Dossier zur Nutzenbewertung gemäß § 35a SGB V

Repotrectinib (AUGTYRO®)

Bristol-Myers Squibb GmbH & Co. KGaA

Modul 4A

Anhang 4-G

Fortgeschrittene solide Tumoren mit NTRK-Genfusion

Ergänzende Analysen

Stand: 28.04.2025

Modul 4A – Anhang 4-G - Ergänzende Analysen

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Anhang 4-G: Ergänzende Analysen der Studie TRIDENT-1

Anhang 4-G 1: Endpunkt Mortalität: Antineoplastische Folgetherapien

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Table B.9.2
Subsequent Anti-Cancer Therapies Summary
Safety Set for NTRK+

ATC Level 2 Generic Drug Names	TKI-naive subjects N = 57	TKI-pretreated subjects N = 83
SUBJECTS WHO DISCONTINUED STUDY TREATMENT, N(%) (1)	25 (43.9)	56 (67.5)
SUBJECTS WITH ANY SUBSEQUENT ANTI-CANCER THERAPY, N(%) (2)	13 (52.0)	23 (41.1)
CHEMOTHERAPY	3 (5.3)	13 (15.7)
CAPECITABINE	0	1 (1.2)
CARBOPLATIN	1 (1.8)	1 (1.2)
CHEMOTHERAPY (NO MORE DETAILS)	0	1 (1.2)
CYCLOPHOSPHAMIDE	0	1 (1.2)
DOXORUBICIN	0	4 (4.8)
ENDOXAN	1 (1.8)	0
ETOPOSIDE	0	1 (1.2)
FOLFIRINOX	0	1 (1.2)
GEMCITABINE	0	2 (2.4)
IFOSFAMIDE	0	1 (1.2)
OXALIPLATIN	0	1 (1.2)
PACLITAXEL	1 (1.8)	1 (1.2)
PEMETREXED	1 (1.8)	0
TRABECTEDIN	0	2 (2.4)
UNKNOWN CHEMOTHERAPY	0	1 (1.2)
VINCRISTINE	0	1 (1.2)
IMMUNOTHERAPY	3 (5.3)	1 (1.2)
ATEZOLIZUMAB	1 (1.8)	1 (1.2)
PEMBROLIZUMAB	2 (3.5)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
(1) Percentages are based on the total number of subjects in the corresponding cohort.
(2) Percentages are based on the total number of subjects who discontinued study treatment.
If a subject received one or more subsequent anti-cancer therapies, the subject is counted once at each level reported.
Categories are sorted alphabetically and within each Category generic drug names are also sorted alphabetically.
All subsequent anti-cancer therapies are included, not only the first one.
Program Path: /pic/projects5/blinded/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
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Table B.9.2
Subsequent Anti-Cancer Therapies Summary
Safety Set for NTRK+

ATC Level 2 Generic Drug Names	TKI-naive subjects N = 57	TKI-pretreated subjects N = 83
OTHER TARGETED THERAPY	6 (10.5)	1 (1.2)
ANLOTINIB	1 (1.8)	0
BEVACIZUMAB	4 (7.0)	0
LENVATINIB	1 (1.8)	0
PAZOPANIB	1 (1.8)	0
SELUMETINIB	0	1 (1.2)
OTHER THERAPY	0	2 (2.4)
BICALUTAMIDE	0	1 (1.2)
PREDNISOLONE	0	1 (1.2)
SURGERY	0	1
(1.2) SURGICAL REMOVAL	0	
1 (1.2)		
TKI	5 (8.8)	6 (7.2)
CABOZANTINIB	0	1 (1.2)
ENTRECTINIB	0	1 (1.2)
LAROTRECTINIB	4 (7.0)	2 (2.4)
SELITRECTINIB	0	2 (2.4)
TQB3811-NFI	1 (1.8)	0

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(1) Percentages are based on the total number of subjects in the corresponding cohort.
(2) Percentages are based on the total number of subjects who discontinued study treatment.
If a subject received one or more subsequent anti-cancer therapies, the subject is counted once at each level reported.
Categories are sorted alphabetically and within each Category generic drug names are also sorted alphabetically.
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Anhang 4-G 2: Endpunkte Morbidität und Lebensqualität gemäß EORTC QLQ-C30: Zusatzanalyse

Deskription der einzelnen Skalen des EORTC QLC-C30 sowie deren Veränderung gegenüber Baseline im Studienverlauf

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
GLOBAL HEALTH STATUS		
BASELINE		
N	52	81
MEAN	66.03	63.68
SD	24.357	22.099
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	50.00, 83.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	46	73
MEAN	62.50	70.32
SD	21.855	18.373
MEDIAN	62.50	66.67
Q1, Q3	50.00, 83.33	66.67, 83.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	45	72
MEAN	-5.00	6.02
SD	25.893	23.745
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 8.33	-8.33, 16.67
MIN, MAX	-83.3, 83.3	-50.0, 83.3

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EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;
QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 3		
N	40	58
MEAN	65.63	69.25
SD	19.170	22.739
MEDIAN	66.67	75.00
Q1, Q3	50.00, 83.33	66.67, 83.33
MIN, MAX	25.0, 91.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	39	57
MEAN	-2.14	3.36
SD	22.190	28.254
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 8.33	-8.33, 16.67
MIN, MAX	-50.0, 83.3	-75.0, 83.3
CYCLE 4		
N	39	53
MEAN	66.03	72.17
SD	19.719	17.058
MEDIAN	75.00	66.67
Q1, Q3	50.00, 83.33	58.33, 83.33
MIN, MAX	16.7, 91.7	33.3, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 4		
N	38	52
MEAN	-2.41	7.53
SD	27.187	23.411
MEDIAN	-8.33	0.00
Q1, Q3	-16.67, 8.33	-8.33, 16.67
MIN, MAX	-41.7, 83.3	-41.7, 83.3
CYCLE 5		
N	39	44
MEAN	65.60	74.24
SD	18.255	16.842
MEDIAN	66.67	79.17
Q1, Q3	50.00, 83.33	66.67, 83.33
MIN, MAX	16.7, 100.0	25.0, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	38	43
MEAN	-3.73	8.14
SD	28.389	24.498
MEDIAN	-8.33	8.33
Q1, Q3	-16.67, 8.33	0.00, 16.67
MIN, MAX	-50.0, 83.3	-58.3, 83.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 6		
N	36	38
MEAN	66.67	73.68
SD	21.082	18.434
MEDIAN	66.67	79.17
Q1, Q3	50.00, 83.33	66.67, 83.33
MIN, MAX	16.7, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	35	38
MEAN	-2.86	6.80
SD	26.425	22.994
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 8.33	-8.33, 16.67
MIN, MAX	-50.0, 100.0	-33.3, 75.0
CYCLE 7		
N	35	38
MEAN	67.62	74.34
SD	18.827	19.412
MEDIAN	66.67	83.33
Q1, Q3	50.00, 83.33	66.67, 83.33
MIN, MAX	33.3, 100.0	25.0, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 7		
N	34	38
MEAN	-0.49	7.46
SD	24.355	22.410
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-8.33, 25.00
MIN, MAX	-50.0, 83.3	-25.0, 75.0
CYCLE 8		
N	34	38
MEAN	66.18	72.15
SD	19.671	18.510
MEDIAN	66.67	75.00
Q1, Q3	58.33, 83.33	66.67, 83.33
MIN, MAX	16.7, 100.0	25.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	33	38
MEAN	-1.52	3.29
SD	26.307	21.880
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 8.33	-8.33, 16.67
MIN, MAX	-41.7, 83.3	-41.7, 75.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 9		
N	32	32
MEAN	66.93	70.57
SD	17.388	20.411
MEDIAN	66.67	70.83
Q1, Q3	50.00, 83.33	66.67, 83.33
MIN, MAX	33.3, 100.0	25.0, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	31	32
MEAN	-0.27	3.39
SD	27.427	21.467
MEDIAN	-8.33	0.00
Q1, Q3	-16.67, 8.33	-12.50, 16.67
MIN, MAX	-41.7, 83.3	-33.3, 75.0
CYCLE 10		
N	31	30
MEAN	66.40	70.56
SD	19.660	17.055
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	66.67, 83.33
MIN, MAX	16.7, 100.0	33.3, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 10		
N	30	30
MEAN	-0.83	4.44
SD	29.308	21.855
MEDIAN	-8.33	0.00
Q1, Q3	-16.67, 8.33	-16.67, 16.67
MIN, MAX	-41.7, 83.3	-33.3, 75.0
CYCLE 11		
N	30	27
MEAN	64.17	71.91
SD	22.334	18.655
MEDIAN	66.67	75.00
Q1, Q3	50.00, 83.33	66.67, 83.33
MIN, MAX	16.7, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	29	27
MEAN	-2.30	3.70
SD	25.578	23.721
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 8.33	-8.33, 16.67
MIN, MAX	-41.7, 83.3	-33.3, 75.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 12		
N	27	23
MEAN	69.14	74.64
SD	19.450	17.313
MEDIAN	66.67	75.00
Q1, Q3	58.33, 83.33	66.67, 83.33
MIN, MAX	16.7, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	26	23
MEAN	0.96	6.88
SD	24.304	22.981
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-8.33, 16.67
MIN, MAX	-50.0, 83.3	-33.3, 75.0
CYCLE 13		
N	28	21
MEAN	66.37	68.65
SD	18.493	27.247
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	66.67, 83.33
MIN, MAX	25.0, 100.0	0.0, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 13		
N	27	21
MEAN	-1.85	2.38
SD	23.495	28.031
MEDIAN	-8.33	0.00
Q1, Q3	-16.67, 16.67	-16.67, 16.67
MIN, MAX	-33.3, 50.0	-50.0, 75.0
CYCLE 14		
N	21	13
MEAN	65.08	67.95
SD	19.476	23.035
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	58.33, 83.33
MIN, MAX	25.0, 83.3	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	20	13
MEAN	1.67	7.69
SD	27.118	27.735
MEDIAN	0.00	0.00
Q1, Q3	-12.50, 12.50	-16.67, 16.67
MIN, MAX	-41.7, 83.3	-16.7, 75.0

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 15		
N	28	16
MEAN	66.07	74.48
SD	20.403	19.830
MEDIAN	66.67	79.17
Q1, Q3	50.00, 83.33	66.67, 83.33
MIN, MAX	16.7, 100.0	25.0, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	27	16
MEAN	-1.23	7.29
SD	25.810	25.797
MEDIAN	-8.33	0.00
Q1, Q3	-16.67, 16.67	-12.50, 25.00
MIN, MAX	-33.3, 83.3	-25.0, 58.3
CYCLE 16		
N	21	13
MEAN	62.30	70.51
SD	22.457	24.677
MEDIAN	66.67	83.33
Q1, Q3	50.00, 83.33	58.33, 83.33
MIN, MAX	16.7, 100.0	25.0, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 16		
N	21	13
MEAN	-3.97	8.33
SD	17.404	29.853
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 8.33	-16.67, 33.33
MIN, MAX	-33.3, 16.7	-25.0, 75.0
CYCLE 17		
N	24	13
MEAN	64.24	73.08
SD	18.952	21.288
MEDIAN	66.67	75.00
Q1, Q3	54.17, 79.17	58.33, 83.33
MIN, MAX	25.0, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 17		
N	23	13
MEAN	-1.09	3.85
SD	16.724	21.947
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 8.33	-16.67, 8.33
MIN, MAX	-25.0, 33.3	-16.7, 58.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 18		
N	11	8
MEAN	64.39	73.96
SD	19.036	23.332
MEDIAN	66.67	79.17
Q1, Q3	50.00, 83.33	58.33, 91.67
MIN, MAX	33.3, 91.7	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 18		
N	11	8
MEAN	6.82	17.71
SD	27.085	29.017
MEDIAN	8.33	16.67
Q1, Q3	-25.00, 33.33	-4.17, 29.17
MIN, MAX	-25.0, 50.0	-16.7, 75.0
CYCLE 19		
N	21	12
MEAN	69.84	77.78
SD	15.018	20.205
MEDIAN	66.67	83.33
Q1, Q3	66.67, 83.33	66.67, 95.83
MIN, MAX	33.3, 100.0	33.3, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 19		
N	21	12
MEAN	1.59	10.42
SD	18.185	25.157
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 8.33	0.00, 20.83
MIN, MAX	-25.0, 50.0	-16.7, 75.0
CYCLE 20		
N	10	5
MEAN	61.67	55.00
SD	15.811	21.731
MEDIAN	66.67	58.33
Q1, Q3	50.00, 66.67	33.33, 66.67
MIN, MAX	33.3, 83.3	33.3, 83.3
CHANGE FROM BASELINE AT CYCLE 20		
N	10	5
MEAN	5.83	5.00
SD	34.483	30.391
MEDIAN	0.00	-8.33
Q1, Q3	-16.67, 16.67	-8.33, 0.00
MIN, MAX	-33.3, 83.3	-16.7, 58.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 21		
N	13	7
MEAN	66.03	75.00
SD	20.543	12.729
MEDIAN	66.67	83.33
Q1, Q3	66.67, 83.33	66.67, 83.33
MIN, MAX	25.0, 100.0	50.0, 83.3
CHANGE FROM BASELINE AT CYCLE 21		
N	13	7
MEAN	0.64	8.33
SD	19.680	32.275
MEDIAN	0.00	-8.33
Q1, Q3	-16.67, 8.33	-8.33, 25.00
MIN, MAX	-33.3, 33.3	-16.7, 75.0
CYCLE 22		
N	18	7
MEAN	67.13	72.62
SD	18.628	12.467
MEDIAN	66.67	75.00
Q1, Q3	50.00, 83.33	66.67, 83.33
MIN, MAX	25.0, 100.0	50.0, 83.3

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 22		
N	18	7
MEAN	-2.31	10.71
SD	21.352	33.580
MEDIAN	-4.17	-8.33
Q1, Q3	-16.67, 8.33	-16.67, 25.00
MIN, MAX	-33.3, 41.7	-16.7, 75.0
CYCLE 23		
N	7	4
MEAN	59.52	72.92
SD	13.113	12.500
MEDIAN	50.00	75.00
Q1, Q3	50.00, 66.67	62.50, 83.33
MIN, MAX	50.0, 83.3	58.3, 83.3
CHANGE FROM BASELINE AT CYCLE 23		
N	7	4
MEAN	-4.76	20.83
SD	19.159	39.965
MEDIAN	-8.33	12.50
Q1, Q3	-16.67, 16.67	-8.33, 50.00
MIN, MAX	-33.3, 16.7	-16.7, 75.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 24		
N	11	4
MEAN	67.42	60.42
SD	16.855	12.500
MEDIAN	66.67	58.33
Q1, Q3	50.00, 83.33	50.00, 70.83
MIN, MAX	41.7, 100.0	50.0, 75.0
CHANGE FROM BASELINE AT CYCLE 24		
N	11	4
MEAN	-5.30	10.42
SD	12.513	38.112
MEDIAN	-8.33	-4.17
Q1, Q3	-16.67, 8.33	-12.50, 33.33
MIN, MAX	-16.7, 16.7	-16.7, 66.7
CYCLE 25		
N	12	4
MEAN	70.83	70.83
SD	17.944	15.957
MEDIAN	75.00	75.00
Q1, Q3	54.17, 83.33	58.33, 83.33
MIN, MAX	41.7, 100.0	50.0, 83.3

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Table P.2.2
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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 25		
N	12	4
MEAN	-5.56	10.42
SD	14.361	43.234
MEDIAN	-8.33	-8.33
Q1, Q3	-16.67, 4.17	-12.50, 33.33
MIN, MAX	-25.0, 16.7	-16.7, 75.0
CYCLE 26		
N	4	2
MEAN	47.92	66.67
SD	4.167	23.570
MEDIAN	50.00	66.67
Q1, Q3	45.83, 50.00	50.00, 83.33
MIN, MAX	41.7, 50.0	50.0, 83.3
CHANGE FROM BASELINE AT CYCLE 26		
N	4	2
MEAN	-12.50	33.33
SD	17.347	58.926
MEDIAN	-12.50	33.33
Q1, Q3	-25.00, 0.00	-8.33, 75.00
MIN, MAX	-33.3, 8.3	-8.3, 75.0

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Table P.2.2
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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 27		
N	6	4
MEAN	63.89	62.50
SD	24.533	15.957
MEDIAN	58.33	58.33
Q1, Q3	50.00, 83.33	50.00, 75.00
MIN, MAX	33.3, 100.0	50.0, 83.3
CHANGE FROM BASELINE AT CYCLE 27		
N	6	4
MEAN	-8.33	12.50
SD	10.541	42.219
MEDIAN	-12.50	-4.17
Q1, Q3	-16.67, 0.00	-12.50, 37.50
MIN, MAX	-16.7, 8.3	-16.7, 75.0
CYCLE 28		
N	9	4
MEAN	62.96	70.83
SD	21.291	15.957
MEDIAN	66.67	75.00
Q1, Q3	50.00, 75.00	58.33, 83.33
MIN, MAX	33.3, 100.0	50.0, 83.3

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 28		
N	9	4
MEAN	-12.96	0.00
SD	15.087	11.785
MEDIAN	-16.67	-4.17
Q1, Q3	-16.67, -8.33	-8.33, 8.33
MIN, MAX	-33.3, 8.3	-8.3, 16.7
CYCLE 29		
N	5	2
MEAN	56.67	66.67
SD	9.129	0.000
MEDIAN	50.00	66.67
Q1, Q3	50.00, 66.67	66.67, 66.67
MIN, MAX	50.0, 66.7	66.7, 66.7
CHANGE FROM BASELINE AT CYCLE 29		
N	5	2
MEAN	-5.00	33.33
SD	13.944	35.355
MEDIAN	-8.33	33.33
Q1, Q3	-16.67, 0.00	8.33, 58.33
MIN, MAX	-16.7, 16.7	8.3, 58.3

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 30		
N	2	3
MEAN	45.83	50.00
SD	5.893	8.333
MEDIAN	45.83	50.00
Q1, Q3	41.67, 50.00	41.67, 58.33
MIN, MAX	41.7, 50.0	41.7, 58.3
CHANGE FROM BASELINE AT CYCLE 30		
N	2	3
MEAN	0.00	11.11
SD	11.785	34.694
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 8.33	-16.67, 50.00
MIN, MAX	-8.3, 8.3	-16.7, 50.0
CYCLE 31		
N	7	2
MEAN	58.33	58.33
SD	14.434	11.785
MEDIAN	50.00	58.33
Q1, Q3	50.00, 66.67	50.00, 66.67
MIN, MAX	41.7, 83.3	50.0, 66.7

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 31		
N	7	2
MEAN	-14.29	4.17
SD	12.467	17.678
MEDIAN	-16.67	4.17
Q1, Q3	-16.67, -8.33	-8.33, 16.67
MIN, MAX	-33.3, 8.3	-8.3, 16.7
CYCLE 32		
N	3	1
MEAN	47.22	50.00
SD	4.811	N.A.
MEDIAN	50.00	50.00
Q1, Q3	41.67, 50.00	50.00, 50.00
MIN, MAX	41.7, 50.0	50.0, 50.0
CHANGE FROM BASELINE AT CYCLE 32		
N	3	1
MEAN	-11.11	-8.33
SD	29.266	N.A.
MEDIAN	-8.33	-8.33
Q1, Q3	-41.67, 16.67	-8.33, -8.33
MIN, MAX	-41.7, 16.7	-8.3, -8.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 33		
N	1	2
MEAN	50.00	41.67
SD	N.A.	11.785
MEDIAN	50.00	41.67
Q1, Q3	50.00, 50.00	33.33, 50.00
MIN, MAX	50.0, 50.0	33.3, 50.0
CHANGE FROM BASELINE AT CYCLE 33		
N	1	2
MEAN	-16.67	-12.50
SD	N.A.	5.893
MEDIAN	-16.67	-12.50
Q1, Q3	-16.67, -16.67	-16.67, -8.33
MIN, MAX	-16.7, -16.7	-16.7, -8.3
CYCLE 34		
N	5	1
MEAN	66.67	66.67
SD	13.176	N.A.
MEDIAN	66.67	66.67
Q1, Q3	58.33, 75.00	66.67, 66.67
MIN, MAX	50.0, 83.3	66.7, 66.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 34		
N	5	1
MEAN	-10.00	16.67
SD	16.029	N.A.
MEDIAN	-16.67	16.67
Q1, Q3	-16.67, -8.33	16.67, 16.67
MIN, MAX	-25.0, 16.7	16.7, 16.7
CYCLE 36		
N	1	0
MEAN	50.00	
SD	N.A.	
MEDIAN	50.00	
Q1, Q3	50.00, 50.00	
MIN, MAX	50.0, 50.0	
CHANGE FROM BASELINE AT CYCLE 36		
N	1	0
MEAN	-16.67	
SD	N.A.	
MEDIAN	-16.67	
Q1, Q3	-16.67, -16.67	
MIN, MAX	-16.7, -16.7	

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 37		
N	3	0
MEAN	61.11	
SD	9.623	
MEDIAN	66.67	
Q1, Q3	50.00, 66.67	
MIN, MAX	50.0, 66.7	
CHANGE FROM BASELINE AT CYCLE 37		
N	3	0
MEAN	-11.11	
SD	9.623	
MEDIAN	-16.67	
Q1, Q3	-16.67, 0.00	
MIN, MAX	-16.7, 0.0	
CYCLE 38		
N	1	0
MEAN	50.00	
SD	N.A.	
MEDIAN	50.00	
Q1, Q3	50.00, 50.00	
MIN, MAX	50.0, 50.0	

