13/72 (18.1)	N.E. [24.9; N.E.]	12/53 (22.6)	N.E. [N.E.; N.E.]	0.70	[0.32; 1.56]	0.390
Others	8/74 (10.8)	N.E. [N.E.; N.E.]	17/89 (19.1)	N.E. [N.E.; N.E.]	0.50	[0.21; 1.16]	0.101
Rash maculo-papular							
Age groups							
(Interaction test: p = 1.000)							
18 - < 65 years	2/237 (0.8)	N.E. [N.E.; N.E.]	11/246 (4.5)	N.E. [N.E.; N.E.]	0.18	[0.04; 0.83]	0.013
65 - < 75 years	1/38 (2.6)	N.E. [N.E.; N.E.]	0/24	N.E. [N.E.; N.E.]	1.45	[0.02; 139.78]	0.495
>= 75 years	0/9	N.E. [N.E.; N.E.]	1/12 (8.3)	N.E. [N.E.; N.E.]	0.39	[0.00; 38.92]	0.371

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = 1.000)							
Europe excluding Germany	0/138	N.E. [N.E.; N.E.]	3/140 (2.1)	N.E. [N.E.; N.E.]	0.14	[0.00; 4.20]	0.077
Germany	0/72	N.E. [N.E.; N.E.]	0/53	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.
Others	3/74 (4.1)	N.E. [N.E.; N.E.]	9/89 (10.1)	N.E. [N.E.; N.E.]	0.36	[0.10; 1.33]	0.108

N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
PT: Preferred Term
.....
If there are not at least 10 patients in every subgroup or not at least 10 events in at least one subgroup, no subgroup analyses were performed for the corresponding attribute.
Results on AEs differentiated by SOC or PT are only reported if the given result is statistically significant for the total population.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variable ELTS Score (IRT) and covariate treatment arm.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variable ELTS Score (IRT).
For the subgroups of Stratification factor: ELTS based on IRT randomisation data no stratification variable was used.
The reference group in the stratified Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 4-2.3 Time to first any AE by PT: Time to event analysis by subgroups: Kaplan-Meier plot by subgroups (Safety Analysis Set)

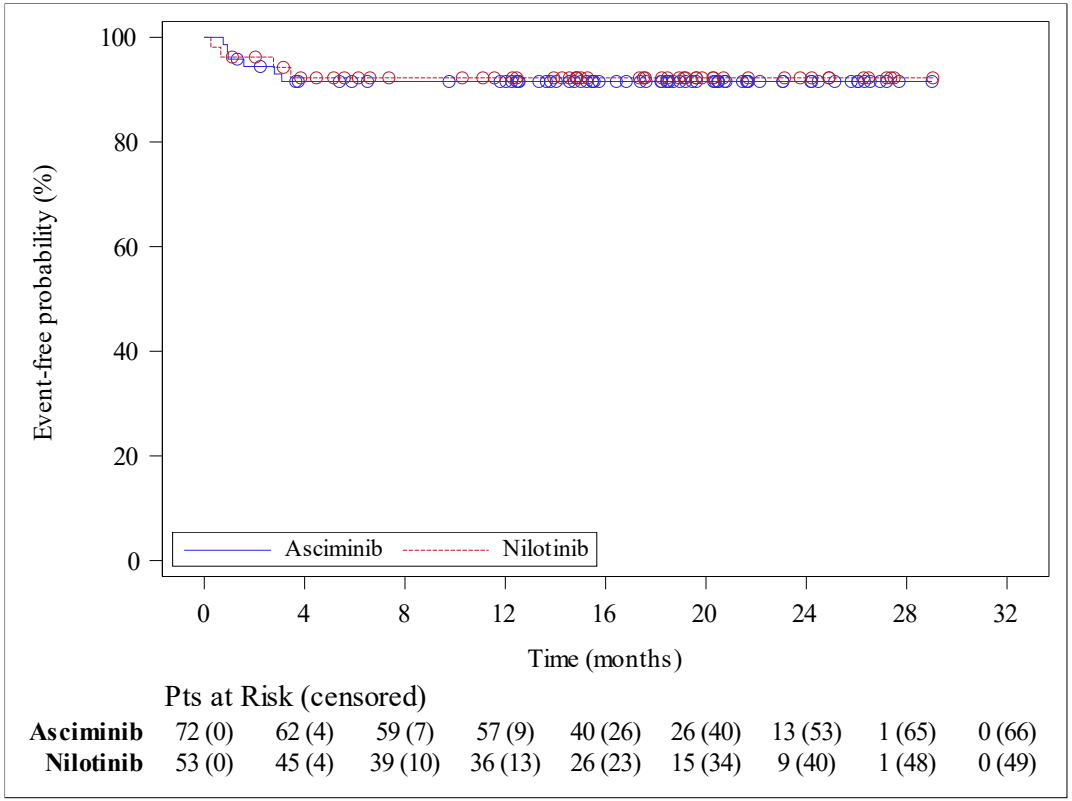
Alopecia: Geographic region: Europe excluding Germany



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/15MAY2025

Figure 4-2.3 Time to first any AE by PT: Time to event analysis by subgroups: Kaplan-Meier plot by subgroups (Safety Analysis Set)

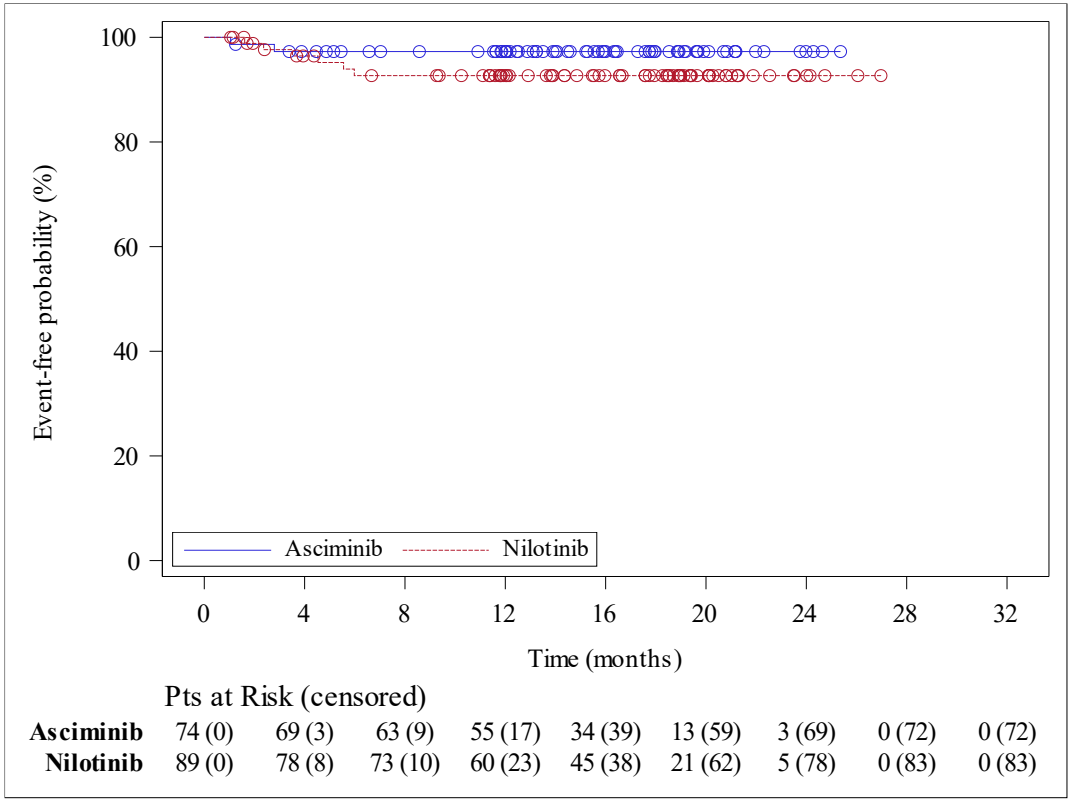
Alopecia: Geographic region: Germany



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/15MAY2025

Figure 4-2.3 Time to first any AE by PT: Time to event analysis by subgroups: Kaplan-Meier plot by subgroups (Safety Analysis Set)

Alopecia: Geographic region: Others



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/15MAY2025

Table 4-2.4 Time to first AE with grade >=3: Time to event analysis by subgroups (Safety Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.106)							
Low	53/171 (31.0)	N.E. [N.E.; N.E.]	64/172 (37.2)	N.E. [22.2; N.E.]	0.77	[0.53; 1.11]	0.162
Intermediate	25/75 (33.3)	N.E. [20.0; N.E.]	33/73 (45.2)	26.4 [8.3; N.E.]	0.61	[0.36; 1.03]	0.063
High	24/38 (63.2)	10.8 [2.8; N.E.]	17/37 (45.9)	N.E. [2.8; N.E.]	1.44	[0.77; 2.69]	0.246
Sex							
(Interaction test: p = 0.151)							
Female	38/107 (35.5)	N.E. [N.E.; N.E.]	57/124 (46.0)	N.E. [8.3; N.E.]	0.64	[0.43; 0.97]	0.035
Male	64/177 (36.2)	N.E. [22.0; N.E.]	57/158 (36.1)	N.E. [26.4; N.E.]	0.96	[0.67; 1.38]	0.852
Race							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.531)							
Asian	14/40 (35.0)	N.E. [15.0; N.E.]	22/45 (48.9)	13.8 [7.6; N.E.]	0.57	[0.29; 1.12]	0.099
White	78/227 (34.4)	N.E. [26.2; N.E.]	81/216 (37.5)	N.E. [26.4; N.E.]	0.85	[0.62; 1.16]	0.310
Other	10/17 (58.8)	8.3 [2.8; N.E.]	11/21 (52.4)	8.3 [1.0; N.E.]	1.18	[0.48; 2.90]	0.691
Age groups							
(Interaction test: p = 0.180)							
18 - < 65 years	85/237 (35.9)	N.E. [26.2; N.E.]	97/246 (39.4)	N.E. [N.E.; N.E.]	0.84	[0.63; 1.12]	0.240
65 - < 75 years	11/38 (28.9)	N.E. [20.0; N.E.]	12/24 (50.0)	26.4 [2.8; N.E.]	0.51	[0.22; 1.21]	0.127
>= 75 years	6/9 (66.7)	10.1 [1.0; N.E.]	5/12 (41.7)	N.E. [2.3; N.E.]	1.41	[0.42; 4.66]	0.567
Geographic region							
(Interaction test: p = 0.507)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Europe excluding Germany	47/138 (34.1)	N.E. [N.E.; N.E.]	51/140 (36.4)	N.E. [N.E.; N.E.]	0.90	[0.60; 1.33]	0.587
Germany	21/72 (29.2)	26.2 [26.2; N.E.]	22/53 (41.5)	26.4 [5.6; N.E.]	0.62	[0.34; 1.14]	0.120
Others	34/74 (45.9)	16.6 [11.0; N.E.]	41/89 (46.1)	N.E. [8.2; N.E.]	0.92	[0.58; 1.46]	0.747

N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
If there are not at least 10 patients in every subgroup or not at least 10 events in at least one subgroup, no subgroup analyses were performed for the corresponding attribute.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variable ELTS Score (IRT) and covariate treatment arm.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variable ELTS Score (IRT).
For the subgroups of Stratification factor: ELTS based on IRT randomisation data no stratification variable was used.
The reference group in the stratified Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
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Table 4-2.5 Time to first AE with grade >=3 by SOC: Time to event analysis by subgroups (Safety Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Investigations							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.903)							
Low	11/171 (6.4)	N.E. [N.E.; N.E.]	27/172 (15.7)	N.E. [N.E.; N.E.]	0.39	[0.19; 0.78]	0.006
Intermediate	5/75 (6.7)	N.E. [N.E.; N.E.]	12/73 (16.4)	N.E. [N.E.; N.E.]	0.37	[0.13; 1.06]	0.054
High	5/38 (13.2)	N.E. [N.E.; N.E.]	9/37 (24.3)	N.E. [N.E.; N.E.]	0.50	[0.17; 1.50]	0.210
Sex							
(Interaction test: p = 0.069)							
Female	6/107 (5.6)	N.E. [N.E.; N.E.]	27/124 (21.8)	N.E. [N.E.; N.E.]	0.22	[0.09; 0.53]	<0.001
Male	15/177 (8.5)	N.E. [N.E.; N.E.]	21/158 (13.3)	N.E. [N.E.; N.E.]	0.62	[0.32; 1.20]	0.151

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Race							
(Interaction test: p = 0.516)							
Asian	6/40 (15.0)	N.E. [N.E.; N.E.]	9/45 (20.0)	N.E. [N.E.; N.E.]	0.70	[0.25; 1.97]	0.491
White	14/227 (6.2)	N.E. [N.E.; N.E.]	34/216 (15.7)	N.E. [N.E.; N.E.]	0.37	[0.20; 0.68]	0.001
Other	1/17 (5.9)	N.E. [N.E.; N.E.]	5/21 (23.8)	N.E. [N.E.; N.E.]	0.36	[0.04; 3.30]	0.344
Age groups							
(Interaction test: p = 0.663)							
18 - < 65 years	18/237 (7.6)	N.E. [N.E.; N.E.]	36/246 (14.6)	N.E. [N.E.; N.E.]	0.49	[0.28; 0.86]	0.011
65 - < 75 years	3/38 (7.9)	N.E. [N.E.; N.E.]	7/24 (29.2)	N.E. [8.3; N.E.]	0.24	[0.06; 0.97]	0.035
>= 75 years	0/9	N.E. [N.E.; N.E.]	5/12 (41.7)	N.E. [2.3; N.E.]	0.10	[0.00; 2.48]	0.037
Geographic region							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.117)							
Europe excluding Germany	12/138 (8.7)	N.E. [N.E.; N.E.]	20/140 (14.3)	N.E. [N.E.; N.E.]	0.58	[0.29; 1.20]	0.139
Germany	1/72 (1.4)	N.E. [N.E.; N.E.]	11/53 (20.8)	N.E. [N.E.; N.E.]	0.05	[0.01; 0.42]	<0.001
Others	8/74 (10.8)	N.E. [N.E.; N.E.]	17/89 (19.1)	N.E. [N.E.; N.E.]	0.56	[0.24; 1.30]	0.167
Vascular disorders							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.729)							
Low	6/171 (3.5)	N.E. [N.E.; N.E.]	3/172 (1.7)	N.E. [N.E.; N.E.]	1.89	[0.47; 7.58]	0.358
Intermediate	9/75 (12.0)	N.E. [N.E.; N.E.]	2/73 (2.7)	N.E. [26.4; N.E.]	4.17	[0.90; 19.32]	0.047
High	2/38 (5.3)	N.E. [N.E.; N.E.]	1/37 (2.7)	N.E. [N.E.; N.E.]	1.85	[0.17; 20.46]	0.608

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Sex							
(Interaction test: p = 0.695)							
Female	6/107 (5.6)	N.E. [N.E.; N.E.]	2/124 (1.6)	N.E. [N.E.; N.E.]	3.12	[0.63; 15.47]	0.142
Male	11/177 (6.2)	N.E. [N.E.; N.E.]	4/158 (2.5)	N.E. [26.4; N.E.]	2.24	[0.71; 7.04]	0.157
Race							
(Interaction test: p = 1.000)							
Asian	0/40	N.E. [N.E.; N.E.]	0/45	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.
White	15/227 (6.6)	N.E. [N.E.; N.E.]	6/216 (2.8)	N.E. [N.E.; N.E.]	2.16	[0.84; 5.57]	0.102
Other	2/17 (11.8)	N.E. [N.E.; N.E.]	0/21	N.E. [N.E.; N.E.]	4.33	[0.11; 178.67]	0.188
Age groups							
(Interaction test: p = 0.735)							
18 - < 65 years	9/237	N.E. [N.E.; N.E.]	4/246	N.E. [N.E.; N.E.]	2.18	[0.67; 7.10]	0.182

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(3.8)		(1.6)				
65 - < 75 years	3/38	N.E. [N.E.; N.E.]	2/24	26.4 [N.E.; N.E.]	1.61	[0.17; 15.44]	0.679
	(7.9)		(8.3)				
>= 75 years	5/9	10.1 [1.0; N.E.]	0/12	N.E. [N.E.; N.E.]	16.42	[0.68; 396.25]	0.007
	(55.6)						
Geographic region							
(Interaction test: p = 0.819)							
Europe excluding Germany	12/138	N.E. [N.E.; N.E.]	4/140	N.E. [N.E.; N.E.]	2.80	[0.90; 8.68]	0.063
	(8.7)		(2.9)				
Germany	3/72	N.E. [N.E.; N.E.]	2/53	N.E. [26.4; N.E.]	1.45	[0.22; 9.54]	0.696
	(4.2)		(3.8)				
Others	2/74	N.E. [N.E.; N.E.]	0/89	N.E. [N.E.; N.E.]	6.46	[0.16; 266.14]	0.108
	(2.7)						

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			

N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
SOC: System Organ Class
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If there are not at least 10 patients in every subgroup or not at least 10 events in at least one subgroup, no subgroup analyses were performed for the corresponding attribute.
Results on AEs differentiated by SOC or PT are only reported if the given result is statistically significant for the total population.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variable ELTS Score (IRT) and covariate treatment arm.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variable ELTS Score (IRT).
For the subgroups of Stratification factor: ELTS based on IRT randomisation data no stratification variable was used.
The reference group in the stratified Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
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Table 4-2.6 Time to first AE with grade >=3 by PT: Time to event analysis by subgroups (Safety Analysis Set)

No subgroup analyses by PTs were performed, because there are not enough patients with an event.

