Dossier zur Nutzenbewertung gemäß § 35a SGB V

Fedratinib (Inrebic®)

Bristol-Myers Squibb GmbH & Co. KGaA

Modul 4 A – Anhang 4-G

Behandlung krankheitsbedingter Splenomegalie oder Symptome bei erwachsenen Patient:innen mit primärer Myelofibrose, Post Polycythaemia Vera-Myelofibrose oder Post-Essentielle Thrombozythämie-Myelofibrose, die mit Ruxolitinib behandelt wurden

Ergänzende Analysen

Stand: 24.02.2025

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1 Studie FREEDOM2

1.1 Studienpopulation

1.1.1 Disposition

Table 14.1.3.1
Subject Disposition
Intent-to-treat Population

	Fedratinib (N=134) n (%)	BAT (N=67) n (%)	Total (N=201) n (%)
Subjects Randomized but not Treated	0	0	0
Subjects Randomized and Treated	134 (100.0)	67 (100.0)	201 (100.0)
Subjects with Treatment Completed	0	0	0
Subjects with Treatment Ongoing	43 (32.1)	28 (41.8)	71 (35.3)
Subjects who Discontinued Treatment	91 (67.9)	39 (58.2)	130 (64.7)
Subjects who Discontinued Treatment due to COVID-19	2 (1.5)	5 (7.5)	7 (3.5)
Primary Reason for Treatment Discontinuation [a]			
Adverse Event	22 (24.2)	8 (20.5)	30 (23.1)
Withdrawal by Subject	17 (18.7)	12 (30.8)	29 (22.3)
Death	13 (14.3)	6 (15.4)	19 (14.6)
Other	12 (13.2)	4 (10.3)	16 (12.3)
Lack of Efficacy	12 (13.2)	2 (5.1)	14 (10.8)
Physician Decision	9 (9.9)	3 (7.7)	12 (9.2)
Progressive Disease	6 (6.6)	4 (10.3)	10 (7.7)
Lost to Follow-Up	0	0	0
Pregnancy	0	0	0
Protocol Deviation	0	0	0

[a] Reasons are sorted by decreasing frequency of Total. Percentages are calculated using subjects who discontinued treatment.
[b] Reasons are sorted by decreasing frequency of Total. Percentages are calculated using subjects who did not continue to the survival follow-up period.
[c] Percentages are calculated using subjects who continued to the survival follow-up period.
[d] Reasons are sorted by decreasing frequency of Total. Percentages are calculated using subjects who were discontinued from survival follow-up.

Program Name: t_disp.sas
Version: Final
Data Source: ADSL

Table 14.1.3.1
Subject Disposition
Intent-to-treat Population

	Fedratinib (N=134) n (%)	BAT (N=67) n (%)	Total (N=201) n (%)
Subjects with Crossover	NA	46 (68.7)	46 (22.9)
Primary Reason for Crossover			
Completion of end of cycle 6 assessments	NA	43 (64.2)	43 (21.4)
Progression of splenomegaly	NA	3 (4.5)	3 (1.5)
Subjects Completed/Discontinued Treatment and Did Not Continue to Survival Follow-up Period [b]	40 (29.9)	20 (29.9)	60 (29.9)
Primary reason for not continuing			
Death	18 (45.0)	8 (40.0)	26 (43.3)
Withdrawal by Subject	9 (22.5)	7 (35.0)	16 (26.7)
Other	10 (25.0)	4 (20.0)	14 (23.3)
Adverse Event	3 (7.5)	1 (5.0)	4 (6.7)
Lost to Follow-Up	0	0	0
Pregnancy	0	0	0
Study Terminated by Sponsor	0	0	0

[a] Reasons are sorted by decreasing frequency of Total. Percentages are calculated using subjects who discontinued treatment.
[b] Reasons are sorted by decreasing frequency of Total. Percentages are calculated using subjects who did not continue to the survival follow-up period.
[c] Percentages are calculated using subjects who continued to the survival follow-up period.
[d] Reasons are sorted by decreasing frequency of Total. Percentages are calculated using subjects who were discontinued from survival follow-up.

Program Name: t_disp.sas
Version: Final
Data Source: ADSL

Table 14.1.3.1
Subject Disposition
Intent-to-treat Population

	Fedratinib (N=134) n (%)	BAT (N=67) n (%)	Total (N=201) n (%)
Subjects Completed/Discontinued Treatment and Continued to Survival Follow-up Period [c]	51 (38.1)	19 (28.4)	70 (34.8)
Subjects with Survival Follow-up Completed	0	0	0
Subjects with Survival Follow-up Ongoing	26 (51.0)	10 (52.6)	36 (51.4)
Subjects with Survival Follow-up Discontinued	25 (49.0)	9 (47.4)	34 (48.6)
Subjects with Survival Follow-up Discontinued due to COVID-19	0	0	0
Primary reason for Survival Follow-up Discontinuation [d]			
Death	20 (80.0)	7 (77.8)	27 (79.4)
Withdrawal by Subject	4 (16.0)	2 (22.2)	6 (17.6)
Study Terminated by Sponsor	1 (4.0)	0	1 (2.9)
Adverse Event	0	0	0
Lost to Follow-Up	0	0	0
Other	0	0	0
Pregnancy	0	0	0

[a] Reasons are sorted by decreasing frequency of Total. Percentages are calculated using subjects who discontinued treatment.
[b] Reasons are sorted by decreasing frequency of Total. Percentages are calculated using subjects who did not continue to the survival follow-up period.
[c] Percentages are calculated using subjects who continued to the survival follow-up period.
[d] Reasons are sorted by decreasing frequency of Total. Percentages are calculated using subjects who were discontinued from survival follow-up.

Program Name: t_disp.sas
Version: Final
Data Source: ADSL

1.1.2 Therapieabbrüche

Table 14.1.3.3
Treatment Discontinuation by Cycle up to 6 Cycles with Subject at Risk as Denominator
Safety Population

	Fedratinib (N=134) n (%)	BAT (N=67) n (%)	Total (N=201) n (%)
Discontinued study treatment up to 6 cycles	38 (28.4)	11 (16.4)	49 (24.4)
Primary reason for discontinuation: up to 6 cycles			
Death	6 (4.5)	1 (1.5)	7 (3.5)
Adverse Event	10 (7.5)	3 (4.5)	13 (6.5)
Pregnancy	0	0	0
Progressive Disease	1 (0.7)	2 (3.0)	3 (1.5)
Withdrawal by Subject	5 (3.7)	3 (4.5)	8 (4.0)
Lost to Follow-Up	0	0	0
Protocol Deviation	0	0	0
Physician Decision	7 (5.2)	1 (1.5)	8 (4.0)
Lack of Efficacy	4 (3.0)	0	4 (2.0)
Other	5 (3.7)	1 (1.5)	6 (3.0)
Number of subjects at risk at cycle 1	134	67	201
Reason for discontinuation: at cycle 1	6 (4.5)	1 (1.5)	7 (3.5)
Death	2 (1.5)	0	2 (1.0)
Adverse Event	2 (1.5)	0	2 (1.0)
Pregnancy	0	0	0
Progressive Disease	1 (0.7)	0	1 (0.5)
Withdrawal by Subject	1 (0.7)	1 (1.5)	2 (1.0)
Lost to Follow-Up	0	0	0
Protocol Deviation	0	0	0
Physician Decision	0	0	0
Lack of Efficacy	0	0	0
Other	0	0	0

Table 14.1.3.3
Treatment Discontinuation by Cycle up to 6 Cycles with Subject at Risk as Denominator
Safety Population

	Fedratinib (N=134) n (%)	BAT (N=67) n (%)	Total (N=201) n (%)
Number of subjects at risk at cycle 2	128	66	194
Reason for discontinuation: at cycle 2	3 (2.3)	1 (1.5)	4 (2.1)
Death	0	0	0
Adverse Event	2 (1.6)	0	2 (1.0)
Pregnancy	0	0	0
Progressive Disease	0	1 (1.5)	1 (0.5)
Withdrawal by Subject	1 (0.8)	0	1 (0.5)
Lost to Follow-Up	0	0	0
Protocol Deviation	0	0	0
Physician Decision	0	0	0
Lack of Efficacy	0	0	0
Other	0	0	0
Number of subjects at risk at cycle 3	125	65	190
Reason for discontinuation: at cycle 3	10 (8.0)	2 (3.1)	12 (6.3)
Death	2 (1.6)	0	2 (1.1)
Adverse Event	0	1 (1.5)	1 (0.5)
Pregnancy	0	0	0
Progressive Disease	0	0	0
Withdrawal by Subject	2 (1.6)	0	2 (1.1)
Lost to Follow-Up	0	0	0
Protocol Deviation	0	0	0
Physician Decision	1 (0.8)	1 (1.5)	2 (1.1)
Lack of Efficacy	3 (2.4)	0	3 (1.6)
Other	2 (1.6)	0	2 (1.1)

Table 14.1.3.3
Treatment Discontinuation by Cycle up to 6 Cycles with Subject at Risk as Denominator
Safety Population

	Fedratinib (N=134) n (%)	BAT (N=67) n (%)	Total (N=201) n (%)
Number of subjects at risk at cycle 4	115	63	178
Reason for discontinuation: at cycle 4	7 (6.1)	3 (4.8)	10 (5.6)
Death	0	1 (1.6)	1 (0.6)
Adverse Event	3 (2.6)	1 (1.6)	4 (2.2)
Pregnancy	0	0	0
Progressive Disease	0	0	0
Withdrawal by Subject	0	1 (1.6)	1 (0.6)
Lost to Follow-Up	0	0	0
Protocol Deviation	0	0	0
Physician Decision	2 (1.7)	0	2 (1.1)
Lack of Efficacy	1 (0.9)	0	1 (0.6)
Other	1 (0.9)	0	1 (0.6)
Number of subjects at risk at cycle 5	108	60	168
Reason for discontinuation: at cycle 5	8 (7.4)	1 (1.7)	9 (5.4)
Death	2 (1.9)	0	2 (1.2)
Adverse Event	0	0	0
Pregnancy	0	0	0
Progressive Disease	0	0	0
Withdrawal by Subject	1 (0.9)	0	1 (0.6)
Lost to Follow-Up	0	0	0
Protocol Deviation	0	0	0
Physician Decision	3 (2.8)	0	3 (1.8)
Lack of Efficacy	0	0	0
Other	2 (1.9)	1 (1.7)	3 (1.8)

Table 14.1.3.3
Treatment Discontinuation by Cycle up to 6 Cycles with Subject at Risk as Denominator
Safety Population

	Fedratinib (N=134) n (%)	BAT (N=67) n (%)	Total (N=201) n (%)
Number of subjects at risk at cycle 6	100	59	159
Reason for discontinuation: at cycle 6	4 (4.0)	3 (5.1)	7 (4.4)
Death	0	0	0
Adverse Event	3 (3.0)	1 (1.7)	4 (2.5)
Pregnancy	0	0	0
Progressive Disease	0	1 (1.7)	1 (0.6)
Withdrawal by Subject	0	1 (1.7)	1 (0.6)
Lost to Follow-Up	0	0	0
Protocol Deviation	0	0	0
Physician Decision	1 (1.0)	0	1 (0.6)
Lack of Efficacy	0	0	0
Other	0	0	0

1.1.3 Behandlungsdauer

Table 14.3.1.1.1.1
Treatment Exposure
Safety Population

Parameter	Fedratinib (N=134)		BAT (N=67)	
	First 6 Cycles	Full Treatment	First 6 Cycles	Full Treatment
Treatment Duration (Weeks) [a]				
n	134	134	67	67
Mean	20.6	52.5	22.0	27.7
SD	6.32	39.68	4.53	15.29
Median	23.9	43.0	23.7	24.7
Q1, Q3	19.0, 24.0	19.0, 75.1	22.1, 24.0	22.6, 26.7
Min, Max	1, 26	1, 151	1, 30	1, 97
Number of Cycles				
n	134	134	67	67
Mean	5.3	13.5	5.7	7.3
SD	1.39	9.65	0.99	3.63
Median	6.0	11.0	6.0	7.0
Q1, Q3	5.0, 6.0	5.0, 19.0	6.0, 6.0	6.0, 7.0
Min, Max	1, 6	1, 38	1, 6	1, 23

SD = Standard deviation; Q1 = First quartile; Q3 = Third quartile; Min = Minimum; Max = Maximum.
Note: For Fedratinib group, only subjects who initially treated with fedratinib is summarized. For BAT group, subjects didn't take any medication or transfusion as BAT are excluded.
[a] Treatment Duration = (last dose date − first dose date + 1)/7, regardless of unplanned intermittent discontinuations. For subjects in BAT group, C1D1 is treated as first dose date. For last dose date (treatment end date), treatment discontinuation date is used if patient discontinues the study treatment without crossover; (Crossover date-1) is used if patient crosses over to fedratinib group; for ongoing patients, data cutoff date is used.
[b] Average daily dose = Cumulative dose / number of days dosed (received non-zero dose).
[c] Actual Dose Intensity = Cumulative dose / Treatment Duration.
[d] Relative Dose Intensity = Actual Dose Intensity / Planned Dose Intensity (of 2800 mg/week), presented as a percentage.

Program Name: t_expsaf.sas
Version: Final
Data Source: ADSL, ADEX

Table 14.3.1.1.1.1
Treatment Exposure
Safety Population

Parameter	Fedratinib (N=134)		BAT (N=67)	
	First 6 Cycles	Full Treatment	First 6 Cycles	Full Treatment
Number of Cycles Completed – n (%)				
1 cycle	134 (100)	134 (100)	67 (100)	67 (100)
2 cycles	128 (95.5)	128 (95.5)	66 (98.5)	66 (98.5)
3 cycles	125 (93.3)	125 (93.3)	65 (97.0)	65 (97.0)
4 cycles	115 (85.8)	115 (85.8)	63 (94.0)	63 (94.0)
5 cycles	108 (80.6)	108 (80.6)	60 (89.6)	60 (89.6)
6 cycles	100 (74.6)	100 (74.6)	59 (88.1)	59 (88.1)
9 cycles	NA	85 (63.4)	NA	8 (11.9)
12 cycles	NA	66 (49.3)	NA	7 (10.4)
15 cycles	NA	56 (41.8)	NA	4 (6.0)
18 cycles	NA	38 (28.4)	NA	3 (4.5)
21 cycles	NA	30 (22.4)	NA	1 (1.5)
24 cycles	NA	24 (17.9)	NA	0

SD = Standard deviation; Q1 = First quartile; Q3 = Third quartile; Min = Minimum; Max = Maximum.
Note: For Fedratinib group, only subjects who initially treated with fedratinib is summarized. For BAT group, subjects didn't take any medication or transfusion as BAT are excluded.
[a] Treatment Duration = (last dose date – first dose date + 1)/7, regardless of unplanned intermittent discontinuations. For subjects in BAT group, C1D1 is treated as first dose date. For last dose date (treatment end date), treatment discontinuation date is used if patient discontinues the study treatment without crossover; (Crossover date-1) is used if patient crosses over to fedratinib group; for ongoing patients, data cutoff date is used.
[b] Average daily dose = Cumulative dose / number of days dosed (received non-zero dose).
[c] Actual Dose Intensity = Cumulative dose / Treatment Duration.
[d] Relative Dose Intensity = Actual Dose Intensity / Planned Dose Intensity (of 2800 mg/week), presented as a percentage.