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 38		
N	1	0
MEAN	-16.67	
SD	N.A.	
MEDIAN	-16.67	
Q1, Q3	-16.67, -16.67	
MIN, MAX	-16.7, -16.7	
CYCLE 40		
N	1	0
MEAN	50.00	
SD	N.A.	
MEDIAN	50.00	
Q1, Q3	50.00, 50.00	
MIN, MAX	50.0, 50.0	
CHANGE FROM BASELINE AT CYCLE 40		
N	1	0
MEAN	-16.67	
SD	N.A.	
MEDIAN	-16.67	
Q1, Q3	-16.67, -16.67	
MIN, MAX	-16.7, -16.7	

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 41		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 41		
N	1	0
MEAN	-33.33	
SD	N.A.	
MEDIAN	-33.33	
Q1, Q3	-33.33, -33.33	
MIN, MAX	-33.3, -33.3	
CYCLE 43		
N	1	0
MEAN	50.00	
SD	N.A.	
MEDIAN	50.00	
Q1, Q3	50.00, 50.00	
MIN, MAX	50.0, 50.0	

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 43		
N	1	0
MEAN	-16.67	
SD	N.A.	
MEDIAN	-16.67	
Q1, Q3	-16.67, -16.67	
MIN, MAX	-16.7, -16.7	
END OF TREATMENT		
N	14	22
MEAN	51.79	57.58
SD	16.072	25.834
MEDIAN	50.00	66.67
Q1, Q3	41.67, 58.33	50.00, 66.67
MIN, MAX	25.0, 83.3	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	14	22
MEAN	-10.12	-11.36
SD	28.528	20.501
MEDIAN	-16.67	-8.33
Q1, Q3	-25.00, 8.33	-25.00, 0.00
MIN, MAX	-50.0, 58.3	-66.7, 16.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
PHYSICAL FUNCTIONING		
BASELINE		
N	52	81
MEAN	81.92	78.02
SD	20.123	24.231
MEDIAN	86.67	86.67
Q1, Q3	73.33, 100.00	66.67, 100.00
MIN, MAX	6.7, 100.0	13.3, 100.0
CYCLE 2		
N	46	74
MEAN	80.14	81.62
SD	18.243	21.335
MEDIAN	80.00	86.67
Q1, Q3	66.67, 93.33	73.33, 100.00
MIN, MAX	26.7, 100.0	6.7, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	45	73
MEAN	-1.63	2.56
SD	16.585	22.761
MEDIAN	0.00	0.00
Q1, Q3	-6.67, 6.67	-6.67, 13.33
MIN, MAX	-33.3, 60.0	-80.0, 66.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 3		
N	41	58
MEAN	81.63	80.63
SD	16.383	21.371
MEDIAN	86.67	86.67
Q1, Q3	73.33, 100.00	73.33, 100.00
MIN, MAX	46.7, 100.0	6.7, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	40	57
MEAN	-2.00	0.64
SD	17.684	20.504
MEDIAN	0.00	0.00
Q1, Q3	-13.33, 6.67	-6.67, 6.67
MIN, MAX	-40.0, 46.7	-60.0, 73.3
CYCLE 4		
N	39	53
MEAN	79.06	84.40
SD	17.753	17.538
MEDIAN	83.33	86.67
Q1, Q3	66.67, 93.33	80.00, 100.00
MIN, MAX	20.0, 100.0	26.7, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 4		
N	38	52
MEAN	-4.12	3.85
SD	22.157	22.418
MEDIAN	0.00	0.00
Q1, Q3	-13.33, 6.67	-6.67, 16.67
MIN, MAX	-60.0, 73.3	-46.7, 73.3
CYCLE 5		
N	39	45
MEAN	80.34	83.11
SD	20.055	20.479
MEDIAN	86.67	86.67
Q1, Q3	73.33, 93.33	73.33, 100.00
MIN, MAX	13.3, 100.0	20.0, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	38	44
MEAN	-3.16	5.30
SD	23.391	22.068
MEDIAN	-3.33	0.00
Q1, Q3	-13.33, 0.00	-6.67, 6.67
MIN, MAX	-66.7, 73.3	-40.0, 73.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
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Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 6		
N	37	38
MEAN	79.82	84.39
SD	18.953	18.553
MEDIAN	86.67	86.67
Q1, Q3	66.67, 100.00	80.00, 100.00
MIN, MAX	26.7, 100.0	26.7, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	36	38
MEAN	-3.70	2.46
SD	21.407	19.753
MEDIAN	0.00	0.00
Q1, Q3	-13.33, 0.00	-6.67, 13.33
MIN, MAX	-53.3, 73.3	-40.0, 53.3
CYCLE 7		
N	35	38
MEAN	81.71	85.79
SD	18.880	18.931
MEDIAN	86.67	93.33
Q1, Q3	66.67, 100.00	80.00, 100.00
MIN, MAX	20.0, 100.0	33.3, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 7		
N	34	38
MEAN	-1.76	3.86
SD	16.273	22.009
MEDIAN	0.00	0.00
Q1, Q3	-6.67, 6.67	-6.67, 13.33
MIN, MAX	-46.7, 33.3	-46.7, 53.3
CYCLE 8		
N	34	38
MEAN	81.57	85.44
SD	18.058	18.526
MEDIAN	86.67	93.33
Q1, Q3	73.33, 100.00	80.00, 100.00
MIN, MAX	33.3, 100.0	20.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	33	38
MEAN	-1.41	1.75
SD	21.328	21.571
MEDIAN	-6.67	0.00
Q1, Q3	-13.33, 6.67	-13.33, 13.33
MIN, MAX	-40.0, 66.7	-40.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 9		
N	32	32
MEAN	81.67	81.67
SD	16.763	22.337
MEDIAN	83.33	86.67
Q1, Q3	73.33, 100.00	76.67, 100.00
MIN, MAX	33.3, 100.0	20.0, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	31	32
MEAN	-0.86	-0.42
SD	21.482	18.927
MEDIAN	0.00	0.00
Q1, Q3	-13.33, 6.67	-6.67, 6.67
MIN, MAX	-60.0, 66.7	-40.0, 60.0
CYCLE 10		
N	31	30
MEAN	81.72	81.56
SD	18.214	21.774
MEDIAN	86.67	86.67
Q1, Q3	66.67, 100.00	73.33, 100.00
MIN, MAX	40.0, 100.0	26.7, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 10		
N	30	30
MEAN	-0.22	0.89
SD	17.981	22.742
MEDIAN	0.00	0.00
Q1, Q3	-13.33, 6.67	-6.67, 6.67
MIN, MAX	-53.3, 46.7	-53.3, 66.7
CYCLE 11		
N	30	27
MEAN	80.22	83.46
SD	19.455	21.433
MEDIAN	83.33	86.67
Q1, Q3	66.67, 100.00	80.00, 100.00
MIN, MAX	33.3, 100.0	13.3, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	29	27
MEAN	-1.61	0.25
SD	16.199	23.423
MEDIAN	0.00	0.00
Q1, Q3	-13.33, 6.67	-6.67, 13.33
MIN, MAX	-33.3, 33.3	-66.7, 53.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 12		
N	27	23
MEAN	80.99	83.48
SD	18.738	21.165
MEDIAN	86.67	86.67
Q1, Q3	66.67, 100.00	80.00, 100.00
MIN, MAX	46.7, 100.0	26.7, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	26	23
MEAN	-2.31	-0.29
SD	16.647	21.879
MEDIAN	0.00	0.00
Q1, Q3	-6.67, 6.67	-6.67, 6.67
MIN, MAX	-40.0, 33.3	-53.3, 46.7
CYCLE 13		
N	28	21
MEAN	81.90	80.00
SD	18.402	25.122
MEDIAN	90.00	86.67
Q1, Q3	66.67, 100.00	80.00, 100.00
MIN, MAX	46.7, 100.0	20.0, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 13		
N	27	21
MEAN	-1.98	-1.90
SD	16.100	27.010
MEDIAN	0.00	0.00
Q1, Q3	-13.33, 6.67	-13.33, 6.67
MIN, MAX	-33.3, 33.3	-53.3, 53.3
CYCLE 14		
N	21	13
MEAN	79.68	84.10
SD	17.059	22.033
MEDIAN	80.00	93.33
Q1, Q3	66.67, 93.33	80.00, 100.00
MIN, MAX	40.0, 100.0	20.0, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	20	13
MEAN	-6.33	4.10
SD	21.464	31.802
MEDIAN	-6.67	0.00
Q1, Q3	-16.67, 0.00	-13.33, 13.33
MIN, MAX	-46.7, 40.0	-53.3, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 15		
N	28	16
MEAN	80.24	85.83
SD	18.278	16.307
MEDIAN	86.67	86.67
Q1, Q3	66.67, 96.67	80.00, 96.67
MIN, MAX	40.0, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	27	16
MEAN	-2.72	3.75
SD	16.040	24.702
MEDIAN	-6.67	0.00
Q1, Q3	-13.33, 6.67	-10.00, 16.67
MIN, MAX	-33.3, 26.7	-46.7, 53.3
CYCLE 16		
N	21	13
MEAN	79.68	89.23
SD	17.189	15.285
MEDIAN	86.67	93.33
Q1, Q3	66.67, 100.00	80.00, 100.00
MIN, MAX	53.3, 100.0	46.7, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 16		
N	21	13
MEAN	-5.08	9.23
SD	16.853	26.741
MEDIAN	-6.67	0.00
Q1, Q3	-13.33, 6.67	-6.67, 26.67
MIN, MAX	-33.3, 26.7	-33.3, 53.3
CYCLE 17		
N	24	13
MEAN	77.78	82.05
SD	18.407	19.699
MEDIAN	80.00	86.67
Q1, Q3	63.33, 93.33	73.33, 100.00
MIN, MAX	46.7, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 17		
N	23	13
MEAN	-4.64	-1.54
SD	15.100	23.906
MEDIAN	-6.67	0.00
Q1, Q3	-13.33, 0.00	-13.33, 0.00
MIN, MAX	-33.3, 26.7	-46.7, 53.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 18		
N	11	8
MEAN	80.00	86.67
SD	18.379	18.516
MEDIAN	73.33	93.33
Q1, Q3	66.67, 100.00	80.00, 100.00
MIN, MAX	46.7, 100.0	46.7, 100.0
CHANGE FROM BASELINE AT CYCLE 18		
N	11	8
MEAN	-0.61	12.50
SD	15.622	28.158
MEDIAN	0.00	3.33
Q1, Q3	-20.00, 6.67	-10.00, 40.00
MIN, MAX	-20.0, 26.7	-20.0, 53.3
CYCLE 19		
N	21	12
MEAN	80.00	85.56
SD	19.090	19.245
MEDIAN	86.67	93.33
Q1, Q3	66.67, 100.00	76.67, 100.00
MIN, MAX	40.0, 100.0	33.3, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 19		
N	21	12
MEAN	-3.49	3.33
SD	15.580	27.780
MEDIAN	0.00	0.00
Q1, Q3	-13.33, 0.00	-10.00, 16.67
MIN, MAX	-46.7, 20.0	-46.7, 53.3
CYCLE 20		
N	10	5
MEAN	74.67	73.33
SD	15.963	26.667
MEDIAN	73.33	86.67
Q1, Q3	66.67, 86.67	60.00, 86.67
MIN, MAX	46.7, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 20		
N	10	5
MEAN	-4.00	1.33
SD	16.982	30.332
MEDIAN	-6.67	0.00
Q1, Q3	-20.00, 0.00	0.00, 20.00
MIN, MAX	-20.0, 33.3	-46.7, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 21		
N	13	8
MEAN	80.00	88.54
SD	18.257	10.213
MEDIAN	86.67	86.67
Q1, Q3	66.67, 100.00	80.00, 100.00
MIN, MAX	46.7, 100.0	75.0, 100.0
CHANGE FROM BASELINE AT CYCLE 21		
N	13	8
MEAN	-2.05	4.38
SD	12.586	19.699
MEDIAN	0.00	0.00
Q1, Q3	-6.67, 0.00	-6.67, 6.67
MIN, MAX	-26.7, 20.0	-13.3, 48.3
CYCLE 22		
N	18	7
MEAN	83.70	85.71
SD	15.033	8.968
MEDIAN	86.67	86.67
Q1, Q3	73.33, 93.33	80.00, 93.33
MIN, MAX	46.7, 100.0	73.3, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 22		
N	18	7
MEAN	0.37	5.71
SD	13.426	20.522
MEDIAN	0.00	0.00
Q1, Q3	-6.67, 6.67	-13.33, 13.33
MIN, MAX	-20.0, 33.3	-13.3, 46.7
CYCLE 23		
N	7	4
MEAN	68.57	90.00
SD	13.724	8.607
MEDIAN	73.33	90.00
Q1, Q3	60.00, 80.00	83.33, 96.67
MIN, MAX	46.7, 86.7	80.0, 100.0
CHANGE FROM BASELINE AT CYCLE 23		
N	7	4
MEAN	-6.67	20.00
SD	13.878	25.531
MEDIAN	-6.67	13.33
Q1, Q3	-13.33, 6.67	0.00, 40.00
MIN, MAX	-33.3, 6.7	0.0, 53.3

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Table P.2.2
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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 24		
N	11	4
MEAN	80.00	61.67
SD	18.856	41.231
MEDIAN	86.67	80.00
Q1, Q3	66.67, 100.00	40.00, 83.33
MIN, MAX	40.0, 100.0	0.0, 86.7
CHANGE FROM BASELINE AT CYCLE 24		
N	11	4
MEAN	-5.45	-15.00
SD	11.858	63.333
MEDIAN	-6.67	-6.67
Q1, Q3	-13.33, 0.00	-53.33, 23.33
MIN, MAX	-20.0, 13.3	-100.0, 53.3
CYCLE 25		
N	12	4
MEAN	85.56	78.33
SD	19.034	3.333
MEDIAN	93.33	80.00
Q1, Q3	76.67, 100.00	76.67, 80.00
MIN, MAX	46.7, 100.0	73.3, 80.0

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 25		
N	12	4
MEAN	-3.89	5.00
SD	10.429	32.375
MEDIAN	0.00	-10.00
Q1, Q3	-10.00, 0.00	-13.33, 23.33
MIN, MAX	-26.7, 13.3	-13.3, 53.3
CYCLE 26		
N	4	2
MEAN	66.67	86.67
SD	9.428	0.000
MEDIAN	70.00	86.67
Q1, Q3	60.00, 73.33	86.67, 86.67
MIN, MAX	53.3, 73.3	86.7, 86.7
CHANGE FROM BASELINE AT CYCLE 26		
N	4	2
MEAN	-10.00	30.00
SD	17.638	42.426
MEDIAN	-13.33	30.00
Q1, Q3	-23.33, 3.33	0.00, 60.00
MIN, MAX	-26.7, 13.3	0.0, 60.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 27		
N	6	4
MEAN	77.78	81.67
SD	23.727	3.333
MEDIAN	83.33	80.00
Q1, Q3	53.33, 100.00	80.00, 83.33
MIN, MAX	46.7, 100.0	80.0, 86.7
CHANGE FROM BASELINE AT CYCLE 27		
N	6	4
MEAN	-7.78	5.00
SD	16.555	32.375
MEDIAN	-3.33	-10.00
Q1, Q3	-20.00, 0.00	-13.33, 23.33
MIN, MAX	-33.3, 13.3	-13.3, 53.3
CYCLE 28		
N	9	4
MEAN	80.00	78.75
SD	20.000	5.990
MEDIAN	80.00	77.50
Q1, Q3	60.00, 100.00	74.17, 83.33
MIN, MAX	53.3, 100.0	73.3, 86.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 28		
N	9	4
MEAN	-7.41	-12.92
SD	14.699	0.833
MEDIAN	0.00	-13.33
Q1, Q3	-13.33, 0.00	-13.33, -12.50
MIN, MAX	-33.3, 13.3	-13.3, -11.7
CYCLE 29		
N	5	2
MEAN	69.33	76.67
SD	10.111	4.714
MEDIAN	73.33	76.67
Q1, Q3	66.67, 73.33	73.33, 80.00
MIN, MAX	53.3, 80.0	73.3, 80.0
CHANGE FROM BASELINE AT CYCLE 29		
N	5	2
MEAN	-10.67	20.00
SD	15.348	37.712
MEDIAN	-13.33	20.00
Q1, Q3	-20.00, -6.67	-6.67, 46.67
MIN, MAX	-26.7, 13.3	-6.7, 46.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 30		
N	2	3
MEAN	63.33	75.56
SD	14.142	7.698
MEDIAN	63.33	80.00
Q1, Q3	53.33, 73.33	66.67, 80.00
MIN, MAX	53.3, 73.3	66.7, 80.0
CHANGE FROM BASELINE AT CYCLE 30		
N	2	3
MEAN	-23.33	4.44
SD	4.714	42.339
MEDIAN	-23.33	-20.00
Q1, Q3	-26.67, -20.00	-20.00, 53.33
MIN, MAX	-26.7, -20.0	-20.0, 53.3
CYCLE 31		
N	7	2
MEAN	72.38	63.33
SD	16.966	4.714
MEDIAN	66.67	63.33
Q1, Q3	66.67, 86.67	60.00, 66.67
MIN, MAX	46.7, 100.0	60.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 31		
N	7	2
MEAN	-13.33	-30.00
SD	18.459	4.714
MEDIAN	-13.33	-30.00
Q1, Q3	-20.00, 0.00	-33.33, -26.67
MIN, MAX	-46.7, 13.3	-33.3, -26.7
CYCLE 32		
N	3	1
MEAN	60.00	86.67
SD	6.667	N.A.
MEDIAN	60.00	86.67
Q1, Q3	53.33, 66.67	86.67, 86.67
MIN, MAX	53.3, 66.7	86.7, 86.7
CHANGE FROM BASELINE AT CYCLE 32		
N	3	1
MEAN	-24.44	0.00
SD	10.184	N.A.
MEDIAN	-26.67	0.00
Q1, Q3	-33.33, -13.33	0.00, 0.00
MIN, MAX	-33.3, -13.3	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 33		
N	1	2
MEAN	60.00	83.33
SD	N.A.	4.714
MEDIAN	60.00	83.33
Q1, Q3	60.00, 60.00	80.00, 86.67
MIN, MAX	60.0, 60.0	80.0, 86.7
CHANGE FROM BASELINE AT CYCLE 33		
N	1	2
MEAN	6.67	-10.00
SD	N.A.	4.714
MEDIAN	6.67	-10.00
Q1, Q3	6.67, 6.67	-13.33, -6.67
MIN, MAX	6.7, 6.7	-13.3, -6.7
CYCLE 34		
N	5	1
MEAN	73.33	93.33
SD	21.602	N.A.
MEDIAN	60.00	93.33
Q1, Q3	60.00, 93.33	93.33, 93.33
MIN, MAX	53.3, 100.0	93.3, 93.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 34		
N	5	1
MEAN	-10.67	-6.67
SD	19.206	N.A.
MEDIAN	0.00	-6.67
Q1, Q3	-20.00, 0.00	-6.67, -6.67
MIN, MAX	-40.0, 6.7	-6.7, -6.7
CYCLE 36		
N	1	0
MEAN	60.00	
SD	N.A.	
MEDIAN	60.00	
Q1, Q3	60.00, 60.00	
MIN, MAX	60.0, 60.0	
CHANGE FROM BASELINE AT CYCLE 36		
N	1	0
MEAN	6.67	
SD	N.A.	
MEDIAN	6.67	
Q1, Q3	6.67, 6.67	
MIN, MAX	6.7, 6.7	

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Table P.2.2
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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 37		
N	3	0
MEAN	82.22	
SD	25.240	
MEDIAN	93.33	
Q1, Q3	53.33, 100.00	
MIN, MAX	53.3, 100.0	
CHANGE FROM BASELINE AT CYCLE 37		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 38		
N	1	0
MEAN	53.33	
SD	N.A.	
MEDIAN	53.33	
Q1, Q3	53.33, 53.33	
MIN, MAX	53.3, 53.3	

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 38		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 40		
N	1	0
MEAN	53.33	
SD	N.A.	
MEDIAN	53.33	
Q1, Q3	53.33, 53.33	
MIN, MAX	53.3, 53.3	
CHANGE FROM BASELINE AT CYCLE 40		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

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Safety Set for NTRK+
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	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 41		
N	1	0
MEAN	53.33	
SD	N.A.	
MEDIAN	53.33	
Q1, Q3	53.33, 53.33	
MIN, MAX	53.3, 53.3	
CHANGE FROM BASELINE AT CYCLE 41		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 43		
N	1	0
MEAN	53.33	
SD	N.A.	
MEDIAN	53.33	
Q1, Q3	53.33, 53.33	
MIN, MAX	53.3, 53.3	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 43		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
END OF TREATMENT		
N	14	22
MEAN	61.90	69.39
SD	26.722	29.144
MEDIAN	70.00	76.67
Q1, Q3	40.00, 80.00	60.00, 93.33
MIN, MAX	13.3, 100.0	6.7, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	14	22
MEAN	-18.10	-12.12
SD	23.884	20.014
MEDIAN	-13.33	-6.67
Q1, Q3	-33.33, 0.00	-20.00, 0.00
MIN, MAX	-66.7, 13.3	-60.0, 33.3

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
ROLE FUNCTIONING		
BASELINE		
N	52	81
MEAN	81.09	71.60
SD	26.615	31.672
MEDIAN	100.00	83.33
Q1, Q3	66.67, 100.00	50.00, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	46	74
MEAN	75.72	79.95
SD	25.020	26.313
MEDIAN	83.33	91.67
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	45	73
MEAN	-6.30	7.53
SD	30.832	32.160
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 16.67
MIN, MAX	-83.3, 66.7	-66.7, 100.0