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Table 4-2.7 Time to first serious AE: Time to event analysis by subgroups (Safety Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.879)							
Low	29/171 (17.0)	N.E. [N.E.; N.E.]	25/172 (14.5)	N.E. [N.E.; N.E.]	1.14	[0.67; 1.94]	0.633
Intermediate	10/75 (13.3)	N.E. [N.E.; N.E.]	10/73 (13.7)	N.E. [N.E.; N.E.]	0.86	[0.36; 2.08]	0.743
High	8/38 (21.1)	N.E. [26.2; N.E.]	7/37 (18.9)	N.E. [N.E.; N.E.]	1.09	[0.40; 3.02]	0.865
Sex							
(Interaction test: p = 0.696)							
Female	21/107 (19.6)	N.E. [N.E.; N.E.]	20/124 (16.1)	N.E. [N.E.; N.E.]	1.16	[0.63; 2.15]	0.631
Male	26/177 (14.7)	N.E. [N.E.; N.E.]	22/158 (13.9)	N.E. [N.E.; N.E.]	1.00	[0.56; 1.76]	0.990
Race							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.336)							
Asian	5/40 (12.5)	N.E. [N.E.; N.E.]	10/45 (22.2)	N.E. [24.6; N.E.]	0.56	[0.19; 1.64]	0.281
White	37/227 (16.3)	N.E. [N.E.; N.E.]	29/216 (13.4)	N.E. [N.E.; N.E.]	1.16	[0.71; 1.88]	0.559
Other	5/17 (29.4)	N.E. [12.6; N.E.]	3/21 (14.3)	N.E. [N.E.; N.E.]	3.41	[0.64; 18.10]	0.128
Age groups							
(Interaction test: p = 0.376)							
18 - < 65 years	37/237 (15.6)	N.E. [N.E.; N.E.]	38/246 (15.4)	N.E. [N.E.; N.E.]	0.97	[0.62; 1.53]	0.913
65 - < 75 years	6/38 (15.8)	N.E. [N.E.; N.E.]	1/24 (4.2)	N.E. [N.E.; N.E.]	3.48	[0.42; 29.08]	0.221
>= 75 years	4/9 (44.4)	19.9 [2.4; N.E.]	3/12 (25.0)	N.E. [2.5; N.E.]	1.75	[0.39; 7.92]	0.459
Geographic region							
(Interaction test: p = 0.654)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Europe excluding Germany	19/138 (13.8)	N.E. [N.E.; N.E.]	18/140 (12.9)	N.E. [N.E.; N.E.]	0.97	[0.51; 1.85]	0.921
Germany	14/72 (19.4)	N.E. [26.2; N.E.]	6/53 (11.3)	N.E. [N.E.; N.E.]	1.57	[0.60; 4.12]	0.356
Others	14/74 (18.9)	N.E. [N.E.; N.E.]	18/89 (20.2)	N.E. [24.6; N.E.]	0.99	[0.49; 2.01]	0.979

N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
If there are not at least 10 patients in every subgroup or not at least 10 events in at least one subgroup, no subgroup analyses were performed for the corresponding attribute.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variable ELTS Score (IRT) and covariate treatment arm.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variable ELTS Score (IRT).
For the subgroups of Stratification factor: ELTS based on IRT randomisation data no stratification variable was used.
The reference group in the stratified Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
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Table 4-2.8 Time to first serious AE by SOC: Time to event analysis by subgroups (Safety Analysis Set)

No subgroup analyses by SOCs were performed, because there are not enough patients with an event.

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Table 4-2.9 Time to first serious AE by PT: Time to event analysis by subgroups (Safety Analysis Set)

No subgroup analyses by PTs were performed, because there are not enough patients with an event.

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Table 4-2.10 Time to first AESI all grades: Time to event analysis by subgroups (Safety Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Acute pancreatitis (including isolated pancreatic enzyme elevations)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.458)							
Low	23/171 (13.5)	N.E. [N.E.; N.E.]	28/172 (16.3)	N.E. [N.E.; N.E.]	0.79	[0.46; 1.37]	0.402
Intermediate	5/75 (6.7)	N.E. [N.E.; N.E.]	9/73 (12.3)	N.E. [N.E.; N.E.]	0.50	[0.17; 1.48]	0.199
High	5/38 (13.2)	N.E. [N.E.; N.E.]	3/37 (8.1)	N.E. [N.E.; N.E.]	1.55	[0.37; 6.49]	0.545
Sex							
(Interaction test: p = 0.064)							
Female	8/107 (7.5)	N.E. [N.E.; N.E.]	20/124 (16.1)	N.E. [N.E.; N.E.]	0.42	[0.18; 0.95]	0.031
Male	25/177	N.E. [N.E.; N.E.]	20/158	N.E. [N.E.; N.E.]	1.10	[0.61; 1.98]	0.747

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(14.1)		(12.7)				
Race							
(Interaction test: p = 0.491)							
Asian	7/40	N.E. [16.8; N.E.]	6/45	N.E. [N.E.; N.E.]	1.59	[0.53; 4.76]	0.406
	(17.5)		(13.3)				
White	24/227	N.E. [N.E.; N.E.]	31/216	N.E. [N.E.; N.E.]	0.69	[0.41; 1.18]	0.173
	(10.6)		(14.4)				
Other	2/17	N.E. [N.E.; N.E.]	3/21	N.E. [16.6; N.E.]	0.93	[0.15; 5.84]	0.941
	(11.8)		(14.3)				
Age groups							
(Interaction test: p = 0.546)							
18 - < 65 years	31/237	N.E. [N.E.; N.E.]	34/246	N.E. [N.E.; N.E.]	0.92	[0.56; 1.49]	0.728
	(13.1)		(13.8)				
65 - < 75 years	2/38	N.E. [N.E.; N.E.]	3/24	N.E. [N.E.; N.E.]	0.34	[0.06; 2.06]	0.218
	(5.3)		(12.5)				
>= 75 years	0/9	N.E. [N.E.; N.E.]	3/12	N.E. [1.0; N.E.]	0.18	[0.01; 5.39]	0.119
			(25.0)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = 0.736)							
Europe excluding Germany	14/138 (10.1)	N.E. [N.E.; N.E.]	18/140 (12.9)	N.E. [N.E.; N.E.]	0.72	[0.36; 1.45]	0.359
Germany	10/72 (13.9)	N.E. [N.E.; N.E.]	6/53 (11.3)	N.E. [N.E.; N.E.]	1.02	[0.37; 2.85]	0.970
Others	9/74 (12.2)	N.E. [N.E.; N.E.]	16/89 (18.0)	N.E. [N.E.; N.E.]	0.68	[0.30; 1.56]	0.362
Arterial-occlusive events (AOE)							
Sex							
(Interaction test: p = 0.226)							
Female	1/107 (0.9)	N.E. [N.E.; N.E.]	5/124 (4.0)	N.E. [N.E.; N.E.]	0.21	[0.02; 1.77]	0.111
Male	6/177 (3.4)	N.E. [N.E.; N.E.]	5/158 (3.2)	N.E. [26.4; N.E.]	0.95	[0.29; 3.11]	0.927
Race							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.990)							
Asian	1/40 (2.5)	N.E. [20.0; N.E.]	2/45 (4.4)	N.E. [N.E.; N.E.]	0.68	[0.06; 8.26]	0.760
White	5/227 (2.2)	N.E. [N.E.; N.E.]	8/216 (3.7)	N.E. [N.E.; N.E.]	0.50	[0.16; 1.54]	0.220
Other	1/17 (5.9)	N.E. [N.E.; N.E.]	0/21	N.E. [N.E.; N.E.]	2.48	[0.03; 245.03]	0.378
Edema and fluid retention							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.435)							
Low	9/171 (5.3)	N.E. [N.E.; N.E.]	11/172 (6.4)	N.E. [N.E.; N.E.]	0.80	[0.33; 1.94]	0.627
Intermediate	1/75 (1.3)	N.E. [N.E.; N.E.]	5/73 (6.8)	N.E. [N.E.; N.E.]	0.18	[0.02; 1.53]	0.076
High	0/38	N.E. [N.E.; N.E.]	2/37 (5.4)	N.E. [N.E.; N.E.]	0.18	[0.00; 7.31]	0.133

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Sex							
(Interaction test: p = 0.641)							
Female	7/107 (6.5)	N.E. [N.E.; N.E.]	12/124 (9.7)	N.E. [N.E.; N.E.]	0.65	[0.26; 1.65]	0.362
Male	3/177 (1.7)	N.E. [N.E.; N.E.]	6/158 (3.8)	N.E. [N.E.; N.E.]	0.43	[0.11; 1.74]	0.224
Race							
(Interaction test: p = 1.000)							
Asian	0/40	N.E. [N.E.; N.E.]	5/45 (11.1)	N.E. [N.E.; N.E.]	0.09	[0.00; 2.31]	0.030
White	10/227 (4.4)	N.E. [N.E.; N.E.]	11/216 (5.1)	N.E. [N.E.; N.E.]	0.84	[0.36; 1.98]	0.695
Other	0/17	N.E. [N.E.; N.E.]	2/21 (9.5)	N.E. [N.E.; N.E.]	0.25	[0.01; 11.81]	0.219
Age groups							
(Interaction test: p = 1.000)							
18 - < 65 years	9/237	N.E. [N.E.; N.E.]	15/246	N.E. [N.E.; N.E.]	0.61	[0.27; 1.40]	0.243

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(3.8)		(6.1)				
65 - < 75 years	1/38	N.E. [N.E.; N.E.]	0/24	N.E. [N.E.; N.E.]	0.52	[0.01; 45.81]	0.670
	(2.6)						
>= 75 years	0/9	N.E. [N.E.; N.E.]	3/12	N.E. [1.6; N.E.]	0.18	[0.01; 5.51]	0.123
			(25.0)				
Geographic region							
(Interaction test: p = 0.651)							
Europe excluding Germany	0/138	N.E. [N.E.; N.E.]	4/140	N.E. [N.E.; N.E.]	0.12	[0.00; 3.09]	0.052
			(2.9)				
Germany	7/72	N.E. [N.E.; N.E.]	5/53	N.E. [N.E.; N.E.]	0.89	[0.28; 2.85]	0.844
	(9.7)		(9.4)				
Others	3/74	N.E. [N.E.; N.E.]	9/89	N.E. [N.E.; N.E.]	0.39	[0.10; 1.43]	0.140
	(4.1)		(10.1)				
Gastrointestinal toxicity							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.992)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Low	55/171 (32.2)	N.E. [N.E.; N.E.]	51/172 (29.7)	N.E. [N.E.; N.E.]	1.10	[0.75; 1.61]	0.632
Intermediate	21/75 (28.0)	N.E. [N.E.; N.E.]	18/73 (24.7)	N.E. [N.E.; N.E.]	1.15	[0.62; 2.17]	0.656
High	9/38 (23.7)	N.E. [16.6; N.E.]	8/37 (21.6)	N.E. [N.E.; N.E.]	1.08	[0.42; 2.80]	0.868
Sex							
(Interaction test: p = 0.565)							
Female	34/107 (31.8)	N.E. [19.4; N.E.]	39/124 (31.5)	N.E. [N.E.; N.E.]	1.01	[0.64; 1.60]	0.960
Male	51/177 (28.8)	N.E. [N.E.; N.E.]	38/158 (24.1)	N.E. [N.E.; N.E.]	1.21	[0.79; 1.84]	0.375
Race							
(Interaction test: p = 0.388)							
Asian	12/40 (30.0)	N.E. [13.8; N.E.]	14/45 (31.1)	N.E. [N.E.; N.E.]	1.00	[0.46; 2.17]	0.994
White	69/227	N.E. [N.E.; N.E.]	55/216	N.E. [N.E.; N.E.]	1.22	[0.86; 1.74]	0.263

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(30.4)		(25.5)				
Other	4/17	N.E. [10.2; N.E.]	8/21	N.E. [0.5; N.E.]	0.63	[0.18; 2.19]	0.466
	(23.5)		(38.1)				
Age groups							
(Interaction test: p = 0.517)							
18 - < 65 years	71/237	N.E. [N.E.; N.E.]	65/246	N.E. [N.E.; N.E.]	1.16	[0.83; 1.62]	0.396
	(30.0)		(26.4)				
65 - < 75 years	11/38	N.E. [17.0; N.E.]	5/24	N.E. [N.E.; N.E.]	1.30	[0.45; 3.81]	0.625
	(28.9)		(20.8)				
>= 75 years	3/9	18.9 [0.1; N.E.]	7/12	7.0 [0.2; N.E.]	0.58	[0.14; 2.34]	0.439
	(33.3)		(58.3)				
Geographic region							
(Interaction test: p = 0.463)							
Europe excluding Germany	40/138	N.E. [N.E.; N.E.]	34/140	N.E. [N.E.; N.E.]	1.21	[0.76; 1.91]	0.414
	(29.0)		(24.3)				
Germany	24/72	N.E. [19.4; N.E.]	13/53	N.E. [22.2; N.E.]	1.34	[0.68; 2.64]	0.407
	(33.3)		(24.5)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Others	21/74 (28.4)	N.E. [N.E.; N.E.]	30/89 (33.7)	N.E. [N.E.; N.E.]	0.83	[0.47; 1.45]	0.509
Hemorrhage							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.588)							
Low	9/171 (5.3)	N.E. [N.E.; N.E.]	11/172 (6.4)	N.E. [N.E.; N.E.]	0.79	[0.33; 1.91]	0.605
Intermediate	5/75 (6.7)	N.E. [N.E.; N.E.]	3/73 (4.1)	N.E. [N.E.; N.E.]	1.50	[0.36; 6.27]	0.578
High	3/38 (7.9)	N.E. [N.E.; N.E.]	5/37 (13.5)	N.E. [N.E.; N.E.]	0.53	[0.13; 2.20]	0.372
Sex							
(Interaction test: p = 0.016)							
Female	12/107 (11.2)	N.E. [N.E.; N.E.]	7/124 (5.6)	N.E. [N.E.; N.E.]	1.91	[0.75; 4.86]	0.166
Male	5/177	N.E. [N.E.; N.E.]	12/158	N.E. [N.E.; N.E.]	0.34	[0.12; 0.96]	0.032

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(2.8)		(7.6)				
Race							
(Interaction test: p = 0.240)							
Asian	1/40	N.E. [N.E.; N.E.]	4/45	N.E. [N.E.; N.E.]	0.28	[0.03; 2.55]	0.231
	(2.5)		(8.9)				
White	13/227	N.E. [N.E.; N.E.]	14/216	N.E. [N.E.; N.E.]	0.82	[0.39; 1.75]	0.613
	(5.7)		(6.5)				
Other	3/17	N.E. [N.E.; N.E.]	1/21	N.E. [N.E.; N.E.]	5.09	[0.48; 54.08]	0.144
	(17.6)		(4.8)				
Age groups							
(Interaction test: p = 0.865)							
18 - < 65 years	13/237	N.E. [N.E.; N.E.]	17/246	N.E. [N.E.; N.E.]	0.72	[0.35; 1.49]	0.376
	(5.5)		(6.9)				
65 - < 75 years	4/38	N.E. [N.E.; N.E.]	2/24	N.E. [N.E.; N.E.]	1.01	[0.18; 5.52]	0.992
	(10.5)		(8.3)				
>= 75 years	0/9	N.E. [N.E.; N.E.]	0/12	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = 0.638)							
Europe excluding Germany	6/138 (4.3)	N.E. [N.E.; N.E.]	9/140 (6.4)	N.E. [N.E.; N.E.]	0.60	[0.21; 1.69]	0.327
Germany	4/72 (5.6)	N.E. [N.E.; N.E.]	3/53 (5.7)	N.E. [N.E.; N.E.]	1.01	[0.22; 4.57]	0.995
Others	7/74 (9.5)	N.E. [22.1; N.E.]	7/89 (7.9)	N.E. [N.E.; N.E.]	1.24	[0.43; 3.60]	0.690
Hepatotoxicity (clinical events)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 1.000)							
Low	6/171 (3.5)	N.E. [N.E.; N.E.]	9/172 (5.2)	N.E. [N.E.; N.E.]	0.65	[0.23; 1.82]	0.409
Intermediate	1/75 (1.3)	N.E. [N.E.; N.E.]	0/73	N.E. [N.E.; N.E.]	2.64	[0.03; 254.86]	0.358
High	0/38	N.E. [N.E.; N.E.]	5/37	N.E. [N.E.; N.E.]	0.08	[0.00; 1.96]	0.019

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
			(13.5)				
Sex							
(Interaction test: p = 0.472)							
Female	2/107 (1.9)	N.E. [N.E.; N.E.]	7/124 (5.6)	N.E. [N.E.; N.E.]	0.30	[0.06; 1.46]	0.115
Male	5/177 (2.8)	N.E. [N.E.; N.E.]	7/158 (4.4)	N.E. [N.E.; N.E.]	0.63	[0.20; 1.99]	0.426
Race							
(Interaction test: p = 0.624)							
Asian	2/40 (5.0)	N.E. [N.E.; N.E.]	8/45 (17.8)	N.E. [N.E.; N.E.]	0.30	[0.06; 1.41]	0.106
White	5/227 (2.2)	N.E. [N.E.; N.E.]	6/216 (2.8)	N.E. [N.E.; N.E.]	0.76	[0.23; 2.50]	0.651
Other	0/17	N.E. [N.E.; N.E.]	0/21	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.
Age groups							
(Interaction test: p = 0.994)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
18 - < 65 years	6/237 (2.5)	N.E. [N.E.; N.E.]	12/246 (4.9)	N.E. [N.E.; N.E.]	0.50	[0.19; 1.33]	0.158
65 - < 75 years	1/38 (2.6)	N.E. [N.E.; N.E.]	1/24 (4.2)	N.E. [N.E.; N.E.]	0.66	[0.04; 11.22]	0.773
>= 75 years	0/9	N.E. [N.E.; N.E.]	1/12 (8.3)	N.E. [10.3; N.E.]	0.53	[0.01; 51.67]	0.439
Geographic region (Interaction test: p = 0.580)							
Europe excluding Germany	5/138 (3.6)	N.E. [N.E.; N.E.]	5/140 (3.6)	N.E. [N.E.; N.E.]	0.98	[0.28; 3.38]	0.968
Germany	0/72	N.E. [N.E.; N.E.]	1/53 (1.9)	N.E. [N.E.; N.E.]	0.24	[0.00; 21.52]	0.232
Others	2/74 (2.7)	N.E. [N.E.; N.E.]	8/89 (9.0)	N.E. [N.E.; N.E.]	0.34	[0.07; 1.60]	0.153
Hepatotoxicity (including laboratory terms)							
Stratification factor: ELTS based on randomization data from IRT							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.539)							
Low	24/171 (14.0)	N.E. [N.E.; N.E.]	53/172 (30.8)	N.E. [N.E.; N.E.]	0.40	[0.24; 0.64]	<0.001
Intermediate	5/75 (6.7)	N.E. [N.E.; N.E.]	19/73 (26.0)	N.E. [N.E.; N.E.]	0.21	[0.08; 0.57]	<0.001
High	6/38 (15.8)	N.E. [N.E.; N.E.]	14/37 (37.8)	N.E. [7.4; N.E.]	0.35	[0.14; 0.92]	0.026
Sex							
(Interaction test: p = 0.475)							
Female	18/107 (16.8)	N.E. [N.E.; N.E.]	42/124 (33.9)	N.E. [N.E.; N.E.]	0.41	[0.23; 0.71]	<0.001
Male	17/177 (9.6)	N.E. [N.E.; N.E.]	44/158 (27.8)	N.E. [N.E.; N.E.]	0.31	[0.18; 0.54]	<0.001
Race							
(Interaction test: p = 0.561)							
Asian	8/40 (20.0)	N.E. [N.E.; N.E.]	17/45 (37.8)	N.E. [9.3; N.E.]	0.47	[0.20; 1.09]	0.070