Program Name: t_expsaf.sas
Version: Final
Data Source: ADSL, ADEX

Table 14.3.1.1.1.1
Treatment Exposure
Safety Population

Parameter	Fedratinib (N=134)		BAT (N=67)	
	First 6 Cycles	Full Treatment	First 6 Cycles	Full Treatment
Cumulative Dose (mg)				
n	134	134	NA	NA
Mean	51155.2	128019.4	NA	NA
SD	19017.10	98123.08	NA	NA
Median	60700.0	113600.0	NA	NA
Q1, Q3	37200.0, 66800.0	41600.0, 181600.0	NA	NA
Min, Max	2000, 69200	2000, 416000	NA	NA
Average Daily Dose (mg/day) [b]				
n	134	134	NA	NA
Mean	366.7	359.2	NA	NA
SD	55.52	59.28	NA	NA
Median	400.0	398.4	NA	NA
Q1, Q3	350.0, 400.0	322.0, 400.0	NA	NA
Min, Max	200, 400	200, 400	NA	NA

SD = Standard deviation; Q1 = First quartile; Q3 = Third quartile; Min = Minimum; Max = Maximum.
Note: For Fedratinib group, only subjects who initially treated with fedratinib is summarized. For BAT group, subjects didn't take any medication or transfusion as BAT are excluded.
[a] Treatment Duration = (last dose date – first dose date + 1)/7, regardless of unplanned intermittent discontinuations. For subjects in BAT group, C1D1 is treated as first dose date. For last dose date (treatment end date), treatment discontinuation date is used if patient discontinues the study treatment without crossover; (Crossover date-1) is used if patient crosses over to fedratinib group; for ongoing patients, data cutoff date is used.
[b] Average daily dose = Cumulative dose / number of days dosed (received non-zero dose).
[c] Actual Dose Intensity = Cumulative dose / Treatment Duration.
[d] Relative Dose Intensity = Actual Dose Intensity / Planned Dose Intensity (of 2800 mg/week), presented as a percentage.

Program Name: t_expsaf.sas
Version: Final
Data Source: ADSL, ADEX

Table 14.3.1.1.1.1
Treatment Exposure
Safety Population

Parameter	Fedratinib (N=134)		BAT (N=67)	
	First 6 Cycles	Full Treatment	First 6 Cycles	Full Treatment
Actual Dose Intensity (mg/week) [c]				
n	134	134	NA	NA
Mean	2483.3	2434.0	NA	NA
SD	460.37	473.24	NA	NA
Median	2750.1	2708.1	NA	NA
Q1, Q3	2263.7, 2800.0	2116.3, 2800.0	NA	NA
Min, Max	1148, 2800	1148, 2800	NA	NA
Relative Dose Intensity (%) [d]				
n	134	134	NA	NA
Mean	88.7	86.9	NA	NA
SD	16.44	16.90	NA	NA
Median	98.2	96.7	NA	NA
Q1, Q3	80.8, 100.0	75.6, 100.0	NA	NA
Min, Max	41, 100	41, 100	NA	NA

SD = Standard deviation; Q1 = First quartile; Q3 = Third quartile; Min = Minimum; Max = Maximum.
Note: For Fedratinib group, only subjects who initially treated with fedratinib is summarized. For BAT group, subjects didn't take any medication or transfusion as BAT are excluded.
[a] Treatment Duration = (last dose date – first dose date + 1)/7, regardless of unplanned intermittent discontinuations. For subjects in BAT group, C1D1 is treated as first dose date. For last dose date (treatment end date), treatment discontinuation date is used if patient discontinues the study treatment without crossover; (Crossover date-1) is used if patient crosses over to fedratinib group; for ongoing patients, data cutoff date is used.
[b] Average daily dose = Cumulative dose / number of days dosed (received non-zero dose).
[c] Actual Dose Intensity = Cumulative dose / Treatment Duration.
[d] Relative Dose Intensity = Actual Dose Intensity / Planned Dose Intensity (of 2800 mg/week), presented as a percentage.

Program Name: t_expsaf.sas
Version: Final
Data Source: ADSL, ADEX

1.2 Rücklaufquoten

1.2.1 Rücklaufquoten des MFSAF v4.0 je Erhebungszeitpunkt

Table 14.2.2.1
MFSAF -- Compliance Rate by Cycle
Intent-to-treat Population with Non-zero Baseline TSS

	Fedratinib (N=126)	BAT (N=65)
Baseline		
Patients with questionnaires expected [a]	126 (100.0)	65 (100.0)
Patients with questionnaires received [b]	126 (100.0)	65 (100.0)
Patients evaluable (completion rate) [c]	126 (100.0)	65 (100.0)
Patients evaluable (compliance rate) [c]	126 (100.0)	65 (100.0)
Cycle 2		
Patients with questionnaires expected [a]	121 (96.0)	64 (98.5)
Patients with questionnaires received [b]	105 (86.8)	47 (73.4)
Patients evaluable (completion rate) [c]	105 (83.3)	47 (72.3)
Patients evaluable (compliance rate) [c]	105 (86.8)	47 (73.4)
Cycle 3		
Patients with questionnaires expected [a]	118 (93.7)	63 (96.9)
Patients with questionnaires received [b]	98 (83.1)	54 (85.7)
Patients evaluable (completion rate) [c]	98 (77.8)	54 (83.1)
Patients evaluable (compliance rate) [c]	98 (83.1)	54 (85.7)

Note: MFSAF: Myelofibrosis Symptom Assessment Form; PRO: Patient-reported outcomes; TSS: Total symptom score
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on number of subjects randomized with non-zero baseline TSS.
[b] Patients with questionnaires received at a cycle: number of patients answered assessment at the cycle. Percent is based on number of subjects with questionnaires expected for that cycle.
[c] Patients evaluable at a cycle: number of patients with total symptom score calculable (i.e. answered all questions) for that cycle. Completion rate is based on number of subjects randomized with non-zero baseline TSS; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_procomp.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.2.1
MFSAF -- Compliance Rate by Cycle
Intent-to-treat Population with Non-zero Baseline TSS

	Fedratinib (N=126)	BAT (N=65)
Cycle 4		
Patients with questionnaires expected [a]	109 (86.5)	61 (93.8)
Patients with questionnaires received [b]	29 (26.6)	7 (11.5)
Patients evaluable (completion rate) [c]	29 (23.0)	7 (10.8)
Patients evaluable (compliance rate) [c]	29 (26.6)	7 (11.5)
Cycle 5		
Patients with questionnaires expected [a]	103 (81.7)	58 (89.2)
Patients with questionnaires received [b]	89 (86.4)	49 (84.5)
Patients evaluable (completion rate) [c]	89 (70.6)	49 (75.4)
Patients evaluable (compliance rate) [c]	89 (86.4)	49 (84.5)
Cycle 6		
Patients with questionnaires expected [a]	97 (77.0)	57 (87.7)
Patients with questionnaires received [b]	85 (87.6)	49 (86.0)
Patients evaluable (completion rate) [c]	85 (67.5)	49 (75.4)
Patients evaluable (compliance rate) [c]	85 (87.6)	49 (86.0)

Note: MFSAF: Myelofibrosis Symptom Assessment Form; PRO: Patient-reported outcomes; TSS: Total symptom score
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on number of subjects randomized with non-zero baseline TSS.
[b] Patients with questionnaires received at a cycle: number of patients answered assessment at the cycle. Percent is based on number of subjects with questionnaires expected for that cycle.
[c] Patients evaluable at a cycle: number of patients with total symptom score calculable (i.e. answered all questions) for that cycle. Completion rate is based on number of subjects randomized with non-zero baseline TSS; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_procomp.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.2.1
MFSAF -- Compliance Rate by Cycle
Intent-to-treat Population with Non-zero Baseline TSS

	Fedratinib (N=126)	BAT (N=65)
Cycle 7		
Patients with questionnaires expected [a]	90 (71.4)	33 (50.8)
Patients with questionnaires received [b]	25 (27.8)	4 (12.1)
Patients evaluable (completion rate) [c]	25 (19.8)	4 (6.2)
Patients evaluable (compliance rate) [c]	25 (27.8)	4 (12.1)
Cycle 8		
Patients with questionnaires expected [a]	84 (66.7)	9 (13.8)
Patients with questionnaires received [b]	79 (94.0)	7 (77.8)
Patients evaluable (completion rate) [c]	79 (62.7)	7 (10.8)
Patients evaluable (compliance rate) [c]	79 (94.0)	7 (77.8)
Cycle 9		
Patients with questionnaires expected [a]	83 (65.9)	7 (10.8)
Patients with questionnaires received [b]	76 (91.6)	6 (85.7)
Patients evaluable (completion rate) [c]	76 (60.3)	6 (9.2)
Patients evaluable (compliance rate) [c]	76 (91.6)	6 (85.7)

Note: MFSAF: Myelofibrosis Symptom Assessment Form; PRO: Patient-reported outcomes; TSS: Total symptom score
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on number of subjects randomized with non-zero baseline TSS.
[b] Patients with questionnaires received at a cycle: number of patients answered assessment at the cycle. Percent is based on number of subjects with questionnaires expected for that cycle.
[c] Patients evaluable at a cycle: number of patients with total symptom score calculable (i.e. answered all questions) for that cycle. Completion rate is based on number of subjects randomized with non-zero baseline TSS; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_procomp.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.2.1
MFSAF -- Compliance Rate by Cycle
Intent-to-treat Population with Non-zero Baseline TSS

	Fedratinib (N=126)	BAT (N=65)
Cycle 10		
Patients with questionnaires expected [a]	77 (61.1)	7 (10.8)
Patients with questionnaires received [b]	67 (87.0)	6 (85.7)
Patients evaluable (completion rate) [c]	67 (53.2)	6 (9.2)
Patients evaluable (compliance rate) [c]	67 (87.0)	6 (85.7)
Cycle 11		
Patients with questionnaires expected [a]	71 (56.3)	7 (10.8)
Patients with questionnaires received [b]	63 (88.7)	6 (85.7)
Patients evaluable (completion rate) [c]	63 (50.0)	6 (9.2)
Patients evaluable (compliance rate) [c]	63 (88.7)	6 (85.7)
Cycle 12		
Patients with questionnaires expected [a]	65 (51.6)	6 (9.2)
Patients with questionnaires received [b]	59 (90.8)	6 (100.0)
Patients evaluable (completion rate) [c]	59 (46.8)	6 (9.2)
Patients evaluable (compliance rate) [c]	59 (90.8)	6 (100.0)

Note: MFSAF: Myelofibrosis Symptom Assessment Form; PRO: Patient-reported outcomes; TSS: Total symptom score
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on number of subjects randomized with non-zero baseline TSS.
[b] Patients with questionnaires received at a cycle: number of patients answered assessment at the cycle. Percent is based on number of subjects with questionnaires expected for that cycle.
[c] Patients evaluable at a cycle: number of patients with total symptom score calculable (i.e. answered all questions) for that cycle. Completion rate is based on number of subjects randomized with non-zero baseline TSS; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_procomp.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.2.1
MFSAF -- Compliance Rate by Cycle
Intent-to-treat Population with Non-zero Baseline TSS

	Fedratinib (N=126)	BAT (N=65)
Cycle 13		
Patients with questionnaires expected [a]	63 (50.0)	5 (7.7)
Patients with questionnaires received [b]	16 (25.4)	1 (20.0)
Patients evaluable (completion rate) [c]	16 (12.7)	1 (1.5)
Patients evaluable (compliance rate) [c]	16 (25.4)	1 (20.0)
Cycle 14		
Patients with questionnaires expected [a]	56 (44.4)	4 (6.2)
Patients with questionnaires received [b]	51 (91.1)	3 (75.0)
Patients evaluable (completion rate) [c]	51 (40.5)	3 (4.6)
Patients evaluable (compliance rate) [c]	51 (91.1)	3 (75.0)
Cycle 15		
Patients with questionnaires expected [a]	55 (43.7)	4 (6.2)
Patients with questionnaires received [b]	50 (90.9)	3 (75.0)
Patients evaluable (completion rate) [c]	50 (39.7)	3 (4.6)
Patients evaluable (compliance rate) [c]	50 (90.9)	3 (75.0)

Note: MFSAF: Myelofibrosis Symptom Assessment Form; PRO: Patient-reported outcomes; TSS: Total symptom score
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on number of subjects randomized with non-zero baseline TSS.
[b] Patients with questionnaires received at a cycle: number of patients answered assessment at the cycle. Percent is based on number of subjects with questionnaires expected for that cycle.
[c] Patients evaluable at a cycle: number of patients with total symptom score calculable (i.e. answered all questions) for that cycle. Completion rate is based on number of subjects randomized with non-zero baseline TSS; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_procomp.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.2.1
MFSAF -- Compliance Rate by Cycle
Intent-to-treat Population with Non-zero Baseline TSS

	Fedratinib (N=126)	BAT (N=65)
Cycle 16		
Patients with questionnaires expected [a]	47 (37.3)	4 (6.2)
Patients with questionnaires received [b]	39 (83.0)	4 (100.0)
Patients evaluable (completion rate) [c]	39 (31.0)	4 (6.2)
Patients evaluable (compliance rate) [c]	39 (83.0)	4 (100.0)
Cycle 17		
Patients with questionnaires expected [a]	40 (31.7)	4 (6.2)
Patients with questionnaires received [b]	34 (85.0)	4 (100.0)
Patients evaluable (completion rate) [c]	34 (27.0)	4 (6.2)
Patients evaluable (compliance rate) [c]	34 (85.0)	4 (100.0)
Cycle 18		
Patients with questionnaires expected [a]	38 (30.2)	3 (4.6)
Patients with questionnaires received [b]	35 (92.1)	3 (100.0)
Patients evaluable (completion rate) [c]	35 (27.8)	3 (4.6)
Patients evaluable (compliance rate) [c]	35 (92.1)	3 (100.0)