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Table P.2.2
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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 3		
N	41	58
MEAN	76.42	77.87
SD	21.723	26.926
MEDIAN	66.67	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	40	57
MEAN	-6.67	3.80
SD	28.445	27.821
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-16.67, 0.00
MIN, MAX	-66.7, 66.7	-50.0, 100.0
CYCLE 4		
N	39	53
MEAN	72.65	77.67
SD	28.482	24.448
MEDIAN	66.67	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0

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Table P.2.2
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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 4		
N	38	52
MEAN	-9.65	3.21
SD	36.685	32.680
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-16.67, 25.00
MIN, MAX	-83.3, 83.3	-66.7, 83.3
CYCLE 5		
N	39	45
MEAN	75.21	78.15
SD	26.455	27.483
MEDIAN	66.67	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	38	44
MEAN	-7.89	6.82
SD	33.274	38.766
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 16.67	-16.67, 33.33
MIN, MAX	-83.3, 83.3	-66.7, 83.3

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 6		
N	36	38
MEAN	74.54	83.77
SD	26.573	21.743
MEDIAN	83.33	100.00
Q1, Q3	58.33, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	35	38
MEAN	-9.05	9.21
SD	32.172	37.508
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 16.67
MIN, MAX	-66.7, 83.3	-66.7, 100.0
CYCLE 7		
N	35	38
MEAN	80.00	77.19
SD	23.501	28.322
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	0.0, 100.0

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Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 7		
N	34	38
MEAN	-4.41	3.95
SD	26.050	35.816
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-66.7, 50.0	-50.0, 100.0
CYCLE 8		
N	34	38
MEAN	73.53	81.14
SD	25.662	25.460
MEDIAN	66.67	100.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	33	38
MEAN	-10.61	7.02
SD	33.546	32.101
MEDIAN	-16.67	0.00
Q1, Q3	-33.33, 0.00	0.00, 16.67
MIN, MAX	-66.7, 66.7	-50.0, 83.3

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 9		
N	32	32
MEAN	74.48	77.60
SD	24.313	24.174
MEDIAN	66.67	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	31	32
MEAN	-9.68	4.17
SD	32.709	30.527
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-16.67, 0.00
MIN, MAX	-66.7, 66.7	-50.0, 83.3
CYCLE 10		
N	31	30
MEAN	76.88	75.56
SD	23.835	25.421
MEDIAN	83.33	66.67
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	0.0, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 10		
N	30	30
MEAN	-6.67	5.00
SD	30.513	34.782
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-16.67, 16.67
MIN, MAX	-66.7, 66.7	-66.7, 83.3
CYCLE 11		
N	30	27
MEAN	74.44	81.48
SD	28.945	25.459
MEDIAN	83.33	83.33
Q1, Q3	50.00, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	29	27
MEAN	-8.62	6.79
SD	35.529	34.672
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 16.67
MIN, MAX	-100.0, 66.7	-66.7, 100.0

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 12		
N	27	23
MEAN	76.54	83.33
SD	23.687	24.618
MEDIAN	83.33	100.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	26	23
MEAN	-8.33	8.70
SD	27.588	33.284
MEDIAN	-8.33	0.00
Q1, Q3	-33.33, 0.00	0.00, 16.67
MIN, MAX	-50.0, 50.0	-50.0, 83.3
CYCLE 13		
N	28	21
MEAN	76.19	79.37
SD	22.874	32.874
MEDIAN	66.67	100.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	0.0, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 13		
N	27	21
MEAN	-9.26	6.35
SD	28.620	38.542
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 50.0	-66.7, 100.0
CYCLE 14		
N	21	13
MEAN	72.22	84.62
SD	23.174	20.929
MEDIAN	66.67	100.00
Q1, Q3	50.00, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	20	13
MEAN	-17.50	17.95
SD	33.102	38.165
MEDIAN	-33.33	0.00
Q1, Q3	-33.33, 0.00	0.00, 66.67
MIN, MAX	-66.7, 66.7	-33.3, 83.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 15		
N	28	16
MEAN	73.81	85.42
SD	26.227	20.069
MEDIAN	66.67	100.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	27	16
MEAN	-9.26	14.58
SD	28.244	33.264
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 50.00
MIN, MAX	-66.7, 33.3	-33.3, 66.7
CYCLE 16		
N	21	13
MEAN	75.40	87.18
SD	20.152	21.681
MEDIAN	66.67	100.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	50.0, 100.0	33.3, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 16		
N	21	13
MEAN	-10.32	21.79
SD	27.627	38.118
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 66.67
MIN, MAX	-50.0, 33.3	-33.3, 66.7
CYCLE 17		
N	24	13
MEAN	72.92	82.05
SD	22.421	24.964
MEDIAN	66.67	100.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 17		
N	23	13
MEAN	-10.14	6.41
SD	28.311	32.302
MEDIAN	-16.67	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 50.0	-50.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 18		
N	11	8
MEAN	74.24	77.08
SD	18.803	33.259
MEDIAN	66.67	83.33
Q1, Q3	66.67, 83.33	75.00, 100.00
MIN, MAX	33.3, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 18		
N	11	8
MEAN	-9.09	18.75
SD	30.151	42.199
MEDIAN	-16.67	8.33
Q1, Q3	-33.33, 16.67	-16.67, 66.67
MIN, MAX	-66.7, 33.3	-33.3, 66.7
CYCLE 19		
N	21	12
MEAN	75.40	83.33
SD	23.932	21.320
MEDIAN	66.67	91.67
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	33.3, 100.0

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 19		
N	21	12
MEAN	-9.52	9.72
SD	29.614	37.240
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-16.67, 41.67
MIN, MAX	-66.7, 50.0	-33.3, 66.7
CYCLE 20		
N	10	5
MEAN	66.67	70.00
SD	15.713	29.814
MEDIAN	66.67	66.67
Q1, Q3	66.67, 83.33	50.00, 100.00
MIN, MAX	33.3, 83.3	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 20		
N	10	5
MEAN	-13.33	16.67
SD	34.066	40.825
MEDIAN	-16.67	0.00
Q1, Q3	-33.33, 0.00	0.00, 50.00
MIN, MAX	-66.7, 50.0	-33.3, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 21		
N	13	8
MEAN	76.92	93.75
SD	22.088	8.626
MEDIAN	83.33	100.00
Q1, Q3	66.67, 83.33	83.33, 100.00
MIN, MAX	33.3, 100.0	83.3, 100.0
CHANGE FROM BASELINE AT CYCLE 21		
N	13	8
MEAN	-10.26	20.83
SD	26.821	34.215
MEDIAN	-16.67	0.00
Q1, Q3	-16.67, 0.00	0.00, 41.67
MIN, MAX	-66.7, 50.0	0.0, 83.3
CYCLE 22		
N	18	7
MEAN	76.85	85.71
SD	22.966	14.996
MEDIAN	75.00	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	66.7, 100.0

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Table P.2.2
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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 22		
N	18	7
MEAN	-9.26	16.67
SD	25.707	34.694
MEDIAN	-8.33	0.00
Q1, Q3	-16.67, 0.00	0.00, 66.67
MIN, MAX	-66.7, 50.0	-16.7, 66.7
CYCLE 23		
N	7	4
MEAN	64.29	83.33
SD	20.250	19.245
MEDIAN	66.67	83.33
Q1, Q3	50.00, 66.67	66.67, 100.00
MIN, MAX	33.3, 100.0	66.7, 100.0
CHANGE FROM BASELINE AT CYCLE 23		
N	7	4
MEAN	-19.05	33.33
SD	20.250	38.490
MEDIAN	-33.33	33.33
Q1, Q3	-33.33, 0.00	0.00, 66.67
MIN, MAX	-33.3, 16.7	0.0, 66.7

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 24		
N	11	4
MEAN	74.24	58.33
SD	23.995	41.944
MEDIAN	66.67	66.67
Q1, Q3	50.00, 100.00	33.33, 83.33
MIN, MAX	33.3, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 24		
N	11	4
MEAN	-19.70	-4.17
SD	17.979	82.074
MEDIAN	-16.67	-8.33
Q1, Q3	-33.33, 0.00	-58.33, 50.00
MIN, MAX	-50.0, 0.0	-100.0, 100.0
CYCLE 25		
N	12	4
MEAN	75.00	75.00
SD	25.126	16.667
MEDIAN	66.67	66.67
Q1, Q3	66.67, 100.00	66.67, 83.33
MIN, MAX	33.3, 100.0	66.7, 100.0

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 25		
N	12	4
MEAN	-18.06	12.50
SD	20.669	59.900
MEDIAN	-16.67	-8.33
Q1, Q3	-33.33, 0.00	-25.00, 50.00
MIN, MAX	-66.7, 0.0	-33.3, 100.0
CYCLE 26		
N	4	2
MEAN	45.83	75.00
SD	15.957	11.785
MEDIAN	41.67	75.00
Q1, Q3	33.33, 58.33	66.67, 83.33
MIN, MAX	33.3, 66.7	66.7, 83.3
CHANGE FROM BASELINE AT CYCLE 26		
N	4	2
MEAN	-37.50	41.67
SD	25.000	58.926
MEDIAN	-33.33	41.67
Q1, Q3	-58.33, -16.67	0.00, 83.33
MIN, MAX	-66.7, -16.7	0.0, 83.3

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 27		
N	6	4
MEAN	69.44	75.00
SD	34.021	9.623
MEDIAN	75.00	75.00
Q1, Q3	33.33, 100.00	66.67, 83.33
MIN, MAX	33.3, 100.0	66.7, 83.3
CHANGE FROM BASELINE AT CYCLE 27		
N	6	4
MEAN	-22.22	12.50
SD	29.187	47.871
MEDIAN	-8.33	-8.33
Q1, Q3	-50.00, 0.00	-16.67, 41.67
MIN, MAX	-66.7, 0.0	-16.7, 83.3
CYCLE 28		
N	9	4
MEAN	68.52	75.00
SD	31.672	9.623
MEDIAN	66.67	75.00
Q1, Q3	33.33, 100.00	66.67, 83.33
MIN, MAX	33.3, 100.0	66.7, 83.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 28		
N	9	4
MEAN	-24.07	-12.50
SD	29.001	15.957
MEDIAN	-16.67	-8.33
Q1, Q3	-50.00, 0.00	-25.00, 0.00
MIN, MAX	-66.7, 0.0	-33.3, 0.0
CYCLE 29		
N	5	2
MEAN	53.33	66.67
SD	18.257	0.000
MEDIAN	66.67	66.67
Q1, Q3	33.33, 66.67	66.67, 66.67
MIN, MAX	33.3, 66.7	66.7, 66.7
CHANGE FROM BASELINE AT CYCLE 29		
N	5	2
MEAN	-33.33	33.33
SD	20.412	47.140
MEDIAN	-33.33	33.33
Q1, Q3	-33.33, -16.67	0.00, 66.67
MIN, MAX	-66.7, -16.7	0.0, 66.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 30		
N	2	3
MEAN	41.67	66.67
SD	11.785	28.868
MEDIAN	41.67	83.33
Q1, Q3	33.33, 50.00	33.33, 83.33
MIN, MAX	33.3, 50.0	33.3, 83.3
CHANGE FROM BASELINE AT CYCLE 30		
N	2	3
MEAN	-58.33	11.11
SD	11.785	63.099
MEDIAN	-58.33	-16.67
Q1, Q3	-66.67, -50.00	-33.33, 83.33
MIN, MAX	-66.7, -50.0	-33.3, 83.3
CYCLE 31		
N	7	2
MEAN	64.29	58.33
SD	26.227	11.785
MEDIAN	66.67	58.33
Q1, Q3	33.33, 83.33	50.00, 66.67
MIN, MAX	33.3, 100.0	50.0, 66.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 31		
N	7	2
MEAN	-26.19	-25.00
SD	25.198	35.355
MEDIAN	-16.67	-25.00
Q1, Q3	-50.00, 0.00	-50.00, 0.00
MIN, MAX	-66.7, 0.0	-50.0, 0.0
CYCLE 32		
N	3	1
MEAN	50.00	66.67
SD	16.667	N.A.
MEDIAN	50.00	66.67
Q1, Q3	33.33, 66.67	66.67, 66.67
MIN, MAX	33.3, 66.7	66.7, 66.7
CHANGE FROM BASELINE AT CYCLE 32		
N	3	1
MEAN	-44.44	0.00
SD	19.245	N.A.
MEDIAN	-33.33	0.00
Q1, Q3	-66.67, -33.33	0.00, 0.00
MIN, MAX	-66.7, -33.3	0.0, 0.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 33		
N	1	2
MEAN	33.33	75.00
SD	N.A.	11.785
MEDIAN	33.33	75.00
Q1, Q3	33.33, 33.33	66.67, 83.33
MIN, MAX	33.3, 33.3	66.7, 83.3
CHANGE FROM BASELINE AT CYCLE 33		
N	1	2
MEAN	-16.67	-8.33
SD	N.A.	11.785
MEDIAN	-16.67	-8.33
Q1, Q3	-16.67, -16.67	-16.67, 0.00
MIN, MAX	-16.7, -16.7	-16.7, 0.0
CYCLE 34		
N	5	1
MEAN	56.67	83.33
SD	22.361	N.A.
MEDIAN	66.67	83.33
Q1, Q3	33.33, 66.67	83.33, 83.33
MIN, MAX	33.3, 83.3	83.3, 83.3

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 34		
N	5	1
MEAN	-30.00	-16.67
SD	21.731	N.A.
MEDIAN	-16.67	-16.67
Q1, Q3	-33.33, -16.67	-16.67, -16.67
MIN, MAX	-66.7, -16.7	-16.7, -16.7
CYCLE 36		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 36		
N	1	0
MEAN	-16.67	
SD	N.A.	
MEDIAN	-16.67	
Q1, Q3	-16.67, -16.67	
MIN, MAX	-16.7, -16.7	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 37		
N	3	0
MEAN	77.78	
SD	38.490	
MEDIAN	100.00	
Q1, Q3	33.33, 100.00	
MIN, MAX	33.3, 100.0	
CHANGE FROM BASELINE AT CYCLE 37		
N	3	0
MEAN	-5.56	
SD	9.623	
MEDIAN	0.00	
Q1, Q3	-16.67, 0.00	
MIN, MAX	-16.7, 0.0	
CYCLE 38		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

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Table P.2.2
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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 38		
N	1	0
MEAN	-16.67	
SD	N.A.	
MEDIAN	-16.67	
Q1, Q3	-16.67, -16.67	
MIN, MAX	-16.7, -16.7	
CYCLE 40		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 40		
N	1	0
MEAN	-16.67	
SD	N.A.	
MEDIAN	-16.67	
Q1, Q3	-16.67, -16.67	
MIN, MAX	-16.7, -16.7	

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 41		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 41		
N	1	0
MEAN	-16.67	
SD	N.A.	
MEDIAN	-16.67	
Q1, Q3	-16.67, -16.67	
MIN, MAX	-16.7, -16.7	
CYCLE 43		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 43		
N	1	0
MEAN	-16.67	
SD	N.A.	
MEDIAN	-16.67	
Q1, Q3	-16.67, -16.67	
MIN, MAX	-16.7, -16.7	
END OF TREATMENT		
N	14	22
MEAN	55.95	66.67
SD	39.009	35.635
MEDIAN	66.67	75.00
Q1, Q3	16.67, 100.00	33.33, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	14	22
MEAN	-21.43	-6.82
SD	29.547	29.840
MEDIAN	-8.33	0.00
Q1, Q3	-33.33, 0.00	-16.67, 0.00
MIN, MAX	-83.3, 0.0	-66.7, 66.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
EMOTIONAL FUNCTIONING		
BASELINE		
N	52	81
MEAN	81.25	82.82
SD	18.807	18.696
MEDIAN	83.33	91.67
Q1, Q3	75.00, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	16.7, 100.0
CYCLE 2		
N	46	73
MEAN	80.25	84.82
SD	19.981	18.755
MEDIAN	83.33	91.67
Q1, Q3	66.67, 100.00	75.00, 100.00
MIN, MAX	33.3, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	45	72
MEAN	-0.74	1.62
SD	16.459	18.001
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 0.00	-8.33, 8.33
MIN, MAX	-33.3, 50.0	-58.3, 50.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 3		
N	40	58
MEAN	81.46	85.49
SD	19.746	19.594
MEDIAN	83.33	91.67
Q1, Q3	66.67, 100.00	75.00, 100.00
MIN, MAX	16.7, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	39	57
MEAN	0.85	1.46
SD	16.423	19.037
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 8.33	0.00, 8.33
MIN, MAX	-33.3, 58.3	-91.7, 41.7
CYCLE 4		
N	39	53
MEAN	83.33	88.31
SD	19.683	14.115
MEDIAN	91.67	91.67
Q1, Q3	75.00, 100.00	75.00, 100.00
MIN, MAX	8.3, 100.0	55.6, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 4		
N	38	52
MEAN	2.85	3.79
SD	18.306	12.783
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 16.67	0.00, 8.33
MIN, MAX	-33.3, 58.3	-25.0, 33.3
CYCLE 5		
N	39	44
MEAN	82.48	86.81
SD	20.749	17.009
MEDIAN	91.67	91.67
Q1, Q3	66.67, 100.00	75.00, 100.00
MIN, MAX	25.0, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	38	43
MEAN	3.07	3.36
SD	25.293	18.728
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 16.67	-8.33, 8.33
MIN, MAX	-41.7, 66.7	-33.3, 50.0

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 6		
N	37	38
MEAN	81.76	87.28
SD	21.681	18.297
MEDIAN	91.67	95.83
Q1, Q3	66.67, 100.00	83.33, 100.00
MIN, MAX	8.3, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	36	38
MEAN	1.85	3.51
SD	22.810	17.120
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 16.67	-8.33, 8.33
MIN, MAX	-58.3, 66.7	-25.0, 50.0
CYCLE 7		
N	35	38
MEAN	84.52	88.82
SD	20.823	17.680
MEDIAN	91.67	100.00
Q1, Q3	75.00, 100.00	83.33, 100.00
MIN, MAX	8.3, 100.0	41.7, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 7		
N	34	38
MEAN	3.92	3.29
SD	24.893	15.923
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 8.33
MIN, MAX	-58.3, 58.3	-25.0, 50.0
CYCLE 8		
N	34	38
MEAN	83.09	88.38
SD	21.951	14.439
MEDIAN	87.50	91.67
Q1, Q3	75.00, 100.00	83.33, 100.00
MIN, MAX	0.0, 100.0	50.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	33	38
MEAN	2.78	2.63
SD	25.144	13.851
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 16.67	0.00, 8.33
MIN, MAX	-66.7, 58.3	-25.0, 41.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 9		
N	32	32
MEAN	82.55	83.59
SD	19.325	21.112
MEDIAN	91.67	91.67
Q1, Q3	66.67, 100.00	70.83, 100.00
MIN, MAX	16.7, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	31	32
MEAN	1.08	-0.26
SD	24.319	15.908
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 16.67	-8.33, 0.00
MIN, MAX	-50.0, 58.3	-33.3, 33.3
CYCLE 10		
N	31	30
MEAN	84.68	87.50
SD	19.257	17.473
MEDIAN	91.67	95.83
Q1, Q3	66.67, 100.00	75.00, 100.00
MIN, MAX	16.7, 100.0	33.3, 100.0

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Safety Set for NTRK+
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	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 10		
N	30	30
MEAN	3.61	3.61
SD	24.534	15.580
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 16.67	0.00, 8.33
MIN, MAX	-50.0, 66.7	-33.3, 41.7
CYCLE 11		
N	30	27
MEAN	85.28	88.99
SD	20.492	17.010
MEDIAN	95.83	100.00
Q1, Q3	66.67, 100.00	83.33, 100.00
MIN, MAX	8.3, 100.0	41.7, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	29	27
MEAN	4.31	3.19
SD	24.763	13.689
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 16.67	0.00, 8.33
MIN, MAX	-58.3, 66.7	-25.0, 33.3

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 12		
N	27	23
MEAN	85.19	88.04
SD	22.329	20.540
MEDIAN	100.00	100.00
Q1, Q3	66.67, 100.00	83.33, 100.00
MIN, MAX	0.0, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	26	23
MEAN	2.88	3.99
SD	23.326	15.865
MEDIAN	0.00	0.00
Q1, Q3	0.00, 8.33	0.00, 8.33
MIN, MAX	-66.7, 58.3	-41.7, 33.3
CYCLE 13		
N	28	21
MEAN	83.93	84.13
SD	18.830	25.125
MEDIAN	91.67	100.00
Q1, Q3	66.67, 100.00	83.33, 100.00
MIN, MAX	41.7, 100.0	25.0, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 13		
N	27	21
MEAN	2.16	-2.38
SD	18.139	20.774
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 16.67	0.00, 0.00
MIN, MAX	-41.7, 41.7	-66.7, 41.7
CYCLE 14		
N	21	13
MEAN	87.70	85.90
SD	16.163	23.419
MEDIAN	100.00	91.67
Q1, Q3	75.00, 100.00	83.33, 100.00
MIN, MAX	50.0, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	20	13
MEAN	5.83	1.92
SD	21.815	21.558
MEDIAN	0.00	0.00
Q1, Q3	-12.50, 16.67	0.00, 16.67
MIN, MAX	-16.7, 58.3	-41.7, 41.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 15		
N	28	16
MEAN	81.85	86.46
SD	21.642	23.936
MEDIAN	91.67	100.00
Q1, Q3	66.67, 100.00	79.17, 100.00
MIN, MAX	25.0, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	27	16
MEAN	0.00	-1.04
SD	20.412	17.970
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-4.17, 4.17
MIN, MAX	-41.7, 50.0	-41.7, 41.7
CYCLE 16		
N	21	13
MEAN	82.94	84.62
SD	17.175	22.783
MEDIAN	83.33	91.67
Q1, Q3	66.67, 100.00	75.00, 100.00
MIN, MAX	50.0, 100.0	33.3, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 16		
N	21	13
MEAN	1.59	0.00
SD	22.457	14.027
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 16.67	0.00, 8.33
MIN, MAX	-50.0, 50.0	-25.0, 25.0
CYCLE 17		
N	24	13
MEAN	85.07	88.46
SD	17.021	14.248
MEDIAN	87.50	100.00
Q1, Q3	70.83, 100.00	83.33, 100.00
MIN, MAX	41.7, 100.0	66.7, 100.0
CHANGE FROM BASELINE AT CYCLE 17		
N	23	13
MEAN	3.99	0.64
SD	20.546	9.293
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 16.67	0.00, 0.00
MIN, MAX	-33.3, 50.0	-25.0, 16.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 18		
N	11	8
MEAN	87.12	85.42
SD	15.970	19.796
MEDIAN	100.00	91.67
Q1, Q3	75.00, 100.00	79.17, 100.00
MIN, MAX	58.3, 100.0	41.7, 100.0
CHANGE FROM BASELINE AT CYCLE 18		
N	11	8
MEAN	11.36	6.25
SD	18.735	13.176
MEDIAN	0.00	8.33
Q1, Q3	0.00, 16.67	0.00, 12.50
MIN, MAX	-8.3, 50.0	-16.7, 25.0
CYCLE 19		
N	21	12
MEAN	80.95	89.58
SD	16.903	22.508
MEDIAN	83.33	100.00
Q1, Q3	66.67, 91.67	91.67, 100.00
MIN, MAX	33.3, 100.0	25.0, 100.0