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
White	26/227 (11.5)	N.E. [N.E.; N.E.]	61/216 (28.2)	N.E. [N.E.; N.E.]	0.35	[0.22; 0.56]	<0.001
Other	1/17 (5.9)	N.E. [N.E.; N.E.]	8/21 (38.1)	N.E. [2.7; N.E.]	0.13	[0.02; 1.03]	0.023
Age groups (Interaction test: p = 0.821)							
18 - < 65 years	29/237 (12.2)	N.E. [N.E.; N.E.]	73/246 (29.7)	N.E. [N.E.; N.E.]	0.36	[0.23; 0.55]	<0.001
65 - < 75 years	5/38 (13.2)	N.E. [N.E.; N.E.]	7/24 (29.2)	N.E. [8.3; N.E.]	0.32	[0.10; 1.06]	0.056
>= 75 years	1/9 (11.1)	N.E. [0.5; N.E.]	6/12 (50.0)	11.3 [0.5; N.E.]	0.17	[0.02; 1.40]	0.052
Geographic region (Interaction test: p = 0.368)							
Europe excluding Germany	16/138 (11.6)	N.E. [N.E.; N.E.]	31/140 (22.1)	N.E. [N.E.; N.E.]	0.47	[0.26; 0.87]	0.014
Germany	10/72	N.E. [N.E.; N.E.]	20/53	N.E. [8.3; N.E.]	0.29	[0.13; 0.62]	<0.001

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(13.9)		(37.7)				
Others	9/74	N.E. [N.E.; N.E.]	35/89	N.E. [11.1; N.E.]	0.27	[0.13; 0.56]	<0.001
	(12.2)		(39.3)				
Hypersensitivity							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.400)							
Low	30/171	N.E. [N.E.; N.E.]	49/172	N.E. [N.E.; N.E.]	0.54	[0.34; 0.85]	0.007
	(17.5)		(28.5)				
Intermediate	16/75	N.E. [N.E.; N.E.]	19/73	N.E. [N.E.; N.E.]	0.69	[0.35; 1.34]	0.264
	(21.3)		(26.0)				
High	4/38	N.E. [N.E.; N.E.]	11/37	N.E. [N.E.; N.E.]	0.29	[0.09; 0.92]	0.026
	(10.5)		(29.7)				
Sex							
(Interaction test: p = 0.077)							
Female	20/107	N.E. [N.E.; N.E.]	46/124	N.E. [N.E.; N.E.]	0.39	[0.23; 0.66]	<0.001
	(18.7)		(37.1)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Male	30/177 (16.9)	N.E. [N.E.; N.E.]	33/158 (20.9)	N.E. [N.E.; N.E.]	0.75	[0.46; 1.23]	0.254
Race							
(Interaction test: p = 0.258)							
Asian	6/40 (15.0)	N.E. [N.E.; N.E.]	17/45 (37.8)	N.E. [8.3; N.E.]	0.30	[0.12; 0.76]	0.008
White	39/227 (17.2)	N.E. [N.E.; N.E.]	57/216 (26.4)	N.E. [N.E.; N.E.]	0.57	[0.38; 0.85]	0.006
Other	5/17 (29.4)	N.E. [3.2; N.E.]	5/21 (23.8)	N.E. [N.E.; N.E.]	1.47	[0.41; 5.22]	0.550
Age groups							
(Interaction test: p = 0.905)							
18 - < 65 years	44/237 (18.6)	N.E. [N.E.; N.E.]	71/246 (28.9)	N.E. [N.E.; N.E.]	0.56	[0.38; 0.81]	0.002
65 - < 75 years	5/38 (13.2)	N.E. [N.E.; N.E.]	6/24 (25.0)	N.E. [3.1; N.E.]	0.38	[0.12; 1.27]	0.104
>= 75 years	1/9	N.E. [0.5; N.E.]	2/12	N.E. [0.5; N.E.]	1.12	[0.07; 17.96]	0.937

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(11.1)		(16.7)				
Geographic region							
(Interaction test: p = 0.942)							
Europe excluding Germany	17/138	N.E. [N.E.; N.E.]	30/140	N.E. [N.E.; N.E.]	0.52	[0.28; 0.94]	0.027
	(12.3)		(21.4)				
Germany	14/72	N.E. [N.E.; N.E.]	15/53	N.E. [N.E.; N.E.]	0.60	[0.29; 1.25]	0.169
	(19.4)		(28.3)				
Others	19/74	N.E. [N.E.; N.E.]	34/89	N.E. [13.0; N.E.]	0.54	[0.31; 0.95]	0.032
	(25.7)		(38.2)				
Ischemic heart and CNS conditions							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.893)							
Low	5/171	N.E. [N.E.; N.E.]	8/172	N.E. [N.E.; N.E.]	0.61	[0.20; 1.85]	0.375
	(2.9)		(4.7)				
Intermediate	4/75	N.E. [N.E.; N.E.]	7/73	N.E. [N.E.; N.E.]	0.50	[0.15; 1.70]	0.255
	(5.3)		(9.6)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
High	2/38 (5.3)	N.E. [N.E.; N.E.]	2/37 (5.4)	N.E. [N.E.; N.E.]	0.89	[0.13; 6.34]	0.909
Sex							
(Interaction test: p = 0.203)							
Female	1/107 (0.9)	N.E. [N.E.; N.E.]	6/124 (4.8)	N.E. [N.E.; N.E.]	0.18	[0.02; 1.49]	0.074
Male	10/177 (5.6)	N.E. [N.E.; N.E.]	11/158 (7.0)	N.E. [N.E.; N.E.]	0.77	[0.33; 1.81]	0.541
Race							
(Interaction test: p = 0.988)							
Asian	2/40 (5.0)	N.E. [20.0; N.E.]	4/45 (8.9)	N.E. [N.E.; N.E.]	0.58	[0.10; 3.28]	0.531
White	7/227 (3.1)	N.E. [N.E.; N.E.]	13/216 (6.0)	N.E. [N.E.; N.E.]	0.47	[0.19; 1.18]	0.100
Other	2/17 (11.8)	N.E. [N.E.; N.E.]	0/21	N.E. [N.E.; N.E.]	4.25	[0.10; 175.93]	0.193
Age groups							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.652)							
18 - < 65 years	7/237 (3.0)	N.E. [N.E.; N.E.]	13/246 (5.3)	N.E. [N.E.; N.E.]	0.53	[0.21; 1.33]	0.171
65 - < 75 years	3/38 (7.9)	N.E. [N.E.; N.E.]	1/24 (4.2)	N.E. [N.E.; N.E.]	1.40	[0.14; 13.54]	0.772
>= 75 years	1/9 (11.1)	N.E. [2.4; N.E.]	3/12 (25.0)	N.E. [2.5; N.E.]	0.40	[0.04; 3.81]	0.406
Geographic region							
(Interaction test: p = 0.792)							
Europe excluding Germany	5/138 (3.6)	N.E. [N.E.; N.E.]	5/140 (3.6)	N.E. [N.E.; N.E.]	0.88	[0.25; 3.09]	0.847
Germany	2/72 (2.8)	N.E. [N.E.; N.E.]	3/53 (5.7)	N.E. [N.E.; N.E.]	0.53	[0.08; 3.30]	0.489
Others	4/74 (5.4)	N.E. [N.E.; N.E.]	9/89 (10.1)	N.E. [N.E.; N.E.]	0.48	[0.15; 1.56]	0.210
Ischemic heart conditions							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.967)							
Low	4/171 (2.3)	N.E. [N.E.; N.E.]	8/172 (4.7)	N.E. [N.E.; N.E.]	0.49	[0.15; 1.62]	0.229
Intermediate	3/75 (4.0)	N.E. [N.E.; N.E.]	7/73 (9.6)	N.E. [N.E.; N.E.]	0.37	[0.10; 1.44]	0.137
High	1/38 (2.6)	N.E. [N.E.; N.E.]	2/37 (5.4)	N.E. [N.E.; N.E.]	0.45	[0.04; 4.97]	0.504
Sex							
(Interaction test: p = 0.991)							
Female	0/107	N.E. [N.E.; N.E.]	6/124 (4.8)	N.E. [N.E.; N.E.]	0.09	[0.00; 1.95]	0.021
Male	8/177 (4.5)	N.E. [N.E.; N.E.]	11/158 (7.0)	N.E. [N.E.; N.E.]	0.61	[0.25; 1.52]	0.287
Race							
(Interaction test: p = 0.889)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Asian	2/40 (5.0)	N.E. [20.0; N.E.]	4/45 (8.9)	N.E. [N.E.; N.E.]	0.58	[0.10; 3.28]	0.531
White	5/227 (2.2)	N.E. [N.E.; N.E.]	13/216 (6.0)	N.E. [N.E.; N.E.]	0.34	[0.12; 0.96]	0.032
Other	1/17 (5.9)	N.E. [N.E.; N.E.]	0/21	N.E. [N.E.; N.E.]	2.77	[0.03; 255.52]	0.337
Age groups (Interaction test: p = 0.812)							
18 - < 65 years	6/237 (2.5)	N.E. [N.E.; N.E.]	13/246 (5.3)	N.E. [N.E.; N.E.]	0.46	[0.17; 1.20]	0.103
65 - < 75 years	2/38 (5.3)	N.E. [N.E.; N.E.]	1/24 (4.2)	N.E. [N.E.; N.E.]	0.96	[0.09; 10.73]	0.975
>= 75 years	0/9	N.E. [N.E.; N.E.]	3/12 (25.0)	N.E. [2.5; N.E.]	0.18	[0.01; 5.51]	0.123
Geographic region (Interaction test: p = 0.385)							
Europe excluding Germany	5/138	N.E. [N.E.; N.E.]	5/140	N.E. [N.E.; N.E.]	0.88	[0.25; 3.09]	0.847

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(3.6)		(3.6)				
Germany	1/72	N.E. [N.E.; N.E.]	3/53	N.E. [N.E.; N.E.]	0.23	[0.02; 2.30]	0.176
	(1.4)		(5.7)				
Others	2/74	N.E. [N.E.; N.E.]	9/89	N.E. [N.E.; N.E.]	0.23	[0.05; 1.07]	0.041
	(2.7)		(10.1)				
Myelosuppression							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.946)							
Low	40/171	N.E. [N.E.; N.E.]	39/172	N.E. [N.E.; N.E.]	1.05	[0.68; 1.64]	0.815
	(23.4)		(22.7)				
Intermediate	21/75	N.E. [N.E.; N.E.]	17/73	N.E. [N.E.; N.E.]	1.19	[0.63; 2.26]	0.578
	(28.0)		(23.3)				
High	17/38	N.E. [2.0; N.E.]	13/37	N.E. [2.8; N.E.]	1.17	[0.57; 2.41]	0.656
	(44.7)		(35.1)				
Sex							
(Interaction test: p = 0.827)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Female	28/107 (26.2)	N.E. [N.E.; N.E.]	27/124 (21.8)	N.E. [N.E.; N.E.]	1.15	[0.68; 1.95]	0.597
Male	50/177 (28.2)	N.E. [N.E.; N.E.]	42/158 (26.6)	N.E. [N.E.; N.E.]	1.07	[0.71; 1.61]	0.758
Race							
(Interaction test: p = 0.246)							
Asian	8/40 (20.0)	N.E. [N.E.; N.E.]	13/45 (28.9)	N.E. [N.E.; N.E.]	0.57	[0.24; 1.39]	0.221
White	60/227 (26.4)	N.E. [N.E.; N.E.]	47/216 (21.8)	N.E. [N.E.; N.E.]	1.24	[0.85; 1.82]	0.268
Other	10/17 (58.8)	1.2 [1.0; N.E.]	9/21 (42.9)	N.E. [1.0; N.E.]	1.73	[0.67; 4.46]	0.228
Age groups							
(Interaction test: p = 0.632)							
18 - < 65 years	71/237 (30.0)	N.E. [N.E.; N.E.]	64/246 (26.0)	N.E. [N.E.; N.E.]	1.14	[0.81; 1.60]	0.434
65 - < 75 years	5/38	N.E. [N.E.; N.E.]	5/24	N.E. [N.E.; N.E.]	0.64	[0.18; 2.23]	0.472

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(13.2)		(20.8)				
>= 75 years	2/9	N.E. [1.0; N.E.]	0/12	N.E. [N.E.; N.E.]	6.13	[0.15; 252.58]	0.118
	(22.2)						
Geographic region							
(Interaction test: p = 0.380)							
Europe excluding Germany	28/138	N.E. [N.E.; N.E.]	19/140	N.E. [N.E.; N.E.]	1.53	[0.86; 2.75]	0.147
	(20.3)		(13.6)				
Germany	17/72	N.E. [N.E.; N.E.]	15/53	N.E. [N.E.; N.E.]	0.81	[0.40; 1.63]	0.579
	(23.6)		(28.3)				
Others	33/74	N.E. [2.8; N.E.]	35/89	N.E. [2.8; N.E.]	1.10	[0.68; 1.78]	0.654
	(44.6)		(39.3)				
Myelosuppression (Erythropenia)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.851)							
Low	13/171	N.E. [N.E.; N.E.]	15/172	N.E. [N.E.; N.E.]	0.88	[0.42; 1.85]	0.730
	(7.6)		(8.7)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Intermediate	8/75 (10.7)	N.E. [N.E.; N.E.]	6/73 (8.2)	N.E. [N.E.; N.E.]	1.23	[0.43; 3.55]	0.698
High	5/38 (13.2)	N.E. [N.E.; N.E.]	4/37 (10.8)	N.E. [N.E.; N.E.]	1.13	[0.30; 4.22]	0.858
Sex							
(Interaction test: p = 0.242)							
Female	16/107 (15.0)	N.E. [N.E.; N.E.]	13/124 (10.5)	N.E. [N.E.; N.E.]	1.40	[0.67; 2.92]	0.373
Male	10/177 (5.6)	N.E. [N.E.; N.E.]	12/158 (7.6)	N.E. [N.E.; N.E.]	0.70	[0.30; 1.63]	0.408
Race							
(Interaction test: p = 0.936)							
Asian	4/40 (10.0)	N.E. [N.E.; N.E.]	5/45 (11.1)	N.E. [N.E.; N.E.]	0.85	[0.23; 3.17]	0.822
White	18/227 (7.9)	N.E. [N.E.; N.E.]	15/216 (6.9)	N.E. [N.E.; N.E.]	1.13	[0.57; 2.25]	0.723
Other	4/17	N.E. [13.8; N.E.]	5/21	N.E. [8.3; N.E.]	1.09	[0.28; 4.21]	0.910

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(23.5)		(23.8)				
Age groups							
(Interaction test: p = 0.994)							
18 - < 65 years	24/237	N.E. [N.E.; N.E.]	24/246	N.E. [N.E.; N.E.]	1.02	[0.58; 1.80]	0.952
	(10.1)		(9.8)				
65 - < 75 years	2/38	N.E. [N.E.; N.E.]	1/24	N.E. [N.E.; N.E.]	1.41	[0.12; 15.84]	0.782
	(5.3)		(4.2)				
>= 75 years	0/9	N.E. [N.E.; N.E.]	0/12	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.
Geographic region							
(Interaction test: p = 0.515)							
Europe excluding Germany	12/138	N.E. [N.E.; N.E.]	8/140	N.E. [N.E.; N.E.]	1.54	[0.63; 3.77]	0.347
	(8.7)		(5.7)				
Germany	2/72	N.E. [N.E.; N.E.]	3/53	N.E. [N.E.; N.E.]	0.50	[0.08; 3.01]	0.437
	(2.8)		(5.7)				
Others	12/74	N.E. [N.E.; N.E.]	14/89	N.E. [N.E.; N.E.]	1.02	[0.47; 2.21]	0.963
	(16.2)		(15.7)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Myelosuppression (Leukopenia)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.927)							
Low	25/171 (14.6)	N.E. [N.E.; N.E.]	21/172 (12.2)	N.E. [N.E.; N.E.]	1.20	[0.67; 2.15]	0.520
Intermediate	8/75 (10.7)	N.E. [N.E.; N.E.]	5/73 (6.8)	N.E. [N.E.; N.E.]	1.49	[0.49; 4.55]	0.482
High	11/38 (28.9)	N.E. [N.E.; N.E.]	9/37 (24.3)	N.E. [N.E.; N.E.]	1.17	[0.49; 2.83]	0.727
Sex							
(Interaction test: p = 0.892)							
Female	16/107 (15.0)	N.E. [N.E.; N.E.]	14/124 (11.3)	N.E. [N.E.; N.E.]	1.27	[0.62; 2.60]	0.519
Male	28/177 (15.8)	N.E. [N.E.; N.E.]	21/158 (13.3)	N.E. [N.E.; N.E.]	1.19	[0.68; 2.10]	0.531
Race							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.490)							
Asian	5/40 (12.5)	N.E. [N.E.; N.E.]	7/45 (15.6)	N.E. [N.E.; N.E.]	0.74	[0.23; 2.35]	0.609
White	30/227 (13.2)	N.E. [N.E.; N.E.]	22/216 (10.2)	N.E. [N.E.; N.E.]	1.27	[0.73; 2.20]	0.394
Other	9/17 (52.9)	8.3 [1.1; N.E.]	6/21 (28.6)	N.E. [5.6; N.E.]	2.22	[0.77; 6.38]	0.104
Age groups							
(Interaction test: p = 0.447)							
18 - < 65 years	41/237 (17.3)	N.E. [N.E.; N.E.]	32/246 (13.0)	N.E. [N.E.; N.E.]	1.32	[0.83; 2.09]	0.236
65 - < 75 years	2/38 (5.3)	N.E. [N.E.; N.E.]	3/24 (12.5)	N.E. [N.E.; N.E.]	0.49	[0.08; 2.96]	0.424
>= 75 years	1/9 (11.1)	N.E. [1.5; N.E.]	0/12	N.E. [N.E.; N.E.]	3.71	[0.04; 338.14]	0.264
Geographic region							
(Interaction test: p = 0.315)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Europe excluding Germany	16/138 (11.6)	N.E. [N.E.; N.E.]	8/140 (5.7)	N.E. [N.E.; N.E.]	2.05	[0.87; 4.79]	0.093
Germany	8/72 (11.1)	N.E. [N.E.; N.E.]	7/53 (13.2)	N.E. [N.E.; N.E.]	0.81	[0.29; 2.24]	0.685
Others	20/74 (27.0)	N.E. [N.E.; N.E.]	20/89 (22.5)	N.E. [N.E.; N.E.]	1.26	[0.68; 2.36]	0.437
Myelosuppression (Thrombocytopenia)							
Stratification factor: ELTS based on randomization data from IRT (Interaction test: p = 0.635)							
Low	25/171 (14.6)	N.E. [N.E.; N.E.]	24/172 (14.0)	N.E. [N.E.; N.E.]	1.07	[0.61; 1.88]	0.813
Intermediate	16/75 (21.3)	N.E. [N.E.; N.E.]	11/73 (15.1)	N.E. [N.E.; N.E.]	1.43	[0.66; 3.08]	0.354
High	17/38 (44.7)	N.E. [2.0; N.E.]	10/37 (27.0)	N.E. [N.E.; N.E.]	1.67	[0.77; 3.66]	0.193
Sex							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.540)							
Female	19/107 (17.8)	N.E. [N.E.; N.E.]	14/124 (11.3)	N.E. [N.E.; N.E.]	1.48	[0.74; 2.97]	0.266
Male	39/177 (22.0)	N.E. [N.E.; N.E.]	31/158 (19.6)	N.E. [N.E.; N.E.]	1.15	[0.72; 1.85]	0.549
Race							
(Interaction test: p = 0.900)							
Asian	8/40 (20.0)	N.E. [N.E.; N.E.]	8/45 (17.8)	N.E. [N.E.; N.E.]	1.04	[0.39; 2.77]	0.943
White	45/227 (19.8)	N.E. [N.E.; N.E.]	32/216 (14.8)	N.E. [N.E.; N.E.]	1.37	[0.87; 2.15]	0.173
Other	5/17 (29.4)	N.E. [1.1; N.E.]	5/21 (23.8)	N.E. [N.E.; N.E.]	2.00	[0.51; 7.79]	0.275
Age groups							
(Interaction test: p = 0.727)							
18 - < 65 years	53/237 (22.4)	N.E. [N.E.; N.E.]	42/246 (17.1)	N.E. [N.E.; N.E.]	1.31	[0.87; 1.96]	0.188