Note: MFSAF: Myelofibrosis Symptom Assessment Form; PRO: Patient-reported outcomes; TSS: Total symptom score
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on number of subjects randomized with non-zero baseline TSS.
[b] Patients with questionnaires received at a cycle: number of patients answered assessment at the cycle. Percent is based on number of subjects with questionnaires expected for that cycle.
[c] Patients evaluable at a cycle: number of patients with total symptom score calculable (i.e. answered all questions) for that cycle. Completion rate is based on number of subjects randomized with non-zero baseline TSS; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_procomp.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.2.1
MFSAF -- Compliance Rate by Cycle
Intent-to-treat Population with Non-zero Baseline TSS

	Fedratinib (N=126)	BAT (N=65)
Cycle 19		
Patients with questionnaires expected [a]	37 (29.4)	2 (3.1)
Patients with questionnaires received [b]	12 (32.4)	1 (50.0)
Patients evaluable (completion rate) [c]	12 (9.5)	1 (1.5)
Patients evaluable (compliance rate) [c]	12 (32.4)	1 (50.0)
Cycle 20		
Patients with questionnaires expected [a]	32 (25.4)	1 (1.5)
Patients with questionnaires received [b]	28 (87.5)	1 (100.0)
Patients evaluable (completion rate) [c]	28 (22.2)	1 (1.5)
Patients evaluable (compliance rate) [c]	28 (87.5)	1 (100.0)
Cycle 21		
Patients with questionnaires expected [a]	30 (23.8)	1 (1.5)
Patients with questionnaires received [b]	28 (93.3)	1 (100.0)
Patients evaluable (completion rate) [c]	28 (22.2)	1 (1.5)
Patients evaluable (compliance rate) [c]	28 (93.3)	1 (100.0)

Note: MFSAF: Myelofibrosis Symptom Assessment Form; PRO: Patient-reported outcomes; TSS: Total symptom score
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on number of subjects randomized with non-zero baseline TSS.
[b] Patients with questionnaires received at a cycle: number of patients answered assessment at the cycle. Percent is based on number of subjects with questionnaires expected for that cycle.
[c] Patients evaluable at a cycle: number of patients with total symptom score calculable (i.e. answered all questions) for that cycle. Completion rate is based on number of subjects randomized with non-zero baseline TSS; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_procomp.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.2.1
MFSAF -- Compliance Rate by Cycle
Intent-to-treat Population with Non-zero Baseline TSS

	Fedratinib (N=126)	BAT (N=65)
Cycle 22		
Patients with questionnaires expected [a]	27 (21.4)	1 (1.5)
Patients with questionnaires received [b]	23 (85.2)	1 (100.0)
Patients evaluable (completion rate) [c]	23 (18.3)	1 (1.5)
Patients evaluable (compliance rate) [c]	23 (85.2)	1 (100.0)
Cycle 23		
Patients with questionnaires expected [a]	25 (19.8)	1 (1.5)
Patients with questionnaires received [b]	19 (76.0)	1 (100.0)
Patients evaluable (completion rate) [c]	19 (15.1)	1 (1.5)
Patients evaluable (compliance rate) [c]	19 (76.0)	1 (100.0)
Cycle 24		
Patients with questionnaires expected [a]	24 (19.0)	0
Patients with questionnaires received [b]	17 (70.8)	0
Patients evaluable (completion rate) [c]	17 (13.5)	0
Patients evaluable (compliance rate) [c]	17 (70.8)	0

Note: MFSAF: Myelofibrosis Symptom Assessment Form; PRO: Patient-reported outcomes; TSS: Total symptom score
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on number of subjects randomized with non-zero baseline TSS.
[b] Patients with questionnaires received at a cycle: number of patients answered assessment at the cycle. Percent is based on number of subjects with questionnaires expected for that cycle.
[c] Patients evaluable at a cycle: number of patients with total symptom score calculable (i.e. answered all questions) for that cycle. Completion rate is based on number of subjects randomized with non-zero baseline TSS; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_procomp.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.2.1
MFSAF -- Compliance Rate by Cycle
Intent-to-treat Population with Non-zero Baseline TSS

	Fedratinib (N=126)	BAT (N=65)
Cycle 25		
Patients with questionnaires expected [a]	19 (15.1)	0
Patients with questionnaires received [b]	6 (31.6)	0
Patients evaluable (completion rate) [c]	6 (4.8)	0
Patients evaluable (compliance rate) [c]	6 (31.6)	0
Cycle 26		
Patients with questionnaires expected [a]	18 (14.3)	0
Patients with questionnaires received [b]	17 (94.4)	0
Patients evaluable (completion rate) [c]	17 (13.5)	0
Patients evaluable (compliance rate) [c]	17 (94.4)	0
Cycle 27		
Patients with questionnaires expected [a]	17 (13.5)	0
Patients with questionnaires received [b]	14 (82.4)	0
Patients evaluable (completion rate) [c]	14 (11.1)	0
Patients evaluable (compliance rate) [c]	14 (82.4)	0

Note: MFSAF: Myelofibrosis Symptom Assessment Form; PRO: Patient-reported outcomes; TSS: Total symptom score
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on number of subjects randomized with non-zero baseline TSS.
[b] Patients with questionnaires received at a cycle: number of patients answered assessment at the cycle. Percent is based on number of subjects with questionnaires expected for that cycle.
[c] Patients evaluable at a cycle: number of patients with total symptom score calculable (i.e. answered all questions) for that cycle. Completion rate is based on number of subjects randomized with non-zero baseline TSS; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_procomp.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.2.1
MFSAF -- Compliance Rate by Cycle
Intent-to-treat Population with Non-zero Baseline TSS

	Fedratinib (N=126)	BAT (N=65)
Cycle 28		
Patients with questionnaires expected [a]	16 (12.7)	0
Patients with questionnaires received [b]	15 (93.8)	0
Patients evaluable (completion rate) [c]	15 (11.9)	0
Patients evaluable (compliance rate) [c]	15 (93.8)	0
Cycle 29		
Patients with questionnaires expected [a]	14 (11.1)	0
Patients with questionnaires received [b]	12 (85.7)	0
Patients evaluable (completion rate) [c]	12 (9.5)	0
Patients evaluable (compliance rate) [c]	12 (85.7)	0
Cycle 30		
Patients with questionnaires expected [a]	12 (9.5)	0
Patients with questionnaires received [b]	10 (83.3)	0
Patients evaluable (completion rate) [c]	10 (7.9)	0
Patients evaluable (compliance rate) [c]	10 (83.3)	0

Note: MFSAF: Myelofibrosis Symptom Assessment Form; PRO: Patient-reported outcomes; TSS: Total symptom score
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on number of subjects randomized with non-zero baseline TSS.
[b] Patients with questionnaires received at a cycle: number of patients answered assessment at the cycle. Percent is based on number of subjects with questionnaires expected for that cycle.
[c] Patients evaluable at a cycle: number of patients with total symptom score calculable (i.e. answered all questions) for that cycle. Completion rate is based on number of subjects randomized with non-zero baseline TSS; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_procomp.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.2.1
MFSAF -- Compliance Rate by Cycle
Intent-to-treat Population with Non-zero Baseline TSS

	Fedratinib (N=126)	BAT (N=65)
Cycle 31		
Patients with questionnaires expected [a]	10 (7.9)	0
Patients with questionnaires received [b]	2 (20.0)	0
Patients evaluable (completion rate) [c]	2 (1.6)	0
Patients evaluable (compliance rate) [c]	2 (20.0)	0
Cycle 32		
Patients with questionnaires expected [a]	8 (6.3)	0
Patients with questionnaires received [b]	7 (87.5)	0
Patients evaluable (completion rate) [c]	7 (5.6)	0
Patients evaluable (compliance rate) [c]	7 (87.5)	0
Cycle 33		
Patients with questionnaires expected [a]	7 (5.6)	0
Patients with questionnaires received [b]	6 (85.7)	0
Patients evaluable (completion rate) [c]	6 (4.8)	0
Patients evaluable (compliance rate) [c]	6 (85.7)	0

Note: MFSAF: Myelofibrosis Symptom Assessment Form; PRO: Patient-reported outcomes; TSS: Total symptom score
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on number of subjects randomized with non-zero baseline TSS.
[b] Patients with questionnaires received at a cycle: number of patients answered assessment at the cycle. Percent is based on number of subjects with questionnaires expected for that cycle.
[c] Patients evaluable at a cycle: number of patients with total symptom score calculable (i.e. answered all questions) for that cycle. Completion rate is based on number of subjects randomized with non-zero baseline TSS; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_procomp.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.2.1
MFSAF -- Compliance Rate by Cycle
Intent-to-treat Population with Non-zero Baseline TSS

	Fedratinib (N=126)	BAT (N=65)
Cycle 34		
Patients with questionnaires expected [a]	7 (5.6)	0
Patients with questionnaires received [b]	6 (85.7)	0
Patients evaluable (completion rate) [c]	6 (4.8)	0
Patients evaluable (compliance rate) [c]	6 (85.7)	0
Cycle 35		
Patients with questionnaires expected [a]	7 (5.6)	0
Patients with questionnaires received [b]	6 (85.7)	0
Patients evaluable (completion rate) [c]	6 (4.8)	0
Patients evaluable (compliance rate) [c]	6 (85.7)	0
Cycle 36		
Patients with questionnaires expected [a]	5 (4.0)	0
Patients with questionnaires received [b]	5 (100.0)	0
Patients evaluable (completion rate) [c]	5 (4.0)	0
Patients evaluable (compliance rate) [c]	5 (100.0)	0

Note: MFSAF: Myelofibrosis Symptom Assessment Form; PRO: Patient-reported outcomes; TSS: Total symptom score
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on number of subjects randomized with non-zero baseline TSS.
[b] Patients with questionnaires received at a cycle: number of patients answered assessment at the cycle. Percent is based on number of subjects with questionnaires expected for that cycle.
[c] Patients evaluable at a cycle: number of patients with total symptom score calculable (i.e. answered all questions) for that cycle. Completion rate is based on number of subjects randomized with non-zero baseline TSS; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_procomp.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.2.1
MFSAF -- Compliance Rate by Cycle
Intent-to-treat Population with Non-zero Baseline TSS

	Fedratinib (N=126)	BAT (N=65)
Cycle 37		
Patients with questionnaires expected [a]	2 (1.6)	0
Patients with questionnaires received [b]	2 (100.0)	0
Patients evaluable (completion rate) [c]	2 (1.6)	0
Patients evaluable (compliance rate) [c]	2 (100.0)	0
Cycle 38		
Patients with questionnaires expected [a]	1 (0.8)	0
Patients with questionnaires received [b]	1 (100.0)	0
Patients evaluable (completion rate) [c]	1 (0.8)	0
Patients evaluable (compliance rate) [c]	1 (100.0)	0

Note: MFSAF: Myelofibrosis Symptom Assessment Form; PRO: Patient-reported outcomes; TSS: Total symptom score
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on number of subjects randomized with non-zero baseline TSS.
[b] Patients with questionnaires received at a cycle: number of patients answered assessment at the cycle. Percent is based on number of subjects with questionnaires expected for that cycle.
[c] Patients evaluable at a cycle: number of patients with total symptom score calculable (i.e. answered all questions) for that cycle. Completion rate is based on number of subjects randomized with non-zero baseline TSS; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_procomp.sas
Version: Final
Data Source: ADSL, ADQS

1.2.2 Rücklaufquoten des EORTC QLQ-C30 je Erhebungszeitpunkt

Table 14.2.6.1
EORTC QLQ-C30: Compliance Rate by Cycle
HRQoL Evaluable Population

	Fedratinib (N=105)	BAT (N=50)
Baseline		
Patients with questionnaires expected [a]	105 (100.0)	50 (100.0)
Patients with questionnaires completed (completion rate) [b]	105 (100.0)	50 (100.0)
Patients with questionnaires completed (compliance rate) [b]	105 (100.0)	50 (100.0)
Cycle 2 Day 1		
Patients with questionnaires expected [a]	104 (99.0)	50 (100.0)
Patients with questionnaires completed (completion rate) [b]	94 (89.5)	39 (78.0)
Patients with questionnaires completed (compliance rate) [b]	94 (90.4)	39 (78.0)
Cycle 3 Day 1		
Patients with questionnaires expected [a]	103 (98.1)	50 (100.0)
Patients with questionnaires completed (completion rate) [b]	89 (84.8)	46 (92.0)
Patients with questionnaires completed (compliance rate) [b]	89 (86.4)	46 (92.0)
Cycle 4 Day 1		
Patients with questionnaires expected [a]	94 (89.5)	50 (100.0)
Patients with questionnaires completed (completion rate) [b]	85 (81.0)	40 (80.0)
Patients with questionnaires completed (compliance rate) [b]	85 (90.4)	40 (80.0)

Note: EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life C30.
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on HRQoL-evaluable population.
[b] Patients with questionnaires completed at a cycle: number of patients answered assessment at the cycle. Completion rate is based on HRQoL-evaluable population, compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_eortc30.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.6.1
EORTC QLQ-C30: Compliance Rate by Cycle
HRQoL Evaluable Population

	Fedratinib (N=105)	BAT (N=50)
Cycle 5 Day 1		
Patients with questionnaires expected [a]	89 (84.8)	47 (94.0)
Patients with questionnaires completed (completion rate) [b]	79 (75.2)	41 (82.0)
Patients with questionnaires completed (compliance rate) [b]	79 (88.8)	41 (87.2)
Cycle 6 Day 1		
Patients with questionnaires expected [a]	84 (80.0)	46 (92.0)
Patients with questionnaires completed (completion rate) [b]	76 (72.4)	41 (82.0)
Patients with questionnaires completed (compliance rate) [b]	76 (90.5)	41 (89.1)
Cycle 7 Day 1		
Patients with questionnaires expected [a]	78 (74.3)	26 (52.0)
Patients with questionnaires completed (completion rate) [b]	69 (65.7)	21 (42.0)
Patients with questionnaires completed (compliance rate) [b]	69 (88.5)	21 (80.8)
Cycle 8 Day 1		
Patients with questionnaires expected [a]	74 (70.5)	8 (16.0)
Patients with questionnaires completed (completion rate) [b]	68 (64.8)	7 (14.0)
Patients with questionnaires completed (compliance rate) [b]	68 (91.9)	7 (87.5)

Note: EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life C30.
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on HRQoL-evaluable population.
[b] Patients with questionnaires completed at a cycle: number of patients answered assessment at the cycle. Completion rate is based on HRQoL-evaluable population, compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_eortc30.sas
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Data Source: ADSL, ADQS

Table 14.2.6.1
EORTC QLQ-C30: Compliance Rate by Cycle
HRQoL Evaluable Population