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 19		
N	21	12
MEAN	-0.40	2.78
SD	19.628	16.023
MEDIAN	0.00	4.17
Q1, Q3	-8.33, 0.00	0.00, 8.33
MIN, MAX	-41.7, 41.7	-41.7, 25.0
CYCLE 20		
N	10	5
MEAN	80.83	75.00
SD	15.738	27.639
MEDIAN	83.33	75.00
Q1, Q3	66.67, 91.67	66.67, 100.00
MIN, MAX	58.3, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 20		
N	10	5
MEAN	10.00	-1.67
SD	16.102	19.003
MEDIAN	8.33	0.00
Q1, Q3	0.00, 16.67	0.00, 8.33
MIN, MAX	-8.3, 41.7	-33.3, 16.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 21		
N	13	8
MEAN	83.33	93.75
SD	12.729	11.573
MEDIAN	83.33	100.00
Q1, Q3	75.00, 91.67	91.67, 100.00
MIN, MAX	66.7, 100.0	66.7, 100.0
CHANGE FROM BASELINE AT CYCLE 21		
N	13	8
MEAN	6.41	6.25
SD	19.882	7.387
MEDIAN	0.00	4.17
Q1, Q3	-8.33, 16.67	0.00, 12.50
MIN, MAX	-16.7, 50.0	0.0, 16.7
CYCLE 22		
N	18	7
MEAN	80.71	96.43
SD	18.264	6.557
MEDIAN	80.56	100.00
Q1, Q3	66.67, 100.00	91.67, 100.00
MIN, MAX	41.7, 100.0	83.3, 100.0

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Table P.2.2
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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 22		
N	18	7
MEAN	0.62	10.71
SD	17.349	12.467
MEDIAN	0.00	8.33
Q1, Q3	-8.33, 16.67	0.00, 16.67
MIN, MAX	-33.3, 36.1	0.0, 33.3
CYCLE 23		
N	7	4
MEAN	72.62	91.67
SD	12.467	6.804
MEDIAN	66.67	91.67
Q1, Q3	66.67, 75.00	87.50, 95.83
MIN, MAX	66.7, 100.0	83.3, 100.0
CHANGE FROM BASELINE AT CYCLE 23		
N	7	4
MEAN	-2.38	12.50
SD	14.996	15.957
MEDIAN	-8.33	8.33
Q1, Q3	-8.33, 16.67	0.00, 25.00
MIN, MAX	-25.0, 16.7	0.0, 33.3

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 24		
N	11	4
MEAN	86.36	85.42
SD	15.034	17.180
MEDIAN	91.67	87.50
Q1, Q3	66.67, 100.00	70.83, 100.00
MIN, MAX	66.7, 100.0	66.7, 100.0
CHANGE FROM BASELINE AT CYCLE 24		
N	11	4
MEAN	5.30	8.33
SD	13.577	9.623
MEDIAN	0.00	8.33
Q1, Q3	0.00, 16.67	0.00, 16.67
MIN, MAX	-16.7, 25.0	0.0, 16.7
CYCLE 25		
N	12	4
MEAN	77.08	93.75
SD	15.128	7.979
MEDIAN	70.83	95.83
Q1, Q3	66.67, 91.67	87.50, 100.00
MIN, MAX	58.3, 100.0	83.3, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 25		
N	12	4
MEAN	-2.08	12.50
SD	11.307	19.837
MEDIAN	0.00	4.17
Q1, Q3	-8.33, 0.00	0.00, 25.00
MIN, MAX	-25.0, 16.7	0.0, 41.7
CYCLE 26		
N	4	2
MEAN	62.50	83.33
SD	4.811	11.785
MEDIAN	62.50	83.33
Q1, Q3	58.33, 66.67	75.00, 91.67
MIN, MAX	58.3, 66.7	75.0, 91.7
CHANGE FROM BASELINE AT CYCLE 26		
N	4	2
MEAN	-4.17	20.83
SD	10.758	29.463
MEDIAN	-4.17	20.83
Q1, Q3	-12.50, 4.17	0.00, 41.67
MIN, MAX	-16.7, 8.3	0.0, 41.7

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Table P.2.2
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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 27		
N	6	4
MEAN	77.78	89.58
SD	22.153	12.500
MEDIAN	79.17	91.67
Q1, Q3	58.33, 100.00	79.17, 100.00
MIN, MAX	50.0, 100.0	75.0, 100.0
CHANGE FROM BASELINE AT CYCLE 27		
N	6	4
MEAN	-4.17	12.50
SD	4.564	25.000
MEDIAN	-4.17	0.00
Q1, Q3	-8.33, 0.00	0.00, 25.00
MIN, MAX	-8.3, 0.0	0.0, 50.0
CYCLE 28		
N	9	4
MEAN	83.33	95.83
SD	16.667	4.811
MEDIAN	83.33	95.83
Q1, Q3	66.67, 100.00	91.67, 100.00
MIN, MAX	66.7, 100.0	91.7, 100.0

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Table P.2.2
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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 28		
N	9	4
MEAN	3.70	6.25
SD	13.249	7.979
MEDIAN	0.00	4.17
Q1, Q3	0.00, 0.00	0.00, 12.50
MIN, MAX	-8.3, 33.3	0.0, 16.7
CYCLE 29		
N	5	2
MEAN	71.67	70.83
SD	16.245	5.893
MEDIAN	66.67	70.83
Q1, Q3	66.67, 66.67	66.67, 75.00
MIN, MAX	58.3, 100.0	66.7, 75.0
CHANGE FROM BASELINE AT CYCLE 29		
N	5	2
MEAN	-1.67	8.33
SD	12.360	11.785
MEDIAN	0.00	8.33
Q1, Q3	-8.33, 0.00	0.00, 16.67
MIN, MAX	-16.7, 16.7	0.0, 16.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 30		
N	2	3
MEAN	66.67	77.78
SD	0.000	17.347
MEDIAN	66.67	83.33
Q1, Q3	66.67, 66.67	58.33, 91.67
MIN, MAX	66.7, 66.7	58.3, 91.7
CHANGE FROM BASELINE AT CYCLE 30		
N	2	3
MEAN	8.33	8.33
SD	11.785	25.000
MEDIAN	8.33	8.33
Q1, Q3	0.00, 16.67	-16.67, 33.33
MIN, MAX	0.0, 16.7	-16.7, 33.3
CYCLE 31		
N	7	2
MEAN	71.43	87.50
SD	23.500	17.678
MEDIAN	66.67	87.50
Q1, Q3	58.33, 100.00	75.00, 100.00
MIN, MAX	33.3, 100.0	75.0, 100.0

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 31		
N	7	2
MEAN	-2.38	8.33
SD	20.250	11.785
MEDIAN	0.00	8.33
Q1, Q3	-8.33, 8.33	0.00, 16.67
MIN, MAX	-41.7, 25.0	0.0, 16.7
CYCLE 32		
N	3	1
MEAN	55.56	75.00
SD	19.245	N.A.
MEDIAN	66.67	75.00
Q1, Q3	33.33, 66.67	75.00, 75.00
MIN, MAX	33.3, 66.7	75.0, 75.0
CHANGE FROM BASELINE AT CYCLE 32		
N	3	1
MEAN	-8.33	0.00
SD	30.046	N.A.
MEDIAN	0.00	0.00
Q1, Q3	-41.67, 16.67	0.00, 0.00
MIN, MAX	-41.7, 16.7	0.0, 0.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 33		
N	1	2
MEAN	66.67	91.67
SD	N.A.	11.785
MEDIAN	66.67	91.67
Q1, Q3	66.67, 66.67	83.33, 100.00
MIN, MAX	66.7, 66.7	83.3, 100.0
CHANGE FROM BASELINE AT CYCLE 33		
N	1	2
MEAN	-8.33	12.50
SD	N.A.	5.893
MEDIAN	-8.33	12.50
Q1, Q3	-8.33, -8.33	8.33, 16.67
MIN, MAX	-8.3, -8.3	8.3, 16.7
CYCLE 34		
N	5	1
MEAN	81.67	100.00
SD	19.003	N.A.
MEDIAN	83.33	100.00
Q1, Q3	66.67, 100.00	100.00, 100.00
MIN, MAX	58.3, 100.0	100.0, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 34		
N	5	1
MEAN	1.67	16.67
SD	19.003	N.A.
MEDIAN	0.00	16.67
Q1, Q3	-8.33, 0.00	16.67, 16.67
MIN, MAX	-16.7, 33.3	16.7, 16.7
CYCLE 36		
N	1	0
MEAN	41.67	
SD	N.A.	
MEDIAN	41.67	
Q1, Q3	41.67, 41.67	
MIN, MAX	41.7, 41.7	
CHANGE FROM BASELINE AT CYCLE 36		
N	1	0
MEAN	-33.33	
SD	N.A.	
MEDIAN	-33.33	
Q1, Q3	-33.33, -33.33	
MIN, MAX	-33.3, -33.3	

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 37		
N	3	0
MEAN	75.00	
SD	22.048	
MEDIAN	66.67	
Q1, Q3	58.33, 100.00	
MIN, MAX	58.3, 100.0	
CHANGE FROM BASELINE AT CYCLE 37		
N	3	0
MEAN	0.00	
SD	16.667	
MEDIAN	0.00	
Q1, Q3	-16.67, 16.67	
MIN, MAX	-16.7, 16.7	
CYCLE 38		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 38		
N	1	0
MEAN	-8.33	
SD	N.A.	
MEDIAN	-8.33	
Q1, Q3	-8.33, -8.33	
MIN, MAX	-8.3, -8.3	
CYCLE 40		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	
CHANGE FROM BASELINE AT CYCLE 40		
N	1	0
MEAN	-8.33	
SD	N.A.	
MEDIAN	-8.33	
Q1, Q3	-8.33, -8.33	
MIN, MAX	-8.3, -8.3	

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 41		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	
CHANGE FROM BASELINE AT CYCLE 41		
N	1	0
MEAN	-8.33	
SD	N.A.	
MEDIAN	-8.33	
Q1, Q3	-8.33, -8.33	
MIN, MAX	-8.3, -8.3	
CYCLE 43		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	

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	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 43		
N	1	0
MEAN	-8.33	
SD	N.A.	
MEDIAN	-8.33	
Q1, Q3	-8.33, -8.33	
MIN, MAX	-8.3, -8.3	
END OF TREATMENT		
N	14	22
MEAN	82.74	75.38
SD	18.908	27.031
MEDIAN	87.50	83.33
Q1, Q3	75.00, 100.00	58.33, 100.00
MIN, MAX	41.7, 100.0	25.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	14	22
MEAN	-2.38	-4.92
SD	9.489	19.697
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 0.00	-8.33, 8.33
MIN, MAX	-25.0, 16.7	-50.0, 33.3

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
COGNITIVE FUNCTIONING		
BASELINE		
N	52	81
MEAN	82.69	87.86
SD	26.189	16.876
MEDIAN	91.67	100.00
Q1, Q3	83.33, 100.00	83.33, 100.00
MIN, MAX	0.0, 100.0	33.3, 100.0
CYCLE 2		
N	46	72
MEAN	79.35	85.42
SD	19.933	20.352
MEDIAN	83.33	100.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	45	71
MEAN	-4.81	-1.88
SD	22.925	13.671
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 0.00
MIN, MAX	-50.0, 83.3	-50.0, 33.3

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 3		
N	40	58
MEAN	79.58	85.34
SD	24.889	22.958
MEDIAN	83.33	100.00
Q1, Q3	66.67, 100.00	83.33, 100.00
MIN, MAX	16.7, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	39	57
MEAN	-4.27	-2.34
SD	27.762	13.887
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-66.7, 33.3
CYCLE 4		
N	39	53
MEAN	80.77	84.59
SD	26.084	21.145
MEDIAN	100.00	100.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	16.7, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 4		
N	38	52
MEAN	-3.07	-2.56
SD	28.437	13.360
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-8.33, 0.00
MIN, MAX	-66.7, 100.0	-33.3, 33.3
CYCLE 5		
N	39	44
MEAN	76.50	83.33
SD	23.792	21.265
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	38	43
MEAN	-7.02	-3.49
SD	32.334	12.888
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-16.67, 0.00
MIN, MAX	-83.3, 100.0	-33.3, 16.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 6		
N	37	38
MEAN	76.13	86.40
SD	26.510	23.524
MEDIAN	83.33	100.00
Q1, Q3	66.67, 100.00	83.33, 100.00
MIN, MAX	0.0, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	36	38
MEAN	-6.02	-1.75
SD	32.159	13.858
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-50.0, 33.3
CYCLE 7		
N	35	38
MEAN	76.19	86.40
SD	25.657	21.173
MEDIAN	83.33	100.00
Q1, Q3	66.67, 100.00	83.33, 100.00
MIN, MAX	0.0, 100.0	16.7, 100.0

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Safety Set for NTRK+
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	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 7		
N	34	38
MEAN	-8.33	-0.44
SD	31.315	13.693
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 0.00
MIN, MAX	-83.3, 100.0	-33.3, 33.3
CYCLE 8		
N	34	38
MEAN	77.94	85.53
SD	25.200	22.980
MEDIAN	83.33	100.00
Q1, Q3	66.67, 100.00	83.33, 100.00
MIN, MAX	0.0, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	33	38
MEAN	-6.06	-2.19
SD	32.226	15.582
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 0.00
MIN, MAX	-83.3, 100.0	-50.0, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 9		
N	32	32
MEAN	77.08	84.38
SD	24.593	23.546
MEDIAN	83.33	100.00
Q1, Q3	66.67, 100.00	75.00, 100.00
MIN, MAX	16.7, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	31	32
MEAN	-6.45	-1.04
SD	33.244	12.656
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-33.3, 33.3
CYCLE 10		
N	31	30
MEAN	78.49	84.44
SD	22.850	20.960
MEDIAN	83.33	100.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	33.3, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 10		
N	30	30
MEAN	-3.89	-1.11
SD	31.769	13.082
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-50.0, 16.7
CYCLE 11		
N	30	27
MEAN	75.00	82.72
SD	27.246	25.521
MEDIAN	83.33	100.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	29	27
MEAN	-7.47	-3.70
SD	32.910	12.518
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-83.3, 100.0	-33.3, 16.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 12		
N	27	23
MEAN	80.86	83.33
SD	21.535	27.061
MEDIAN	83.33	100.00
Q1, Q3	66.67, 100.00	83.33, 100.00
MIN, MAX	33.3, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	26	23
MEAN	-3.21	-0.72
SD	25.828	12.790
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 0.00
MIN, MAX	-50.0, 100.0	-33.3, 16.7
CYCLE 13		
N	28	21
MEAN	80.36	84.92
SD	18.732	22.916
MEDIAN	83.33	100.00
Q1, Q3	66.67, 100.00	83.33, 100.00
MIN, MAX	33.3, 100.0	16.7, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 13		
N	27	21
MEAN	-4.32	-2.38
SD	27.578	7.968
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-16.7, 16.7
CYCLE 14		
N	21	13
MEAN	80.16	85.90
SD	20.152	17.803
MEDIAN	83.33	100.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	50.0, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	20	13
MEAN	-5.00	1.28
SD	33.377	15.901
MEDIAN	0.00	0.00
Q1, Q3	-25.00, 0.00	0.00, 16.67
MIN, MAX	-66.7, 100.0	-33.3, 16.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 15		
N	28	16
MEAN	77.38	90.63
SD	22.321	16.066
MEDIAN	83.33	100.00
Q1, Q3	66.67, 100.00	83.33, 100.00
MIN, MAX	33.3, 100.0	50.0, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	27	16
MEAN	-7.41	2.08
SD	27.085	8.333
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-16.7, 16.7
CYCLE 16		
N	21	13
MEAN	79.37	87.18
SD	20.348	16.879
MEDIAN	83.33	100.00
Q1, Q3	66.67, 100.00	83.33, 100.00
MIN, MAX	16.7, 100.0	50.0, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 16		
N	21	13
MEAN	-6.35	0.00
SD	29.096	13.608
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 0.00
MIN, MAX	-83.3, 83.3	-33.3, 16.7
CYCLE 17		
N	24	13
MEAN	78.47	84.62
SD	20.548	17.296
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	50.0, 100.0
CHANGE FROM BASELINE AT CYCLE 17		
N	23	13
MEAN	-5.07	-5.13
SD	28.175	14.248
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-66.7, 83.3	-33.3, 16.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 18		
N	11	8
MEAN	75.76	85.42
SD	22.808	16.517
MEDIAN	66.67	91.67
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	66.7, 100.0
CHANGE FROM BASELINE AT CYCLE 18		
N	11	8
MEAN	-3.03	2.08
SD	40.701	20.774
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-8.33, 16.67
MIN, MAX	-66.7, 100.0	-33.3, 33.3
CYCLE 19		
N	21	12
MEAN	77.78	87.50
SD	21.300	12.563
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	83.33, 100.00
MIN, MAX	33.3, 100.0	66.7, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 19		
N	21	12
MEAN	-5.56	-1.39
SD	28.054	11.143
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-8.33, 0.00
MIN, MAX	-66.7, 83.3	-16.7, 16.7
CYCLE 20		
N	10	5
MEAN	66.67	80.00
SD	20.787	36.132
MEDIAN	66.67	100.00
Q1, Q3	66.67, 83.33	83.33, 100.00
MIN, MAX	33.3, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 20		
N	10	5
MEAN	-8.33	-6.67
SD	34.471	25.276
MEDIAN	-16.67	0.00
Q1, Q3	-16.67, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-50.0, 16.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 21		
N	13	8
MEAN	73.08	91.67
SD	21.014	8.909
MEDIAN	66.67	91.67
Q1, Q3	66.67, 83.33	83.33, 100.00
MIN, MAX	33.3, 100.0	83.3, 100.0
CHANGE FROM BASELINE AT CYCLE 21		
N	13	8
MEAN	-5.13	-4.17
SD	26.688	11.785
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-33.3, 66.7	-16.7, 16.7
CYCLE 22		
N	18	7
MEAN	73.15	85.71
SD	23.666	11.501
MEDIAN	75.00	83.33
Q1, Q3	66.67, 100.00	83.33, 100.00
MIN, MAX	33.3, 100.0	66.7, 100.0

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	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 22		
N	18	7
MEAN	-11.11	-4.76
SD	26.197	12.599
MEDIAN	-16.67	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-66.7, 66.7	-16.7, 16.7
CYCLE 23		
N	7	4
MEAN	50.00	91.67
SD	25.459	9.623
MEDIAN	50.00	91.67
Q1, Q3	33.33, 83.33	83.33, 100.00
MIN, MAX	16.7, 83.3	83.3, 100.0
CHANGE FROM BASELINE AT CYCLE 23		
N	7	4
MEAN	-28.57	0.00
SD	28.406	13.608
MEDIAN	-33.33	0.00
Q1, Q3	-33.33, 0.00	-8.33, 8.33
MIN, MAX	-83.3, 0.0	-16.7, 16.7

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	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 24		
N	11	4
MEAN	71.21	91.67
SD	23.677	9.623
MEDIAN	83.33	91.67
Q1, Q3	50.00, 83.33	83.33, 100.00
MIN, MAX	33.3, 100.0	83.3, 100.0
CHANGE FROM BASELINE AT CYCLE 24		
N	11	4
MEAN	-15.15	0.00
SD	20.350	13.608
MEDIAN	-16.67	0.00
Q1, Q3	-16.67, 0.00	-8.33, 8.33
MIN, MAX	-66.7, 0.0	-16.7, 16.7
CYCLE 25		
N	12	4
MEAN	75.00	83.33
SD	23.028	13.608
MEDIAN	83.33	83.33
Q1, Q3	66.67, 91.67	75.00, 91.67
MIN, MAX	33.3, 100.0	66.7, 100.0