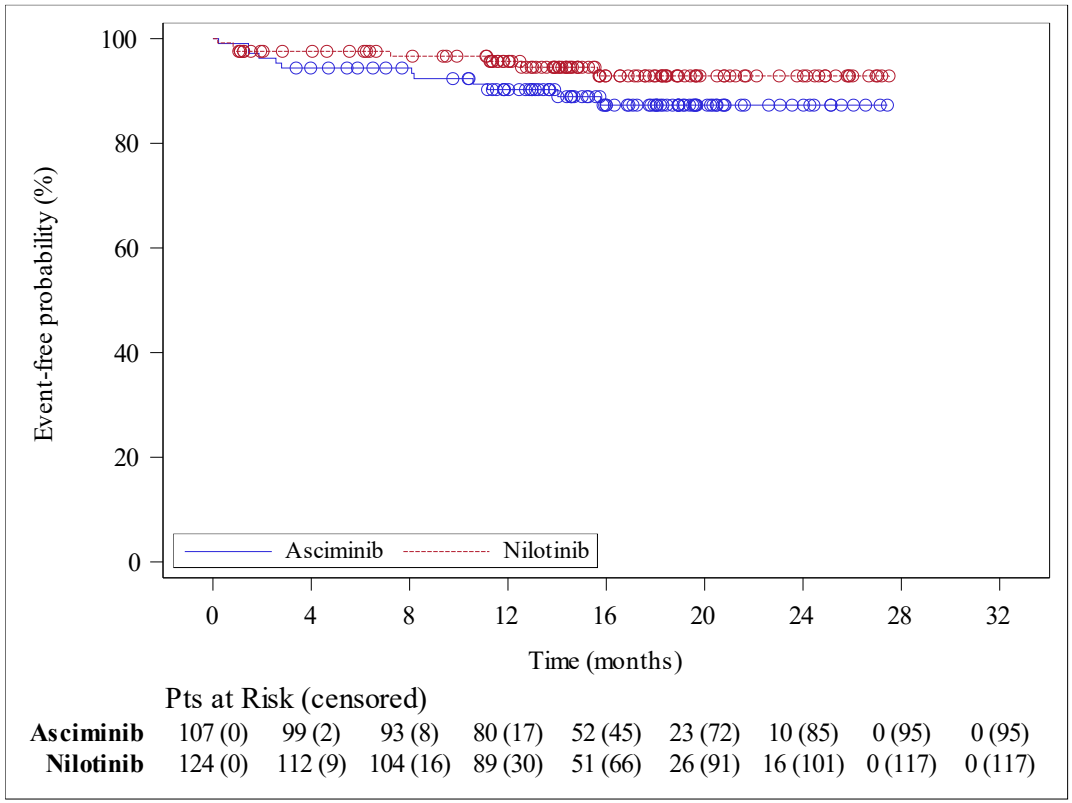
	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
65 - < 75 years	3/38 (7.9)	N.E. [N.E.; N.E.]	3/24 (12.5)	N.E. [N.E.; N.E.]	0.76	[0.15; 3.81]	0.742
>= 75 years	2/9 (22.2)	N.E. [1.0; N.E.]	0/12	N.E. [N.E.; N.E.]	6.13	[0.15; 252.58]	0.118
Geographic region (Interaction test: p = 0.387)							
Europe excluding Germany	20/138 (14.5)	N.E. [N.E.; N.E.]	10/140 (7.1)	N.E. [N.E.; N.E.]	1.98	[0.93; 4.24]	0.073
Germany	15/72 (20.8)	N.E. [N.E.; N.E.]	12/53 (22.6)	N.E. [N.E.; N.E.]	0.91	[0.42; 1.95]	0.826
Others	23/74 (31.1)	N.E. [N.E.; N.E.]	23/89 (25.8)	N.E. [N.E.; N.E.]	1.25	[0.70; 2.24]	0.453
QTc prolongation							
Race (Interaction test: p = 1.000)							
Asian	0/40	N.E. [N.E.; N.E.]	0/45	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
White	5/227 (2.2)	N.E. [N.E.; N.E.]	5/216 (2.3)	N.E. [N.E.; N.E.]	0.92	[0.27; 3.19]	0.900
Other	0/17	N.E. [N.E.; N.E.]	1/21 (4.8)	N.E. [N.E.; N.E.]	0.64	[0.01; 62.05]	0.480

N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
If there are not at least 10 patients in every subgroup or not at least 10 events in at least one subgroup, no subgroup analyses were performed for the corresponding attribute.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variable ELTS Score (IRT) and covariate treatment arm.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variable ELTS Score (IRT).
For the subgroups of Stratification factor: ELTS based on IRT randomisation data no stratification variable was used.
The reference group in the stratified Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 4-2.10 Time to first AESI all grades: Time to event analysis by subgroups: Kaplan-Meier plot by subgroups (Safety Analysis Set)

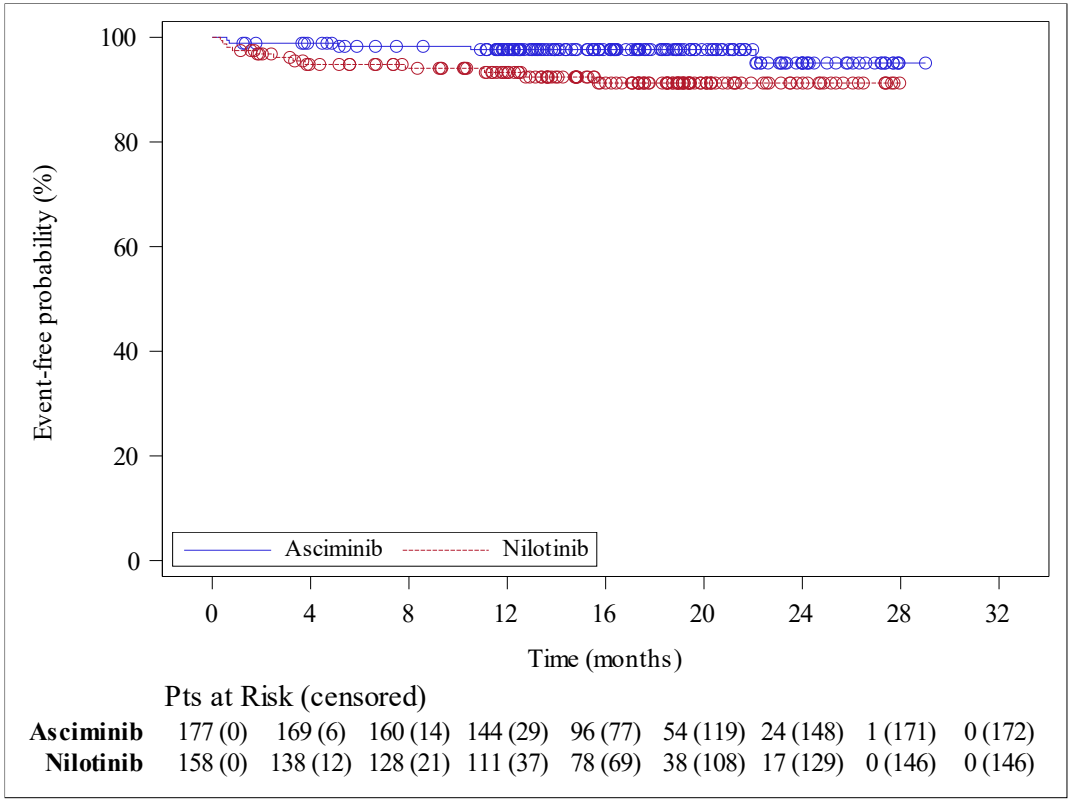
Hemorrhage: Sex: Female



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/15MAY2025

Figure 4-2.10 Time to first AESI all grades: Time to event analysis by subgroups: Kaplan-Meier plot by subgroups (Safety Analysis Set)

Hemorrhage: Sex: Male



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
Data Cut/15MAY2025

Table 4-2.11 Time to first grade 1/2 AESI: Time to event analysis by subgroups (Safety Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Acute pancreatitis (including isolated pancreatic enzyme elevations)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.590)							
Low	22/171 (12.9)	N.E. [N.E.; N.E.]	26/172 (15.1)	N.E. [N.E.; N.E.]	0.82	[0.46; 1.44]	0.478
Intermediate	5/75 (6.7)	N.E. [N.E.; N.E.]	7/73 (9.6)	N.E. [N.E.; N.E.]	0.64	[0.20; 2.02]	0.444
High	4/38 (10.5)	N.E. [N.E.; N.E.]	2/37 (5.4)	N.E. [N.E.; N.E.]	1.84	[0.34; 10.05]	0.475
Sex							
(Interaction test: p = 0.291)							
Female	8/107 (7.5)	N.E. [N.E.; N.E.]	15/124 (12.1)	N.E. [N.E.; N.E.]	0.56	[0.24; 1.33]	0.187
Male	23/177	N.E. [N.E.; N.E.]	20/158	N.E. [N.E.; N.E.]	1.01	[0.55; 1.84]	0.981

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(13.0)		(12.7)				
Race							
(Interaction test: p = 0.725)							
Asian	6/40	N.E. [N.E.; N.E.]	6/45	N.E. [N.E.; N.E.]	1.35	[0.43; 4.21]	0.609
	(15.0)		(13.3)				
White	23/227	N.E. [N.E.; N.E.]	27/216	N.E. [N.E.; N.E.]	0.76	[0.44; 1.33]	0.338
	(10.1)		(12.5)				
Other	2/17	N.E. [N.E.; N.E.]	2/21	N.E. [16.6; N.E.]	1.37	[0.18; 10.39]	0.762
	(11.8)		(9.5)				
Age groups							
(Interaction test: p = 0.463)							
18 - < 65 years	29/237	N.E. [N.E.; N.E.]	29/246	N.E. [N.E.; N.E.]	1.01	[0.60; 1.69]	0.967
	(12.2)		(11.8)				
65 - < 75 years	2/38	N.E. [N.E.; N.E.]	3/24	N.E. [N.E.; N.E.]	0.34	[0.06; 2.06]	0.218
	(5.3)		(12.5)				
>= 75 years	0/9	N.E. [N.E.; N.E.]	3/12	N.E. [1.0; N.E.]	0.18	[0.01; 5.39]	0.119
			(25.0)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = 0.586)							
Europe excluding Germany	13/138 (9.4)	N.E. [N.E.; N.E.]	15/140 (10.7)	N.E. [N.E.; N.E.]	0.81	[0.38; 1.70]	0.568
Germany	10/72 (13.9)	N.E. [N.E.; N.E.]	5/53 (9.4)	N.E. [N.E.; N.E.]	1.19	[0.40; 3.52]	0.756
Others	8/74 (10.8)	N.E. [N.E.; N.E.]	15/89 (16.9)	N.E. [N.E.; N.E.]	0.63	[0.27; 1.49]	0.287
Edema and fluid retention							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.435)							
Low	9/171 (5.3)	N.E. [N.E.; N.E.]	11/172 (6.4)	N.E. [N.E.; N.E.]	0.80	[0.33; 1.94]	0.627
Intermediate	1/75 (1.3)	N.E. [N.E.; N.E.]	5/73 (6.8)	N.E. [N.E.; N.E.]	0.18	[0.02; 1.53]	0.076
High	0/38	N.E. [N.E.; N.E.]	2/37	N.E. [N.E.; N.E.]	0.18	[0.00; 7.31]	0.133

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
			(5.4)				
Sex							
(Interaction test: p = 0.641)							
Female	7/107 (6.5)	N.E. [N.E.; N.E.]	12/124 (9.7)	N.E. [N.E.; N.E.]	0.65	[0.26; 1.65]	0.362
Male	3/177 (1.7)	N.E. [N.E.; N.E.]	6/158 (3.8)	N.E. [N.E.; N.E.]	0.43	[0.11; 1.74]	0.224
Race							
(Interaction test: p = 1.000)							
Asian	0/40	N.E. [N.E.; N.E.]	5/45 (11.1)	N.E. [N.E.; N.E.]	0.09	[0.00; 2.31]	0.030
White	10/227 (4.4)	N.E. [N.E.; N.E.]	11/216 (5.1)	N.E. [N.E.; N.E.]	0.84	[0.36; 1.98]	0.695
Other	0/17	N.E. [N.E.; N.E.]	2/21 (9.5)	N.E. [N.E.; N.E.]	0.25	[0.01; 11.81]	0.219
Age groups							
(Interaction test: p = 1.000)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
18 - < 65 years	9/237 (3.8)	N.E. [N.E.; N.E.]	15/246 (6.1)	N.E. [N.E.; N.E.]	0.61	[0.27; 1.40]	0.243
65 - < 75 years	1/38 (2.6)	N.E. [N.E.; N.E.]	0/24	N.E. [N.E.; N.E.]	0.52	[0.01; 45.81]	0.670
>= 75 years	0/9	N.E. [N.E.; N.E.]	3/12 (25.0)	N.E. [1.6; N.E.]	0.18	[0.01; 5.51]	0.123
Geographic region (Interaction test: p = 0.651)							
Europe excluding Germany	0/138	N.E. [N.E.; N.E.]	4/140 (2.9)	N.E. [N.E.; N.E.]	0.12	[0.00; 3.09]	0.052
Germany	7/72 (9.7)	N.E. [N.E.; N.E.]	5/53 (9.4)	N.E. [N.E.; N.E.]	0.89	[0.28; 2.85]	0.844
Others	3/74 (4.1)	N.E. [N.E.; N.E.]	9/89 (10.1)	N.E. [N.E.; N.E.]	0.39	[0.10; 1.43]	0.140
Gastrointestinal toxicity							
Stratification factor: ELTS based on randomization data from IRT							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.949)							
Low	55/171 (32.2)	N.E. [N.E.; N.E.]	51/172 (29.7)	N.E. [N.E.; N.E.]	1.10	[0.75; 1.61]	0.632
Intermediate	21/75 (28.0)	N.E. [N.E.; N.E.]	18/73 (24.7)	N.E. [N.E.; N.E.]	1.15	[0.62; 2.17]	0.656
High	8/38 (21.1)	N.E. [N.E.; N.E.]	8/37 (21.6)	N.E. [N.E.; N.E.]	0.96	[0.36; 2.55]	0.936
Sex							
(Interaction test: p = 0.612)							
Female	34/107 (31.8)	N.E. [19.4; N.E.]	39/124 (31.5)	N.E. [N.E.; N.E.]	1.01	[0.64; 1.60]	0.960
Male	50/177 (28.2)	N.E. [N.E.; N.E.]	38/158 (24.1)	N.E. [N.E.; N.E.]	1.19	[0.78; 1.81]	0.430
Race							
(Interaction test: p = 0.238)							
Asian	12/40 (30.0)	N.E. [13.8; N.E.]	14/45 (31.1)	N.E. [N.E.; N.E.]	1.00	[0.46; 2.17]	0.994

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
White	69/227 (30.4)	N.E. [N.E.; N.E.]	55/216 (25.5)	N.E. [N.E.; N.E.]	1.22	[0.86; 1.74]	0.263
Other	3/17 (17.6)	N.E. [10.2; N.E.]	8/21 (38.1)	N.E. [0.5; N.E.]	0.43	[0.11; 1.69]	0.215
Age groups (Interaction test: p = 0.514)							
18 - < 65 years	70/237 (29.5)	N.E. [N.E.; N.E.]	65/246 (26.4)	N.E. [N.E.; N.E.]	1.14	[0.81; 1.60]	0.443
65 - < 75 years	11/38 (28.9)	N.E. [17.0; N.E.]	5/24 (20.8)	N.E. [N.E.; N.E.]	1.30	[0.45; 3.81]	0.625
>= 75 years	3/9 (33.3)	18.9 [0.1; N.E.]	7/12 (58.3)	7.0 [0.2; N.E.]	0.58	[0.14; 2.34]	0.439
Geographic region (Interaction test: p = 0.471)							
Europe excluding Germany	39/138 (28.3)	N.E. [N.E.; N.E.]	34/140 (24.3)	N.E. [N.E.; N.E.]	1.19	[0.75; 1.88]	0.465
Germany	24/72	N.E. [19.4; N.E.]	13/53	N.E. [22.2; N.E.]	1.34	[0.68; 2.64]	0.407