	Fedratinib (N=105)	BAT (N=50)
Cycle 9 Day 1		
Patients with questionnaires expected [a]	73 (69.5)	6 (12.0)
Patients with questionnaires completed (completion rate) [b]	69 (65.7)	5 (10.0)
Patients with questionnaires completed (compliance rate) [b]	69 (94.5)	5 (83.3)
Cycle 10 Day 1		
Patients with questionnaires expected [a]	67 (63.8)	6 (12.0)
Patients with questionnaires completed (completion rate) [b]	59 (56.2)	6 (12.0)
Patients with questionnaires completed (compliance rate) [b]	59 (88.1)	6 (100.0)
Cycle 11 Day 1		
Patients with questionnaires expected [a]	62 (59.0)	6 (12.0)
Patients with questionnaires completed (completion rate) [b]	55 (52.4)	6 (12.0)
Patients with questionnaires completed (compliance rate) [b]	55 (88.7)	6 (100.0)
Cycle 12 Day 1		
Patients with questionnaires expected [a]	59 (56.2)	6 (12.0)
Patients with questionnaires completed (completion rate) [b]	52 (49.5)	6 (12.0)
Patients with questionnaires completed (compliance rate) [b]	52 (88.1)	6 (100.0)

Note: EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life C30.
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on HRQoL-evaluable population.
[b] Patients with questionnaires completed at a cycle: number of patients answered assessment at the cycle. Completion rate is based on HRQoL-evaluable population, compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_eortc30.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.6.1
EORTC QLQ-C30: Compliance Rate by Cycle
HRQoL Evaluable Population

	Fedratinib (N=105)	BAT (N=50)
Cycle 13 Day 1		
Patients with questionnaires expected [a]	58 (55.2)	5 (10.0)
Patients with questionnaires completed (completion rate) [b]	51 (48.6)	5 (10.0)
Patients with questionnaires completed (compliance rate) [b]	51 (87.9)	5 (100.0)
Cycle 14 Day 1		
Patients with questionnaires expected [a]	52 (49.5)	4 (8.0)
Patients with questionnaires completed (completion rate) [b]	47 (44.8)	3 (6.0)
Patients with questionnaires completed (compliance rate) [b]	47 (90.4)	3 (75.0)
Cycle 15 Day 1		
Patients with questionnaires expected [a]	51 (48.6)	4 (8.0)
Patients with questionnaires completed (completion rate) [b]	47 (44.8)	3 (6.0)
Patients with questionnaires completed (compliance rate) [b]	47 (92.2)	3 (75.0)
Cycle 16 Day 1		
Patients with questionnaires expected [a]	43 (41.0)	4 (8.0)
Patients with questionnaires completed (completion rate) [b]	36 (34.3)	4 (8.0)
Patients with questionnaires completed (compliance rate) [b]	36 (83.7)	4 (100.0)

Note: EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life C30.
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on HRQoL-evaluable population.
[b] Patients with questionnaires completed at a cycle: number of patients answered assessment at the cycle. Completion rate is based on HRQoL-evaluable population, compliance rate is based on number of subjects with questionnaires expected for that cycle.

Table 14.2.6.1
EORTC QLQ-C30: Compliance Rate by Cycle
HRQoL Evaluable Population

	Fedratinib (N=105)	BAT (N=50)
Cycle 17 Day 1		
Patients with questionnaires expected [a]	36 (34.3)	4 (8.0)
Patients with questionnaires completed (completion rate) [b]	30 (28.6)	4 (8.0)
Patients with questionnaires completed (compliance rate) [b]	30 (83.3)	4 (100.0)
Cycle 18 Day 1		
Patients with questionnaires expected [a]	34 (32.4)	3 (6.0)
Patients with questionnaires completed (completion rate) [b]	33 (31.4)	3 (6.0)
Patients with questionnaires completed (compliance rate) [b]	33 (97.1)	3 (100.0)
Cycle 19 Day 1		
Patients with questionnaires expected [a]	33 (31.4)	2 (4.0)
Patients with questionnaires completed (completion rate) [b]	31 (29.5)	2 (4.0)
Patients with questionnaires completed (compliance rate) [b]	31 (93.9)	2 (100.0)
Cycle 20 Day 1		
Patients with questionnaires expected [a]	29 (27.6)	1 (2.0)
Patients with questionnaires completed (completion rate) [b]	27 (25.7)	1 (2.0)
Patients with questionnaires completed (compliance rate) [b]	27 (93.1)	1 (100.0)

Note: EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life C30.
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on HRQoL-evaluable population.
[b] Patients with questionnaires completed at a cycle: number of patients answered assessment at the cycle. Completion rate is based on HRQoL-evaluable population, compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_eortc30.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.6.1
EORTC QLQ-C30: Compliance Rate by Cycle
HRQoL Evaluable Population

	Fedratinib (N=105)	BAT (N=50)
Cycle 21 Day 1		
Patients with questionnaires expected [a]	27 (25.7)	1 (2.0)
Patients with questionnaires completed (completion rate) [b]	25 (23.8)	1 (2.0)
Patients with questionnaires completed (compliance rate) [b]	25 (92.6)	1 (100.0)
Cycle 22 Day 1		
Patients with questionnaires expected [a]	24 (22.9)	1 (2.0)
Patients with questionnaires completed (completion rate) [b]	22 (21.0)	1 (2.0)
Patients with questionnaires completed (compliance rate) [b]	22 (91.7)	1 (100.0)
Cycle 23 Day 1		
Patients with questionnaires expected [a]	22 (21.0)	1 (2.0)
Patients with questionnaires completed (completion rate) [b]	17 (16.2)	1 (2.0)
Patients with questionnaires completed (compliance rate) [b]	17 (77.3)	1 (100.0)
Cycle 24 Day 1		
Patients with questionnaires expected [a]	21 (20.0)	0
Patients with questionnaires completed (completion rate) [b]	15 (14.3)	0
Patients with questionnaires completed (compliance rate) [b]	15 (71.4)	0

Note: EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life C30.
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on HRQoL-evaluable population.
[b] Patients with questionnaires completed at a cycle: number of patients answered assessment at the cycle. Completion rate is based on HRQoL-evaluable population, compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_eortc30.sas
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Data Source: ADSL, ADQS

Table 14.2.6.1
EORTC QLQ-C30: Compliance Rate by Cycle
HRQoL Evaluable Population

	Fedratinib (N=105)	BAT (N=50)
Cycle 25 Day 1		
Patients with questionnaires expected [a]	16 (15.2)	0
Patients with questionnaires completed (completion rate) [b]	15 (14.3)	0
Patients with questionnaires completed (compliance rate) [b]	15 (93.8)	0
Cycle 26 Day 1		
Patients with questionnaires expected [a]	15 (14.3)	0
Patients with questionnaires completed (completion rate) [b]	14 (13.3)	0
Patients with questionnaires completed (compliance rate) [b]	14 (93.3)	0
Cycle 27 Day 1		
Patients with questionnaires expected [a]	14 (13.3)	0
Patients with questionnaires completed (completion rate) [b]	11 (10.5)	0
Patients with questionnaires completed (compliance rate) [b]	11 (78.6)	0
Cycle 28 Day 1		
Patients with questionnaires expected [a]	14 (13.3)	0
Patients with questionnaires completed (completion rate) [b]	13 (12.4)	0
Patients with questionnaires completed (compliance rate) [b]	13 (92.9)	0

Note: EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life C30.
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on HRQoL-evaluable population.
[b] Patients with questionnaires completed at a cycle: number of patients answered assessment at the cycle. Completion rate is based on HRQoL-evaluable population, compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_eortc30.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.6.1
EORTC QLQ-C30: Compliance Rate by Cycle
HRQoL Evaluable Population

	Fedratinib (N=105)	BAT (N=50)
Cycle 29 Day 1		
Patients with questionnaires expected [a]	12 (11.4)	0
Patients with questionnaires completed (completion rate) [b]	11 (10.5)	0
Patients with questionnaires completed (compliance rate) [b]	11 (91.7)	0
Cycle 30 Day 1		
Patients with questionnaires expected [a]	10 (9.5)	0
Patients with questionnaires completed (completion rate) [b]	9 (8.6)	0
Patients with questionnaires completed (compliance rate) [b]	9 (90.0)	0
Cycle 31 Day 1		
Patients with questionnaires expected [a]	8 (7.6)	0
Patients with questionnaires completed (completion rate) [b]	7 (6.7)	0
Patients with questionnaires completed (compliance rate) [b]	7 (87.5)	0
Cycle 32 Day 1		
Patients with questionnaires expected [a]	6 (5.7)	0
Patients with questionnaires completed (completion rate) [b]	6 (5.7)	0
Patients with questionnaires completed (compliance rate) [b]	6 (100.0)	0

Note: EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life C30.
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on HRQoL-evaluable population.
[b] Patients with questionnaires completed at a cycle: number of patients answered assessment at the cycle. Completion rate is based on HRQoL-evaluable population, compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_eortc30.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.6.1
EORTC QLQ-C30: Compliance Rate by Cycle
HRQoL Evaluable Population

	Fedratinib (N=105)	BAT (N=50)
Cycle 33 Day 1		
Patients with questionnaires expected [a]	5 (4.8)	0
Patients with questionnaires completed (completion rate) [b]	5 (4.8)	0
Patients with questionnaires completed (compliance rate) [b]	5 (100.0)	0
Cycle 34 Day 1		
Patients with questionnaires expected [a]	5 (4.8)	0
Patients with questionnaires completed (completion rate) [b]	5 (4.8)	0
Patients with questionnaires completed (compliance rate) [b]	5 (100.0)	0
Cycle 35 Day 1		
Patients with questionnaires expected [a]	5 (4.8)	0
Patients with questionnaires completed (completion rate) [b]	5 (4.8)	0
Patients with questionnaires completed (compliance rate) [b]	5 (100.0)	0
Cycle 36 Day 1		
Patients with questionnaires expected [a]	4 (3.8)	0
Patients with questionnaires completed (completion rate) [b]	4 (3.8)	0
Patients with questionnaires completed (compliance rate) [b]	4 (100.0)	0

Note: EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life C30.
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on HRQoL-evaluable population.
[b] Patients with questionnaires completed at a cycle: number of patients answered assessment at the cycle. Completion rate is based on HRQoL-evaluable population, compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_eortc30.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.6.1
EORTC QLQ-C30: Compliance Rate by Cycle
HRQoL Evaluable Population

	Fedratinib (N=105)	BAT (N=50)
Cycle 37 Day 1		
Patients with questionnaires expected [a]	2 (1.9)	0
Patients with questionnaires completed (completion rate) [b]	2 (1.9)	0
Patients with questionnaires completed (compliance rate) [b]	2 (100.0)	0
Cycle 38 Day 1		
Patients with questionnaires expected [a]	1 (1.0)	0
Patients with questionnaires completed (completion rate) [b]	1 (1.0)	0
Patients with questionnaires completed (compliance rate) [b]	1 (100.0)	0
End Of Treatment		
Patients with questionnaires expected [a]	66 (62.9)	30 (60.0)
Patients with questionnaires completed (completion rate) [b]	40 (38.1)	5 (10.0)
Patients with questionnaires completed (compliance rate) [b]	40 (60.6)	5 (16.7)
30-Day Follow-up		
Patients with questionnaires expected [a]	66 (62.9)	30 (60.0)
Patients with questionnaires completed (completion rate) [b]	7 (6.7)	0
Patients with questionnaires completed (compliance rate) [b]	7 (10.6)	0

Note: EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life C30.
[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on HRQoL-evaluable population.
[b] Patients with questionnaires completed at a cycle: number of patients answered assessment at the cycle. Completion rate is based on HRQoL-evaluable population, compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_eortc30.sas
Version: Final
Data Source: ADSL, ADQS

1.2.3 Rücklaufquoten des EQ-5D-5L je Erhebungszeitpunkt

Table 14.2.7.1
EQ-5D-5L: Compliance Rate by Cycle
HRQoL Evaluable Population

	Fedratinib (N=103)	BAT (N=52)
Baseline		
Patients with questionnaires expected [a]	103 (100.0)	52 (100.0)
Patients with questionnaires completed (completion rate) [b]	103 (100.0)	52 (100.0)
Patients with questionnaires completed (compliance rate) [b]	103 (100.0)	52 (100.0)
Cycle 2 Day 1		
Patients with questionnaires expected [a]	102 (99.0)	52 (100.0)
Patients with questionnaires completed (completion rate) [b]	94 (91.3)	41 (78.8)
Patients with questionnaires completed (compliance rate) [b]	94 (92.2)	41 (78.8)
Cycle 3 Day 1		
Patients with questionnaires expected [a]	101 (98.1)	52 (100.0)
Patients with questionnaires completed (completion rate) [b]	88 (85.4)	48 (92.3)
Patients with questionnaires completed (compliance rate) [b]	88 (87.1)	48 (92.3)
Cycle 4 Day 1		
Patients with questionnaires expected [a]	93 (90.3)	52 (100.0)
Patients with questionnaires completed (completion rate) [b]	84 (81.6)	43 (82.7)
Patients with questionnaires completed (compliance rate) [b]	84 (90.3)	43 (82.7)

[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on HRQoL-evaluable population.
[b] Patients with questionnaires completed at a cycle: number of patients answered assessment at the cycle. Completion rate is based on HRQoL-evaluable population; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_eq5d.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.7.1
EQ-5D-5L: Compliance Rate by Cycle
HRQoL Evaluable Population

	Fedratinib (N=103)	BAT (N=52)
Cycle 5 Day 1		
Patients with questionnaires expected [a]	88 (85.4)	49 (94.2)
Patients with questionnaires completed (completion rate) [b]	78 (75.7)	43 (82.7)
Patients with questionnaires completed (compliance rate) [b]	78 (88.6)	43 (87.8)
Cycle 6 Day 1		
Patients with questionnaires expected [a]	83 (80.6)	48 (92.3)
Patients with questionnaires completed (completion rate) [b]	75 (72.8)	42 (80.8)
Patients with questionnaires completed (compliance rate) [b]	75 (90.4)	42 (87.5)
Cycle 7 Day 1		
Patients with questionnaires expected [a]	77 (74.8)	27 (51.9)
Patients with questionnaires completed (completion rate) [b]	69 (67.0)	22 (42.3)
Patients with questionnaires completed (compliance rate) [b]	69 (89.6)	22 (81.5)
Cycle 8 Day 1		
Patients with questionnaires expected [a]	73 (70.9)	8 (15.4)
Patients with questionnaires completed (completion rate) [b]	68 (66.0)	7 (13.5)
Patients with questionnaires completed (compliance rate) [b]	68 (93.2)	7 (87.5)