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Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 25		
N	12	4
MEAN	-13.89	0.00
SD	13.914	13.608
MEDIAN	-16.67	0.00
Q1, Q3	-25.00, 0.00	-8.33, 8.33
MIN, MAX	-33.3, 0.0	-16.7, 16.7
CYCLE 26		
N	4	2
MEAN	54.17	83.33
SD	15.957	0.000
MEDIAN	58.33	83.33
Q1, Q3	41.67, 66.67	83.33, 83.33
MIN, MAX	33.3, 66.7	83.3, 83.3
CHANGE FROM BASELINE AT CYCLE 26		
N	4	2
MEAN	-16.67	0.00
SD	13.608	0.000
MEDIAN	-16.67	0.00
Q1, Q3	-25.00, -8.33	0.00, 0.00
MIN, MAX	-33.3, 0.0	0.0, 0.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 27		
N	6	4
MEAN	72.22	91.67
SD	31.032	9.623
MEDIAN	83.33	91.67
Q1, Q3	33.33, 100.00	83.33, 100.00
MIN, MAX	33.3, 100.0	83.3, 100.0
CHANGE FROM BASELINE AT CYCLE 27		
N	6	4
MEAN	-11.11	0.00
SD	13.608	13.608
MEDIAN	-8.33	0.00
Q1, Q3	-16.67, 0.00	-8.33, 8.33
MIN, MAX	-33.3, 0.0	-16.7, 16.7
CYCLE 28		
N	9	4
MEAN	70.37	91.67
SD	29.788	9.623
MEDIAN	83.33	91.67
Q1, Q3	33.33, 100.00	83.33, 100.00
MIN, MAX	33.3, 100.0	83.3, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 28		
N	9	4
MEAN	-16.67	4.17
SD	22.048	15.957
MEDIAN	-16.67	8.33
Q1, Q3	-16.67, 0.00	-8.33, 16.67
MIN, MAX	-66.7, 0.0	-16.7, 16.7
CYCLE 29		
N	5	2
MEAN	56.67	91.67
SD	19.003	11.785
MEDIAN	50.00	91.67
Q1, Q3	50.00, 66.67	83.33, 100.00
MIN, MAX	33.3, 83.3	83.3, 100.0
CHANGE FROM BASELINE AT CYCLE 29		
N	5	2
MEAN	-20.00	8.33
SD	21.731	11.785
MEDIAN	-33.33	8.33
Q1, Q3	-33.33, -16.67	0.00, 16.67
MIN, MAX	-33.3, 16.7	0.0, 16.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 30		
N	2	3
MEAN	58.33	83.33
SD	35.355	16.667
MEDIAN	58.33	83.33
Q1, Q3	33.33, 83.33	66.67, 100.00
MIN, MAX	33.3, 83.3	66.7, 100.0
CHANGE FROM BASELINE AT CYCLE 30		
N	2	3
MEAN	-25.00	-5.56
SD	11.785	19.245
MEDIAN	-25.00	-16.67
Q1, Q3	-33.33, -16.67	-16.67, 16.67
MIN, MAX	-33.3, -16.7	-16.7, 16.7
CYCLE 31		
N	7	2
MEAN	59.52	100.00
SD	26.972	0.000
MEDIAN	66.67	100.00
Q1, Q3	33.33, 83.33	100.00, 100.00
MIN, MAX	33.3, 100.0	100.0, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 31		
N	7	2
MEAN	-23.81	8.33
SD	23.288	11.785
MEDIAN	-16.67	8.33
Q1, Q3	-33.33, 0.00	0.00, 16.67
MIN, MAX	-66.7, 0.0	0.0, 16.7
CYCLE 32		
N	3	1
MEAN	55.56	100.00
SD	25.459	N.A.
MEDIAN	50.00	100.00
Q1, Q3	33.33, 83.33	100.00, 100.00
MIN, MAX	33.3, 83.3	100.0, 100.0
CHANGE FROM BASELINE AT CYCLE 32		
N	3	1
MEAN	-27.78	16.67
SD	9.623	N.A.
MEDIAN	-33.33	16.67
Q1, Q3	-33.33, -16.67	16.67, 16.67
MIN, MAX	-33.3, -16.7	16.7, 16.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 33		
N	1	2
MEAN	33.33	100.00
SD	N.A.	0.000
MEDIAN	33.33	100.00
Q1, Q3	33.33, 33.33	100.00, 100.00
MIN, MAX	33.3, 33.3	100.0, 100.0
CHANGE FROM BASELINE AT CYCLE 33		
N	1	2
MEAN	0.00	8.33
SD	N.A.	11.785
MEDIAN	0.00	8.33
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 0.0	0.0, 16.7
CYCLE 34		
N	5	1
MEAN	60.00	100.00
SD	27.889	N.A.
MEDIAN	66.67	100.00
Q1, Q3	33.33, 66.67	100.00, 100.00
MIN, MAX	33.3, 100.0	100.0, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 34		
N	5	1
MEAN	-23.33	0.00
SD	27.889	N.A.
MEDIAN	-16.67	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 0.0	0.0, 0.0
CYCLE 36		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 36		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 37		
N	3	0
MEAN	72.22	
SD	25.459	
MEDIAN	66.67	
Q1, Q3	50.00, 100.00	
MIN, MAX	50.0, 100.0	
CHANGE FROM BASELINE AT CYCLE 37		
N	3	0
MEAN	-5.56	
SD	25.459	
MEDIAN	0.00	
Q1, Q3	-33.33, 16.67	
MIN, MAX	-33.3, 16.7	
CYCLE 38		
N	1	0
MEAN	50.00	
SD	N.A.	
MEDIAN	50.00	
Q1, Q3	50.00, 50.00	
MIN, MAX	50.0, 50.0	

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Table P.2.2
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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 38		
N	1	0
MEAN	16.67	
SD	N.A.	
MEDIAN	16.67	
Q1, Q3	16.67, 16.67	
MIN, MAX	16.7, 16.7	
CYCLE 40		
N	1	0
MEAN	50.00	
SD	N.A.	
MEDIAN	50.00	
Q1, Q3	50.00, 50.00	
MIN, MAX	50.0, 50.0	
CHANGE FROM BASELINE AT CYCLE 40		
N	1	0
MEAN	16.67	
SD	N.A.	
MEDIAN	16.67	
Q1, Q3	16.67, 16.67	
MIN, MAX	16.7, 16.7	

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 41		
N	1	0
MEAN	50.00	
SD	N.A.	
MEDIAN	50.00	
Q1, Q3	50.00, 50.00	
MIN, MAX	50.0, 50.0	
CHANGE FROM BASELINE AT CYCLE 41		
N	1	0
MEAN	16.67	
SD	N.A.	
MEDIAN	16.67	
Q1, Q3	16.67, 16.67	
MIN, MAX	16.7, 16.7	
CYCLE 43		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 43		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
END OF TREATMENT		
N	14	22
MEAN	80.95	75.76
SD	21.540	23.417
MEDIAN	83.33	83.33
Q1, Q3	83.33, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	14	22
MEAN	0.00	-6.82
SD	29.235	14.235
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-33.3, 83.3	-50.0, 16.7

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
SOCIAL FUNCTIONING		
BASELINE		
N	52	81
MEAN	80.77	79.84
SD	27.093	24.961
MEDIAN	100.00	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	46	73
MEAN	75.00	79.91
SD	25.276	26.199
MEDIAN	75.00	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	45	72
MEAN	-4.81	-0.23
SD	24.262	27.047
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-50.0, 66.7	-66.7, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 3		
N	40	58
MEAN	79.58	81.61
SD	20.145	24.321
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	39	57
MEAN	-2.99	1.46
SD	31.732	26.405
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-66.7, 100.0
CYCLE 4		
N	39	53
MEAN	78.21	83.65
SD	23.925	19.196
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	16.7, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 4		
N	38	52
MEAN	-3.95	3.53
SD	30.372	25.209
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-50.0, 100.0
CYCLE 5		
N	39	44
MEAN	76.50	87.50
SD	28.284	16.125
MEDIAN	83.33	100.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	50.0, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	38	43
MEAN	-5.70	7.75
SD	38.414	25.807
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 16.67
MIN, MAX	-100.0, 100.0	-33.3, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 6		
N	37	38
MEAN	76.58	86.84
SD	27.347	18.647
MEDIAN	83.33	100.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	36	38
MEAN	-6.94	6.14
SD	37.027	23.062
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 16.67
MIN, MAX	-100.0, 100.0	-33.3, 100.0
CYCLE 7		
N	35	38
MEAN	82.38	84.21
SD	24.234	22.907
MEDIAN	100.00	100.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	16.7, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 7		
N	34	38
MEAN	-1.47	3.95
SD	30.805	28.589
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 16.67
MIN, MAX	-66.7, 100.0	-50.0, 100.0
CYCLE 8		
N	34	38
MEAN	79.90	84.21
SD	25.551	23.553
MEDIAN	83.33	100.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	33	38
MEAN	-3.54	3.07
SD	36.505	28.960
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 16.67
MIN, MAX	-66.7, 100.0	-66.7, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 9		
N	32	32
MEAN	80.21	82.81
SD	24.479	22.987
MEDIAN	83.33	100.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	31	32
MEAN	-4.30	3.13
SD	36.507	25.554
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 8.33
MIN, MAX	-66.7, 100.0	-50.0, 100.0
CYCLE 10		
N	31	30
MEAN	82.80	82.78
SD	24.901	20.754
MEDIAN	100.00	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	16.7, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 10		
N	30	30
MEAN	-1.11	3.89
SD	36.340	27.917
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 16.67
MIN, MAX	-66.7, 100.0	-50.0, 100.0
CYCLE 11		
N	30	27
MEAN	79.44	88.27
SD	29.258	22.558
MEDIAN	100.00	100.00
Q1, Q3	66.67, 100.00	83.33, 100.00
MIN, MAX	0.0, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	29	27
MEAN	-4.60	5.56
SD	33.599	29.598
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 16.67
MIN, MAX	-100.0, 83.3	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 12		
N	27	23
MEAN	88.27	86.23
SD	22.558	17.154
MEDIAN	100.00	100.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	50.0, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	26	23
MEAN	2.56	3.62
SD	28.555	23.004
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	-50.0, 100.0	-33.3, 83.3
CYCLE 13		
N	28	21
MEAN	84.52	82.54
SD	21.242	25.537
MEDIAN	100.00	100.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	0.0, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 13		
N	27	21
MEAN	-1.85	3.97
SD	27.863	31.138
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 16.67
MIN, MAX	-50.0, 100.0	-66.7, 83.3
CYCLE 14		
N	21	13
MEAN	89.68	89.74
SD	17.059	16.013
MEDIAN	100.00	100.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	50.0, 100.0	66.7, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	20	13
MEAN	3.33	12.82
SD	31.344	34.125
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 8.33	0.00, 33.33
MIN, MAX	-33.3, 100.0	-33.3, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 15		
N	28	16
MEAN	81.55	86.46
SD	24.985	19.454
MEDIAN	100.00	100.00
Q1, Q3	66.67, 100.00	75.00, 100.00
MIN, MAX	0.0, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	27	16
MEAN	-5.56	7.29
SD	31.351	25.797
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 8.33
MIN, MAX	-50.0, 100.0	-33.3, 83.3
CYCLE 16		
N	21	13
MEAN	84.13	92.31
SD	18.616	18.777
MEDIAN	83.33	100.00
Q1, Q3	66.67, 100.00	100.00, 100.00
MIN, MAX	33.3, 100.0	33.3, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 16		
N	21	13
MEAN	-7.14	15.38
SD	22.713	32.247
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 16.67
MIN, MAX	-33.3, 50.0	-33.3, 100.0
CYCLE 17		
N	24	13
MEAN	84.72	83.33
SD	18.334	18.002
MEDIAN	91.67	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	50.0, 100.0
CHANGE FROM BASELINE AT CYCLE 17		
N	23	13
MEAN	-1.45	5.13
SD	29.264	24.893
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 0.00
MIN, MAX	-33.3, 100.0	-16.7, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 18		
N	11	8
MEAN	77.27	79.17
SD	23.889	24.801
MEDIAN	66.67	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 18		
N	11	8
MEAN	-9.09	10.42
SD	17.262	40.764
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 41.67
MIN, MAX	-33.3, 16.7	-66.7, 66.7
CYCLE 19		
N	21	12
MEAN	78.57	93.06
SD	19.821	13.216
MEDIAN	66.67	100.00
Q1, Q3	66.67, 100.00	91.67, 100.00
MIN, MAX	33.3, 100.0	66.7, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 19		
N	21	12
MEAN	-10.32	16.67
SD	19.348	23.570
MEDIAN	-16.67	0.00
Q1, Q3	-33.33, 0.00	0.00, 33.33
MIN, MAX	-33.3, 33.3	0.0, 66.7
CYCLE 20		
N	10	5
MEAN	76.67	80.00
SD	22.498	18.257
MEDIAN	66.67	66.67
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	66.7, 100.0
CHANGE FROM BASELINE AT CYCLE 20		
N	10	5
MEAN	-8.33	20.00
SD	26.352	29.814
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 33.33
MIN, MAX	-33.3, 50.0	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 21		
N	13	8
MEAN	74.36	91.67
SD	23.189	8.909
MEDIAN	66.67	91.67
Q1, Q3	66.67, 100.00	83.33, 100.00
MIN, MAX	33.3, 100.0	83.3, 100.0
CHANGE FROM BASELINE AT CYCLE 21		
N	13	8
MEAN	-11.54	16.67
SD	24.893	30.861
MEDIAN	-16.67	8.33
Q1, Q3	-33.33, 0.00	0.00, 25.00
MIN, MAX	-33.3, 50.0	-16.7, 83.3
CYCLE 22		
N	18	7
MEAN	75.93	78.57
SD	25.707	15.853
MEDIAN	75.00	66.67
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	66.7, 100.0

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 22		
N	18	7
MEAN	-12.96	7.14
SD	22.547	30.211
MEDIAN	-8.33	0.00
Q1, Q3	-33.33, 0.00	0.00, 16.67
MIN, MAX	-66.7, 16.7	-33.3, 66.7
CYCLE 23		
N	7	4
MEAN	64.29	79.17
SD	26.227	15.957
MEDIAN	66.67	75.00
Q1, Q3	33.33, 83.33	66.67, 91.67
MIN, MAX	33.3, 100.0	66.7, 100.0
CHANGE FROM BASELINE AT CYCLE 23		
N	7	4
MEAN	-19.05	20.83
SD	11.501	31.549
MEDIAN	-16.67	8.33
Q1, Q3	-33.33, -16.67	0.00, 41.67
MIN, MAX	-33.3, 0.0	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 24		
N	11	4
MEAN	78.79	91.67
SD	26.968	9.623
MEDIAN	100.00	91.67
Q1, Q3	66.67, 100.00	83.33, 100.00
MIN, MAX	33.3, 100.0	83.3, 100.0
CHANGE FROM BASELINE AT CYCLE 24		
N	11	4
MEAN	-12.12	33.33
SD	18.395	45.134
MEDIAN	0.00	16.67
Q1, Q3	-33.33, 0.00	8.33, 58.33
MIN, MAX	-33.3, 16.7	0.0, 100.0
CYCLE 25		
N	12	4
MEAN	79.17	79.17
SD	25.746	15.957
MEDIAN	91.67	75.00
Q1, Q3	66.67, 100.00	66.67, 91.67
MIN, MAX	33.3, 100.0	66.7, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 25		
N	12	4
MEAN	-12.50	12.50
SD	17.588	59.900
MEDIAN	-8.33	-8.33
Q1, Q3	-33.33, 0.00	-25.00, 50.00
MIN, MAX	-33.3, 16.7	-33.3, 100.0
CYCLE 26		
N	4	2
MEAN	62.50	75.00
SD	34.359	11.785
MEDIAN	58.33	75.00
Q1, Q3	33.33, 91.67	66.67, 83.33
MIN, MAX	33.3, 100.0	66.7, 83.3
CHANGE FROM BASELINE AT CYCLE 26		
N	4	2
MEAN	-16.67	41.67
SD	13.608	58.926
MEDIAN	-16.67	41.67
Q1, Q3	-25.00, -8.33	0.00, 83.33
MIN, MAX	-33.3, 0.0	0.0, 83.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 27		
N	6	4
MEAN	72.22	79.17
SD	32.773	15.957
MEDIAN	83.33	75.00
Q1, Q3	33.33, 100.00	66.67, 91.67
MIN, MAX	33.3, 100.0	66.7, 100.0
CHANGE FROM BASELINE AT CYCLE 27		
N	6	4
MEAN	-11.11	20.83
SD	20.184	53.359
MEDIAN	-8.33	0.00
Q1, Q3	-33.33, 0.00	-8.33, 50.00
MIN, MAX	-33.3, 16.7	-16.7, 100.0
CYCLE 28		
N	9	4
MEAN	72.22	87.50
SD	23.570	15.957
MEDIAN	66.67	91.67
Q1, Q3	66.67, 100.00	75.00, 100.00
MIN, MAX	33.3, 100.0	66.7, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 28		
N	9	4
MEAN	-16.67	4.17
SD	18.634	20.972
MEDIAN	-16.67	0.00
Q1, Q3	-33.33, 0.00	-8.33, 16.67
MIN, MAX	-33.3, 16.7	-16.7, 33.3
CYCLE 29		
N	5	2
MEAN	66.67	66.67
SD	26.352	0.000
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	66.67, 66.67
MIN, MAX	33.3, 100.0	66.7, 66.7
CHANGE FROM BASELINE AT CYCLE 29		
N	5	2
MEAN	-16.67	33.33
SD	11.785	47.140
MEDIAN	-16.67	33.33
Q1, Q3	-16.67, -16.67	0.00, 66.67
MIN, MAX	-33.3, 0.0	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 30		
N	2	3
MEAN	50.00	77.78
SD	23.570	19.245
MEDIAN	50.00	66.67
Q1, Q3	33.33, 66.67	66.67, 100.00
MIN, MAX	33.3, 66.7	66.7, 100.0
CHANGE FROM BASELINE AT CYCLE 30		
N	2	3
MEAN	-33.33	33.33
SD	0.000	33.333
MEDIAN	-33.33	33.33
Q1, Q3	-33.33, -33.33	0.00, 66.67
MIN, MAX	-33.3, -33.3	0.0, 66.7
CYCLE 31		
N	7	2
MEAN	61.90	66.67
SD	29.991	0.000
MEDIAN	66.67	66.67
Q1, Q3	33.33, 100.00	66.67, 66.67
MIN, MAX	33.3, 100.0	66.7, 66.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 31		
N	7	2
MEAN	-26.19	0.00
SD	23.288	0.000
MEDIAN	-33.33	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 0.0	0.0, 0.0
CYCLE 32		
N	3	1
MEAN	72.22	83.33
SD	34.694	N.A.
MEDIAN	83.33	83.33
Q1, Q3	33.33, 100.00	83.33, 83.33
MIN, MAX	33.3, 100.0	83.3, 83.3
CHANGE FROM BASELINE AT CYCLE 32		
N	3	1
MEAN	-16.67	16.67
SD	16.667	N.A.
MEDIAN	-16.67	16.67
Q1, Q3	-33.33, 0.00	16.67, 16.67
MIN, MAX	-33.3, 0.0	16.7, 16.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 33		
N	1	2
MEAN	33.33	83.33
SD	N.A.	23.570
MEDIAN	33.33	83.33
Q1, Q3	33.33, 33.33	66.67, 100.00
MIN, MAX	33.3, 33.3	66.7, 100.0
CHANGE FROM BASELINE AT CYCLE 33		
N	1	2
MEAN	-16.67	16.67
SD	N.A.	23.570
MEDIAN	-16.67	16.67
Q1, Q3	-16.67, -16.67	0.00, 33.33
MIN, MAX	-16.7, -16.7	0.0, 33.3
CYCLE 34		
N	5	1
MEAN	73.33	100.00
SD	27.889	N.A.
MEDIAN	66.67	100.00
Q1, Q3	66.67, 100.00	100.00, 100.00
MIN, MAX	33.3, 100.0	100.0, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 34		
N	5	1
MEAN	-16.67	33.33
SD	16.667	N.A.
MEDIAN	-16.67	33.33
Q1, Q3	-33.33, 0.00	33.33, 33.33
MIN, MAX	-33.3, 0.0	33.3, 33.3
CYCLE 36		
N	1	0
MEAN	50.00	
SD	N.A.	
MEDIAN	50.00	
Q1, Q3	50.00, 50.00	
MIN, MAX	50.0, 50.0	
CHANGE FROM BASELINE AT CYCLE 36		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 37		
N	3	0
MEAN	66.67	
SD	33.333	
MEDIAN	66.67	
Q1, Q3	33.33, 100.00	
MIN, MAX	33.3, 100.0	
CHANGE FROM BASELINE AT CYCLE 37		
N	3	0
MEAN	-16.67	
SD	16.667	
MEDIAN	-16.67	
Q1, Q3	-33.33, 0.00	
MIN, MAX	-33.3, 0.0	
CYCLE 38		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 38		
N	1	0
MEAN	-16.67	
SD	N.A.	
MEDIAN	-16.67	
Q1, Q3	-16.67, -16.67	
MIN, MAX	-16.7, -16.7	
CYCLE 40		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 40		
N	1	0
MEAN	-16.67	
SD	N.A.	
MEDIAN	-16.67	
Q1, Q3	-16.67, -16.67	
MIN, MAX	-16.7, -16.7	

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Table P.2.2
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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 41		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 41		
N	1	0
MEAN	-16.67	
SD	N.A.	
MEDIAN	-16.67	
Q1, Q3	-16.67, -16.67	
MIN, MAX	-16.7, -16.7	
CYCLE 43		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

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Table P.2.2
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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 43		
N	1	0
MEAN	-16.67	
SD	N.A.	
MEDIAN	-16.67	
Q1, Q3	-16.67, -16.67	
MIN, MAX	-16.7, -16.7	
END OF TREATMENT		
N	14	22
MEAN	70.24	71.97
SD	28.629	33.879
MEDIAN	66.67	83.33
Q1, Q3	50.00, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	14	22
MEAN	-2.38	-15.15
SD	15.821	33.692
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-33.3, 16.7	-83.3, 33.3