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(33.3)		(24.5)				
Others	21/74	N.E. [N.E.; N.E.]	30/89	N.E. [N.E.; N.E.]	0.83	[0.47; 1.45]	0.509
	(28.4)		(33.7)				
Hemorrhage							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.421)							
Low	9/171	N.E. [N.E.; N.E.]	11/172	N.E. [N.E.; N.E.]	0.79	[0.33; 1.91]	0.601
	(5.3)		(6.4)				
Intermediate	5/75	N.E. [N.E.; N.E.]	3/73	N.E. [N.E.; N.E.]	1.50	[0.36; 6.27]	0.578
	(6.7)		(4.1)				
High	2/38	N.E. [N.E.; N.E.]	5/37	N.E. [N.E.; N.E.]	0.35	[0.07; 1.79]	0.186
	(5.3)		(13.5)				
Sex							
(Interaction test: p = 0.009)							
Female	12/107	N.E. [N.E.; N.E.]	7/124	N.E. [N.E.; N.E.]	1.91	[0.75; 4.86]	0.166
	(11.2)		(5.6)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Male	4/177 (2.3)	N.E. [N.E.; N.E.]	12/158 (7.6)	N.E. [N.E.; N.E.]	0.27	[0.09; 0.83]	0.014
Race (Interaction test: p = 0.238)							
Asian	1/40 (2.5)	N.E. [N.E.; N.E.]	4/45 (8.9)	N.E. [N.E.; N.E.]	0.28	[0.03; 2.53]	0.228
White	12/227 (5.3)	N.E. [N.E.; N.E.]	14/216 (6.5)	N.E. [N.E.; N.E.]	0.76	[0.35; 1.65]	0.488
Other	3/17 (17.6)	N.E. [N.E.; N.E.]	1/21 (4.8)	N.E. [N.E.; N.E.]	5.09	[0.48; 54.08]	0.144
Age groups (Interaction test: p = 0.839)							
18 - < 65 years	12/237 (5.1)	N.E. [N.E.; N.E.]	17/246 (6.9)	N.E. [N.E.; N.E.]	0.67	[0.32; 1.40]	0.280
65 - < 75 years	4/38 (10.5)	N.E. [N.E.; N.E.]	2/24 (8.3)	N.E. [N.E.; N.E.]	1.01	[0.18; 5.52]	0.992
>= 75 years	0/9	N.E. [N.E.; N.E.]	0/12	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = 0.621)							
Europe excluding Germany	6/138 (4.3)	N.E. [N.E.; N.E.]	9/140 (6.4)	N.E. [N.E.; N.E.]	0.60	[0.21; 1.69]	0.327
Germany	3/72 (4.2)	N.E. [N.E.; N.E.]	3/53 (5.7)	N.E. [N.E.; N.E.]	0.75	[0.15; 3.79]	0.725
Others	7/74 (9.5)	N.E. [22.1; N.E.]	7/89 (7.9)	N.E. [N.E.; N.E.]	1.24	[0.43; 3.60]	0.689
Hepatotoxicity (clinical events)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 1.000)							
Low	3/171 (1.8)	N.E. [N.E.; N.E.]	9/172 (5.2)	N.E. [N.E.; N.E.]	0.32	[0.09; 1.19]	0.073
Intermediate	1/75 (1.3)	N.E. [N.E.; N.E.]	0/73	N.E. [N.E.; N.E.]	2.64	[0.03; 254.86]	0.358

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
High	0/38	N.E. [N.E.; N.E.]	3/37 (8.1)	N.E. [N.E.; N.E.]	0.13	[0.00; 3.89]	0.066
Age groups (Interaction test: p = 0.926)							
18 - < 65 years	3/237 (1.3)	N.E. [N.E.; N.E.]	10/246 (4.1)	N.E. [N.E.; N.E.]	0.30	[0.08; 1.09]	0.053
65 - < 75 years	1/38 (2.6)	N.E. [N.E.; N.E.]	1/24 (4.2)	N.E. [N.E.; N.E.]	0.66	[0.04; 11.22]	0.773
>= 75 years	0/9	N.E. [N.E.; N.E.]	1/12 (8.3)	N.E. [10.3; N.E.]	0.53	[0.01; 51.67]	0.439
Hepatotoxicity (including laboratory terms)							
Stratification factor: ELTS based on randomization data from IRT (Interaction test: p = 0.698)							
Low	23/171 (13.5)	N.E. [N.E.; N.E.]	53/172 (30.8)	N.E. [N.E.; N.E.]	0.38	[0.23; 0.61]	<0.001
Intermediate	5/75	N.E. [N.E.; N.E.]	17/73	N.E. [N.E.; N.E.]	0.24	[0.09; 0.66]	0.003

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(6.7)		(23.3)				
High	6/38	N.E. [N.E.; N.E.]	12/37	N.E. [11.3; N.E.]	0.43	[0.16; 1.14]	0.081
	(15.8)		(32.4)				
Sex							
(Interaction test: p = 0.397)							
Female	17/107	N.E. [N.E.; N.E.]	38/124	N.E. [N.E.; N.E.]	0.43	[0.24; 0.76]	0.003
	(15.9)		(30.6)				
Male	17/177	N.E. [N.E.; N.E.]	44/158	N.E. [N.E.; N.E.]	0.31	[0.18; 0.54]	<0.001
	(9.6)		(27.8)				
Race							
(Interaction test: p = 0.692)							
Asian	7/40	N.E. [N.E.; N.E.]	17/45	N.E. [9.3; N.E.]	0.40	[0.16; 0.96]	0.034
	(17.5)		(37.8)				
White	26/227	N.E. [N.E.; N.E.]	58/216	N.E. [N.E.; N.E.]	0.37	[0.24; 0.60]	<0.001
	(11.5)		(26.9)				
Other	1/17	N.E. [N.E.; N.E.]	7/21	N.E. [2.7; N.E.]	0.13	[0.02; 1.07]	0.026
	(5.9)		(33.3)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Age groups							
(Interaction test: p = 0.944)							
18 - < 65 years	28/237 (11.8)	N.E. [N.E.; N.E.]	72/246 (29.3)	N.E. [N.E.; N.E.]	0.35	[0.23; 0.54]	<0.001
65 - < 75 years	5/38 (13.2)	N.E. [N.E.; N.E.]	6/24 (25.0)	N.E. [8.3; N.E.]	0.37	[0.11; 1.27]	0.111
>= 75 years	1/9 (11.1)	N.E. [0.5; N.E.]	4/12 (33.3)	N.E. [0.5; N.E.]	0.29	[0.03; 2.62]	0.228
Geographic region							
(Interaction test: p = 0.355)							
Europe excluding Germany	16/138 (11.6)	N.E. [N.E.; N.E.]	31/140 (22.1)	N.E. [N.E.; N.E.]	0.47	[0.26; 0.86]	0.013
Germany	10/72 (13.9)	N.E. [N.E.; N.E.]	17/53 (32.1)	N.E. [N.E.; N.E.]	0.34	[0.15; 0.74]	0.005
Others	8/74 (10.8)	N.E. [N.E.; N.E.]	34/89 (38.2)	N.E. [13.8; N.E.]	0.24	[0.11; 0.52]	<0.001
Hypersensitivity							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.392)							
Low	29/171 (17.0)	N.E. [N.E.; N.E.]	49/172 (28.5)	N.E. [N.E.; N.E.]	0.52	[0.33; 0.82]	0.005
Intermediate	16/75 (21.3)	N.E. [N.E.; N.E.]	19/73 (26.0)	N.E. [N.E.; N.E.]	0.69	[0.35; 1.34]	0.265
High	4/38 (10.5)	N.E. [N.E.; N.E.]	11/37 (29.7)	N.E. [N.E.; N.E.]	0.29	[0.09; 0.92]	0.026
Sex							
(Interaction test: p = 0.095)							
Female	20/107 (18.7)	N.E. [N.E.; N.E.]	46/124 (37.1)	N.E. [N.E.; N.E.]	0.39	[0.23; 0.66]	<0.001
Male	29/177 (16.4)	N.E. [N.E.; N.E.]	33/158 (20.9)	N.E. [N.E.; N.E.]	0.73	[0.44; 1.20]	0.207
Race							
(Interaction test: p = 0.257)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Asian	6/40 (15.0)	N.E. [N.E.; N.E.]	17/45 (37.8)	N.E. [8.3; N.E.]	0.30	[0.12; 0.76]	0.008
White	38/227 (16.7)	N.E. [N.E.; N.E.]	57/216 (26.4)	N.E. [N.E.; N.E.]	0.55	[0.37; 0.83]	0.004
Other	5/17 (29.4)	N.E. [3.2; N.E.]	5/21 (23.8)	N.E. [N.E.; N.E.]	1.47	[0.41; 5.22]	0.550
Age groups (Interaction test: p = 0.915)							
18 - < 65 years	43/237 (18.1)	N.E. [N.E.; N.E.]	71/246 (28.9)	N.E. [N.E.; N.E.]	0.54	[0.37; 0.80]	0.001
65 - < 75 years	5/38 (13.2)	N.E. [N.E.; N.E.]	6/24 (25.0)	N.E. [3.1; N.E.]	0.38	[0.12; 1.27]	0.104
>= 75 years	1/9 (11.1)	N.E. [0.5; N.E.]	2/12 (16.7)	N.E. [0.5; N.E.]	1.12	[0.07; 17.96]	0.937
Geographic region (Interaction test: p = 0.939)							
Europe excluding Germany	17/138	N.E. [N.E.; N.E.]	30/140	N.E. [N.E.; N.E.]	0.52	[0.28; 0.94]	0.027

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(12.3)		(21.4)				
Germany	14/72	N.E. [N.E.; N.E.]	15/53	N.E. [N.E.; N.E.]	0.60	[0.29; 1.26]	0.173
	(19.4)		(28.3)				
Others	18/74	N.E. [N.E.; N.E.]	34/89	N.E. [13.0; N.E.]	0.51	[0.29; 0.91]	0.021
	(24.3)		(38.2)				
Ischemic heart and CNS conditions							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.913)							
Low	4/171	N.E. [N.E.; N.E.]	7/172	N.E. [N.E.; N.E.]	0.56	[0.16; 1.91]	0.348
	(2.3)		(4.1)				
Intermediate	2/75	N.E. [N.E.; N.E.]	4/73	N.E. [N.E.; N.E.]	0.43	[0.08; 2.33]	0.311
	(2.7)		(5.5)				
High	1/38	N.E. [N.E.; N.E.]	1/37	N.E. [N.E.; N.E.]	0.94	[0.06; 15.05]	0.966
	(2.6)		(2.7)				
Sex							
(Interaction test: p = 0.992)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Female	0/107	N.E. [N.E.; N.E.]	4/124 (3.2)	N.E. [N.E.; N.E.]	0.13	[0.00; 3.35]	0.062
Male	7/177 (4.0)	N.E. [N.E.; N.E.]	8/158 (5.1)	N.E. [N.E.; N.E.]	0.74	[0.27; 2.04]	0.558
Race							
(Interaction test: p = 0.997)							
Asian	1/40 (2.5)	N.E. [20.0; N.E.]	3/45 (6.7)	N.E. [N.E.; N.E.]	0.37	[0.04; 3.72]	0.379
White	4/227 (1.8)	N.E. [N.E.; N.E.]	9/216 (4.2)	N.E. [N.E.; N.E.]	0.40	[0.12; 1.29]	0.111
Other	2/17 (11.8)	N.E. [N.E.; N.E.]	0/21	N.E. [N.E.; N.E.]	4.25	[0.10; 175.93]	0.193
Age groups							
(Interaction test: p = 0.997)							
18 - < 65 years	6/237 (2.5)	N.E. [N.E.; N.E.]	10/246 (4.1)	N.E. [N.E.; N.E.]	0.59	[0.22; 1.63]	0.307
65 - < 75 years	1/38	N.E. [N.E.; N.E.]	1/24	N.E. [N.E.; N.E.]	0.46	[0.03; 7.32]	0.570

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(2.6)		(4.2)				
>= 75 years	0/9	N.E. [N.E.; N.E.]	1/12	N.E. [N.E.; N.E.]	0.39	[0.00; 38.92]	0.371
			(8.3)				
Ischemic heart conditions							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.739)							
Low	3/171	N.E. [N.E.; N.E.]	7/172	N.E. [N.E.; N.E.]	0.42	[0.11; 1.63]	0.197
	(1.8)		(4.1)				
Intermediate	1/75	N.E. [N.E.; N.E.]	4/73	N.E. [N.E.; N.E.]	0.21	[0.02; 1.92]	0.129
	(1.3)		(5.5)				
High	1/38	N.E. [N.E.; N.E.]	1/37	N.E. [N.E.; N.E.]	0.94	[0.06; 15.05]	0.966
	(2.6)		(2.7)				
Sex							
(Interaction test: p = 0.989)							
Female	0/107	N.E. [N.E.; N.E.]	4/124	N.E. [N.E.; N.E.]	0.13	[0.00; 3.35]	0.062
			(3.2)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Male	5/177 (2.8)	N.E. [N.E.; N.E.]	8/158 (5.1)	N.E. [N.E.; N.E.]	0.53	[0.17; 1.62]	0.256
Race (Interaction test: p = 0.989)							
Asian	1/40 (2.5)	N.E. [20.0; N.E.]	3/45 (6.7)	N.E. [N.E.; N.E.]	0.37	[0.04; 3.72]	0.379
White	3/227 (1.3)	N.E. [N.E.; N.E.]	9/216 (4.2)	N.E. [N.E.; N.E.]	0.30	[0.08; 1.11]	0.055
Other	1/17 (5.9)	N.E. [N.E.; N.E.]	0/21	N.E. [N.E.; N.E.]	2.77	[0.03; 255.52]	0.337
Age groups (Interaction test: p = 1.000)							
18 - < 65 years	5/237 (2.1)	N.E. [N.E.; N.E.]	10/246 (4.1)	N.E. [N.E.; N.E.]	0.49	[0.17; 1.45]	0.189
65 - < 75 years	0/38	N.E. [N.E.; N.E.]	1/24 (4.2)	N.E. [N.E.; N.E.]	0.17	[0.00; 15.37]	0.157

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
>= 75 years	0/9	N.E. [N.E.; N.E.]	1/12 (8.3)	N.E. [N.E.; N.E.]	0.39	[0.00; 38.92]	0.371
Myelosuppression							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.930)							
Low	37/171 (21.6)	N.E. [N.E.; N.E.]	36/172 (20.9)	N.E. [N.E.; N.E.]	1.04	[0.66; 1.65]	0.860
Intermediate	18/75 (24.0)	N.E. [N.E.; N.E.]	14/73 (19.2)	N.E. [N.E.; N.E.]	1.22	[0.61; 2.46]	0.554
High	15/38 (39.5)	N.E. [3.1; N.E.]	12/37 (32.4)	N.E. [2.8; N.E.]	1.10	[0.52; 2.36]	0.789
Sex							
(Interaction test: p = 0.534)							
Female	27/107 (25.2)	N.E. [N.E.; N.E.]	24/124 (19.4)	N.E. [N.E.; N.E.]	1.23	[0.71; 2.14]	0.448
Male	43/177	N.E. [N.E.; N.E.]	38/158	N.E. [N.E.; N.E.]	1.00	[0.65; 1.55]	0.992

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(24.3)		(24.1)				
Race							
(Interaction test: p = 0.383)							
Asian	8/40	N.E. [N.E.; N.E.]	12/45	N.E. [N.E.; N.E.]	0.59	[0.24; 1.46]	0.260
	(20.0)		(26.7)				
White	53/227	N.E. [N.E.; N.E.]	41/216	N.E. [N.E.; N.E.]	1.25	[0.83; 1.88]	0.283
	(23.3)		(19.0)				
Other	9/17	8.3 [1.0; N.E.]	9/21	N.E. [1.0; N.E.]	1.45	[0.55; 3.87]	0.453
	(52.9)		(42.9)				
Age groups							
(Interaction test: p = 0.880)							
18 - < 65 years	63/237	N.E. [N.E.; N.E.]	58/246	N.E. [N.E.; N.E.]	1.09	[0.77; 1.56]	0.603
	(26.6)		(23.6)				
65 - < 75 years	5/38	N.E. [N.E.; N.E.]	4/24	N.E. [N.E.; N.E.]	0.80	[0.21; 2.99]	0.728
	(13.2)		(16.7)				
>= 75 years	2/9	N.E. [1.0; N.E.]	0/12	N.E. [N.E.; N.E.]	6.13	[0.15; 252.58]	0.118
	(22.2)						

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Geographic region							
(Interaction test: p = 0.512)							
Europe excluding Germany	21/138 (15.2)	N.E. [N.E.; N.E.]	15/140 (10.7)	N.E. [N.E.; N.E.]	1.44	[0.74; 2.80]	0.277
Germany	17/72 (23.6)	N.E. [N.E.; N.E.]	15/53 (28.3)	N.E. [N.E.; N.E.]	0.81	[0.40; 1.63]	0.575
Others	32/74 (43.2)	N.E. [3.3; N.E.]	32/89 (36.0)	N.E. [N.E.; N.E.]	1.16	[0.71; 1.90]	0.525
Myelosuppression (Erythropenia)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.677)							
Low	10/171 (5.8)	N.E. [N.E.; N.E.]	14/172 (8.1)	N.E. [N.E.; N.E.]	0.72	[0.32; 1.61]	0.413
Intermediate	7/75 (9.3)	N.E. [N.E.; N.E.]	5/73 (6.8)	N.E. [N.E.; N.E.]	1.28	[0.41; 4.05]	0.667
High	3/38	N.E. [N.E.; N.E.]	4/37	N.E. [N.E.; N.E.]	0.68	[0.15; 3.02]	0.609

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(7.9)		(10.8)				
Sex							
(Interaction test: p = 0.506)							
Female	12/107	N.E. [N.E.; N.E.]	13/124	N.E. [N.E.; N.E.]	1.05	[0.48; 2.30]	0.908
	(11.2)		(10.5)				
Male	8/177	N.E. [N.E.; N.E.]	10/158	N.E. [N.E.; N.E.]	0.67	[0.26; 1.70]	0.396
	(4.5)		(6.3)				
Race							
(Interaction test: p = 0.958)							
Asian	3/40	N.E. [N.E.; N.E.]	4/45	N.E. [N.E.; N.E.]	0.79	[0.18; 3.57]	0.779
	(7.5)		(8.9)				
White	14/227	N.E. [N.E.; N.E.]	14/216	N.E. [N.E.; N.E.]	0.94	[0.45; 1.97]	0.865
	(6.2)		(6.5)				
Other	3/17	N.E. [13.8; N.E.]	5/21	N.E. [8.3; N.E.]	0.82	[0.19; 3.57]	0.790
	(17.6)		(23.8)				
Age groups							
(Interaction test: p = 0.965)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
18 - < 65 years	18/237 (7.6)	N.E. [N.E.; N.E.]	22/246 (8.9)	N.E. [N.E.; N.E.]	0.83	[0.44; 1.54]	0.548
65 - < 75 years	2/38 (5.3)	N.E. [N.E.; N.E.]	1/24 (4.2)	N.E. [N.E.; N.E.]	1.41	[0.12; 15.84]	0.782
>= 75 years	0/9	N.E. [N.E.; N.E.]	0/12	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.
Geographic region (Interaction test: p = 0.716)							
Europe excluding Germany	8/138 (5.8)	N.E. [N.E.; N.E.]	7/140 (5.0)	N.E. [N.E.; N.E.]	1.16	[0.42; 3.20]	0.779
Germany	2/72 (2.8)	N.E. [N.E.; N.E.]	3/53 (5.7)	N.E. [N.E.; N.E.]	0.50	[0.08; 3.01]	0.437
Others	10/74 (13.5)	N.E. [N.E.; N.E.]	13/89 (14.6)	N.E. [N.E.; N.E.]	0.91	[0.39; 2.08]	0.818
Myelosuppression (Leukopenia)							
Stratification factor: ELTS based on randomization data from IRT							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.426)							
Low	18/171 (10.5)	N.E. [N.E.; N.E.]	14/172 (8.1)	N.E. [N.E.; N.E.]	1.30	[0.65; 2.62]	0.455
Intermediate	8/75 (10.7)	N.E. [N.E.; N.E.]	4/73 (5.5)	N.E. [N.E.; N.E.]	1.86	[0.56; 6.17]	0.302
High	6/38 (15.8)	N.E. [N.E.; N.E.]	8/37 (21.6)	N.E. [N.E.; N.E.]	0.67	[0.23; 1.93]	0.459
Sex							
(Interaction test: p = 0.377)							
Female	14/107 (13.1)	N.E. [N.E.; N.E.]	10/124 (8.1)	N.E. [N.E.; N.E.]	1.56	[0.69; 3.52]	0.276
Male	18/177 (10.2)	N.E. [N.E.; N.E.]	16/158 (10.1)	N.E. [N.E.; N.E.]	0.98	[0.50; 1.93]	0.957
Race							
(Interaction test: p = 0.774)							
Asian	4/40 (10.0)	N.E. [N.E.; N.E.]	5/45 (11.1)	N.E. [N.E.; N.E.]	0.82	[0.22; 3.09]	0.767