[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on HRQoL-evaluable population.
[b] Patients with questionnaires completed at a cycle: number of patients answered assessment at the cycle. Completion rate is based on HRQoL-evaluable population; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_eq5d.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.7.1
EQ-5D-5L: Compliance Rate by Cycle
HRQoL Evaluable Population

	Fedratinib (N=103)	BAT (N=52)
Cycle 9 Day 1		
Patients with questionnaires expected [a]	72 (69.9)	6 (11.5)
Patients with questionnaires completed (completion rate) [b]	68 (66.0)	5 (9.6)
Patients with questionnaires completed (compliance rate) [b]	68 (94.4)	5 (83.3)
Cycle 10 Day 1		
Patients with questionnaires expected [a]	66 (64.1)	6 (11.5)
Patients with questionnaires completed (completion rate) [b]	59 (57.3)	6 (11.5)
Patients with questionnaires completed (compliance rate) [b]	59 (89.4)	6 (100.0)
Cycle 11 Day 1		
Patients with questionnaires expected [a]	61 (59.2)	6 (11.5)
Patients with questionnaires completed (completion rate) [b]	55 (53.4)	6 (11.5)
Patients with questionnaires completed (compliance rate) [b]	55 (90.2)	6 (100.0)
Cycle 12 Day 1		
Patients with questionnaires expected [a]	58 (56.3)	6 (11.5)
Patients with questionnaires completed (completion rate) [b]	52 (50.5)	6 (11.5)
Patients with questionnaires completed (compliance rate) [b]	52 (89.7)	6 (100.0)

[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on HRQoL-evaluable population.
[b] Patients with questionnaires completed at a cycle: number of patients answered assessment at the cycle. Completion rate is based on HRQoL-evaluable population; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_eq5d.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.7.1
EQ-5D-5L: Compliance Rate by Cycle
HRQoL Evaluable Population

	Fedratinib (N=103)	BAT (N=52)
Cycle 13 Day 1		
Patients with questionnaires expected [a]	57 (55.3)	5 (9.6)
Patients with questionnaires completed (completion rate) [b]	50 (48.5)	5 (9.6)
Patients with questionnaires completed (compliance rate) [b]	50 (87.7)	5 (100.0)
Cycle 14 Day 1		
Patients with questionnaires expected [a]	51 (49.5)	4 (7.7)
Patients with questionnaires completed (completion rate) [b]	47 (45.6)	3 (5.8)
Patients with questionnaires completed (compliance rate) [b]	47 (92.2)	3 (75.0)
Cycle 15 Day 1		
Patients with questionnaires expected [a]	50 (48.5)	4 (7.7)
Patients with questionnaires completed (completion rate) [b]	47 (45.6)	3 (5.8)
Patients with questionnaires completed (compliance rate) [b]	47 (94.0)	3 (75.0)
Cycle 16 Day 1		
Patients with questionnaires expected [a]	42 (40.8)	4 (7.7)
Patients with questionnaires completed (completion rate) [b]	35 (34.0)	4 (7.7)
Patients with questionnaires completed (compliance rate) [b]	35 (83.3)	4 (100.0)

[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on HRQoL-evaluable population.
[b] Patients with questionnaires completed at a cycle: number of patients answered assessment at the cycle. Completion rate is based on HRQoL-evaluable population; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_eq5d.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.7.1
EQ-5D-5L: Compliance Rate by Cycle
HRQoL Evaluable Population

	Fedratinib (N=103)	BAT (N=52)
Cycle 17 Day 1		
Patients with questionnaires expected [a]	36 (35.0)	4 (7.7)
Patients with questionnaires completed (completion rate) [b]	30 (29.1)	4 (7.7)
Patients with questionnaires completed (compliance rate) [b]	30 (83.3)	4 (100.0)
Cycle 18 Day 1		
Patients with questionnaires expected [a]	34 (33.0)	3 (5.8)
Patients with questionnaires completed (completion rate) [b]	33 (32.0)	3 (5.8)
Patients with questionnaires completed (compliance rate) [b]	33 (97.1)	3 (100.0)
Cycle 19 Day 1		
Patients with questionnaires expected [a]	33 (32.0)	2 (3.8)
Patients with questionnaires completed (completion rate) [b]	31 (30.1)	2 (3.8)
Patients with questionnaires completed (compliance rate) [b]	31 (93.9)	2 (100.0)
Cycle 20 Day 1		
Patients with questionnaires expected [a]	29 (28.2)	1 (1.9)
Patients with questionnaires completed (completion rate) [b]	27 (26.2)	1 (1.9)
Patients with questionnaires completed (compliance rate) [b]	27 (93.1)	1 (100.0)

[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on HRQoL-evaluable population.
[b] Patients with questionnaires completed at a cycle: number of patients answered assessment at the cycle. Completion rate is based on HRQoL-evaluable population; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_eq5d.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.7.1
EQ-5D-5L: Compliance Rate by Cycle
HRQoL Evaluable Population

	Fedratinib (N=103)	BAT (N=52)
Cycle 21 Day 1		
Patients with questionnaires expected [a]	27 (26.2)	1 (1.9)
Patients with questionnaires completed (completion rate) [b]	26 (25.2)	1 (1.9)
Patients with questionnaires completed (compliance rate) [b]	26 (96.3)	1 (100.0)
Cycle 22 Day 1		
Patients with questionnaires expected [a]	24 (23.3)	1 (1.9)
Patients with questionnaires completed (completion rate) [b]	22 (21.4)	1 (1.9)
Patients with questionnaires completed (compliance rate) [b]	22 (91.7)	1 (100.0)
Cycle 23 Day 1		
Patients with questionnaires expected [a]	22 (21.4)	1 (1.9)
Patients with questionnaires completed (completion rate) [b]	17 (16.5)	1 (1.9)
Patients with questionnaires completed (compliance rate) [b]	17 (77.3)	1 (100.0)
Cycle 24 Day 1		
Patients with questionnaires expected [a]	21 (20.4)	0
Patients with questionnaires completed (completion rate) [b]	15 (14.6)	0
Patients with questionnaires completed (compliance rate) [b]	15 (71.4)	0

[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on HRQoL-evaluable population.
[b] Patients with questionnaires completed at a cycle: number of patients answered assessment at the cycle. Completion rate is based on HRQoL-evaluable population; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_eq5d.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.7.1
EQ-5D-5L: Compliance Rate by Cycle
HRQoL Evaluable Population

	Fedratinib (N=103)	BAT (N=52)
Cycle 25 Day 1		
Patients with questionnaires expected [a]	16 (15.5)	0
Patients with questionnaires completed (completion rate) [b]	16 (15.5)	0
Patients with questionnaires completed (compliance rate) [b]	16 (100.0)	0
Cycle 26 Day 1		
Patients with questionnaires expected [a]	15 (14.6)	0
Patients with questionnaires completed (completion rate) [b]	14 (13.6)	0
Patients with questionnaires completed (compliance rate) [b]	14 (93.3)	0
Cycle 27 Day 1		
Patients with questionnaires expected [a]	14 (13.6)	0
Patients with questionnaires completed (completion rate) [b]	12 (11.7)	0
Patients with questionnaires completed (compliance rate) [b]	12 (85.7)	0
Cycle 28 Day 1		
Patients with questionnaires expected [a]	14 (13.6)	0
Patients with questionnaires completed (completion rate) [b]	13 (12.6)	0
Patients with questionnaires completed (compliance rate) [b]	13 (92.9)	0

[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on HRQoL-evaluable population.
[b] Patients with questionnaires completed at a cycle: number of patients answered assessment at the cycle. Completion rate is based on HRQoL-evaluable population; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_eq5d.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.7.1
EQ-5D-5L: Compliance Rate by Cycle
HRQoL Evaluable Population

	Fedratinib (N=103)	BAT (N=52)
Cycle 29 Day 1		
Patients with questionnaires expected [a]	12 (11.7)	0
Patients with questionnaires completed (completion rate) [b]	11 (10.7)	0
Patients with questionnaires completed (compliance rate) [b]	11 (91.7)	0
Cycle 30 Day 1		
Patients with questionnaires expected [a]	10 (9.7)	0
Patients with questionnaires completed (completion rate) [b]	9 (8.7)	0
Patients with questionnaires completed (compliance rate) [b]	9 (90.0)	0
Cycle 31 Day 1		
Patients with questionnaires expected [a]	8 (7.8)	0
Patients with questionnaires completed (completion rate) [b]	7 (6.8)	0
Patients with questionnaires completed (compliance rate) [b]	7 (87.5)	0
Cycle 32 Day 1		
Patients with questionnaires expected [a]	6 (5.8)	0
Patients with questionnaires completed (completion rate) [b]	6 (5.8)	0
Patients with questionnaires completed (compliance rate) [b]	6 (100.0)	0

[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on HRQoL-evaluable population.
[b] Patients with questionnaires completed at a cycle: number of patients answered assessment at the cycle. Completion rate is based on HRQoL-evaluable population; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_eq5d.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.7.1
EQ-5D-5L: Compliance Rate by Cycle
HRQoL Evaluable Population

	Fedratinib (N=103)	BAT (N=52)
Cycle 33 Day 1		
Patients with questionnaires expected [a]	5 (4.9)	0
Patients with questionnaires completed (completion rate) [b]	5 (4.9)	0
Patients with questionnaires completed (compliance rate) [b]	5 (100.0)	0
Cycle 34 Day 1		
Patients with questionnaires expected [a]	5 (4.9)	0
Patients with questionnaires completed (completion rate) [b]	5 (4.9)	0
Patients with questionnaires completed (compliance rate) [b]	5 (100.0)	0
Cycle 35 Day 1		
Patients with questionnaires expected [a]	5 (4.9)	0
Patients with questionnaires completed (completion rate) [b]	5 (4.9)	0
Patients with questionnaires completed (compliance rate) [b]	5 (100.0)	0
Cycle 36 Day 1		
Patients with questionnaires expected [a]	4 (3.9)	0
Patients with questionnaires completed (completion rate) [b]	4 (3.9)	0
Patients with questionnaires completed (compliance rate) [b]	4 (100.0)	0

[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on HRQoL-evaluable population.
[b] Patients with questionnaires completed at a cycle: number of patients answered assessment at the cycle. Completion rate is based on HRQoL-evaluable population; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_eq5d.sas
Version: Final
Data Source: ADSL, ADQS

Table 14.2.7.1
EQ-5D-5L: Compliance Rate by Cycle
HRQoL Evaluable Population

	Fedratinib (N=103)	BAT (N=52)
Cycle 37 Day 1		
Patients with questionnaires expected [a]	2 (1.9)	0
Patients with questionnaires completed (completion rate) [b]	2 (1.9)	0
Patients with questionnaires completed (compliance rate) [b]	2 (100.0)	0
Cycle 38 Day 1		
Patients with questionnaires expected [a]	1 (1.0)	0
Patients with questionnaires completed (completion rate) [b]	1 (1.0)	0
Patients with questionnaires completed (compliance rate) [b]	1 (100.0)	0
End Of Treatment		
Patients with questionnaires expected [a]	64 (62.1)	31 (59.6)
Patients with questionnaires completed (completion rate) [b]	39 (37.9)	6 (11.5)
Patients with questionnaires completed (compliance rate) [b]	39 (60.9)	6 (19.4)
30-Day Follow-up		
Patients with questionnaires expected [a]	64 (62.1)	31 (59.6)
Patients with questionnaires completed (completion rate) [b]	7 (6.8)	0
Patients with questionnaires completed (compliance rate) [b]	7 (10.9)	0

[a] Patients with questionnaires expected at a cycle: number of patients that are on-treatment at the cycle. Percent is based on HRQoL-evaluable population.
[b] Patients with questionnaires completed at a cycle: number of patients answered assessment at the cycle. Completion rate is based on HRQoL-evaluable population; compliance rate is based on number of subjects with questionnaires expected for that cycle.

Program Name: t_eq5d.sas
Version: Final
Data Source: ADSL, ADQS

1.3 Deskriptive Darstellung der Gesamtraten der UE nach SOC und PT

1.3.1 Jegliche UE nach SOC und PT

Table 14.3.1.3.1
Treatment-emergent Adverse Events (TEAEs) by Treatment, System Organ Class and Preferred Term - First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Subjects With at Least One TEAE	132 (98.5)	65 (97.0)
Gastrointestinal disorders	95 (70.9)	32 (47.8)
Diarrhoea	56 (41.8)	2 (3.0)
Nausea	49 (36.6)	10 (14.9)
Constipation	28 (20.9)	6 (9.0)
Vomiting	21 (15.7)	3 (4.5)
Abdominal pain	12 (9.0)	9 (13.4)
Abdominal distension	5 (3.7)	3 (4.5)
Abdominal pain upper	5 (3.7)	5 (7.5)
Abdominal discomfort	4 (3.0)	3 (4.5)
Dyspepsia	4 (3.0)	1 (1.5)
Ascites	3 (2.2)	1 (1.5)
Flatulence	2 (1.5)	1 (1.5)
Gastrointestinal haemorrhage	2 (1.5)	0
Melaena	2 (1.5)	0
Toothache	2 (1.5)	1 (1.5)
Aphthous ulcer	1 (0.7)	1 (1.5)
Dry mouth	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_teae_f6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.1.3.1
Treatment-emergent Adverse Events (TEAEs) by Treatment, System Organ Class and Preferred Term - First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Gastrointestinal disorders		
Duodenal ulcer	1 (0.7)	0
Gastric ulcer	1 (0.7)	0
Gingival pain	1 (0.7)	0
Haemorrhoids	1 (0.7)	0
Mouth ulceration	1 (0.7)	0
Rectal haemorrhage	1 (0.7)	0
Rectal tenesmus	1 (0.7)	0
Subileus	1 (0.7)	0
Upper gastrointestinal haemorrhage	1 (0.7)	0
Varices oesophageal	1 (0.7)	0
Diverticulum	0	1 (1.5)
Diverticulum intestinal	0	1 (1.5)
Gastritis	0	1 (1.5)
Gingival bleeding	0	1 (1.5)
Blood and lymphatic system disorders	69 (51.5)	34 (50.7)
Anaemia	52 (38.8)	23 (34.3)
Thrombocytopenia	36 (26.9)	11 (16.4)
Neutropenia	6 (4.5)	2 (3.0)