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
FATIGUE		
BASELINE		
N	52	81
MEAN	26.71	31.69
SD	23.104	26.064
MEDIAN	22.22	33.33
Q1, Q3	11.11, 33.33	11.11, 44.44
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	46	74
MEAN	28.74	24.77
SD	22.046	21.726
MEDIAN	22.22	22.22
Q1, Q3	11.11, 33.33	11.11, 33.33
MIN, MAX	0.0, 88.9	0.0, 88.9
CHANGE FROM BASELINE AT CYCLE 2		
N	45	73
MEAN	2.22	-6.24
SD	22.918	24.913
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 11.11	-22.22, 0.00
MIN, MAX	-77.8, 66.7	-66.7, 66.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 3		
N	41	58
MEAN	26.02	24.71
SD	20.429	24.276
MEDIAN	33.33	22.22
Q1, Q3	11.11, 33.33	0.00, 33.33
MIN, MAX	0.0, 77.8	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	40	57
MEAN	2.50	-4.48
SD	23.669	23.084
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 11.11	-11.11, 11.11
MIN, MAX	-66.7, 66.7	-66.7, 33.3
CYCLE 4		
N	39	53
MEAN	25.07	23.69
SD	20.507	22.306
MEDIAN	22.22	22.22
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 83.3

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 4		
N	38	52
MEAN	1.17	-6.62
SD	27.435	24.304
MEDIAN	0.00	0.00
Q1, Q3	0.00, 22.22	-19.44, 11.11
MIN, MAX	-100.0, 44.4	-55.6, 66.7
CYCLE 5		
N	39	45
MEAN	23.93	25.31
SD	20.158	24.029
MEDIAN	33.33	22.22
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 83.3
CHANGE FROM BASELINE AT CYCLE 5		
N	38	44
MEAN	-0.58	-6.69
SD	28.760	24.630
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 22.22	-22.22, 8.33
MIN, MAX	-88.9, 44.4	-66.7, 44.4

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 6		
N	37	38
MEAN	26.13	19.30
SD	22.256	24.600
MEDIAN	22.22	11.11
Q1, Q3	11.11, 44.44	0.00, 33.33
MIN, MAX	0.0, 77.8	0.0, 88.9
CHANGE FROM BASELINE AT CYCLE 6		
N	36	38
MEAN	1.54	-9.36
SD	29.595	22.301
MEDIAN	0.00	-5.56
Q1, Q3	-11.11, 22.22	-22.22, 0.00
MIN, MAX	-100.0, 44.4	-55.6, 33.3
CYCLE 7		
N	35	38
MEAN	22.22	19.88
SD	21.047	22.246
MEDIAN	22.22	11.11
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 77.8	0.0, 77.8

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 7		
N	34	38
MEAN	-1.31	-10.53
SD	25.771	24.771
MEDIAN	0.00	-11.11
Q1, Q3	-22.22, 22.22	-33.33, 11.11
MIN, MAX	-77.8, 33.3	-66.7, 33.3
CYCLE 8		
N	34	38
MEAN	21.90	22.22
SD	21.966	21.458
MEDIAN	22.22	22.22
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 77.8
CHANGE FROM BASELINE AT CYCLE 8		
N	33	38
MEAN	-1.68	-6.73
SD	25.778	22.303
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 22.22	-22.22, 11.11
MIN, MAX	-66.7, 44.4	-55.6, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 9		
N	32	32
MEAN	25.00	27.08
SD	21.120	26.163
MEDIAN	22.22	33.33
Q1, Q3	5.56, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	31	32
MEAN	1.08	-4.86
SD	30.001	21.849
MEDIAN	0.00	-5.56
Q1, Q3	-11.11, 22.22	-22.22, 5.56
MIN, MAX	-77.8, 55.6	-44.4, 33.3
CYCLE 10		
N	31	30
MEAN	21.51	23.33
SD	19.444	22.479
MEDIAN	22.22	22.22
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 88.9

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 10		
N	30	30
MEAN	-3.33	-8.15
SD	30.763	20.619
MEDIAN	0.00	-11.11
Q1, Q3	-22.22, 22.22	-22.22, 0.00
MIN, MAX	-77.8, 44.4	-44.4, 33.3
CYCLE 11		
N	30	27
MEAN	24.81	21.40
SD	22.730	23.046
MEDIAN	22.22	22.22
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 77.8	0.0, 88.9
CHANGE FROM BASELINE AT CYCLE 11		
N	29	27
MEAN	-0.38	-4.94
SD	24.030	23.537
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 11.11	-22.22, 0.00
MIN, MAX	-77.8, 44.4	-44.4, 55.6

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 12		
N	27	23
MEAN	22.63	18.84
SD	20.783	23.073
MEDIAN	22.22	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 77.8	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 12		
N	26	23
MEAN	-2.14	-7.73
SD	25.145	21.303
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 11.11	-22.22, 0.00
MIN, MAX	-77.8, 55.6	-55.6, 33.3
CYCLE 13		
N	28	21
MEAN	21.03	23.28
SD	21.242	25.557
MEDIAN	22.22	22.22
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 13		
N	27	21
MEAN	-2.06	-2.12
SD	24.467	23.470
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 22.22	-11.11, 11.11
MIN, MAX	-66.7, 33.3	-44.4, 55.6
CYCLE 14		
N	21	13
MEAN	26.98	23.93
SD	17.768	22.611
MEDIAN	33.33	11.11
Q1, Q3	11.11, 33.33	11.11, 33.33
MIN, MAX	0.0, 66.7	0.0, 77.8
CHANGE FROM BASELINE AT CYCLE 14		
N	20	13
MEAN	2.78	-3.42
SD	27.894	24.589
MEDIAN	11.11	0.00
Q1, Q3	-11.11, 16.67	-11.11, 11.11
MIN, MAX	-77.8, 44.4	-44.4, 33.3

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 15		
N	28	16
MEAN	26.59	16.67
SD	25.362	24.343
MEDIAN	27.78	0.00
Q1, Q3	0.00, 44.44	0.00, 27.78
MIN, MAX	0.0, 88.9	0.0, 77.8
CHANGE FROM BASELINE AT CYCLE 15		
N	27	16
MEAN	3.29	-6.94
SD	28.381	23.263
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 22.22	-22.22, 0.00
MIN, MAX	-66.7, 44.4	-44.4, 44.4
CYCLE 16		
N	21	13
MEAN	26.46	14.53
SD	23.695	17.792
MEDIAN	22.22	0.00
Q1, Q3	0.00, 44.44	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 44.4

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 16		
N	21	13
MEAN	4.23	-11.11
SD	29.706	24.003
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 22.22	-33.33, 0.00
MIN, MAX	-55.6, 66.7	-44.4, 33.3
CYCLE 17		
N	24	13
MEAN	28.24	19.66
SD	20.974	23.198
MEDIAN	33.33	11.11
Q1, Q3	11.11, 38.89	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 17		
N	23	13
MEAN	1.45	-0.85
SD	22.549	22.435
MEDIAN	11.11	0.00
Q1, Q3	-22.22, 22.22	-11.11, 11.11
MIN, MAX	-44.4, 33.3	-44.4, 33.3

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 18		
N	11	8
MEAN	27.27	22.22
SD	20.101	22.222
MEDIAN	33.33	16.67
Q1, Q3	11.11, 44.44	5.56, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 18		
N	11	8
MEAN	0.00	-9.72
SD	30.631	19.188
MEDIAN	0.00	-5.56
Q1, Q3	-22.22, 33.33	-22.22, 5.56
MIN, MAX	-55.6, 44.4	-44.4, 11.1
CYCLE 19		
N	21	12
MEAN	26.46	17.59
SD	20.928	21.947
MEDIAN	22.22	5.56
Q1, Q3	11.11, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 55.6

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
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Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 19		
N	21	12
MEAN	3.70	-4.63
SD	21.469	16.723
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 22.22	-11.11, 0.00
MIN, MAX	-44.4, 44.4	-44.4, 22.2
CYCLE 20		
N	10	5
MEAN	32.22	24.44
SD	14.296	25.337
MEDIAN	33.33	22.22
Q1, Q3	22.22, 44.44	0.00, 44.44
MIN, MAX	11.1, 55.6	0.0, 55.6
CHANGE FROM BASELINE AT CYCLE 20		
N	10	5
MEAN	1.11	-4.44
SD	25.364	16.851
MEDIAN	5.56	-11.11
Q1, Q3	-11.11, 22.22	-11.11, 0.00
MIN, MAX	-55.6, 22.2	-22.2, 22.2

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 21		
N	13	8
MEAN	27.35	6.94
SD	20.090	8.267
MEDIAN	22.22	5.56
Q1, Q3	11.11, 33.33	0.00, 11.11
MIN, MAX	0.0, 66.7	0.0, 22.2
CHANGE FROM BASELINE AT CYCLE 21		
N	13	8
MEAN	2.56	-8.33
SD	21.350	16.534
MEDIAN	0.00	-5.56
Q1, Q3	-11.11, 22.22	-22.22, 5.56
MIN, MAX	-44.4, 33.3	-33.3, 11.1
CYCLE 22		
N	18	7
MEAN	23.46	12.70
SD	21.181	13.500
MEDIAN	22.22	11.11
Q1, Q3	0.00, 33.33	0.00, 22.22
MIN, MAX	0.0, 66.7	0.0, 33.3

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Table P.2.2
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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 22		
N	18	7
MEAN	0.00	-9.52
SD	20.523	11.878
MEDIAN	0.00	-11.11
Q1, Q3	-11.11, 11.11	-11.11, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 0.0
CYCLE 23		
N	7	4
MEAN	33.33	13.89
SD	18.144	16.667
MEDIAN	33.33	11.11
Q1, Q3	22.22, 44.44	0.00, 27.78
MIN, MAX	11.1, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 23		
N	7	4
MEAN	7.94	-16.67
SD	18.937	6.415
MEDIAN	22.22	-16.67
Q1, Q3	-11.11, 22.22	-22.22, -11.11
MIN, MAX	-22.2, 22.2	-22.2, -11.1

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 24		
N	11	4
MEAN	23.23	25.00
SD	21.346	16.667
MEDIAN	33.33	22.22
Q1, Q3	0.00, 33.33	11.11, 38.89
MIN, MAX	0.0, 66.7	11.1, 44.4
CHANGE FROM BASELINE AT CYCLE 24		
N	11	4
MEAN	7.07	2.78
SD	16.683	33.179
MEDIAN	0.00	11.11
Q1, Q3	0.00, 22.22	-16.67, 22.22
MIN, MAX	-22.2, 33.3	-44.4, 33.3
CYCLE 25		
N	12	4
MEAN	25.00	16.67
SD	24.675	14.344
MEDIAN	22.22	16.67
Q1, Q3	0.00, 38.89	5.56, 27.78
MIN, MAX	0.0, 66.7	0.0, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 25		
N	12	4
MEAN	6.48	-13.89
SD	21.429	21.033
MEDIAN	11.11	-5.56
Q1, Q3	-5.56, 22.22	-27.78, 0.00
MIN, MAX	-33.3, 44.4	-44.4, 0.0
CYCLE 26		
N	4	2
MEAN	55.56	27.78
SD	15.713	7.857
MEDIAN	61.11	27.78
Q1, Q3	44.44, 66.67	22.22, 33.33
MIN, MAX	33.3, 66.7	22.2, 33.3
CHANGE FROM BASELINE AT CYCLE 26		
N	4	2
MEAN	27.78	-16.67
SD	6.415	23.570
MEDIAN	27.78	-16.67
Q1, Q3	22.22, 33.33	-33.33, 0.00
MIN, MAX	22.2, 33.3	-33.3, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 27		
N	6	4
MEAN	27.78	19.44
SD	28.760	16.667
MEDIAN	22.22	22.22
Q1, Q3	0.00, 55.56	5.56, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 27		
N	6	4
MEAN	9.26	-2.78
SD	20.387	13.981
MEDIAN	11.11	0.00
Q1, Q3	0.00, 22.22	-11.11, 5.56
MIN, MAX	-22.2, 33.3	-22.2, 11.1
CYCLE 28		
N	9	4
MEAN	28.40	22.22
SD	26.124	27.217
MEDIAN	33.33	16.67
Q1, Q3	0.00, 33.33	0.00, 44.44
MIN, MAX	0.0, 66.7	0.0, 55.6

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 28		
N	9	4
MEAN	8.64	5.56
SD	20.621	11.111
MEDIAN	0.00	0.00
Q1, Q3	0.00, 22.22	0.00, 11.11
MIN, MAX	-22.2, 44.4	0.0, 22.2
CYCLE 29		
N	5	2
MEAN	42.22	33.33
SD	14.487	0.000
MEDIAN	44.44	33.33
Q1, Q3	33.33, 55.56	33.33, 33.33
MIN, MAX	22.2, 55.6	33.3, 33.3
CHANGE FROM BASELINE AT CYCLE 29		
N	5	2
MEAN	17.78	-11.11
SD	9.938	15.713
MEDIAN	11.11	-11.11
Q1, Q3	11.11, 22.22	-22.22, 0.00
MIN, MAX	11.1, 33.3	-22.2, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 30		
N	2	3
MEAN	38.89	37.04
SD	7.857	23.130
MEDIAN	38.89	44.44
Q1, Q3	33.33, 44.44	11.11, 55.56
MIN, MAX	33.3, 44.4	11.1, 55.6
CHANGE FROM BASELINE AT CYCLE 30		
N	2	3
MEAN	22.22	7.41
SD	0.000	6.415
MEDIAN	22.22	11.11
Q1, Q3	22.22, 22.22	0.00, 11.11
MIN, MAX	22.2, 22.2	0.0, 11.1
CYCLE 31		
N	7	2
MEAN	38.10	22.22
SD	28.586	31.427
MEDIAN	44.44	22.22
Q1, Q3	0.00, 66.67	0.00, 44.44
MIN, MAX	0.0, 66.7	0.0, 44.4

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 31		
N	7	2
MEAN	17.46	5.56
SD	25.545	7.857
MEDIAN	33.33	5.56
Q1, Q3	0.00, 33.33	0.00, 11.11
MIN, MAX	-33.3, 33.3	0.0, 11.1
CYCLE 32		
N	3	1
MEAN	51.85	33.33
SD	25.660	N.A.
MEDIAN	66.67	33.33
Q1, Q3	22.22, 66.67	33.33, 33.33
MIN, MAX	22.2, 66.7	33.3, 33.3
CHANGE FROM BASELINE AT CYCLE 32		
N	3	1
MEAN	29.63	0.00
SD	16.973	N.A.
MEDIAN	33.33	0.00
Q1, Q3	11.11, 44.44	0.00, 0.00
MIN, MAX	11.1, 44.4	0.0, 0.0

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 33		
N	1	2
MEAN	66.67	11.11
SD	N.A.	15.713
MEDIAN	66.67	11.11
Q1, Q3	66.67, 66.67	0.00, 22.22
MIN, MAX	66.7, 66.7	0.0, 22.2
CHANGE FROM BASELINE AT CYCLE 33		
N	1	2
MEAN	22.22	-5.56
SD	N.A.	7.857
MEDIAN	22.22	-5.56
Q1, Q3	22.22, 22.22	-11.11, 0.00
MIN, MAX	22.2, 22.2	-11.1, 0.0
CYCLE 34		
N	5	1
MEAN	37.78	0.00
SD	23.040	N.A.
MEDIAN	33.33	0.00
Q1, Q3	22.22, 55.56	0.00, 0.00
MIN, MAX	11.1, 66.7	0.0, 0.0

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 34		
N	5	1
MEAN	13.33	0.00
SD	18.257	N.A.
MEDIAN	22.22	0.00
Q1, Q3	0.00, 22.22	0.00, 0.00
MIN, MAX	-11.1, 33.3	0.0, 0.0
CYCLE 36		
N	1	0
MEAN	55.56	
SD	N.A.	
MEDIAN	55.56	
Q1, Q3	55.56, 55.56	
MIN, MAX	55.6, 55.6	
CHANGE FROM BASELINE AT CYCLE 36		
N	1	0
MEAN	11.11	
SD	N.A.	
MEDIAN	11.11	
Q1, Q3	11.11, 11.11	
MIN, MAX	11.1, 11.1	

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 37		
N	3	0
MEAN	33.33	
SD	33.333	
MEDIAN	33.33	
Q1, Q3	0.00, 66.67	
MIN, MAX	0.0, 66.7	
CHANGE FROM BASELINE AT CYCLE 37		
N	3	0
MEAN	3.70	
SD	32.075	
MEDIAN	22.22	
Q1, Q3	-33.33, 22.22	
MIN, MAX	-33.3, 22.2	
CYCLE 38		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 38		
N	1	0
MEAN	22.22	
SD	N.A.	
MEDIAN	22.22	
Q1, Q3	22.22, 22.22	
MIN, MAX	22.2, 22.2	
CYCLE 40		
N	1	0
MEAN	77.78	
SD	N.A.	
MEDIAN	77.78	
Q1, Q3	77.78, 77.78	
MIN, MAX	77.8, 77.8	
CHANGE FROM BASELINE AT CYCLE 40		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 41		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	
CHANGE FROM BASELINE AT CYCLE 41		
N	1	0
MEAN	22.22	
SD	N.A.	
MEDIAN	22.22	
Q1, Q3	22.22, 22.22	
MIN, MAX	22.2, 22.2	
CYCLE 43		
N	1	0
MEAN	55.56	
SD	N.A.	
MEDIAN	55.56	
Q1, Q3	55.56, 55.56	
MIN, MAX	55.6, 55.6	

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 43		
N	1	0
MEAN	11.11	
SD	N.A.	
MEDIAN	11.11	
Q1, Q3	11.11, 11.11	
MIN, MAX	11.1, 11.1	
END OF TREATMENT		
N	14	22
MEAN	44.44	31.31
SD	28.578	32.645
MEDIAN	33.33	27.78
Q1, Q3	33.33, 66.67	0.00, 44.44
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	14	22
MEAN	10.32	1.01
SD	14.098	25.867
MEDIAN	11.11	0.00
Q1, Q3	0.00, 22.22	-11.11, 11.11
MIN, MAX	-22.2, 33.3	-44.4, 66.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
NAUSEA AND VOMITING		
BASELINE		
N	52	81
MEAN	3.85	6.58
SD	8.489	14.356
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 83.3
CYCLE 2		
N	46	74
MEAN	4.71	4.05
SD	10.342	13.176
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	45	73
MEAN	1.11	-2.51
SD	13.007	17.931
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-83.3, 83.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 3		
N	41	58
MEAN	2.44	3.45
SD	7.959	10.705
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 3		
N	40	57
MEAN	-0.83	-3.22
SD	11.291	16.797
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-83.3, 33.3
CYCLE 4		
N	39	53
MEAN	2.14	1.57
SD	5.645	5.905
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 16.7	0.0, 33.3

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 4		
N	38	52
MEAN	-0.88	-4.17
SD	9.450	12.294
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 16.7	-66.7, 16.7
CYCLE 5		
N	39	45
MEAN	2.14	2.96
SD	6.818	9.593
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 50.0
CHANGE FROM BASELINE AT CYCLE 5		
N	38	44
MEAN	-1.32	-3.41
SD	11.218	13.246
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-50.0, 33.3

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Table P.2.2
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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 6		
N	37	38
MEAN	3.60	1.32
SD	8.902	5.980
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 6		
N	36	38
MEAN	0.00	-3.07
SD	12.599	13.342
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-50.0, 33.3
CYCLE 7		
N	35	38
MEAN	3.81	1.32
SD	11.494	5.980
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 50.0	0.0, 33.3

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Table P.2.2
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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 7		
N	34	38
MEAN	0.49	-3.07
SD	15.616	9.376
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 50.0	-33.3, 16.7
CYCLE 8		
N	34	38
MEAN	1.96	3.51
SD	6.822	12.350
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 8		
N	33	38
MEAN	-1.52	-0.44
SD	12.050	13.693
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 9		
N	32	32
MEAN	2.60	3.13
SD	7.465	9.871
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 50.0
CHANGE FROM BASELINE AT CYCLE 9		
N	31	32
MEAN	-1.08	-1.56
SD	12.864	10.676
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 16.7
CYCLE 10		
N	31	30
MEAN	1.08	2.78
SD	5.987	7.686
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3

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Table P.2.2
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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 10		
N	30	30
MEAN	-2.78	-2.22
SD	11.649	12.172
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 33.3
CYCLE 11		
N	30	27
MEAN	2.22	3.09
SD	7.236	8.056
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 11		
N	29	27
MEAN	-1.72	1.23
SD	12.867	9.159
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-16.7, 33.3

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 12		
N	27	23
MEAN	3.09	2.90
SD	8.056	6.459
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 16.7
CHANGE FROM BASELINE AT CYCLE 12		
N	26	23
MEAN	0.00	0.72
SD	12.472	9.372
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-16.7, 16.7
CYCLE 13		
N	28	21
MEAN	3.57	0.79
SD	8.311	3.637
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 16.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 13		
N	27	21
MEAN	0.62	-1.59
SD	10.822	7.274
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-16.7, 16.7
CYCLE 14		
N	21	13
MEAN	6.35	6.41
SD	16.224	8.439
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 16.7
CHANGE FROM BASELINE AT CYCLE 14		
N	20	13
MEAN	1.67	3.85
SD	9.208	7.309
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-16.7, 33.3	0.0, 16.7