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
White	21/227 (9.3)	N.E. [N.E.; N.E.]	15/216 (6.9)	N.E. [N.E.; N.E.]	1.29	[0.67; 2.51]	0.446
Other	7/17 (41.2)	N.E. [2.8; N.E.]	6/21 (28.6)	N.E. [5.6; N.E.]	1.92	[0.62; 5.93]	0.218
Age groups (Interaction test: p = 0.511)							
18 - < 65 years	30/237 (12.7)	N.E. [N.E.; N.E.]	24/246 (9.8)	N.E. [N.E.; N.E.]	1.26	[0.74; 2.16]	0.394
65 - < 75 years	1/38 (2.6)	N.E. [N.E.; N.E.]	2/24 (8.3)	N.E. [N.E.; N.E.]	0.37	[0.03; 4.13]	0.401
>= 75 years	1/9 (11.1)	N.E. [1.5; N.E.]	0/12	N.E. [N.E.; N.E.]	3.71	[0.04; 338.14]	0.264
Geographic region (Interaction test: p = 0.384)							
Europe excluding Germany	9/138 (6.5)	N.E. [N.E.; N.E.]	5/140 (3.6)	N.E. [N.E.; N.E.]	1.84	[0.62; 5.50]	0.270
Germany	7/72	N.E. [N.E.; N.E.]	7/53	N.E. [N.E.; N.E.]	0.72	[0.25; 2.05]	0.533

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(9.7)		(13.2)				
Others	16/74	N.E. [N.E.; N.E.]	14/89	N.E. [N.E.; N.E.]	1.49	[0.72; 3.08]	0.273
	(21.6)		(15.7)				
Myelosuppression (Thrombocytopenia)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.580)							
Low	24/171	N.E. [N.E.; N.E.]	24/172	N.E. [N.E.; N.E.]	1.02	[0.58; 1.79]	0.949
	(14.0)		(14.0)				
Intermediate	14/75	N.E. [N.E.; N.E.]	9/73	N.E. [N.E.; N.E.]	1.52	[0.66; 3.51]	0.318
	(18.7)		(12.3)				
High	15/38	N.E. [3.8; N.E.]	9/37	N.E. [N.E.; N.E.]	1.63	[0.71; 3.72]	0.243
	(39.5)		(24.3)				
Sex							
(Interaction test: p = 0.609)							
Female	18/107	N.E. [N.E.; N.E.]	14/124	N.E. [N.E.; N.E.]	1.38	[0.69; 2.78]	0.364
	(16.8)		(11.3)				

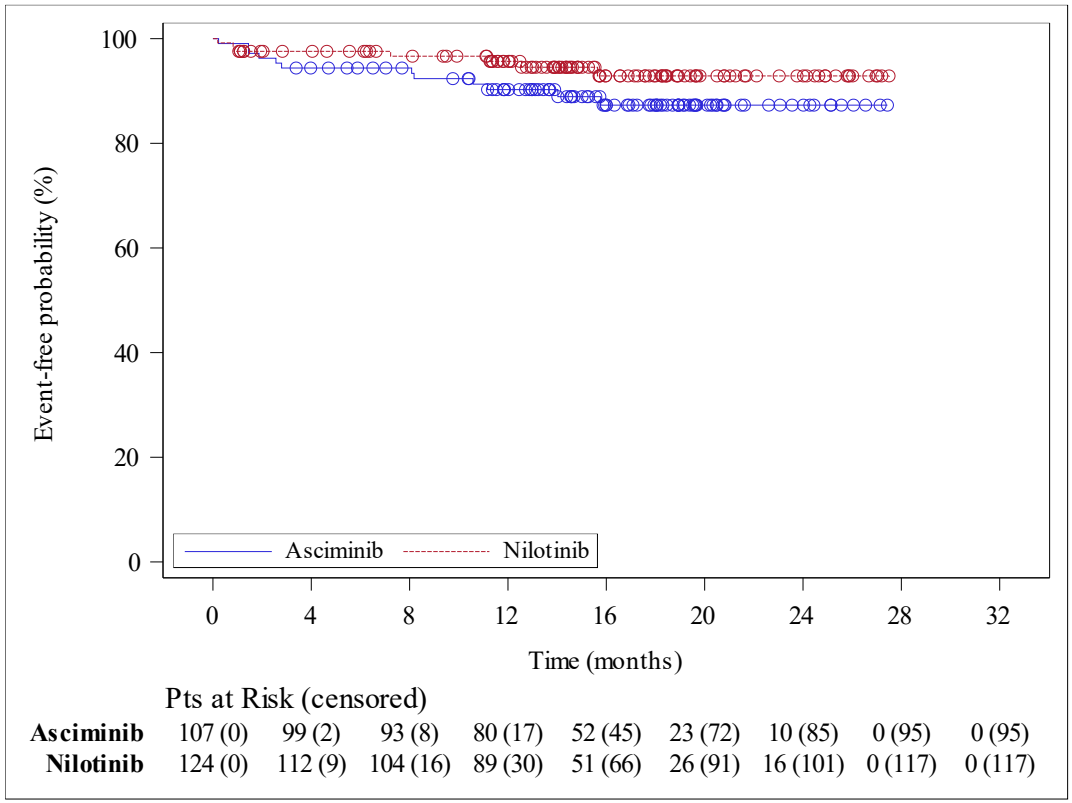
	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Male	35/177 (19.8)	N.E. [N.E.; N.E.]	28/158 (17.7)	N.E. [N.E.; N.E.]	1.14	[0.69; 1.87]	0.598
Race (Interaction test: p = 0.899)							
Asian	8/40 (20.0)	N.E. [N.E.; N.E.]	8/45 (17.8)	N.E. [N.E.; N.E.]	0.98	[0.37; 2.63]	0.974
White	40/227 (17.6)	N.E. [N.E.; N.E.]	29/216 (13.4)	N.E. [N.E.; N.E.]	1.34	[0.83; 2.16]	0.230
Other	5/17 (29.4)	N.E. [1.1; N.E.]	5/21 (23.8)	N.E. [N.E.; N.E.]	2.00	[0.51; 7.79]	0.311
Age groups (Interaction test: p = 0.760)							
18 - < 65 years	48/237 (20.3)	N.E. [N.E.; N.E.]	39/246 (15.9)	N.E. [N.E.; N.E.]	1.26	[0.83; 1.93]	0.272
65 - < 75 years	3/38 (7.9)	N.E. [N.E.; N.E.]	3/24 (12.5)	N.E. [N.E.; N.E.]	0.75	[0.15; 3.77]	0.731
>= 75 years	2/9	N.E. [1.0; N.E.]	0/12	N.E. [N.E.; N.E.]	6.13	[0.15; 252.58]	0.118

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(22.2)						
Geographic region							
(Interaction test: p = 0.534)							
Europe excluding Germany	15/138	N.E. [N.E.; N.E.]	8/140	N.E. [N.E.; N.E.]	1.84	[0.78; 4.36]	0.160
	(10.9)		(5.7)				
Germany	15/72	N.E. [N.E.; N.E.]	12/53	N.E. [N.E.; N.E.]	0.91	[0.42; 1.96]	0.830
	(20.8)		(22.6)				
Others	23/74	N.E. [N.E.; N.E.]	22/89	N.E. [N.E.; N.E.]	1.28	[0.71; 2.30]	0.406
	(31.1)		(24.7)				

N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
If there are not at least 10 patients in every subgroup or not at least 10 events in at least one subgroup, no subgroup analyses were performed for the corresponding attribute.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variable ELTS Score (IRT) and covariate treatment arm.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variable ELTS Score (IRT).
For the subgroups of Stratification factor: ELTS based on IRT randomisation data no stratification variable was used.
The reference group in the stratified Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
Data Cut/15MAY2025

Figure 4-2.11 Time to first grade 1/2 AESI: Time to event analysis by subgroups: Kaplan-Meier plot by subgroups (Safety Analysis Set)

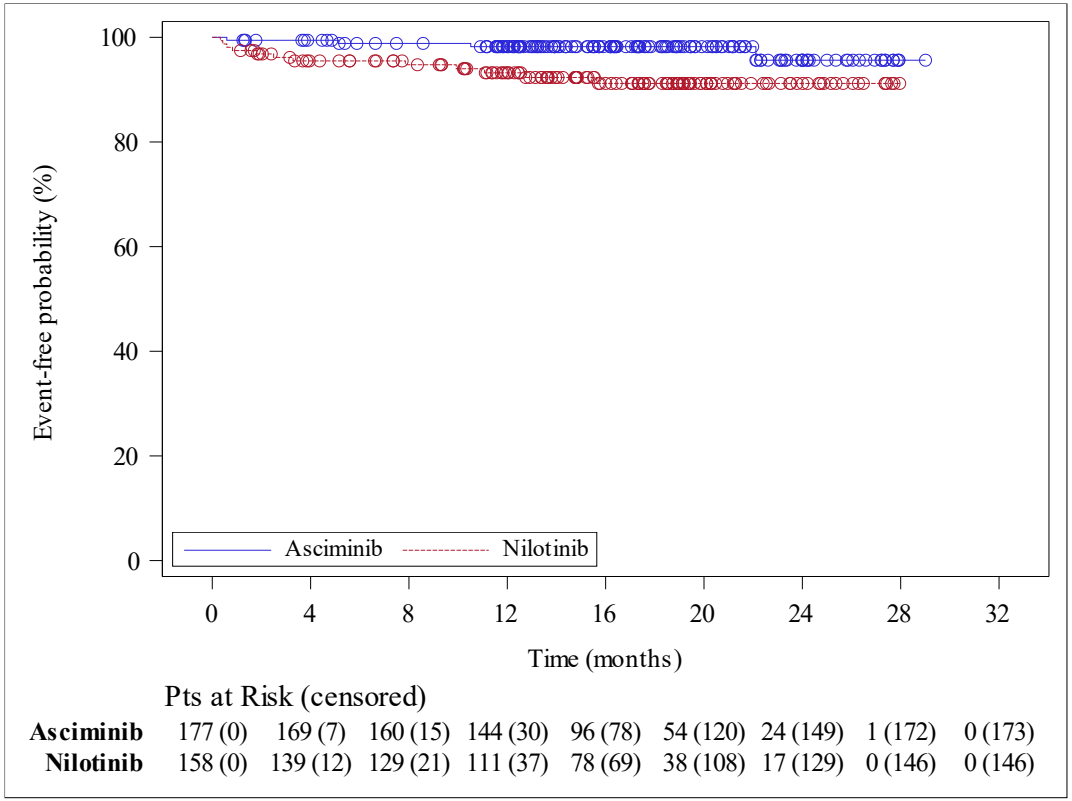
Hemorrhage: Sex: Female



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
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Figure 4-2.11 Time to first grade 1/2 AESI: Time to event analysis by subgroups: Kaplan-Meier plot by subgroups (Safety Analysis Set)

Hemorrhage: Sex: Male



Note: o = Censored observations
Kaplan-Meier curves are only presented for subgroup analyses with a statistically significant interaction term ($p < 0.05$).
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Table 4-2.12 Time to first grade >=3 AESI: Time to event analysis by subgroups (Safety Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Acute pancreatitis (including isolated pancreatic enzyme elevations)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.375)							
Low	2/171 (1.2)	N.E. [N.E.; N.E.]	8/172 (4.7)	N.E. [N.E.; N.E.]	0.24	[0.05; 1.14]	0.051
Intermediate	0/75	N.E. [N.E.; N.E.]	5/73 (6.8)	N.E. [N.E.; N.E.]	0.09	[0.00; 2.04]	0.021
High	2/38 (5.3)	N.E. [N.E.; N.E.]	1/37 (2.7)	N.E. [N.E.; N.E.]	1.84	[0.17; 20.27]	0.614
Sex							
(Interaction test: p = 0.989)							
Female	0/107	N.E. [N.E.; N.E.]	8/124 (6.5)	N.E. [N.E.; N.E.]	0.06	[0.00; 1.33]	0.007
Male	4/177	N.E. [N.E.; N.E.]	6/158	N.E. [N.E.; N.E.]	0.56	[0.16; 1.99]	0.366

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(2.3)		(3.8)				
Race							
(Interaction test: p = 0.131)							
Asian	2/40	N.E. [N.E.; N.E.]	2/45	N.E. [N.E.; N.E.]	1.15	[0.16; 8.26]	0.889
	(5.0)		(4.4)				
White	1/227	N.E. [N.E.; N.E.]	11/216	N.E. [N.E.; N.E.]	0.08	[0.01; 0.65]	0.002
	(0.4)		(5.1)				
Other	1/17	N.E. [N.E.; N.E.]	1/21	N.E. [N.E.; N.E.]	2.24	[0.14; 35.90]	0.560
	(5.9)		(4.8)				
Age groups							
(Interaction test: p = 1.000)							
18 - < 65 years	4/237	N.E. [N.E.; N.E.]	11/246	N.E. [N.E.; N.E.]	0.36	[0.11; 1.13]	0.067
	(1.7)		(4.5)				
65 - < 75 years	0/38	N.E. [N.E.; N.E.]	2/24	N.E. [N.E.; N.E.]	0.11	[0.00; 4.45]	0.054
			(8.3)				
>= 75 years	0/9	N.E. [N.E.; N.E.]	1/12	N.E. [N.E.; N.E.]	0.39	[0.00; 37.18]	0.361
			(8.3)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Hepatotoxicity (including laboratory terms)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.666)							
Low	7/171 (4.1)	N.E. [N.E.; N.E.]	16/172 (9.3)	N.E. [N.E.; N.E.]	0.42	[0.17; 1.03]	0.050
Intermediate	0/75	N.E. [N.E.; N.E.]	7/73 (9.6)	N.E. [N.E.; N.E.]	0.06	[0.00; 1.24]	0.005
High	1/38 (2.6)	N.E. [N.E.; N.E.]	6/37 (16.2)	N.E. [N.E.; N.E.]	0.14	[0.02; 1.20]	0.037
Sex							
(Interaction test: p = 0.666)							
Female	5/107 (4.7)	N.E. [N.E.; N.E.]	17/124 (13.7)	N.E. [N.E.; N.E.]	0.30	[0.11; 0.81]	0.012
Male	3/177 (1.7)	N.E. [N.E.; N.E.]	12/158 (7.6)	N.E. [N.E.; N.E.]	0.22	[0.06; 0.77]	0.009
Race							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.851)							
Asian	2/40 (5.0)	N.E. [N.E.; N.E.]	5/45 (11.1)	N.E. [N.E.; N.E.]	0.46	[0.09; 2.40]	0.345
White	6/227 (2.6)	N.E. [N.E.; N.E.]	20/216 (9.3)	N.E. [N.E.; N.E.]	0.27	[0.11; 0.66]	0.002
Other	0/17	N.E. [N.E.; N.E.]	4/21 (19.0)	N.E. [N.E.; N.E.]	0.15	[0.01; 4.41]	0.096
Age groups							
(Interaction test: p = 0.754)							
18 - < 65 years	7/237 (3.0)	N.E. [N.E.; N.E.]	22/246 (8.9)	N.E. [N.E.; N.E.]	0.32	[0.14; 0.74]	0.005
65 - < 75 years	1/38 (2.6)	N.E. [N.E.; N.E.]	4/24 (16.7)	N.E. [8.3; N.E.]	0.11	[0.01; 0.97]	0.019
>= 75 years	0/9	N.E. [N.E.; N.E.]	3/12 (25.0)	N.E. [2.8; N.E.]	0.18	[0.01; 5.51]	0.123
Geographic region							
(Interaction test: p = 0.268)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Europe excluding Germany	4/138 (2.9)	N.E. [N.E.; N.E.]	13/140 (9.3)	N.E. [N.E.; N.E.]	0.30	[0.10; 0.93]	0.027
Germany	1/72 (1.4)	N.E. [N.E.; N.E.]	9/53 (17.0)	N.E. [N.E.; N.E.]	0.08	[0.01; 0.63]	0.002
Others	3/74 (4.1)	N.E. [N.E.; N.E.]	7/89 (7.9)	N.E. [N.E.; N.E.]	0.58	[0.15; 2.28]	0.434
Myelosuppression							
Stratification factor: ELTS based on randomization data from IRT (Interaction test: p = 0.969)							
Low	20/171 (11.7)	N.E. [N.E.; N.E.]	18/172 (10.5)	N.E. [N.E.; N.E.]	1.12	[0.59; 2.11]	0.725
Intermediate	9/75 (12.0)	N.E. [N.E.; N.E.]	7/73 (9.6)	N.E. [N.E.; N.E.]	1.24	[0.46; 3.32]	0.673
High	12/38 (31.6)	N.E. [N.E.; N.E.]	9/37 (24.3)	N.E. [N.E.; N.E.]	1.26	[0.53; 3.00]	0.599
Sex							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.614)							
Female	14/107 (13.1)	N.E. [N.E.; N.E.]	11/124 (8.9)	N.E. [N.E.; N.E.]	1.35	[0.61; 2.98]	0.458
Male	27/177 (15.3)	N.E. [N.E.; N.E.]	23/158 (14.6)	N.E. [N.E.; N.E.]	1.06	[0.61; 1.85]	0.827
Race							
(Interaction test: p = 0.693)							
Asian	6/40 (15.0)	N.E. [N.E.; N.E.]	8/45 (17.8)	N.E. [N.E.; N.E.]	0.77	[0.26; 2.22]	0.620
White	29/227 (12.8)	N.E. [N.E.; N.E.]	20/216 (9.3)	N.E. [N.E.; N.E.]	1.36	[0.77; 2.40]	0.291
Other	6/17 (35.3)	N.E. [2.8; N.E.]	6/21 (28.6)	N.E. [8.3; N.E.]	1.79	[0.53; 6.02]	0.333
Age groups							
(Interaction test: p = 0.286)							
18 - < 65 years	40/237 (16.9)	N.E. [N.E.; N.E.]	31/246 (12.6)	N.E. [N.E.; N.E.]	1.33	[0.83; 2.12]	0.234