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_teae_f6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.1.3.1
Treatment-emergent Adverse Events (TEAEs) by Treatment, System Organ Class and Preferred Term – First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Blood and lymphatic system disorders		
Leukocytosis	3 (2.2)	4 (6.0)
Leukopenia	2 (1.5)	1 (1.5)
Lymphopenia	1 (0.7)	1 (1.5)
Splenic infarction	1 (0.7)	1 (1.5)
Increased tendency to bruise	0	1 (1.5)
Lymphadenopathy	0	2 (3.0)
Spontaneous haematoma	0	1 (1.5)
General disorders and administration site conditions	60 (44.8)	29 (43.3)
Asthenia	23 (17.2)	15 (22.4)
Oedema peripheral	20 (14.9)	7 (10.4)
Pyrexia	10 (7.5)	7 (10.4)
Fatigue	7 (5.2)	8 (11.9)
General physical health deterioration	7 (5.2)	2 (3.0)
Oedema	3 (2.2)	0
Peripheral swelling	2 (1.5)	1 (1.5)
Illness	1 (0.7)	0
Multiple organ dysfunction syndrome	1 (0.7)	0
Pain	1 (0.7)	1 (1.5)

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_teae_f6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.1.3.1
Treatment-emergent Adverse Events (TEAEs) by Treatment, System Organ Class and Preferred Term – First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
General disorders and administration site conditions		
Discomfort	0	1 (1.5)
Investigations	53 (39.6)	9 (13.4)
Vitamin B1 decreased	14 (10.4)	1 (1.5)
Blood creatinine increased	13 (9.7)	1 (1.5)
Alanine aminotransferase increased	11 (8.2)	1 (1.5)
Glomerular filtration rate decreased	11 (8.2)	1 (1.5)
Aspartate aminotransferase increased	7 (5.2)	0
Blood alkaline phosphatase increased	5 (3.7)	0
Gamma-glutamyltransferase increased	5 (3.7)	0
Weight decreased	5 (3.7)	0
Blood lactate dehydrogenase increased	2 (1.5)	0
Cardiac murmur	2 (1.5)	0
Ejection fraction decreased	2 (1.5)	0
Haemoglobin decreased	2 (1.5)	0
Blast cell count increased	1 (0.7)	0
Blood albumin decreased	1 (0.7)	0
Blood thyroid stimulating hormone increased	1 (0.7)	1 (1.5)
Blood urea increased	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_teae_f6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.1.3.1
Treatment-emergent Adverse Events (TEAEs) by Treatment, System Organ Class and Preferred Term – First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Investigations		
Blood uric acid increased	1 (0.7)	1 (1.5)
C-reactive protein increased	1 (0.7)	1 (1.5)
Creatinine renal clearance decreased	1 (0.7)	0
Glomerular filtration rate increased	1 (0.7)	0
Lipase increased	1 (0.7)	0
Oxygen saturation decreased	1 (0.7)	0
Protein total increased	1 (0.7)	0
Prothrombin time prolonged	1 (0.7)	0
SARS-CoV-2 test positive	1 (0.7)	1 (1.5)
Blood folate decreased	0	1 (1.5)
Blood triglycerides increased	0	1 (1.5)
Metabolism and nutrition disorders	51 (38.1)	13 (19.4)
Decreased appetite	12 (9.0)	8 (11.9)
Hyperkalaemia	12 (9.0)	0
Vitamin B1 deficiency	8 (6.0)	1 (1.5)
Hyperuricaemia	6 (4.5)	1 (1.5)
Hypokalaemia	5 (3.7)	2 (3.0)
Gout	3 (2.2)	3 (4.5)

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_teae_f6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.1.3.1
Treatment-emergent Adverse Events (TEAEs) by Treatment, System Organ Class and Preferred Term – First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Metabolism and nutrition disorders		
Hypocalcaemia	3 (2.2)	0
Hyponatraemia	3 (2.2)	0
Hyperferritinaemia	2 (1.5)	0
Hypertriglyceridaemia	2 (1.5)	1 (1.5)
Hypoalbuminaemia	2 (1.5)	0
Cachexia	1 (0.7)	1 (1.5)
Dehydration	1 (0.7)	0
Hypercreatininaemia	1 (0.7)	0
Hyperglycaemia	1 (0.7)	0
Hyperphosphataemia	1 (0.7)	0
Hypervolaemia	1 (0.7)	0
Hypomagnesaemia	1 (0.7)	0
Metabolic acidosis	1 (0.7)	0
Vitamin D deficiency	1 (0.7)	0
Folate deficiency	0	1 (1.5)
Haemochromatosis	0	1 (1.5)
Hypercalcaemia	0	1 (1.5)

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Table 14.3.1.3.1
Treatment-emergent Adverse Events (TEAEs) by Treatment, System Organ Class and Preferred Term – First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Musculoskeletal and connective tissue disorders	38 (28.4)	16 (23.9)
Bone pain	9 (6.7)	4 (6.0)
Muscle spasms	8 (6.0)	4 (6.0)
Back pain	7 (5.2)	2 (3.0)
Arthralgia	5 (3.7)	3 (4.5)
Pain in extremity	5 (3.7)	0
Bursitis	2 (1.5)	0
Arthritis	1 (0.7)	0
Groin pain	1 (0.7)	0
Muscle contracture	1 (0.7)	0
Myalgia	1 (0.7)	1 (1.5)
Myositis	1 (0.7)	0
Spinal pain	1 (0.7)	1 (1.5)
Coccydynia	0	1 (1.5)
Joint swelling	0	1 (1.5)
Musculoskeletal chest pain	0	2 (3.0)
Osteochondrosis	0	1 (1.5)
Osteolysis	0	1 (1.5)

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_teae_f6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.1.3.1
Treatment-emergent Adverse Events (TEAEs) by Treatment, System Organ Class and Preferred Term – First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Infections and infestations	35 (26.1)	26 (38.8)
COVID-19	8 (6.0)	5 (7.5)
Urinary tract infection	5 (3.7)	4 (6.0)
Pneumonia	3 (2.2)	3 (4.5)
Bronchitis	2 (1.5)	1 (1.5)
Herpes simplex	2 (1.5)	1 (1.5)
Nasopharyngitis	2 (1.5)	2 (3.0)
Respiratory tract infection	2 (1.5)	1 (1.5)
Tooth infection	2 (1.5)	0
Urinary tract infection bacterial	2 (1.5)	0
Bacteraemia	1 (0.7)	0
Bacteriuria	1 (0.7)	0
Capnocytophaga infection	1 (0.7)	0
Cellulitis	1 (0.7)	0
Conjunctivitis bacterial	1 (0.7)	0
Cystitis	1 (0.7)	1 (1.5)
Folliculitis	1 (0.7)	0
Infection	1 (0.7)	0
Localised infection	1 (0.7)	2 (3.0)
Neutropenic sepsis	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_teae_f6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.1.3.1
Treatment-emergent Adverse Events (TEAEs) by Treatment, System Organ Class and Preferred Term – First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Infections and infestations		
Oral fungal infection	1 (0.7)	0
Pyelonephritis chronic	1 (0.7)	0
Pyuria	1 (0.7)	0
Sepsis	1 (0.7)	0
Septic shock	1 (0.7)	0
Suspected COVID-19	1 (0.7)	1 (1.5)
Tuberculosis	1 (0.7)	0
Upper respiratory tract infection	1 (0.7)	0
Vaginal infection	1 (0.7)	0
Biliary tract infection	0	1 (1.5)
COVID-19 pneumonia	0	1 (1.5)
Cholecystitis infective	0	1 (1.5)
Clostridium difficile colitis	0	1 (1.5)
Conjunctivitis	0	1 (1.5)
Erysipelas	0	1 (1.5)
Gastroenteritis	0	1 (1.5)
Herpes zoster	0	1 (1.5)
Lymph node tuberculosis	0	1 (1.5)
Oral herpes	0	1 (1.5)

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Table 14.3.1.3.1
Treatment-emergent Adverse Events (TEAEs) by Treatment, System Organ Class and Preferred Term – First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Infections and infestations		
Peritonitis	0	1 (1.5)
Viral infection	0	1 (1.5)
Skin and subcutaneous tissue disorders	34 (25.4)	17 (25.4)
Pruritus	13 (9.7)	7 (10.4)
Night sweats	5 (3.7)	7 (10.4)
Hyperhidrosis	4 (3.0)	3 (4.5)
Skin exfoliation	3 (2.2)	0
Erythema	2 (1.5)	2 (3.0)
Hyperkeratosis	2 (1.5)	0
Rash	2 (1.5)	0
Skin lesion	2 (1.5)	0
Acne	1 (0.7)	0
Alopecia	1 (0.7)	1 (1.5)
Ecchymosis	1 (0.7)	0
Eczema	1 (0.7)	0
Nail discolouration	1 (0.7)	0
Photosensitivity reaction	1 (0.7)	0
Psoriasis	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_teae_f6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.1.3.1
Treatment-emergent Adverse Events (TEAEs) by Treatment, System Organ Class and Preferred Term – First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Skin and subcutaneous tissue disorders		
Pyoderma gangrenosum	1 (0.7)	0
Skin ulcer	1 (0.7)	1 (1.5)
Urticaria	1 (0.7)	0
Actinic keratosis	0	1 (1.5)
Petechiae	0	1 (1.5)
Purpura	0	1 (1.5)
Seborrhoeic dermatitis	0	1 (1.5)
Respiratory, thoracic and mediastinal disorders	29 (21.6)	13 (19.4)
Dyspnoea	11 (8.2)	3 (4.5)
Cough	6 (4.5)	2 (3.0)
Epistaxis	6 (4.5)	0
Emphysema	2 (1.5)	1 (1.5)
Hypoxia	2 (1.5)	0
Productive cough	2 (1.5)	1 (1.5)
Acute respiratory failure	1 (0.7)	0
Dry throat	1 (0.7)	0
Organising pneumonia	1 (0.7)	0
Oropharyngeal pain	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_teae_f6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.1.3.1
Treatment-emergent Adverse Events (TEAEs) by Treatment, System Organ Class and Preferred Term – First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Respiratory, thoracic and mediastinal disorders		
Pneumonitis	1 (0.7)	0
Pulmonary congestion	1 (0.7)	0
Rales	1 (0.7)	0
Rhinorrhoea	1 (0.7)	0
Dyspnoea exertional	0	3 (4.5)
Lung infiltration	0	1 (1.5)
Pleural effusion	0	2 (3.0)
Pulmonary hypertension	0	3 (4.5)
Respiratory distress	0	1 (1.5)
Renal and urinary disorders	28 (20.9)	4 (6.0)
Acute kidney injury	9 (6.7)	0
Chronic kidney disease	6 (4.5)	0
Renal impairment	6 (4.5)	0
Renal failure	4 (3.0)	0
Dysuria	1 (0.7)	1 (1.5)
Micturition urgency	1 (0.7)	0
Nephropathy toxic	1 (0.7)	0
Renal colic	1 (0.7)	1 (1.5)

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_teae_f6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.1.3.1
Treatment-emergent Adverse Events (TEAEs) by Treatment, System Organ Class and Preferred Term – First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Renal and urinary disorders		
Pollakiuria	0	1 (1.5)
Renal cyst	0	1 (1.5)
Nervous system disorders	25 (18.7)	12 (17.9)
Headache	9 (6.7)	4 (6.0)
Dizziness	4 (3.0)	1 (1.5)
Dysgeusia	4 (3.0)	0
Peripheral sensory neuropathy	4 (3.0)	1 (1.5)
Paraesthesia	2 (1.5)	0
Amnesia	1 (0.7)	0
Burning sensation	1 (0.7)	0
Hypoaesthesia	1 (0.7)	0
Memory impairment	1 (0.7)	0
Metabolic encephalopathy	1 (0.7)	0
Post herpetic neuralgia	1 (0.7)	0
Sciatica	1 (0.7)	3 (4.5)
Somnolence	1 (0.7)	1 (1.5)
Taste disorder	1 (0.7)	0
Tremor	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Table 14.3.1.3.1
Treatment-emergent Adverse Events (TEAEs) by Treatment, System Organ Class and Preferred Term – First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Nervous system disorders		
Wernicke's encephalopathy	1 (0.7)	0
Carotid arteriosclerosis	0	1 (1.5)
Febrile convulsion	0	1 (1.5)
Presyncope	0	1 (1.5)
Vascular disorders	16 (11.9)	7 (10.4)
Pallor	4 (3.0)	0
Hypertension	3 (2.2)	3 (4.5)
Haematoma	2 (1.5)	2 (3.0)
Angiopathy	1 (0.7)	0
Aortic aneurysm	1 (0.7)	0
Aortic stenosis	1 (0.7)	0
Arteriosclerosis	1 (0.7)	0
Haemorrhage	1 (0.7)	0
Hot flush	1 (0.7)	0
Superficial vein thrombosis	1 (0.7)	0
Thrombosis	1 (0.7)	0
Aortic dissection	0	1 (1.5)
Venous thrombosis limb	0	1 (1.5)

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_teae_f6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.1.3.1
Treatment-emergent Adverse Events (TEAEs) by Treatment, System Organ Class and Preferred Term – First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Psychiatric disorders	15 (11.2)	6 (9.0)
Insomnia	5 (3.7)	4 (6.0)
Sleep disorder	4 (3.0)	1 (1.5)
Confusional state	2 (1.5)	0
Depression	2 (1.5)	1 (1.5)
Anxiety	1 (0.7)	1 (1.5)
Anxiety disorder	1 (0.7)	0
Depressed mood	1 (0.7)	0
Mental disorder	1 (0.7)	0
Mood altered	1 (0.7)	0
Cardiac disorders	13 (9.7)	1 (1.5)
Atrial fibrillation	5 (3.7)	0
Tachycardia	4 (3.0)	0
Cardiac failure	2 (1.5)	1 (1.5)
Cardiac failure congestive	2 (1.5)	0
Cardiomyopathy	1 (0.7)	0
Right ventricular failure	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_teae_f6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.1.3.1
Treatment-emergent Adverse Events (TEAEs) by Treatment, System Organ Class and Preferred Term – First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Cardiac disorders		
Stress cardiomyopathy	1 (0.7)	0
Ventricular tachycardia	1 (0.7)	0
Injury, poisoning and procedural complications	10 (7.5)	4 (6.0)
Fall	4 (3.0)	0
Contusion	3 (2.2)	2 (3.0)
Spinal compression fracture	2 (1.5)	0
Head injury	1 (0.7)	0
Post procedural haemorrhage	1 (0.7)	1 (1.5)
Postoperative wound complication	1 (0.7)	0
Transfusion reaction	1 (0.7)	0
Traumatic haematoma	1 (0.7)	0
Vascular pseudoaneurysm	1 (0.7)	0
Skin laceration	0	1 (1.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (5.2)	3 (4.5)
Squamous cell carcinoma	2 (1.5)	2 (3.0)
Squamous cell carcinoma of skin	2 (1.5)	1 (1.5)
Adenocarcinoma gastric	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_teae_f6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.1.3.1
Treatment-emergent Adverse Events (TEAEs) by Treatment, System Organ Class and Preferred Term – First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Basal cell carcinoma	1 (0.7)	0
Renal neoplasm	1 (0.7)	0
Adrenal neoplasm	0	1 (1.5)
Eye disorders	6 (4.5)	1 (1.5)
Cataract	2 (1.5)	0
Dry eye	2 (1.5)	0
Eye haemorrhage	1 (0.7)	0
Lacrimation increased	1 (0.7)	0
Retinal vein thrombosis	1 (0.7)	0
Vitreous haemorrhage	1 (0.7)	1 (1.5)
Ear and labyrinth disorders	5 (3.7)	2 (3.0)
Vertigo	4 (3.0)	2 (3.0)
Tinnitus	1 (0.7)	0
Hepatobiliary disorders	4 (3.0)	0
Portal hypertension	2 (1.5)	0
Cholestasis	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_teae_f6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.1.3.1
Treatment-emergent Adverse Events (TEAEs) by Treatment, System Organ Class and Preferred Term – First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Hepatobiliary disorders		
Hepatosplenomegaly	1 (0.7)	0
Hyperbilirubinaemia	1 (0.7)	0
Endocrine disorders	2 (1.5)	0
Adrenal insufficiency	1 (0.7)	0
Hyperparathyroidism	1 (0.7)	0
Social circumstances	1 (0.7)	0
Physical disability	1 (0.7)	0
Reproductive system and breast disorders	0	1 (1.5)
Premature menopause	0	1 (1.5)