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 15		
N	28	16
MEAN	2.38	2.08
SD	7.473	5.693
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 16.7
CHANGE FROM BASELINE AT CYCLE 15		
N	27	16
MEAN	-0.62	0.00
SD	11.768	8.607
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-16.7, 16.7
CYCLE 16		
N	21	13
MEAN	5.56	1.28
SD	13.264	4.623
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 50.0	0.0, 16.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 16		
N	21	13
MEAN	3.17	-1.28
SD	16.346	8.226
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 50.0	-16.7, 16.7
CYCLE 17		
N	24	13
MEAN	4.17	0.00
SD	10.132	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 17		
N	23	13
MEAN	0.72	-1.28
SD	12.790	4.623
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-16.7, 0.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 18		
N	11	8
MEAN	3.03	10.42
SD	6.742	23.465
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 8.33
MIN, MAX	0.0, 16.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 18		
N	11	8
MEAN	0.00	8.33
SD	10.541	25.198
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 8.33
MIN, MAX	-16.7, 16.7	-16.7, 66.7
CYCLE 19		
N	21	12
MEAN	3.17	0.00
SD	6.706	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 16.7	0.0, 0.0

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	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 19		
N	21	12
MEAN	-0.79	-1.39
SD	11.151	4.811
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 16.7	-16.7, 0.0
CYCLE 20		
N	10	5
MEAN	1.67	0.00
SD	5.270	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 16.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 20		
N	10	5
MEAN	0.00	-3.33
SD	7.857	7.454
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-16.7, 16.7	-16.7, 0.0

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 21		
N	13	8
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 21		
N	13	8
MEAN	-5.13	-2.08
SD	10.507	5.893
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 0.0	-16.7, 0.0
CYCLE 22		
N	18	7
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0

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Safety Set for NTRK+
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	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 22		
N	18	7
MEAN	-3.70	-2.38
SD	9.139	6.299
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 0.0	-16.7, 0.0
CYCLE 23		
N	7	4
MEAN	2.38	0.00
SD	6.299	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 16.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 23		
N	7	4
MEAN	0.00	-4.17
SD	9.623	8.333
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-8.33, 0.00
MIN, MAX	-16.7, 16.7	-16.7, 0.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 24		
N	11	4
MEAN	0.00	4.17
SD	0.000	8.333
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 8.33
MIN, MAX	0.0, 0.0	0.0, 16.7
CHANGE FROM BASELINE AT CYCLE 24		
N	11	4
MEAN	-6.06	0.00
SD	11.237	0.000
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 0.00
MIN, MAX	-33.3, 0.0	0.0, 0.0
CYCLE 25		
N	12	4
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 25		
N	12	4
MEAN	-5.56	-4.17
SD	10.856	8.333
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 0.00	-8.33, 0.00
MIN, MAX	-33.3, 0.0	-16.7, 0.0
CYCLE 26		
N	4	2
MEAN	4.17	0.00
SD	8.333	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 8.33	0.00, 0.00
MIN, MAX	0.0, 16.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 26		
N	4	2
MEAN	0.00	-8.33
SD	13.608	11.785
MEDIAN	0.00	-8.33
Q1, Q3	-8.33, 8.33	-16.67, 0.00
MIN, MAX	-16.7, 16.7	-16.7, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;
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Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas 17JUL2024:09:53:51

Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 27		
N	6	4
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 27		
N	6	4
MEAN	-8.33	-4.17
SD	13.944	8.333
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-8.33, 0.00
MIN, MAX	-33.3, 0.0	-16.7, 0.0
CYCLE 28		
N	9	4
MEAN	7.41	0.00
SD	12.108	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 28		
N	9	4
MEAN	0.00	0.00
SD	16.667	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
MIN, MAX	-33.3, 16.7	0.0, 0.0
CYCLE 29		
N	5	2
MEAN	6.67	0.00
SD	9.129	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
MIN, MAX	0.0, 16.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 29		
N	5	2
MEAN	3.33	-8.33
SD	7.454	11.785
MEDIAN	0.00	-8.33
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	0.0, 16.7	-16.7, 0.0

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Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas 17JUL2024:09:53:51

Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 30		
N	2	3
MEAN	8.33	5.56
SD	11.785	9.623
MEDIAN	8.33	0.00
Q1, Q3	0.00, 16.67	0.00, 16.67
MIN, MAX	0.0, 16.7	0.0, 16.7
CHANGE FROM BASELINE AT CYCLE 30		
N	2	3
MEAN	8.33	0.00
SD	11.785	0.000
MEDIAN	8.33	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
MIN, MAX	0.0, 16.7	0.0, 0.0
CYCLE 31		
N	7	2
MEAN	2.38	0.00
SD	6.299	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 16.7	0.0, 0.0

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Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas 17JUL2024:09:53:51

Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 31		
N	7	2
MEAN	-2.38	0.00
SD	11.501	0.000
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 0.00
MIN, MAX	-16.7, 16.7	0.0, 0.0
CYCLE 32		
N	3	1
MEAN	5.56	0.00
SD	9.623	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
MIN, MAX	0.0, 16.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 32		
N	3	1
MEAN	5.56	0.00
SD	9.623	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
MIN, MAX	0.0, 16.7	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 33		
N	1	2
MEAN	0.00	0.00
SD	N.A.	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 33		
N	1	2
MEAN	-16.67	0.00
SD	N.A.	0.000
MEDIAN	-16.67	0.00
Q1, Q3	-16.67, -16.67	0.00, 0.00
MIN, MAX	-16.7, -16.7	0.0, 0.0
CYCLE 34		
N	5	1
MEAN	3.33	0.00
SD	7.454	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 16.7	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 34		
N	5	1
MEAN	-3.33	0.00
SD	13.944	N.A.
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 0.00
MIN, MAX	-16.7, 16.7	0.0, 0.0
CYCLE 36		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 36		
N	1	0
MEAN	-16.67	
SD	N.A.	
MEDIAN	-16.67	
Q1, Q3	-16.67, -16.67	
MIN, MAX	-16.7, -16.7	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 37		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 37		
N	3	0
MEAN	-11.11	
SD	9.623	
MEDIAN	-16.67	
Q1, Q3	-16.67, 0.00	
MIN, MAX	-16.7, 0.0	
CYCLE 38		
N	1	0
MEAN	16.67	
SD	N.A.	
MEDIAN	16.67	
Q1, Q3	16.67, 16.67	
MIN, MAX	16.7, 16.7	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 38		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 40		
N	1	0
MEAN	16.67	
SD	N.A.	
MEDIAN	16.67	
Q1, Q3	16.67, 16.67	
MIN, MAX	16.7, 16.7	
CHANGE FROM BASELINE AT CYCLE 40		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 41		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 41		
N	1	0
MEAN	-16.67	
SD	N.A.	
MEDIAN	-16.67	
Q1, Q3	-16.67, -16.67	
MIN, MAX	-16.7, -16.7	
CYCLE 43		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 43		
N	1	0
MEAN	-16.67	
SD	N.A.	
MEDIAN	-16.67	
Q1, Q3	-16.67, -16.67	
MIN, MAX	-16.7, -16.7	
END OF TREATMENT		
N	14	22
MEAN	9.52	9.85
SD	14.194	23.378
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	14	22
MEAN	5.95	2.27
SD	15.480	16.504
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
MIN, MAX	-16.7, 33.3	-16.7, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
PAIN		
BASELINE		
N	52	81
MEAN	22.44	30.66
SD	27.788	32.000
MEDIAN	16.67	16.67
Q1, Q3	0.00, 33.33	0.00, 50.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	46	74
MEAN	14.49	13.51
SD	20.370	22.357
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 16.67
MIN, MAX	0.0, 83.3	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	45	73
MEAN	-6.67	-17.81
SD	25.475	30.973
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 3		
N	41	58
MEAN	10.57	11.49
SD	18.164	20.757
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 16.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	40	57
MEAN	-7.92	-17.25
SD	30.426	31.492
MEDIAN	0.00	-16.67
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 83.3	-100.0, 66.7
CYCLE 4		
N	39	53
MEAN	12.39	12.26
SD	22.529	19.653
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 16.67
MIN, MAX	0.0, 100.0	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 4		
N	38	52
MEAN	-6.14	-16.67
SD	30.615	34.141
MEDIAN	0.00	-16.67
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 83.3	-100.0, 66.7
CYCLE 5		
N	39	45
MEAN	11.11	7.78
SD	14.972	14.477
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 16.67
MIN, MAX	0.0, 50.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 5		
N	38	44
MEAN	-6.58	-21.21
SD	29.900	33.788
MEDIAN	0.00	-16.67
Q1, Q3	-16.67, 16.67	-41.67, 0.00
MIN, MAX	-100.0, 50.0	-100.0, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 6		
N	37	38
MEAN	12.61	6.58
SD	26.761	15.759
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 6		
N	36	38
MEAN	-4.17	-21.05
SD	29.107	30.186
MEDIAN	0.00	-16.67
Q1, Q3	-16.67, 8.33	-33.33, 0.00
MIN, MAX	-100.0, 83.3	-100.0, 33.3
CYCLE 7		
N	35	38
MEAN	10.00	8.33
SD	17.712	16.325
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 16.67
MIN, MAX	0.0, 83.3	0.0, 83.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 7		
N	34	38
MEAN	-7.84	-20.18
SD	23.654	28.778
MEDIAN	0.00	-16.67
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 16.7	-100.0, 33.3
CYCLE 8		
N	34	38
MEAN	7.84	8.33
SD	17.521	18.071
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 83.3
CHANGE FROM BASELINE AT CYCLE 8		
N	33	38
MEAN	-10.10	-17.98
SD	29.738	32.043
MEDIAN	0.00	-16.67
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 83.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 9		
N	32	32
MEAN	7.29	14.06
SD	17.422	22.042
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 83.3	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 9		
N	31	32
MEAN	-9.68	-14.06
SD	26.796	30.264
MEDIAN	0.00	-16.67
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 50.0	-100.0, 50.0
CYCLE 10		
N	31	30
MEAN	9.68	13.33
SD	20.080	17.725
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 16.67
MIN, MAX	0.0, 100.0	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 10		
N	30	30
MEAN	-7.78	-15.56
SD	30.867	26.237
MEDIAN	0.00	-16.67
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-83.3, 33.3
CYCLE 11		
N	30	27
MEAN	18.89	9.88
SD	28.612	15.511
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 11		
N	29	27
MEAN	1.15	-12.96
SD	32.712	30.778
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-33.33, 0.00
MIN, MAX	-100.0, 83.3	-100.0, 66.7

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Table P.2.2
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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 12		
N	27	23
MEAN	12.35	11.59
SD	21.972	15.435
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 16.67
MIN, MAX	0.0, 100.0	0.0, 50.0
CHANGE FROM BASELINE AT CYCLE 12		
N	26	23
MEAN	-3.85	-10.14
SD	27.206	27.861
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-100.0, 66.7	-83.3, 33.3
CYCLE 13		
N	28	21
MEAN	15.48	10.32
SD	23.539	16.224
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 100.0	0.0, 50.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 13		
N	27	21
MEAN	0.00	-14.29
SD	25.318	29.480
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-33.33, 0.00
MIN, MAX	-50.0, 66.7	-83.3, 33.3
CYCLE 14		
N	21	13
MEAN	9.52	12.82
SD	23.316	19.429
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 14		
N	20	13
MEAN	-5.83	-19.23
SD	31.192	36.544
MEDIAN	0.00	-16.67
Q1, Q3	-16.67, 0.00	-50.00, 0.00
MIN, MAX	-100.0, 66.7	-83.3, 50.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 15		
N	28	16
MEAN	15.48	7.29
SD	20.250	18.226
MEDIAN	8.33	0.00
Q1, Q3	0.00, 25.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 15		
N	27	16
MEAN	-1.85	-17.71
SD	22.329	41.486
MEDIAN	0.00	-8.33
Q1, Q3	-16.67, 16.67	-50.00, 0.00
MIN, MAX	-83.3, 33.3	-100.0, 66.7
CYCLE 16		
N	21	13
MEAN	13.49	11.54
SD	22.123	15.789
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 83.3	0.0, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 16		
N	21	13
MEAN	-2.38	-16.67
SD	23.738	37.884
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 50.0	-100.0, 33.3
CYCLE 17		
N	24	13
MEAN	11.11	12.82
SD	20.657	20.586
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 17		
N	23	13
MEAN	-7.25	-8.97
SD	21.217	34.437
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 18		
N	11	8
MEAN	15.15	18.75
SD	24.100	24.296
MEDIAN	0.00	8.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 18		
N	11	8
MEAN	-4.55	-18.75
SD	13.104	31.418
MEDIAN	0.00	-16.67
Q1, Q3	-16.67, 0.00	-41.67, 0.00
MIN, MAX	-33.3, 16.7	-66.7, 33.3
CYCLE 19		
N	21	12
MEAN	7.94	6.94
SD	13.560	11.143
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 16.67
MIN, MAX	0.0, 50.0	0.0, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 19		
N	21	12
MEAN	-6.35	-16.67
SD	17.854	29.302
MEDIAN	0.00	-8.33
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-50.0, 16.7	-66.7, 16.7
CYCLE 20		
N	10	5
MEAN	8.33	20.00
SD	14.164	29.814
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 20		
N	10	5
MEAN	-13.33	-16.67
SD	35.832	37.268
MEDIAN	-8.33	-16.67
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 21		
N	13	8
MEAN	11.54	10.42
SD	19.702	15.269
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 25.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 21		
N	13	8
MEAN	-7.69	-14.58
SD	14.618	36.119
MEDIAN	0.00	-8.33
Q1, Q3	-16.67, 0.00	-41.67, 8.33
MIN, MAX	-33.3, 16.7	-66.7, 33.3
CYCLE 22		
N	18	7
MEAN	7.41	7.14
SD	11.747	13.113
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 16.67
MIN, MAX	0.0, 33.3	0.0, 33.3

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 22		
N	18	7
MEAN	-6.48	-21.43
SD	22.966	32.934
MEDIAN	0.00	-16.67
Q1, Q3	-16.67, 0.00	-66.67, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 16.7
CYCLE 23		
N	7	4
MEAN	4.76	0.00
SD	8.133	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
MIN, MAX	0.0, 16.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 23		
N	7	4
MEAN	-2.38	-50.00
SD	14.996	40.825
MEDIAN	0.00	-41.67
Q1, Q3	0.00, 0.00	-83.33, -16.67
MIN, MAX	-33.3, 16.7	-100.0, -16.7

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 24		
N	11	4
MEAN	6.06	33.33
SD	15.407	47.140
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	0.00, 66.67
MIN, MAX	0.0, 50.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 24		
N	11	4
MEAN	-3.03	4.17
SD	20.841	84.300
MEDIAN	0.00	8.33
Q1, Q3	-16.67, 0.00	-58.33, 66.67
MIN, MAX	-33.3, 50.0	-100.0, 100.0
CYCLE 25		
N	12	4
MEAN	9.72	8.33
SD	13.216	9.623
MEDIAN	0.00	8.33
Q1, Q3	0.00, 16.67	0.00, 16.67
MIN, MAX	0.0, 33.3	0.0, 16.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 25		
N	12	4
MEAN	1.39	-20.83
SD	18.060	43.833
MEDIAN	0.00	-8.33
Q1, Q3	-16.67, 8.33	-50.00, 8.33
MIN, MAX	-16.7, 33.3	-83.3, 16.7
CYCLE 26		
N	4	2
MEAN	16.67	0.00
SD	19.245	0.000
MEDIAN	16.67	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 26		
N	4	2
MEAN	8.33	-58.33
SD	16.667	58.926
MEDIAN	0.00	-58.33
Q1, Q3	0.00, 16.67	-100.00, -16.67
MIN, MAX	0.0, 33.3	-100.0, -16.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 27		
N	6	4
MEAN	19.44	12.50
SD	22.153	15.957
MEDIAN	16.67	8.33
Q1, Q3	0.00, 33.33	0.00, 25.00
MIN, MAX	0.0, 50.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 27		
N	6	4
MEAN	8.33	-16.67
SD	27.386	36.004
MEDIAN	0.00	-8.33
Q1, Q3	-16.67, 33.33	-41.67, 8.33
MIN, MAX	-16.7, 50.0	-66.7, 16.7
CYCLE 28		
N	9	4
MEAN	12.96	8.33
SD	16.197	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 33.3	0.0, 33.3

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Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 28		
N	9	4
MEAN	3.70	4.17
SD	20.031	20.972
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-8.33, 16.67
MIN, MAX	-16.7, 33.3	-16.7, 33.3
CYCLE 29		
N	5	2
MEAN	20.00	0.00
SD	18.257	0.000
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 29		
N	5	2
MEAN	13.33	-58.33
SD	18.257	58.926
MEDIAN	0.00	-58.33
Q1, Q3	0.00, 33.33	-100.00, -16.67
MIN, MAX	0.0, 33.3	-100.0, -16.7

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 30		
N	2	3
MEAN	25.00	0.00
SD	11.785	0.000
MEDIAN	25.00	0.00
Q1, Q3	16.67, 33.33	0.00, 0.00
MIN, MAX	16.7, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 30		
N	2	3
MEAN	8.33	-38.89
SD	11.785	53.576
MEDIAN	8.33	-16.67
Q1, Q3	0.00, 16.67	-100.00, 0.00
MIN, MAX	0.0, 16.7	-100.0, 0.0
CYCLE 31		
N	7	2
MEAN	14.29	0.00
SD	14.996	0.000
MEDIAN	16.67	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0

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Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 31		
N	7	2
MEAN	4.76	-8.33
SD	15.853	11.785
MEDIAN	0.00	-8.33
Q1, Q3	0.00, 16.67	-16.67, 0.00
MIN, MAX	-16.7, 33.3	-16.7, 0.0
CYCLE 32		
N	3	1
MEAN	22.22	0.00
SD	19.245	N.A.
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 32		
N	3	1
MEAN	11.11	-16.67
SD	19.245	N.A.
MEDIAN	0.00	-16.67
Q1, Q3	0.00, 33.33	-16.67, -16.67
MIN, MAX	0.0, 33.3	-16.7, -16.7

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 33		
N	1	2
MEAN	33.33	0.00
SD	N.A.	0.000
MEDIAN	33.33	0.00
Q1, Q3	33.33, 33.33	0.00, 0.00
MIN, MAX	33.3, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 33		
N	1	2
MEAN	33.33	-8.33
SD	N.A.	11.785
MEDIAN	33.33	-8.33
Q1, Q3	33.33, 33.33	-16.67, 0.00
MIN, MAX	33.3, 33.3	-16.7, 0.0
CYCLE 34		
N	5	1
MEAN	3.33	0.00
SD	7.454	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 16.7	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 34		
N	5	1
MEAN	0.00	0.00
SD	11.785	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-16.7, 16.7	0.0, 0.0
CYCLE 36		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	
CHANGE FROM BASELINE AT CYCLE 36		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 37		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 37		
N	3	0
MEAN	5.56	
SD	25.459	
MEDIAN	0.00	
Q1, Q3	-16.67, 33.33	
MIN, MAX	-16.7, 33.3	
CYCLE 38		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 38		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CYCLE 40		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 40		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 41		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 41		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 43		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 43		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
END OF TREATMENT		
N	14	22
MEAN	14.29	16.67
SD	22.510	25.717
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 83.3
CHANGE FROM BASELINE AT END OF TREATMENT		
N	14	22
MEAN	-15.48	-11.36
SD	21.147	27.404
MEDIAN	-16.67	0.00
Q1, Q3	-33.33, 0.00	-33.33, 16.67
MIN, MAX	-66.7, 16.7	-83.3, 16.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
DYSPNEA		
BASELINE		
N	52	81
MEAN	21.79	21.81
SD	21.778	27.968
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CYCLE 2		
N	46	74
MEAN	22.46	23.42
SD	22.283	25.121
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	45	73
MEAN	2.22	2.74
SD	21.789	25.309
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 3		
N	41	58
MEAN	21.95	21.84
SD	26.468	25.403
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 3		
N	40	57
MEAN	0.83	0.58
SD	28.731	27.088
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 66.7
CYCLE 4		
N	39	53
MEAN	24.79	23.90
SD	27.272	28.777
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