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
65 - < 75 years	1/38 (2.6)	N.E. [N.E.; N.E.]	3/24 (12.5)	N.E. [N.E.; N.E.]	0.25	[0.03; 2.47]	0.195
>= 75 years	0/9	N.E. [N.E.; N.E.]	0/12	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.
Geographic region (Interaction test: p = 0.216)							
Europe excluding Germany	19/138 (13.8)	N.E. [N.E.; N.E.]	9/140 (6.4)	N.E. [N.E.; N.E.]	2.15	[0.97; 4.76]	0.054
Germany	6/72 (8.3)	N.E. [N.E.; N.E.]	5/53 (9.4)	N.E. [N.E.; N.E.]	0.88	[0.27; 2.90]	0.832
Others	16/74 (21.6)	N.E. [N.E.; N.E.]	20/89 (22.5)	N.E. [N.E.; N.E.]	0.95	[0.49; 1.83]	0.895
Myelosuppression (Erythropenia)							
Sex (Interaction test: p = 0.074)							
Female	9/107	N.E. [N.E.; N.E.]	1/124	N.E. [N.E.; N.E.]	9.35	[1.18; 74.02]	0.010

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(8.4)		(0.8)				
Male	3/177	N.E. [N.E.; N.E.]	3/158	N.E. [N.E.; N.E.]	0.86	[0.17; 4.26]	0.852
	(1.7)		(1.9)				
Age groups							
(Interaction test: p = 1.000)							
18 - < 65 years	11/237	N.E. [N.E.; N.E.]	4/246	N.E. [N.E.; N.E.]	2.74	[0.87; 8.60]	0.072
	(4.6)		(1.6)				
65 - < 75 years	1/38	N.E. [N.E.; N.E.]	0/24	N.E. [N.E.; N.E.]	2.60	[0.03; 250.43]	0.361
	(2.6)						
>= 75 years	0/9	N.E. [N.E.; N.E.]	0/12	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.
Myelosuppression (Leukopenia)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.374)							
Low	10/171	N.E. [N.E.; N.E.]	13/172	N.E. [N.E.; N.E.]	0.76	[0.33; 1.73]	0.521
	(5.8)		(7.6)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Intermediate	4/75 (5.3)	N.E. [N.E.; N.E.]	2/73 (2.7)	N.E. [N.E.; N.E.]	1.87	[0.34; 10.19]	0.463
High	9/38 (23.7)	N.E. [N.E.; N.E.]	5/37 (13.5)	N.E. [N.E.; N.E.]	1.83	[0.61; 5.46]	0.275
Sex							
(Interaction test: p = 0.930)							
Female	8/107 (7.5)	N.E. [N.E.; N.E.]	8/124 (6.5)	N.E. [N.E.; N.E.]	1.05	[0.39; 2.79]	0.946
Male	15/177 (8.5)	N.E. [N.E.; N.E.]	12/158 (7.6)	N.E. [N.E.; N.E.]	1.13	[0.53; 2.42]	0.740
Race							
(Interaction test: p = 0.788)							
Asian	4/40 (10.0)	N.E. [N.E.; N.E.]	4/45 (8.9)	N.E. [N.E.; N.E.]	1.15	[0.28; 4.62]	0.848
White	16/227 (7.0)	N.E. [N.E.; N.E.]	11/216 (5.1)	N.E. [N.E.; N.E.]	1.36	[0.63; 2.93]	0.432
Other	3/17	N.E. [N.E.; N.E.]	5/21	N.E. [8.3; N.E.]	0.92	[0.21; 3.99]	0.927

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
	(17.6)		(23.8)				
Age groups							
(Interaction test: p = 0.317)							
18 - < 65 years	22/237	N.E. [N.E.; N.E.]	17/246	N.E. [N.E.; N.E.]	1.33	[0.71; 2.50]	0.372
	(9.3)		(6.9)				
65 - < 75 years	1/38	N.E. [N.E.; N.E.]	3/24	N.E. [N.E.; N.E.]	0.29	[0.03; 2.75]	0.238
	(2.6)		(12.5)				
>= 75 years	0/9	N.E. [N.E.; N.E.]	0/12	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.
Geographic region							
(Interaction test: p = 0.372)							
Europe excluding Germany	11/138	N.E. [N.E.; N.E.]	5/140	N.E. [N.E.; N.E.]	2.14	[0.74; 6.18]	0.150
	(8.0)		(3.6)				
Germany	3/72	N.E. [N.E.; N.E.]	2/53	N.E. [N.E.; N.E.]	1.01	[0.17; 6.13]	0.987
	(4.2)		(3.8)				
Others	9/74	N.E. [N.E.; N.E.]	13/89	N.E. [N.E.; N.E.]	0.84	[0.36; 1.97]	0.704
	(12.2)		(14.6)				

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Myelosuppression (Thrombocytopenia)							
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.814)							
Low	10/171 (5.8)	N.E. [N.E.; N.E.]	8/172 (4.7)	N.E. [N.E.; N.E.]	1.25	[0.50; 3.18]	0.634
Intermediate	7/75 (9.3)	N.E. [N.E.; N.E.]	6/73 (8.2)	N.E. [N.E.; N.E.]	1.10	[0.37; 3.26]	0.867
High	12/38 (31.6)	N.E. [N.E.; N.E.]	7/37 (18.9)	N.E. [N.E.; N.E.]	1.72	[0.68; 4.38]	0.249
Sex							
(Interaction test: p = 0.351)							
Female	11/107 (10.3)	N.E. [N.E.; N.E.]	6/124 (4.8)	N.E. [N.E.; N.E.]	2.00	[0.74; 5.42]	0.170
Male	18/177 (10.2)	N.E. [N.E.; N.E.]	15/158 (9.5)	N.E. [N.E.; N.E.]	1.10	[0.56; 2.19]	0.783
Race							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.993)							
Asian	5/40 (12.5)	N.E. [N.E.; N.E.]	4/45 (8.9)	N.E. [N.E.; N.E.]	1.27	[0.34; 4.79]	0.721
White	20/227 (8.8)	N.E. [N.E.; N.E.]	13/216 (6.0)	N.E. [N.E.; N.E.]	1.41	[0.70; 2.85]	0.332
Other	4/17 (23.5)	N.E. [5.6; N.E.]	4/21 (19.0)	N.E. [N.E.; N.E.]	3.60	[0.64; 20.24]	0.122
Age groups							
(Interaction test: p = 0.493)							
18 - < 65 years	28/237 (11.8)	N.E. [N.E.; N.E.]	19/246 (7.7)	N.E. [N.E.; N.E.]	1.51	[0.84; 2.70]	0.165
65 - < 75 years	1/38 (2.6)	N.E. [N.E.; N.E.]	2/24 (8.3)	N.E. [N.E.; N.E.]	0.40	[0.04; 4.48]	0.445
>= 75 years	0/9	N.E. [N.E.; N.E.]	0/12	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.
Geographic region							
(Interaction test: p = 0.546)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Europe excluding Germany	13/138 (9.4)	N.E. [N.E.; N.E.]	6/140 (4.3)	N.E. [N.E.; N.E.]	2.11	[0.80; 5.56]	0.124
Germany	5/72 (6.9)	N.E. [N.E.; N.E.]	4/53 (7.5)	N.E. [N.E.; N.E.]	0.95	[0.25; 3.57]	0.940
Others	11/74 (14.9)	N.E. [N.E.; N.E.]	11/89 (12.4)	N.E. [N.E.; N.E.]	1.25	[0.54; 2.90]	0.589

N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
If there are not at least 10 patients in every subgroup or not at least 10 events in at least one subgroup, no subgroup analyses were performed for the corresponding attribute.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variable ELTS Score (IRT) and covariate treatment arm.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variable ELTS Score (IRT).
For the subgroups of Stratification factor: ELTS based on IRT randomisation data no stratification variable was used.
The reference group in the stratified Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
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Table 4-2.13 Time to first serious AESI: Time to event analysis by subgroups (Safety Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Myelosuppression							
Age groups							
(Interaction test: p = 1.000)							
18 - < 65 years	5/237 (2.1)	N.E. [N.E.; N.E.]	5/246 (2.0)	N.E. [N.E.; N.E.]	0.96	[0.28; 3.31]	0.947
65 - < 75 years	0/38	N.E. [N.E.; N.E.]	0/24	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.
>= 75 years	0/9	N.E. [N.E.; N.E.]	0/12	N.E. [N.E.; N.E.]	N.E.	[N.E.; N.E.]	N.E.

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			

N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
.....
If there are not at least 10 patients in every subgroup or not at least 10 events in at least one subgroup, no subgroup analyses were performed for the corresponding attribute.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variable ELTS Score (IRT) and covariate treatment arm.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variable ELTS Score (IRT).
For the subgroups of Stratification factor: ELTS based on IRT randomisation data no stratification variable was used.
The reference group in the stratified Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
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Table 4-2.14 Time to first AE leading to discontinuation of treatment: Time to event analysis by subgroups (Safety Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.408)							
Low	15/171 (8.8)	N.E. [N.E.; N.E.]	22/172 (12.8)	N.E. [N.E.; N.E.]	0.66	[0.34; 1.26]	0.205
Intermediate	5/75 (6.7)	N.E. [N.E.; N.E.]	14/73 (19.2)	N.E. [26.4; N.E.]	0.31	[0.11; 0.86]	0.017
High	3/38 (7.9)	N.E. [N.E.; N.E.]	8/37 (21.6)	N.E. [N.E.; N.E.]	0.34	[0.09; 1.27]	0.093
Sex							
(Interaction test: p = 0.151)							
Female	6/107 (5.6)	N.E. [N.E.; N.E.]	22/124 (17.7)	N.E. [N.E.; N.E.]	0.29	[0.12; 0.71]	0.004
Male	17/177 (9.6)	N.E. [N.E.; N.E.]	22/158 (13.9)	N.E. [26.4; N.E.]	0.65	[0.34; 1.22]	0.177
Race							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.461)							
Asian	2/40 (5.0)	N.E. [N.E.; N.E.]	5/45 (11.1)	N.E. [N.E.; N.E.]	0.44	[0.09; 2.31]	0.323
White	18/227 (7.9)	N.E. [N.E.; N.E.]	36/216 (16.7)	N.E. [N.E.; N.E.]	0.44	[0.25; 0.77]	0.003
Other	3/17 (17.6)	N.E. [12.6; N.E.]	3/21 (14.3)	N.E. [N.E.; N.E.]	1.44	[0.27; 7.59]	0.664
Age groups							
(Interaction test: p = 0.895)							
18 - < 65 years	17/237 (7.2)	N.E. [N.E.; N.E.]	33/246 (13.4)	N.E. [N.E.; N.E.]	0.51	[0.28; 0.91]	0.021
65 - < 75 years	5/38 (13.2)	N.E. [N.E.; N.E.]	7/24 (29.2)	26.4 [N.E.; N.E.]	0.43	[0.13; 1.44]	0.161
>= 75 years	1/9 (11.1)	N.E. [2.4; N.E.]	4/12 (33.3)	N.E. [7.3; N.E.]	0.33	[0.04; 2.97]	0.299
Geographic region							
(Interaction test: p = 0.312)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Europe excluding Germany	9/138 (6.5)	N.E. [N.E.; N.E.]	23/140 (16.4)	N.E. [N.E.; N.E.]	0.37	[0.17; 0.80]	0.008
Germany	6/72 (8.3)	N.E. [N.E.; N.E.]	10/53 (18.9)	N.E. [26.4; N.E.]	0.41	[0.15; 1.14]	0.077
Others	8/74 (10.8)	N.E. [N.E.; N.E.]	11/89 (12.4)	N.E. [N.E.; N.E.]	0.91	[0.36; 2.29]	0.847

N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
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If there are not at least 10 patients in every subgroup or not at least 10 events in at least one subgroup, no subgroup analyses were performed for the corresponding attribute.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variable ELTS Score (IRT) and covariate treatment arm.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variable ELTS Score (IRT).
For the subgroups of Stratification factor: ELTS based on IRT randomisation data no stratification variable was used.
The reference group in the stratified Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
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Table 4-2.15 Time to first severe AE leading to discontinuation of treatment: Time to event analysis by subgroups (Safety Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.279)							
Low	11/171 (6.4)	N.E. [N.E.; N.E.]	12/172 (7.0)	N.E. [N.E.; N.E.]	0.89	[0.39; 2.02]	0.784
Intermediate	4/75 (5.3)	N.E. [N.E.; N.E.]	12/73 (16.4)	N.E. [26.4; N.E.]	0.29	[0.09; 0.90]	0.022
High	3/38 (7.9)	N.E. [N.E.; N.E.]	6/37 (16.2)	N.E. [N.E.; N.E.]	0.46	[0.12; 1.85]	0.263
Sex							
(Interaction test: p = 0.178)							
Female	6/107 (5.6)	N.E. [N.E.; N.E.]	18/124 (14.5)	N.E. [N.E.; N.E.]	0.35	[0.14; 0.89]	0.020
Male	12/177 (6.8)	N.E. [N.E.; N.E.]	12/158 (7.6)	N.E. [26.4; N.E.]	0.84	[0.37; 1.86]	0.660
Race							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.535)							
Asian	1/40 (2.5)	N.E. [N.E.; N.E.]	4/45 (8.9)	N.E. [N.E.; N.E.]	0.27	[0.03; 2.46]	0.215
White	15/227 (6.6)	N.E. [N.E.; N.E.]	24/216 (11.1)	N.E. [N.E.; N.E.]	0.55	[0.29; 1.05]	0.064
Other	2/17 (11.8)	N.E. [N.E.; N.E.]	2/21 (9.5)	N.E. [N.E.; N.E.]	1.47	[0.19; 11.16]	0.709
Age groups							
(Interaction test: p = 0.762)							
18 - < 65 years	14/237 (5.9)	N.E. [N.E.; N.E.]	22/246 (8.9)	N.E. [N.E.; N.E.]	0.63	[0.32; 1.24]	0.177
65 - < 75 years	3/38 (7.9)	N.E. [N.E.; N.E.]	5/24 (20.8)	26.4 [N.E.; N.E.]	0.42	[0.09; 1.90]	0.244
>= 75 years	1/9 (11.1)	N.E. [2.4; N.E.]	3/12 (25.0)	N.E. [7.3; N.E.]	0.44	[0.05; 4.26]	0.467
Geographic region							
(Interaction test: p = 0.531)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Europe excluding Germany	8/138 (5.8)	N.E. [N.E.; N.E.]	17/140 (12.1)	N.E. [N.E.; N.E.]	0.45	[0.19; 1.05]	0.057
Germany	4/72 (5.6)	N.E. [N.E.; N.E.]	5/53 (9.4)	N.E. [26.4; N.E.]	0.59	[0.16; 2.28]	0.443
Others	6/74 (8.1)	N.E. [N.E.; N.E.]	8/89 (9.0)	N.E. [N.E.; N.E.]	0.97	[0.33; 2.84]	0.956

N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
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If there are not at least 10 patients in every subgroup or not at least 10 events in at least one subgroup, no subgroup analyses were performed for the corresponding attribute.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variable ELTS Score (IRT) and covariate treatment arm.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variable ELTS Score (IRT).
For the subgroups of Stratification factor: ELTS based on IRT randomisation data no stratification variable was used.
The reference group in the stratified Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
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Table 4-2.16 Time to first SAE leading to discontinuation of treatment: Time to event analysis by subgroups (Safety Analysis Set)

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Stratification factor: ELTS based on randomization data from IRT							
(Interaction test: p = 0.350)							
Low	10/171 (5.8)	N.E. [N.E.; N.E.]	10/172 (5.8)	N.E. [N.E.; N.E.]	0.97	[0.40; 2.33]	0.949
Intermediate	1/75 (1.3)	N.E. [N.E.; N.E.]	4/73 (5.5)	N.E. [N.E.; N.E.]	0.22	[0.02; 1.97]	0.138
High	1/38 (2.6)	N.E. [N.E.; N.E.]	3/37 (8.1)	N.E. [N.E.; N.E.]	0.32	[0.03; 3.05]	0.294
Sex							
(Interaction test: p = 0.350)							
Female	3/107 (2.8)	N.E. [N.E.; N.E.]	8/124 (6.5)	N.E. [N.E.; N.E.]	0.40	[0.11; 1.52]	0.165
Male	9/177 (5.1)	N.E. [N.E.; N.E.]	9/158 (5.7)	N.E. [N.E.; N.E.]	0.87	[0.34; 2.18]	0.760
Race							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
(Interaction test: p = 0.647)							
Asian	0/40	N.E. [N.E.; N.E.]	3/45 (6.7)	N.E. [N.E.; N.E.]	0.14	[0.00; 4.54]	0.088
White	10/227 (4.4)	N.E. [N.E.; N.E.]	13/216 (6.0)	N.E. [N.E.; N.E.]	0.69	[0.30; 1.58]	0.382
Other	2/17 (11.8)	N.E. [N.E.; N.E.]	1/21 (4.8)	N.E. [N.E.; N.E.]	1.70	[0.15; 18.72]	0.663
Age groups							
(Interaction test: p = 0.826)							
18 - < 65 years	9/237 (3.8)	N.E. [N.E.; N.E.]	16/246 (6.5)	N.E. [N.E.; N.E.]	0.57	[0.25; 1.28]	0.165
65 - < 75 years	2/38 (5.3)	N.E. [N.E.; N.E.]	0/24	N.E. [N.E.; N.E.]	2.16	[0.05; 90.36]	0.353
>= 75 years	1/9 (11.1)	N.E. [2.4; N.E.]	1/12 (8.3)	N.E. [N.E.; N.E.]	1.22	[0.08; 19.58]	0.886
Geographic region							
(Interaction test: p = 0.704)							

	Treatment groups				Comparison		
	Asciminib (N=284)		Nilotinib (N=282)		HR	[95% CI]	p-value
	n/N* (%)	Median (months) [95% CI]	n/N* (%)	Median (months) [95% CI]			
Europe excluding Germany	5/138 (3.6)	N.E. [N.E.; N.E.]	10/140 (7.1)	N.E. [N.E.; N.E.]	0.50	[0.17; 1.48]	0.203
Germany	4/72 (5.6)	N.E. [N.E.; N.E.]	3/53 (5.7)	N.E. [N.E.; N.E.]	0.88	[0.19; 4.01]	0.866
Others	3/74 (4.1)	N.E. [N.E.; N.E.]	4/89 (4.5)	N.E. [N.E.; N.E.]	0.98	[0.22; 4.41]	0.975

N*: Number of patients included in the analysis
n: number of patients with event
N.E.: Not estimable
CI: Confidence Interval
HR: Hazard Ratio
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If there are not at least 10 patients in every subgroup or not at least 10 events in at least one subgroup, no subgroup analyses were performed for the corresponding attribute.
Two-sided 95% CI for KM percentiles are computed by the Brookmeyer and Crowley method (log log transformation).
The HR and 95% CI values are from a stratified Cox proportional hazard model with stratification variable ELTS Score (IRT) and covariate treatment arm.
The model for the interaction p-values includes additionally subgroup and treatment arm*subgroup as covariates.
P-Values are from a stratified logrank test with stratification variable ELTS Score (IRT).
For the subgroups of Stratification factor: ELTS based on IRT randomisation data no stratification variable was used.
The reference group in the stratified Cox proportional hazard model is Nilotinib.
Firth correction is used in the proportional hazard model if indicated by extreme values of the hazard ratio in case of few/zero events.
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Table 4-3.1: Discontinuation of treatment due to AE by SOC and PT (Safety Analysis Set)