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_teae_f6.sas
Version: Final
Data Source: ADSL, ADAE

1.3.2 SUE nach SOC und PT

Table 14.3.2.1.1
Treatment-emergent SAEs by Treatment, System Organ Class and Preferred Term - First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Subjects With at Least One Treatment-emergent SAE	44 (32.8)	16 (23.9)
Gastrointestinal disorders	10 (7.5)	0
Abdominal pain	2 (1.5)	0
Gastrointestinal haemorrhage	2 (1.5)	0
Duodenal ulcer	1 (0.7)	0
Gastric ulcer	1 (0.7)	0
Melaena	1 (0.7)	0
Subileus	1 (0.7)	0
Upper gastrointestinal haemorrhage	1 (0.7)	0
Varices oesophageal	1 (0.7)	0
Vomiting	1 (0.7)	0
Blood and lymphatic system disorders	9 (6.7)	3 (4.5)
Anaemia	8 (6.0)	0
Leukocytosis	1 (0.7)	1 (1.5)
Splenic infarction	0	1 (1.5)
Spontaneous haematoma	0	1 (1.5)

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose; SAE = Serious Adverse Event.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_sae_f6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.2.1.1
Treatment-emergent SAEs by Treatment, System Organ Class and Preferred Term – First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Infections and infestations	9 (6.7)	7 (10.4)
COVID-19	2 (1.5)	2 (3.0)
Pneumonia	2 (1.5)	2 (3.0)
Cellulitis	1 (0.7)	0
Neutropenic sepsis	1 (0.7)	0
Respiratory tract infection	1 (0.7)	1 (1.5)
Sepsis	1 (0.7)	0
Tuberculosis	1 (0.7)	0
Urinary tract infection bacterial	1 (0.7)	0
COVID-19 pneumonia	0	1 (1.5)
Cholecystitis infective	0	1 (1.5)
Lymph node tuberculosis	0	1 (1.5)
Peritonitis	0	1 (1.5)
Renal and urinary disorders	9 (6.7)	1 (1.5)
Acute kidney injury	5 (3.7)	0
Chronic kidney disease	2 (1.5)	0
Renal failure	2 (1.5)	0
Renal colic	0	1 (1.5)

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose; SAE = Serious Adverse Event.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_sae_f6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.2.1.1
Treatment-emergent SAEs by Treatment, System Organ Class and Preferred Term - First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
General disorders and administration site conditions	7 (5.2)	2 (3.0)
General physical health deterioration	5 (3.7)	0
Multiple organ dysfunction syndrome	1 (0.7)	0
Oedema peripheral	1 (0.7)	0
Asthenia	0	1 (1.5)
Pyrexia	0	1 (1.5)
Cardiac disorders	6 (4.5)	1 (1.5)
Atrial fibrillation	2 (1.5)	0
Cardiac failure congestive	2 (1.5)	0
Cardiac failure	1 (0.7)	1 (1.5)
Right ventricular failure	1 (0.7)	0
Metabolism and nutrition disorders	6 (4.5)	0
Hyperkalaemia	2 (1.5)	0
Vitamin B1 deficiency	2 (1.5)	0
Gout	1 (0.7)	0
Hyponatraemia	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose; SAE = Serious Adverse Event.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_sae_f6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.2.1.1
Treatment-emergent SAEs by Treatment, System Organ Class and Preferred Term - First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Respiratory, thoracic and mediastinal disorders	4 (3.0)	3 (4.5)
Dyspnoea	2 (1.5)	0
Acute respiratory failure	1 (0.7)	0
Emphysema	1 (0.7)	0
Organising pneumonia	1 (0.7)	0
Lung infiltration	0	1 (1.5)
Pleural effusion	0	1 (1.5)
Respiratory distress	0	1 (1.5)
Injury, poisoning and procedural complications	3 (2.2)	1 (1.5)
Fall	1 (0.7)	0
Post procedural haemorrhage	1 (0.7)	0
Spinal compression fracture	1 (0.7)	0
Traumatic haematoma	1 (0.7)	0
Skin laceration	0	1 (1.5)
Investigations	2 (1.5)	0
Alanine aminotransferase increased	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose; SAE = Serious Adverse Event.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_sae_f6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.2.1.1
Treatment-emergent SAEs by Treatment, System Organ Class and Preferred Term - First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Investigations		
Aspartate aminotransferase increased	1 (0.7)	0
Ejection fraction decreased	1 (0.7)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (1.5)	1 (1.5)
Adenocarcinoma gastric	1 (0.7)	0
Squamous cell carcinoma of skin	1 (0.7)	0
Adrenal neoplasm	0	1 (1.5)
Eye disorders	1 (0.7)	0
Vitreous haemorrhage	1 (0.7)	0
Hepatobiliary disorders	1 (0.7)	0
Hepatosplenomegaly	1 (0.7)	0
Musculoskeletal and connective tissue disorders	1 (0.7)	1 (1.5)
Bursitis	1 (0.7)	0
Arthralgia	0	1 (1.5)

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose; SAE = Serious Adverse Event.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_sae_f6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.2.1.1
Treatment-emergent SAEs by Treatment, System Organ Class and Preferred Term - First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Nervous system disorders	1 (0.7)	1 (1.5)
Metabolic encephalopathy	1 (0.7)	0
Sciatica	0	1 (1.5)
Vascular disorders	1 (0.7)	2 (3.0)
Haemorrhage	1 (0.7)	0
Aortic dissection	0	1 (1.5)
Haematoma	0	1 (1.5)

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose; SAE = Serious Adverse Event.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_sae_f6.sas
Version: Final
Data Source: ADSL, ADAE

1.3.3 UE mit NCI-CTCAE-Grad 3 oder 4 nach SOC und PT

Table 14.3.1.5.1
CTCAE Grade 3/4 TEAEs by Treatment, System Organ Class and Preferred Term - First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Subjects With at Least One CTCAE Grade 3/4 TEAE	88 (65.7)	29 (43.3)
Blood and lymphatic system disorders	55 (41.0)	19 (28.4)
Anaemia	37 (27.6)	13 (19.4)
Thrombocytopenia	27 (20.1)	4 (6.0)
Leukocytosis	3 (2.2)	3 (4.5)
Neutropenia	3 (2.2)	1 (1.5)
Leukopenia	2 (1.5)	1 (1.5)
Lymphopenia	1 (0.7)	1 (1.5)
Splenic infarction	0	1 (1.5)
Spontaneous haematoma	0	1 (1.5)
Metabolism and nutrition disorders	17 (12.7)	2 (3.0)
Hyperkalaemia	8 (6.0)	0
Decreased appetite	3 (2.2)	0
Hypokalaemia	2 (1.5)	1 (1.5)
Hyponatraemia	2 (1.5)	0
Gout	1 (0.7)	0
Hypertriglyceridaemia	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_gr34saff6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.1.5.1
CTCAE Grade 3/4 TEAEs by Treatment, System Organ Class and Preferred Term - First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Metabolism and nutrition disorders		
Vitamin B1 deficiency	1 (0.7)	0
Hyperuricaemia	0	1 (1.5)
Renal and urinary disorders	17 (12.7)	1 (1.5)
Acute kidney injury	7 (5.2)	0
Chronic kidney disease	5 (3.7)	0
Renal failure	3 (2.2)	0
Renal impairment	3 (2.2)	0
Renal colic	0	1 (1.5)
Gastrointestinal disorders	11 (8.2)	0
Abdominal pain upper	2 (1.5)	0
Diarrhoea	2 (1.5)	0
Gastrointestinal haemorrhage	2 (1.5)	0
Abdominal discomfort	1 (0.7)	0
Abdominal pain	1 (0.7)	0
Ascites	1 (0.7)	0
Gastric ulcer	1 (0.7)	0
Nausea	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_gr34saff6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.1.5.1
CTCAE Grade 3/4 TEAEs by Treatment, System Organ Class and Preferred Term - First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Gastrointestinal disorders		
Subileus	1 (0.7)	0
Upper gastrointestinal haemorrhage	1 (0.7)	0
Varices oesophageal	1 (0.7)	0
Infections and infestations	11 (8.2)	6 (9.0)
COVID-19	2 (1.5)	2 (3.0)
Pneumonia	2 (1.5)	2 (3.0)
Capnocytophaga infection	1 (0.7)	0
Cellulitis	1 (0.7)	0
Neutropenic sepsis	1 (0.7)	0
Pyelonephritis chronic	1 (0.7)	0
Respiratory tract infection	1 (0.7)	1 (1.5)
Septic shock	1 (0.7)	0
Tooth infection	1 (0.7)	0
Urinary tract infection	1 (0.7)	0
Cholecystitis infective	0	1 (1.5)
Lymph node tuberculosis	0	1 (1.5)
Peritonitis	0	1 (1.5)
Suspected COVID-19	0	1 (1.5)

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Table 14.3.1.5.1
CTCAE Grade 3/4 TEAEs by Treatment, System Organ Class and Preferred Term - First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Investigations	11 (8.2)	1 (1.5)
Alanine aminotransferase increased	5 (3.7)	0
Aspartate aminotransferase increased	2 (1.5)	0
Glomerular filtration rate decreased	2 (1.5)	0
Creatinine renal clearance decreased	1 (0.7)	0
Ejection fraction decreased	1 (0.7)	0
Glomerular filtration rate increased	1 (0.7)	0
Haemoglobin decreased	1 (0.7)	0
C-reactive protein increased	0	1 (1.5)
General disorders and administration site conditions	9 (6.7)	3 (4.5)
General physical health deterioration	6 (4.5)	1 (1.5)
Asthenia	3 (2.2)	1 (1.5)
Fatigue	1 (0.7)	1 (1.5)
Pyrexia	0	1 (1.5)
Cardiac disorders	7 (5.2)	1 (1.5)
Atrial fibrillation	2 (1.5)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Table 14.3.1.5.1
CTCAE Grade 3/4 TEAEs by Treatment, System Organ Class and Preferred Term – First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Cardiac disorders		
Cardiac failure congestive	2 (1.5)	0
Cardiac failure	1 (0.7)	1 (1.5)
Stress cardiomyopathy	1 (0.7)	0
Ventricular tachycardia	1 (0.7)	0
Respiratory, thoracic and mediastinal disorders	4 (3.0)	3 (4.5)
Dyspnoea	2 (1.5)	0
Emphysema	2 (1.5)	0
Organising pneumonia	1 (0.7)	0
Lung infiltration	0	1 (1.5)
Pulmonary hypertension	0	1 (1.5)
Respiratory distress	0	1 (1.5)
Injury, poisoning and procedural complications	3 (2.2)	0
Fall	1 (0.7)	0
Post procedural haemorrhage	1 (0.7)	0
Traumatic haematoma	1 (0.7)	0
Vascular pseudoaneurysm	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_gr34saff6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.1.5.1
CTCAE Grade 3/4 TEAEs by Treatment, System Organ Class and Preferred Term - First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Hepatobiliary disorders	2 (1.5)	0
Hepatosplenomegaly	1 (0.7)	0
Portal hypertension	1 (0.7)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (1.5)	0
Adenocarcinoma gastric	1 (0.7)	0
Squamous cell carcinoma of skin	1 (0.7)	0
Nervous system disorders	2 (1.5)	1 (1.5)
Metabolic encephalopathy	1 (0.7)	0
Peripheral sensory neuropathy	1 (0.7)	0
Sciatica	0	1 (1.5)
Vascular disorders	2 (1.5)	3 (4.5)
Hypertension	1 (0.7)	1 (1.5)
Pallor	1 (0.7)	0
Aortic dissection	0	1 (1.5)
Haematoma	0	1 (1.5)

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_gr34saff6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.1.5.1
CTCAE Grade 3/4 TEAEs by Treatment, System Organ Class and Preferred Term – First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Endocrine disorders	1 (0.7)	0
Adrenal insufficiency	1 (0.7)	0
Eye disorders	1 (0.7)	0
Vitreous haemorrhage	1 (0.7)	0
Musculoskeletal and connective tissue disorders	1 (0.7)	1 (1.5)
Bursitis	1 (0.7)	0
Arthralgia	0	1 (1.5)
Psychiatric disorders	1 (0.7)	0
Mental disorder	1 (0.7)	0
Social circumstances	1 (0.7)	0
Physical disability	1 (0.7)	0
Skin and subcutaneous tissue disorders	0	3 (4.5)
Hyperhidrosis	0	1 (1.5)
Night sweats	0	2 (3.0)

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_gr34saff6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.1.5.1
CTCAE Grade 3/4 TEAEs by Treatment, System Organ Class and Preferred Term - First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Skin and subcutaneous tissue disorders		
Pruritus	0	1 (1.5)

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

1.3.4 UE, die zum Therapieabbruch führten nach SOC und PT

Table 14.3.1.9.1
TEAEs Leading to Permanent Treatment Discontinuation by Treatment, System Organ Class and Preferred Term – First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Subjects With at Least One TEAE Leading to Permanent Treatment Discontinuation	13 (9.7)	4 (6.0)
Gastrointestinal disorders	3 (2.2)	0
Abdominal pain	1 (0.7)	0
Diarrhoea	1 (0.7)	0
Nausea	1 (0.7)	0
Vomiting	1 (0.7)	0
Renal and urinary disorders	3 (2.2)	0
Chronic kidney disease	2 (1.5)	0
Acute kidney injury	1 (0.7)	0
Blood and lymphatic system disorders	2 (1.5)	1 (1.5)
Neutropenia	1 (0.7)	0
Thrombocytopenia	1 (0.7)	0
Leukocytosis	0	1 (1.5)
General disorders and administration site conditions	2 (1.5)	0
Asthenia	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_teaediscf6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.1.9.1
TEAEs Leading to Permanent Treatment Discontinuation by Treatment, System Organ Class and Preferred Term - First 6 Cycles
Safety Population

System Organ Class Preferred Term [a]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
General disorders and administration site conditions		
General physical health deterioration	1 (0.7)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (1.5)	0
Adenocarcinoma gastric	1 (0.7)	0
Squamous cell carcinoma	1 (0.7)	0
Hepatobiliary disorders	1 (0.7)	0
Hepatosplenomegaly	1 (0.7)	0
Nervous system disorders	1 (0.7)	0
Wernicke's encephalopathy	1 (0.7)	0
Infections and infestations	0	2 (3.0)
Lymph node tuberculosis	0	1 (1.5)
Pneumonia	0	1 (1.5)
Skin and subcutaneous tissue disorders	0	1 (1.5)
Skin ulcer	0	1 (1.5)

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose.
[a] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/system organ class. System organ class and preferred terms are listed in descending frequency of fedratinib column.
Note: For Fedratinib arm, only subjects who initially randomized to Fedratinib are included. For crossover subjects in BAT arm, only data prior to crossover are included.