System Organ Class Preferred Term	Asciminib (N = 284) n(%)	Nilotinib (N = 282) n(%)	Total (N = 566) n(%)
Patients with any AE leading to discontinuation of treatment	23 (8.1)	44 (15.6)	67 (11.8)
Blood and lymphatic system disorders	5 (1.8)	2 (0.7)	7 (1.2)
Febrile neutropenia	1 (0.4)	0	1 (0.2)
Neutropenia	1 (0.4)	0	1 (0.2)
Thrombocytopenia	5 (1.8)	2 (0.7)	7 (1.2)
Cardiac disorders	2 (0.7)	7 (2.5)	9 (1.6)
Angina unstable	1 (0.4)	0	1 (0.2)
Arteriospasm coronary	0	1 (0.4)	1 (0.2)
Atrial fibrillation	0	2 (0.7)	2 (0.4)
Cardiac arrest	1 (0.4)	1 (0.4)	2 (0.4)
Coronary artery disease	1 (0.4)	1 (0.4)	2 (0.4)
Myocarditis	0	1 (0.4)	1 (0.2)
Prinzmetal angina	0	1 (0.4)	1 (0.2)
Congenital, familial and genetic disorders	0	1 (0.4)	1 (0.2)
Gilbert's syndrome	0	1 (0.4)	1 (0.2)
Eye disorders	1 (0.4)	0	1 (0.2)

System Organ Class Preferred Term	Asciminib (N = 284) n(%)	Nilotinib (N = 282) n(%)	Total (N = 566) n(%)
Optic ischaemic neuropathy	1 (0.4)	0	1 (0.2)
Gastrointestinal disorders	1 (0.4)	6 (2.1)	7 (1.2)
Diarrhoea	0	1 (0.4)	1 (0.2)
Nausea	0	1 (0.4)	1 (0.2)
Pancreatitis	1 (0.4)	1 (0.4)	2 (0.4)
Pancreatitis acute	0	3 (1.1)	3 (0.5)
General disorders and administration site conditions	0	2 (0.7)	2 (0.4)
Asthenia	0	2 (0.7)	2 (0.4)
Hepatobiliary disorders	2 (0.7)	4 (1.4)	6 (1.1)
Drug-induced liver injury	0	3 (1.1)	3 (0.5)
Hepatobiliary disease	1 (0.4)	0	1 (0.2)
Hyperbilirubinaemia	0	1 (0.4)	1 (0.2)
Suspected drug-induced liver injury	1 (0.4)	0	1 (0.2)
Investigations	3 (1.1)	18 (6.4)	21 (3.7)
Alanine aminotransferase increased	1 (0.4)	3 (1.1)	4 (0.7)
Amylase increased	0	3 (1.1)	3 (0.5)
Aspartate aminotransferase increased	1 (0.4)	1 (0.4)	2 (0.4)
Blood bilirubin increased	0	3 (1.1)	3 (0.5)

System Organ Class Preferred Term	Asciminib (N = 284) n(%)	Nilotinib (N = 282) n(%)	Total (N = 566) n(%)
Blood creatine phosphokinase increased	0	1 (0.4)	1 (0.2)
Blood creatinine increased	0	1 (0.4)	1 (0.2)
Ejection fraction decreased	0	1 (0.4)	1 (0.2)
Lipase increased	2 (0.7)	6 (2.1)	8 (1.4)
Neutrophil count decreased	0	1 (0.4)	1 (0.2)
Metabolism and nutrition disorders	0	2 (0.7)	2 (0.4)
Decreased appetite	0	1 (0.4)	1 (0.2)
Hypercholesterolaemia	0	1 (0.4)	1 (0.2)
Musculoskeletal and connective tissue disorders	2 (0.7)	2 (0.7)	4 (0.7)
Muscle spasms	0	1 (0.4)	1 (0.2)
Musculoskeletal pain	1 (0.4)	0	1 (0.2)
Tendonitis	1 (0.4)	1 (0.4)	2 (0.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.4)	0	1 (0.2)
Blast cell crisis	1 (0.4)	0	1 (0.2)
Nervous system disorders	2 (0.7)	1 (0.4)	3 (0.5)
Central nervous system inflammation	0	1 (0.4)	1 (0.2)
Cerebrovascular accident	1 (0.4)	0	1 (0.2)
Transient ischaemic attack	1 (0.4)	0	1 (0.2)

System Organ Class Preferred Term	Asciminib (N = 284) n(%)	Nilotinib (N = 282) n(%)	Total (N = 566) n(%)
Psychiatric disorders	1 (0.4)	0	1 (0.2)
Completed suicide	1 (0.4)	0	1 (0.2)
Respiratory, thoracic and mediastinal disorders	0	1 (0.4)	1 (0.2)
Cough	0	1 (0.4)	1 (0.2)
Skin and subcutaneous tissue disorders	1 (0.4)	1 (0.4)	2 (0.4)
Rash	1 (0.4)	1 (0.4)	2 (0.4)
Vascular disorders	4 (1.4)	3 (1.1)	7 (1.2)
Aortic arteriosclerosis	0	1 (0.4)	1 (0.2)
Hypertension	1 (0.4)	0	1 (0.2)
Hypertensive crisis	1 (0.4)	0	1 (0.2)
Intermittent claudication	0	1 (0.4)	1 (0.2)
Peripheral arterial occlusive disease	1 (0.4)	1 (0.4)	2 (0.4)
Peripheral artery stenosis	0	1 (0.4)	1 (0.2)
Peripheral artery thrombosis	1 (0.4)	0	1 (0.2)

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Table 4-3.2: Discontinuation of treatment due to severe AE by SOC and PT (Safety Analysis Set)

System Organ Class Preferred Term	Asciminib (N = 284) n(%)	Nilotinib (N = 282) n(%)	Total (N = 566) n(%)
Patients with any severe AE leading to discontinuation of treatment	18 (6.3)	30 (10.6)	48 (8.5)
Blood and lymphatic system disorders	5 (1.8)	2 (0.7)	7 (1.2)
Febrile neutropenia	1 (0.4)	0	1 (0.2)
Neutropenia	1 (0.4)	0	1 (0.2)
Thrombocytopenia	5 (1.8)	2 (0.7)	7 (1.2)
Cardiac disorders	2 (0.7)	5 (1.8)	7 (1.2)
Angina unstable	1 (0.4)	0	1 (0.2)
Arteriospasm coronary	0	1 (0.4)	1 (0.2)
Cardiac arrest	1 (0.4)	1 (0.4)	2 (0.4)
Coronary artery disease	1 (0.4)	1 (0.4)	2 (0.4)
Myocarditis	0	1 (0.4)	1 (0.2)
Prinzmetal angina	0	1 (0.4)	1 (0.2)
Gastrointestinal disorders	1 (0.4)	4 (1.4)	5 (0.9)
Pancreatitis	1 (0.4)	1 (0.4)	2 (0.4)
Pancreatitis acute	0	3 (1.1)	3 (0.5)
Hepatobiliary disorders	2 (0.7)	3 (1.1)	5 (0.9)

System Organ Class Preferred Term	Asciminib (N = 284) n(%)	Nilotinib (N = 282) n(%)	Total (N = 566) n(%)
Drug-induced liver injury	0	2 (0.7)	2 (0.4)
Hepatobiliary disease	1 (0.4)	0	1 (0.2)
Hyperbilirubinaemia	0	1 (0.4)	1 (0.2)
Suspected drug-induced liver injury	1 (0.4)	0	1 (0.2)
Investigations	1 (0.4)	12 (4.3)	13 (2.3)
Alanine aminotransferase increased	1 (0.4)	2 (0.7)	3 (0.5)
Amylase increased	0	1 (0.4)	1 (0.2)
Aspartate aminotransferase increased	1 (0.4)	0	1 (0.2)
Blood bilirubin increased	0	1 (0.4)	1 (0.2)
Blood creatine phosphokinase increased	0	1 (0.4)	1 (0.2)
Blood creatinine increased	0	1 (0.4)	1 (0.2)
Ejection fraction decreased	0	1 (0.4)	1 (0.2)
Lipase increased	0	4 (1.4)	4 (0.7)
Neutrophil count decreased	0	1 (0.4)	1 (0.2)
Metabolism and nutrition disorders	0	1 (0.4)	1 (0.2)
Hypercholesterolaemia	0	1 (0.4)	1 (0.2)
Musculoskeletal and connective tissue disorders	2 (0.7)	1 (0.4)	3 (0.5)
Musculoskeletal pain	1 (0.4)	0	1 (0.2)

System Organ Class Preferred Term	Asciminib (N = 284) n(%)	Nilotinib (N = 282) n(%)	Total (N = 566) n(%)
Tendonitis	1 (0.4)	1 (0.4)	2 (0.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.4)	0	1 (0.2)
Blast cell crisis	1 (0.4)	0	1 (0.2)
Nervous system disorders	1 (0.4)	1 (0.4)	2 (0.4)
Central nervous system inflammation	0	1 (0.4)	1 (0.2)
Transient ischaemic attack	1 (0.4)	0	1 (0.2)
Psychiatric disorders	1 (0.4)	0	1 (0.2)
Completed suicide	1 (0.4)	0	1 (0.2)
Skin and subcutaneous tissue disorders	1 (0.4)	1 (0.4)	2 (0.4)
Rash	1 (0.4)	1 (0.4)	2 (0.4)
Vascular disorders	3 (1.1)	1 (0.4)	4 (0.7)
Hypertension	1 (0.4)	0	1 (0.2)
Hypertensive crisis	1 (0.4)	0	1 (0.2)
Peripheral arterial occlusive disease	0	1 (0.4)	1 (0.2)
Peripheral artery thrombosis	1 (0.4)	0	1 (0.2)

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Table 4-3.3: Discontinuation of treatment due to SAE by SOC and PT (Safety Analysis Set)

System Organ Class Preferred Term	Asciminib (N = 284) n(%)	Nilotinib (N = 282) n(%)	Total (N = 566) n(%)
Patients with any SAE leading to discontinuation of treatment	12 (4.2)	17 (6.0)	29 (5.1)
Blood and lymphatic system disorders	1 (0.4)	0	1 (0.2)
Febrile neutropenia	1 (0.4)	0	1 (0.2)
Cardiac disorders	2 (0.7)	6 (2.1)	8 (1.4)
Angina unstable	1 (0.4)	0	1 (0.2)
Arteriospasm coronary	0	1 (0.4)	1 (0.2)
Atrial fibrillation	0	1 (0.4)	1 (0.2)
Cardiac arrest	1 (0.4)	1 (0.4)	2 (0.4)
Coronary artery disease	0	1 (0.4)	1 (0.2)
Myocarditis	0	1 (0.4)	1 (0.2)
Prinzmetal angina	0	1 (0.4)	1 (0.2)
Eye disorders	1 (0.4)	0	1 (0.2)
Optic ischaemic neuropathy	1 (0.4)	0	1 (0.2)
Gastrointestinal disorders	1 (0.4)	4 (1.4)	5 (0.9)
Pancreatitis	1 (0.4)	1 (0.4)	2 (0.4)
Pancreatitis acute	0	3 (1.1)	3 (0.5)

System Organ Class Preferred Term	Asciminib (N = 284) n(%)	Nilotinib (N = 282) n(%)	Total (N = 566) n(%)
Hepatobiliary disorders	2 (0.7)	3 (1.1)	5 (0.9)
Drug-induced liver injury	0	3 (1.1)	3 (0.5)
Hepatobiliary disease	1 (0.4)	0	1 (0.2)
Suspected drug-induced liver injury	1 (0.4)	0	1 (0.2)
Investigations	0	4 (1.4)	4 (0.7)
Alanine aminotransferase increased	0	1 (0.4)	1 (0.2)
Amylase increased	0	1 (0.4)	1 (0.2)
Blood bilirubin increased	0	1 (0.4)	1 (0.2)
Lipase increased	0	1 (0.4)	1 (0.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.4)	0	1 (0.2)
Blast cell crisis	1 (0.4)	0	1 (0.2)
Nervous system disorders	2 (0.7)	1 (0.4)	3 (0.5)
Central nervous system inflammation	0	1 (0.4)	1 (0.2)
Cerebrovascular accident	1 (0.4)	0	1 (0.2)
Transient ischaemic attack	1 (0.4)	0	1 (0.2)
Psychiatric disorders	1 (0.4)	0	1 (0.2)
Completed suicide	1 (0.4)	0	1 (0.2)
Vascular disorders	2 (0.7)	0	2 (0.4)

System Organ Class Preferred Term	Asciminib (N = 284) n(%)	Nilotinib (N = 282) n(%)	Total (N = 566) n(%)
Hypertensive crisis	1 (0.4)	0	1 (0.2)
Peripheral artery thrombosis	1 (0.4)	0	1 (0.2)

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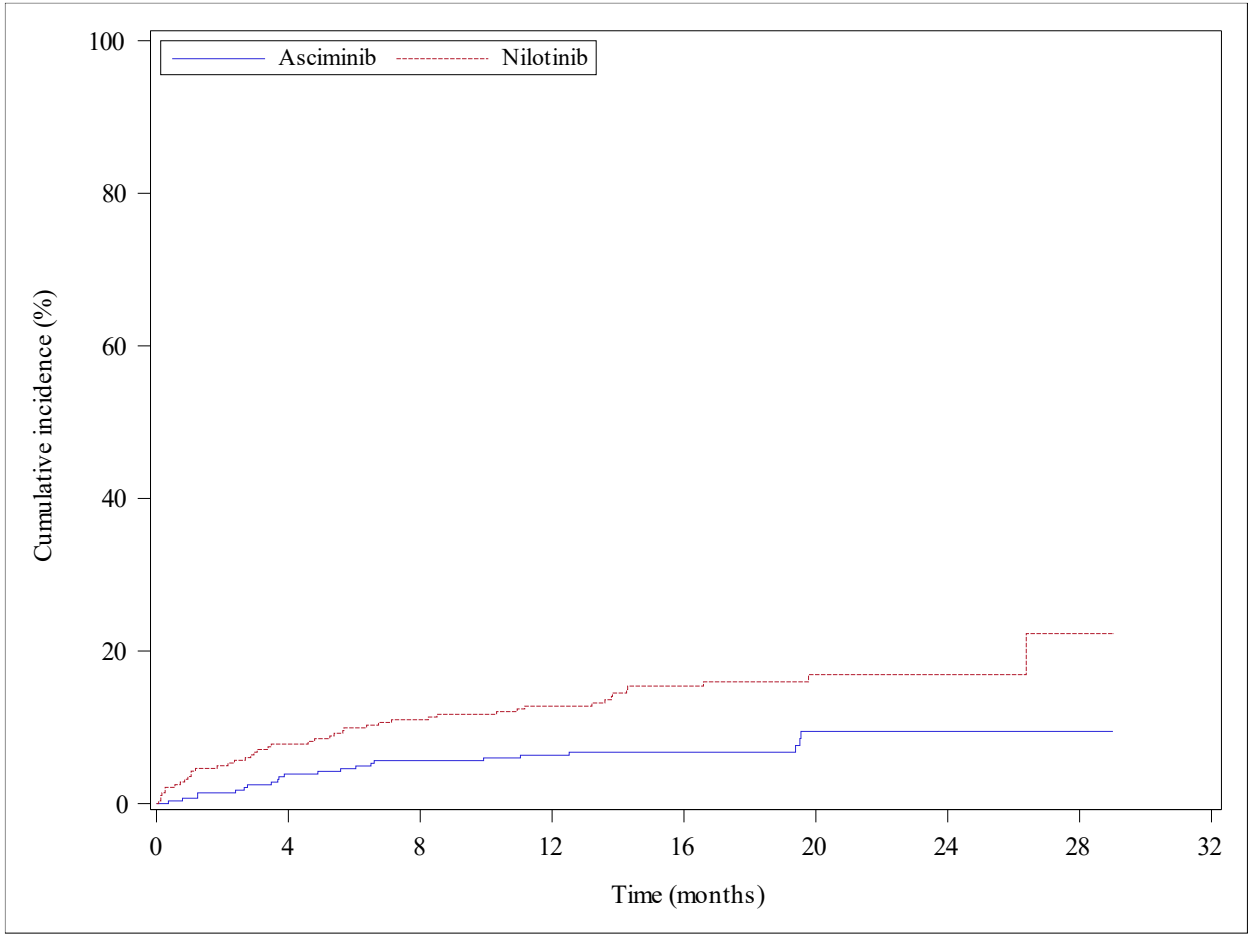
Table 4-4.1 Discontinuation of treatment due to AE: Competing risks analysis (Safety Analysis Set)

	Treatment groups		Comparison		
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**sHR**	**[95%-CI]**	**P-Value**
N*	284	282			
Number of patients with events, n (%)	22 (7.7)	45 (16.0)	0.46	[0.28; 0.77]	0.002
Number of patients with competing risk, n (%)	28 (9.9)	33 (11.7)			
Number of patients censored, n (%)	234 (82.4)	204 (72.3)			
Cumulative incidence (%) [95%-CI]					
Month 4	3.9 [2.1; 6.6]	7.8 [5.0; 11.3]			
Month 8	5.6 [3.4; 8.7]	11.0 [7.7; 15.0]			
Month 12	6.3 [3.9; 9.6]	12.8 [9.2; 17.0]			
Month 16	6.7 [4.2; 10.1]	15.4 [11.4; 20.0]			
Month 20	9.5 [5.8; 14.2]	16.9 [12.5; 21.9]			
Month 24	9.5 [5.8; 14.2]	16.9 [12.5; 21.9]			
Month 28	9.5 [5.8; 14.2]	22.3 [12.1; 34.4]			
Month 32	N.E. [N.E.; N.E.]	N.E. [N.E.; N.E.]			

	Treatment groups		Comparison		
	Asciminib (N = 284)	**Nilotinib (N = 282)**	**sHR**	**[95%-CI]**	**P-Value**

sHR: Sub-distribution Hazard Ratio
CI: Confidence Interval
N*: Number of patients included in the analysis
n (%): Number and percentage of patients
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Competing risk for the event of interest is the premature discontinuation of study medication for any reason except AE.
Two-sided 95% CI for the cumulative incidence functions are computed by Kaplan-Meier methods.
The sub-distribution HR and 95% CI values are from a stratified Fine-Gray proportional hazard model for competing risk analysis with stratification factor ELTS Score (IRT) and covariate treatment arm.
P-Values are from a stratified Gray test for competing risks with stratification factor ELTS Score (IRT).
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Figure 4-4.1 Discontinuation of treatment due to AE: Competing risks analysis: Plot of cumulative incidence functions (Safety Analysis Set)



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