Program Name: t_teaediscf6.sas
Version: Final
Data Source: ADSL, ADAE

1.4 Deskriptive Darstellung der UE von speziellem Interesse nach Kategorie und PT

1.4.1 Jegliche UE von speziellem Interesse nach Kategorie und PT

Table 14.3.2.4.1
Treatment-emergent Adverse Events of Special Interest (AESI) by Treatment, AESI Category and Preferred Term – First 6 Cycles
Safety Population

AESI Category [a] Preferred Term [b]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Subjects With at Least One AESI	88 (65.7)	27 (40.3)
Grade 3 or 4 Anemia	38 (28.4)	13 (19.4)
Anaemia	37 (27.6)	13 (19.4)
Haemoglobin decreased	1 (0.7)	0
Cardiac Failure/Cardiomyopathy	28 (20.9)	8 (11.9)
Oedema peripheral	20 (14.9)	7 (10.4)
Ascites	3 (2.2)	1 (1.5)
Cardiac failure	2 (1.5)	1 (1.5)
Cardiac failure congestive	2 (1.5)	0
Ejection fraction decreased	2 (1.5)	0
Peripheral swelling	2 (1.5)	1 (1.5)
Cardiomyopathy	1 (0.7)	0
Hypervolaemia	1 (0.7)	0
Pulmonary congestion	1 (0.7)	0
Right ventricular failure	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose. A preferred term may be seen in multiple AESI categories.
[a] AESI will be selected using Standardized MedDRA Query (SMQ) definitions or MedDRA System Organ Class (SOC) and/or Preferred Terms (PT). A subject is counted only once for multiple events within each AESI category, listed in descending frequency of Fedratinib column.
[b] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/AESI, listed in descending frequency of Fedratinib column.

Program Name: t_aesif6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.2.4.1
Treatment-emergent Adverse Events of Special Interest (AESI) by Treatment, AESI Category and Preferred Term - First 6 Cycles
Safety Population

AESI Category [a] Preferred Term [b]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Cardiac Failure/Cardiomyopathy		
Stress cardiomyopathy	1 (0.7)	0
Grade 3 or 4 Thrombocytopenia	27 (20.1)	4 (6.0)
Thrombocytopenia	27 (20.1)	4 (6.0)
Thiamine levels below normal range with or without signs or symptoms of WE	22 (16.4)	2 (3.0)
Vitamin B1 decreased	14 (10.4)	1 (1.5)
Vitamin B1 deficiency	8 (6.0)	1 (1.5)
Encephalopathy, Including Wernicke's	18 (13.4)	2 (3.0)
Dysgeusia	4 (3.0)	0
Peripheral sensory neuropathy	4 (3.0)	1 (1.5)
Confusional state	2 (1.5)	0
Paraesthesia	2 (1.5)	0
Amnesia	1 (0.7)	0
Burning sensation	1 (0.7)	0
Hypoaesthesia	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose. A preferred term may be seen in multiple AESI categories.
[a] AESI will be selected using Standardized MedDRA Query (SMQ) definitions or MedDRA System Organ Class (SOC) and/or Preferred Terms (PT). A subject is counted only once for multiple events within each AESI category, listed in descending frequency of Fedratinib column.
[b] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/AESI, listed in descending frequency of Fedratinib column.

Program Name: t_aesif6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.2.4.1
Treatment-emergent Adverse Events of Special Interest (AESI) by Treatment, AESI Category and Preferred Term – First 6 Cycles
Safety Population

AESI Category [a] Preferred Term [b]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Encephalopathy, Including Wernicke's		
Memory impairment	1 (0.7)	0
Metabolic encephalopathy	1 (0.7)	0
Post herpetic neuralgia	1 (0.7)	0
Taste disorder	1 (0.7)	0
Wernicke's encephalopathy	1 (0.7)	0
Febrile convulsion	0	1 (1.5)
Herpes zoster	0	1 (1.5)
Grade 3 or 4 ALT, AST, or Total Bilirubin Elevation	7 (5.2)	0
Alanine aminotransferase increased	5 (3.7)	0
Aspartate aminotransferase increased	2 (1.5)	0
Ascites	1 (0.7)	0
Hepatosplenomegaly	1 (0.7)	0
Portal hypertension	1 (0.7)	0
Varices oesophageal	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose. A preferred term may be seen in multiple AESI categories.
[a] AESI will be selected using Standardized MedDRA Query (SMQ) definitions or MedDRA System Organ Class (SOC) and/or Preferred Terms (PT). A subject is counted only once for multiple events within each AESI category, listed in descending frequency of Fedratinib column.
[b] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/AESI, listed in descending frequency of Fedratinib column.

Program Name: t_aesif6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.2.4.1
Treatment-emergent Adverse Events of Special Interest (AESI) by Treatment, AESI Category and Preferred Term – First 6 Cycles
Safety Population

AESI Category [a] Preferred Term [b]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Secondary Malignancies	7 (5.2)	3 (4.5)
Squamous cell carcinoma	2 (1.5)	2 (3.0)
Squamous cell carcinoma of skin	2 (1.5)	1 (1.5)
Adenocarcinoma gastric	1 (0.7)	0
Basal cell carcinoma	1 (0.7)	0
Renal neoplasm	1 (0.7)	0
Adrenal neoplasm	0	1 (1.5)
Grade 3 or 4 Hyperamylasemia or Hyperlipasemia	4 (3.0)	0
Abdominal pain upper	2 (1.5)	0
Abdominal pain	1 (0.7)	0
Ascites	1 (0.7)	0
Nausea	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose. A preferred term may be seen in multiple AESI categories.
[a] AESI will be selected using Standardized MedDRA Query (SMQ) definitions or MedDRA System Organ Class (SOC) and/or Preferred Terms (PT). A subject is counted only once for multiple events within each AESI category, listed in descending frequency of Fedratinib column.
[b] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/AESI, listed in descending frequency of Fedratinib column.

Program Name: t_aesif6.sas
Version: Final
Data Source: ADSL, ADAE

1.4.2 SUE von speziellem Interesse nach Kategorie und PT

Table 14.3.2.6.1
Treatment-emergent Serious AESIs by Treatment, AESI Category and Preferred Term - First 6 Cycles
Safety Population

AESI Category [a] Preferred Term [b]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Subjects With at Least One Treatment-emergent Serious AESI	18 (13.4)	2 (3.0)
Grade 3 or 4 Anemia	8 (6.0)	0
Anaemia	8 (6.0)	0
Cardiac Failure/Cardiomyopathy	5 (3.7)	1 (1.5)
Cardiac failure congestive	2 (1.5)	0
Cardiac failure	1 (0.7)	1 (1.5)
Ejection fraction decreased	1 (0.7)	0
Oedema peripheral	1 (0.7)	0
Right ventricular failure	1 (0.7)	0
Grade 3 or 4 ALT, AST, or Total Bilirubin Elevation	3 (2.2)	0
Alanine aminotransferase increased	1 (0.7)	0
Aspartate aminotransferase increased	1 (0.7)	0
Hepatosplenomegaly	1 (0.7)	0
Varices oesophageal	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose. A preferred term may be seen in multiple AESI categories.
[a] AESI will be selected using Standardized MedDRA Query (SMQ) definitions or MedDRA System Organ Class (SOC) and/or Preferred Terms (PT). A subject is counted only once for multiple events within each AESI category, listed in descending frequency of Fedratinib column.
[b] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/AESI, listed in descending frequency of Fedratinib column.

Program Name: t_saesif6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.2.6.1
Treatment-emergent Serious AESIs by Treatment, AESI Category and Preferred Term - First 6 Cycles
Safety Population

AESI Category [a] Preferred Term [b]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Secondary Malignancies	2 (1.5)	1 (1.5)
Adenocarcinoma gastric	1 (0.7)	0
Squamous cell carcinoma of skin	1 (0.7)	0
Adrenal neoplasm	0	1 (1.5)
Thiamine levels below normal range with or without signs or symptoms of WE	2 (1.5)	0
Vitamin B1 deficiency	2 (1.5)	0
Encephalopathy, Including Wernicke's	1 (0.7)	0
Metabolic encephalopathy	1 (0.7)	0
Grade 3 or 4 Hyperamylasemia or Hyperlipasemia	1 (0.7)	0
Abdominal pain	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose. A preferred term may be seen in multiple AESI categories.
[a] AESI will be selected using Standardized MedDRA Query (SMQ) definitions or MedDRA System Organ Class (SOC) and/or Preferred Terms (PT). A subject is counted only once for multiple events within each AESI category, listed in descending frequency of Fedratinib column.
[b] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/AESI, listed in descending frequency of Fedratinib column.

Program Name: t_saesif6.sas
Version: Final
Data Source: ADSL, ADAE

1.4.3 UE von speziellem Interesse mit NCI-CTCAE-Grad 3 oder 4 nach Kategorie und PT

Table 14.3.2.8.1
CTCAE Grade 3/4 AESIs by Treatment, AESI Category and Preferred Term - First 6 Cycles
Safety Population

AESI Category [a] Preferred Term [b]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Subjects With at Least One CTCAE Grade 3/4 AESI	62 (46.3)	15 (22.4)
Grade 3 or 4 Anemia	38 (28.4)	13 (19.4)
Anaemia	37 (27.6)	13 (19.4)
Haemoglobin decreased	1 (0.7)	0
Grade 3 or 4 Thrombocytopenia	27 (20.1)	4 (6.0)
Thrombocytopenia	27 (20.1)	4 (6.0)
Grade 3 or 4 ALT, AST, or Total Bilirubin Elevation	7 (5.2)	0
Alanine aminotransferase increased	5 (3.7)	0
Aspartate aminotransferase increased	2 (1.5)	0
Ascites	1 (0.7)	0
Hepatosplenomegaly	1 (0.7)	0
Portal hypertension	1 (0.7)	0
Varices oesophageal	1 (0.7)	0
Cardiac Failure/Cardiomyopathy	6 (4.5)	1 (1.5)
Cardiac failure congestive	2 (1.5)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose. A preferred term may be seen in multiple AESI categories.
[a] AESI will be selected using Standardized MedDRA Query (SMQ) definitions or MedDRA System Organ Class (SOC) and/or Preferred Terms (PT). A subject is counted only once for multiple events within each AESI category, listed in descending frequency of Fedratinib column.
[b] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/AESI, listed in descending frequency of Fedratinib column.

Program Name: t_aesigr34f6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.2.8.1
CTCAE Grade 3/4 AESIs by Treatment, AESI Category and Preferred Term - First 6 Cycles
Safety Population

AESI Category [a] Preferred Term [b]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Cardiac Failure/Cardiomyopathy		
Ascites	1 (0.7)	0
Cardiac failure	1 (0.7)	1 (1.5)
Ejection fraction decreased	1 (0.7)	0
Stress cardiomyopathy	1 (0.7)	0
Grade 3 or 4 Hyperamylasemia or Hyperlipasemia	4 (3.0)	0
Abdominal pain upper	2 (1.5)	0
Abdominal pain	1 (0.7)	0
Ascites	1 (0.7)	0
Nausea	1 (0.7)	0
Encephalopathy, Including Wernicke's	2 (1.5)	0
Metabolic encephalopathy	1 (0.7)	0
Peripheral sensory neuropathy	1 (0.7)	0
Secondary Malignancies	2 (1.5)	0
Adenocarcinoma gastric	1 (0.7)	0
Squamous cell carcinoma of skin	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose. A preferred term may be seen in multiple AESI categories.
[a] AESI will be selected using Standardized MedDRA Query (SMQ) definitions or MedDRA System Organ Class (SOC) and/or Preferred Terms (PT). A subject is counted only once for multiple events within each AESI category, listed in descending frequency of Fedratinib column.
[b] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/AESI, listed in descending frequency of Fedratinib column.

Program Name: t_aesigr34f6.sas
Version: Final
Data Source: ADSL, ADAE

Table 14.3.2.8.1
CTCAE Grade 3/4 AESIs by Treatment, AESI Category and Preferred Term – First 6 Cycles
Safety Population

AESI Category [a] Preferred Term [b]	Fedratinib (N=134) n (%)	BAT (N=67) n (%)
Thiamine levels below normal range with or without signs or symptoms of WE	1 (0.7)	0
Vitamin B1 deficiency	1 (0.7)	0

Treatment-emergent adverse events (TEAEs) include any AEs with onset or worsening in grade between the date of first dose and 30 days after the date of last dose. A preferred term may be seen in multiple AESI categories.
[a] AESI will be selected using Standardized MedDRA Query (SMQ) definitions or MedDRA System Organ Class (SOC) and/or Preferred Terms (PT). A subject is counted only once for multiple events within each AESI category, listed in descending frequency of Fedratinib column.
[b] Coded using MedDRA version 25.1. A subject is counted only once for multiple events within preferred term/AESI, listed in descending frequency of Fedratinib column.

Program Name: t_aesigr34f6.sas
Version: Final
Data Source: ADSL, ADAE