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Safety Set for NTRK+
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	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 4		
N	38	52
MEAN	2.63	2.56
SD	29.390	29.407
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-66.7, 100.0
CYCLE 5		
N	39	45
MEAN	22.22	25.93
SD	26.856	27.422
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	38	44
MEAN	1.75	3.79
SD	27.886	28.042
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 66.7	-66.7, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 6		
N	36	38
MEAN	29.63	19.30
SD	29.577	26.431
MEDIAN	33.33	0.00
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	35	38
MEAN	10.48	0.00
SD	30.002	25.703
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 66.7
CYCLE 7		
N	35	38
MEAN	19.05	26.32
SD	24.636	34.795
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 7		
N	34	38
MEAN	0.00	6.14
SD	23.210	31.817
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 66.7	-66.7, 66.7
CYCLE 8		
N	34	38
MEAN	24.51	17.54
SD	23.654	22.907
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 8		
N	33	38
MEAN	5.05	-1.75
SD	25.168	21.848
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 9		
N	32	32
MEAN	20.83	17.71
SD	21.997	26.753
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	31	32
MEAN	0.00	-3.13
SD	22.771	21.351
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 33.3
CYCLE 10		
N	31	30
MEAN	21.51	23.33
SD	22.024	29.230
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 10		
N	30	30
MEAN	1.11	3.33
SD	22.289	26.767
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 66.7
CYCLE 11		
N	30	27
MEAN	23.33	24.69
SD	23.407	32.807
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	29	27
MEAN	2.30	6.17
SD	21.696	30.714
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 12		
N	27	23
MEAN	24.69	20.29
SD	21.863	32.936
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	26	23
MEAN	2.56	4.35
SD	20.919	30.657
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 66.7
CYCLE 13		
N	28	21
MEAN	23.81	23.81
SD	25.430	28.172
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 13		
N	27	21
MEAN	2.47	7.94
SD	22.505	29.636
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-33.3, 33.3	-33.3, 100.0
CYCLE 14		
N	21	13
MEAN	23.81	20.51
SD	23.905	25.598
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 14		
N	20	13
MEAN	5.00	2.56
SD	27.091	31.802
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	-33.33, 33.33
MIN, MAX	-66.7, 33.3	-33.3, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 15		
N	28	16
MEAN	22.62	25.00
SD	25.746	28.545
MEDIAN	16.67	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	27	16
MEAN	1.23	6.25
SD	23.537	27.806
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-33.3, 33.3	-33.3, 66.7
CYCLE 16		
N	21	13
MEAN	25.40	15.38
SD	23.345	22.008
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 16		
N	21	13
MEAN	3.17	-2.56
SD	20.829	28.744
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 33.3
CYCLE 17		
N	24	13
MEAN	23.61	15.38
SD	23.008	22.008
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 17		
N	23	13
MEAN	1.45	5.13
SD	21.269	22.958
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 33.3	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
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Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 18		
N	11	8
MEAN	24.24	16.67
SD	21.556	25.198
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 18		
N	11	8
MEAN	3.03	-8.33
SD	17.979	23.570
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 33.3
CYCLE 19		
N	21	12
MEAN	23.81	13.89
SD	26.125	22.285
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 19		
N	21	12
MEAN	1.59	2.78
SD	19.653	22.285
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	-33.3, 33.3	-33.3, 33.3
CYCLE 20		
N	10	5
MEAN	36.67	33.33
SD	24.595	40.825
MEDIAN	33.33	33.33
Q1, Q3	33.33, 66.67	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 20		
N	10	5
MEAN	10.00	13.33
SD	27.442	29.814
MEDIAN	16.67	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-33.3, 33.3	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 21		
N	13	8
MEAN	33.33	16.67
SD	23.570	17.817
MEDIAN	33.33	16.67
Q1, Q3	33.33, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 21		
N	13	8
MEAN	7.69	8.33
SD	24.167	15.430
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	-33.3, 33.3	0.0, 33.3
CYCLE 22		
N	18	7
MEAN	27.78	14.29
SD	28.583	17.817
MEDIAN	33.33	0.00
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 22		
N	18	7
MEAN	5.56	4.76
SD	20.612	12.599
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-33.3, 33.3	0.0, 33.3
CYCLE 23		
N	7	4
MEAN	52.38	8.33
SD	17.817	16.667
MEDIAN	66.67	0.00
Q1, Q3	33.33, 66.67	0.00, 16.67
MIN, MAX	33.3, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 23		
N	7	4
MEAN	23.81	-8.33
SD	16.265	31.914
MEDIAN	33.33	-16.67
Q1, Q3	0.00, 33.33	-33.33, 16.67
MIN, MAX	0.0, 33.3	-33.3, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 24		
N	11	4
MEAN	30.30	16.67
SD	27.707	19.245
MEDIAN	33.33	16.67
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 24		
N	11	4
MEAN	6.06	8.33
SD	25.025	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	-33.3, 33.3	0.0, 33.3
CYCLE 25		
N	12	4
MEAN	27.78	16.67
SD	34.329	19.245
MEDIAN	16.67	16.67
Q1, Q3	0.00, 50.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 25		
N	12	4
MEAN	11.11	8.33
SD	29.588	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	-33.3, 66.7	0.0, 33.3
CYCLE 26		
N	4	2
MEAN	58.33	33.33
SD	31.914	0.000
MEDIAN	50.00	33.33
Q1, Q3	33.33, 83.33	33.33, 33.33
MIN, MAX	33.3, 100.0	33.3, 33.3
CHANGE FROM BASELINE AT CYCLE 26		
N	4	2
MEAN	33.33	16.67
SD	27.217	23.570
MEDIAN	33.33	16.67
Q1, Q3	16.67, 50.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 27		
N	6	4
MEAN	27.78	16.67
SD	32.773	19.245
MEDIAN	16.67	16.67
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 27		
N	6	4
MEAN	5.56	8.33
SD	32.773	16.667
MEDIAN	16.67	0.00
Q1, Q3	-33.33, 33.33	0.00, 16.67
MIN, MAX	-33.3, 33.3	0.0, 33.3
CYCLE 28		
N	9	4
MEAN	25.93	0.00
SD	27.778	0.000
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 28		
N	9	4
MEAN	7.41	0.00
SD	22.222	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-33.3, 33.3	0.0, 0.0
CYCLE 29		
N	5	2
MEAN	33.33	16.67
SD	23.570	23.570
MEDIAN	33.33	16.67
Q1, Q3	33.33, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 29		
N	5	2
MEAN	13.33	0.00
SD	18.257	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 30		
N	2	3
MEAN	66.67	0.00
SD	0.000	0.000
MEDIAN	66.67	0.00
Q1, Q3	66.67, 66.67	0.00, 0.00
MIN, MAX	66.7, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 30		
N	2	3
MEAN	50.00	-11.11
SD	23.570	19.245
MEDIAN	50.00	0.00
Q1, Q3	33.33, 66.67	-33.33, 0.00
MIN, MAX	33.3, 66.7	-33.3, 0.0
CYCLE 31		
N	7	2
MEAN	28.57	0.00
SD	29.991	0.000
MEDIAN	33.33	0.00
Q1, Q3	0.00, 66.67	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 31		
N	7	2
MEAN	14.29	0.00
SD	17.817	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CYCLE 32		
N	3	1
MEAN	55.56	0.00
SD	19.245	N.A.
MEDIAN	66.67	0.00
Q1, Q3	33.33, 66.67	0.00, 0.00
MIN, MAX	33.3, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 32		
N	3	1
MEAN	33.33	0.00
SD	0.000	N.A.
MEDIAN	33.33	0.00
Q1, Q3	33.33, 33.33	0.00, 0.00
MIN, MAX	33.3, 33.3	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 33		
N	1	2
MEAN	66.67	0.00
SD	N.A.	0.000
MEDIAN	66.67	0.00
Q1, Q3	66.67, 66.67	0.00, 0.00
MIN, MAX	66.7, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 33		
N	1	2
MEAN	33.33	0.00
SD	N.A.	0.000
MEDIAN	33.33	0.00
Q1, Q3	33.33, 33.33	0.00, 0.00
MIN, MAX	33.3, 33.3	0.0, 0.0
CYCLE 34		
N	5	1
MEAN	26.67	0.00
SD	36.515	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 66.67	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 34		
N	5	1
MEAN	13.33	0.00
SD	18.257	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CYCLE 36		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 36		
N	1	0
MEAN	-33.33	
SD	N.A.	
MEDIAN	-33.33	
Q1, Q3	-33.33, -33.33	
MIN, MAX	-33.3, -33.3	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 37		
N	3	0
MEAN	22.22	
SD	38.490	
MEDIAN	0.00	
Q1, Q3	0.00, 66.67	
MIN, MAX	0.0, 66.7	
CHANGE FROM BASELINE AT CYCLE 37		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CYCLE 38		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 38		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CYCLE 40		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	
CHANGE FROM BASELINE AT CYCLE 40		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 41		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 41		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 43		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 43		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
END OF TREATMENT		
N	14	22
MEAN	33.33	30.30
SD	22.646	35.500
MEDIAN	33.33	33.33
Q1, Q3	33.33, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	14	22
MEAN	7.14	9.09
SD	26.726	25.577
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-33.3, 66.7	-33.3, 66.7

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Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
INSOMNIA		
BASELINE		
N	52	81
MEAN	19.87	21.40
SD	28.207	29.490
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	46	74
MEAN	11.59	12.61
SD	22.462	21.863
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	45	73
MEAN	-9.63	-7.76
SD	31.480	28.065
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 100.0	-100.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 3		
N	41	58
MEAN	8.13	7.47
SD	16.297	15.349
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 3		
N	40	57
MEAN	-11.67	-13.45
SD	25.654	26.622
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 33.3
CYCLE 4		
N	39	53
MEAN	11.97	5.03
SD	16.199	13.707
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 4		
N	38	52
MEAN	-8.77	-14.10
SD	26.491	24.115
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 33.3
CYCLE 5		
N	39	45
MEAN	9.40	10.37
SD	17.012	21.108
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	38	44
MEAN	-9.65	-9.09
SD	30.910	27.245
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-66.7, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 6		
N	37	38
MEAN	9.91	4.39
SD	17.329	11.419
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 6		
N	36	38
MEAN	-9.26	-13.16
SD	30.458	25.160
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 33.3
CYCLE 7		
N	35	38
MEAN	9.52	4.39
SD	17.285	17.623
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 7		
N	34	38
MEAN	-10.78	-10.53
SD	30.396	28.055
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 100.0
CYCLE 8		
N	34	38
MEAN	10.78	7.89
SD	19.627	16.319
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 8		
N	33	38
MEAN	-10.10	-7.89
SD	31.716	19.658
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 9		
N	32	32
MEAN	10.42	9.38
SD	19.743	19.371
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 9		
N	31	32
MEAN	-11.83	-8.33
SD	30.488	25.400
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 33.3
CYCLE 10		
N	31	30
MEAN	15.05	10.00
SD	25.587	17.833
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 10		
N	30	30
MEAN	-7.78	-8.89
SD	31.175	23.050
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 33.3
CYCLE 11		
N	30	27
MEAN	8.89	7.41
SD	17.361	16.879
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 11		
N	29	27
MEAN	-14.94	-6.17
SD	30.324	22.715
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 12		
N	27	23
MEAN	13.58	7.25
SD	23.130	14.058
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 12		
N	26	23
MEAN	-12.82	-7.25
SD	32.764	19.991
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-33.3, 33.3
CYCLE 13		
N	28	21
MEAN	13.10	6.35
SD	20.963	13.412
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 13		
N	27	21
MEAN	-12.35	-4.76
SD	34.774	19.107
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-100.0, 33.3	-33.3, 33.3
CYCLE 14		
N	21	13
MEAN	17.46	17.95
SD	24.987	32.247
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	20	13
MEAN	-11.67	5.13
SD	39.403	26.688
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-100.0, 66.7	-33.3, 66.7

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 15		
N	28	16
MEAN	15.48	8.33
SD	23.098	19.245
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 15		
N	27	16
MEAN	-9.88	-4.17
SD	28.963	16.667
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 33.3
CYCLE 16		
N	21	13
MEAN	15.87	5.13
SD	24.987	18.490
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 16		
N	21	13
MEAN	-12.70	-5.13
SD	30.689	12.518
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 0.0
CYCLE 17		
N	24	13
MEAN	12.50	7.69
SD	16.485	19.971
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 17		
N	23	13
MEAN	-15.94	0.00
SD	34.626	27.217
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-100.0, 33.3	-33.3, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 18		
N	11	8
MEAN	15.15	8.33
SD	22.918	23.570
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 18		
N	11	8
MEAN	-24.24	-4.17
SD	30.151	11.785
MEDIAN	0.00	0.00
Q1, Q3	-66.67, 0.00	0.00, 0.00
MIN, MAX	-66.7, 0.0	-33.3, 0.0
CYCLE 19		
N	21	12
MEAN	14.29	5.56
SD	22.537	19.245
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 19		
N	21	12
MEAN	-11.11	-2.78
SD	30.429	26.432
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-16.67, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 66.7
CYCLE 20		
N	10	5
MEAN	23.33	6.67
SD	35.312	14.907
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 20		
N	10	5
MEAN	-23.33	6.67
SD	47.271	14.907
MEDIAN	-16.67	0.00
Q1, Q3	-66.67, 0.00	0.00, 0.00
MIN, MAX	-100.0, 66.7	0.0, 33.3

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 21		
N	13	8
MEAN	10.26	4.17
SD	16.013	11.785
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 21		
N	13	8
MEAN	-17.95	-4.17
SD	35.001	21.362
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-16.67, 0.00
MIN, MAX	-100.0, 33.3	-33.3, 33.3
CYCLE 22		
N	18	7
MEAN	14.81	0.00
SD	23.493	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 22		
N	18	7
MEAN	-7.41	-9.52
SD	31.427	16.265
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 0.0
CYCLE 23		
N	7	4
MEAN	23.81	8.33
SD	31.706	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 66.67	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 23		
N	7	4
MEAN	-9.52	0.00
SD	37.090	27.217
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 33.33	-16.67, 16.67
MIN, MAX	-66.7, 33.3	-33.3, 33.3

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 24		
N	11	4
MEAN	9.09	33.33
SD	21.556	47.140
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	0.00, 66.67
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 24		
N	11	4
MEAN	-9.09	25.00
SD	26.208	56.928
MEDIAN	0.00	16.67
Q1, Q3	-33.33, 0.00	-16.67, 66.67
MIN, MAX	-66.7, 33.3	-33.3, 100.0
CYCLE 25		
N	12	4
MEAN	13.89	8.33
SD	22.285	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;
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Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 25		
N	12	4
MEAN	0.00	0.00
SD	20.101	27.217
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 16.67
MIN, MAX	-33.3, 33.3	-33.3, 33.3
CYCLE 26		
N	4	2
MEAN	50.00	0.00
SD	19.245	0.000
MEDIAN	50.00	0.00
Q1, Q3	33.33, 66.67	0.00, 0.00
MIN, MAX	33.3, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 26		
N	4	2
MEAN	16.67	0.00
SD	19.245	0.000
MEDIAN	16.67	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 27		
N	6	4
MEAN	27.78	0.00
SD	32.773	0.000
MEDIAN	16.67	0.00
Q1, Q3	0.00, 66.67	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 27		
N	6	4
MEAN	11.11	-8.33
SD	17.213	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	-16.67, 0.00
MIN, MAX	0.0, 33.3	-33.3, 0.0
CYCLE 28		
N	9	4
MEAN	18.52	0.00
SD	29.397	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 28		
N	9	4
MEAN	3.70	-8.33
SD	20.031	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 0.0
CYCLE 29		
N	5	2
MEAN	33.33	0.00
SD	33.333	0.000
MEDIAN	33.33	0.00
Q1, Q3	0.00, 66.67	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 29		
N	5	2
MEAN	6.67	0.00
SD	27.889	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-33.3, 33.3	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 30		
N	2	3
MEAN	50.00	0.00
SD	23.570	0.000
MEDIAN	50.00	0.00
Q1, Q3	33.33, 66.67	0.00, 0.00
MIN, MAX	33.3, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 30		
N	2	3
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CYCLE 31		
N	7	2
MEAN	33.33	0.00
SD	38.490	0.000
MEDIAN	33.33	0.00
Q1, Q3	0.00, 66.67	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 31		
N	7	2
MEAN	14.29	0.00
SD	26.227	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CYCLE 32		
N	3	1
MEAN	44.44	0.00
SD	38.490	N.A.
MEDIAN	66.67	0.00
Q1, Q3	0.00, 66.67	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 32		
N	3	1
MEAN	0.00	0.00
SD	33.333	N.A.
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 33.33	0.00, 0.00
MIN, MAX	-33.3, 33.3	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 33		
N	1	2
MEAN	66.67	0.00
SD	N.A.	0.000
MEDIAN	66.67	0.00
Q1, Q3	66.67, 66.67	0.00, 0.00
MIN, MAX	66.7, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 33		
N	1	2
MEAN	66.67	0.00
SD	N.A.	0.000
MEDIAN	66.67	0.00
Q1, Q3	66.67, 66.67	0.00, 0.00
MIN, MAX	66.7, 66.7	0.0, 0.0
CYCLE 34		
N	5	1
MEAN	20.00	0.00
SD	29.814	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 34		
N	5	1
MEAN	13.33	0.00
SD	18.257	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CYCLE 36		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	
CHANGE FROM BASELINE AT CYCLE 36		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 37		
N	3	0
MEAN	22.22	
SD	38.490	
MEDIAN	0.00	
Q1, Q3	0.00, 66.67	
MIN, MAX	0.0, 66.7	
CHANGE FROM BASELINE AT CYCLE 37		
N	3	0
MEAN	22.22	
SD	38.490	
MEDIAN	0.00	
Q1, Q3	0.00, 66.67	
MIN, MAX	0.0, 66.7	
CYCLE 38		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 38		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CYCLE 40		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 40		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 41		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 41		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CYCLE 43		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 43		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
END OF TREATMENT		
N	14	22
MEAN	21.43	15.15
SD	24.832	26.681
MEDIAN	16.67	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	14	22
MEAN	0.00	-7.58
SD	32.026	28.971
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
APPETITE LOSS		
BASELINE		
N	52	81
MEAN	11.54	17.28
SD	23.694	27.944
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	46	74
MEAN	12.32	4.50
SD	23.684	12.731
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 2		
N	45	73
MEAN	0.74	-13.70
SD	31.373	27.123
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 100.0	-100.0, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 3		
N	40	58
MEAN	16.67	8.05
SD	25.036	19.052
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 3		
N	39	57
MEAN	7.69	-8.19
SD	28.058	25.418
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	-33.33, 0.00
MIN, MAX	-66.7, 100.0	-100.0, 33.3
CYCLE 4		
N	39	53
MEAN	11.97	3.77
SD	20.925	12.507
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 4		
N	38	52
MEAN	4.39	-12.82
SD	25.902	27.339
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 33.3
CYCLE 5		
N	39	45
MEAN	6.84	4.44
SD	15.634	13.484
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 5		
N	38	44
MEAN	-0.88	-13.64
SD	26.266	27.202
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 6		
N	37	38
MEAN	9.91	4.39
SD	22.034	13.800
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 6		
N	36	38
MEAN	1.85	-11.40
SD	30.803	27.154
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 100.0	-100.0, 33.3
CYCLE 7		
N	35	37
MEAN	8.57	2.70
SD	20.361	9.224
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 7		
N	34	37
MEAN	0.00	-10.81
SD	28.427	24.912
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-100.0, 33.3
CYCLE 8		
N	34	38
MEAN	12.75	6.14
SD	24.638	18.753
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	33	38
MEAN	4.04	-7.02
SD	32.013	28.112
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-100.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;
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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 9		
N	32	32
MEAN	13.54	7.29
SD	25.201	21.972
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	31	32
MEAN	4.30	-8.33
SD	30.722	28.081
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-100.0, 33.3
CYCLE 10		
N	31	30
MEAN	11.83	5.56
SD	23.646	12.635
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 10		
N	30	30
MEAN	2.22	-10.00
SD	32.676	26.479
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-100.0, 33.3
CYCLE 11		
N	30	27
MEAN	8.89	6.17
SD	23.050	16.111
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 11		
N	29	27
MEAN	-1.15	-3.70
SD	33.903	21.350
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-66.7, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 12		
N	27	23
MEAN	9.88	13.04
SD	24.134	19.434
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 12		
N	26	23
MEAN	1.28	4.35
SD	30.523	27.163
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-66.7, 100.0	-66.7, 66.7
CYCLE 13		
N	28	21
MEAN	9.52	9.52
SD	21.956	26.125
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 13		
N	27	21
MEAN	1.23	-3.17
SD	28.467	25.614
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-66.7, 66.7
CYCLE 14		
N	21	13
MEAN	14.29	10.26
SD	27.021	21.014
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 14		
N	20	13
MEAN	-1.67	2.56
SD	25.305	21.350
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 15		
N	28	16
MEAN	16.67	12.50
SD	26.450	20.638
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 15		
N	27	16
MEAN	6.17	4.17
SD	30.714	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-66.7, 100.0	-33.3, 33.3
CYCLE 16		
N	21	13
MEAN	19.05	5.13
SD	24.881	18.490
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 16		
N	21	13
MEAN	7.94	0.00
SD	33.174	23.570
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-66.7, 66.7	-33.3, 66.7
CYCLE 17		
N	24	13
MEAN	13.89	7.69
SD	19.453	14.618
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 17		
N	23	13
MEAN	4.35	2.56
SD	28.962	16.452
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-66.7, 66.7	-33.3, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 18		
N	11	8
MEAN	15.15	8.33
SD	22.918	23.570
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 18		
N	11	8
MEAN	-3.03	0.00
SD	31.463	30.861
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 33.33	-16.67, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 66.7
CYCLE 19		
N	21	12
MEAN	11.11	5.56
SD	21.943	12.975
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 19		
N	21	12
MEAN	0.00	0.00
SD	27.889	14.213
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-33.3, 33.3
CYCLE 20		
N	10	5
MEAN	13.33	0.00
SD	23.307	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 20		
N	10	5
MEAN	-6.67	-6.67
SD	30.631	14.907
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 21		
N	13	8
MEAN	12.82	4.17
SD	25.598	11.785
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 21		
N	13	8
MEAN	2.56	0.00
SD	25.318	17.817
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 33.3
CYCLE 22		
N	18	7
MEAN	9.26	0.00
SD	22.304	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 22		
N	18	7
MEAN	0.00	-4.76
SD	22.866	12.599
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 0.0
CYCLE 23		
N	7	4
MEAN	23.81	0.00
SD	31.706	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 66.67	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 23		
N	7	4
MEAN	4.76	-8.33
SD	35.635	16.667
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 33.33	-16.67, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 24		
N	11	4
MEAN	12.12	0.00
SD	22.473	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 24		
N	11	4
MEAN	3.03	-8.33
SD	17.979	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 0.0
CYCLE 25		
N	12	4
MEAN	13.89	8.33
SD	22.285	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 25		
N	12	4
MEAN	8.33	0.00
SD	20.719	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-33.3, 33.3	0.0, 0.0
CYCLE 26		
N	4	2
MEAN	33.33	0.00
SD	27.217	0.000
MEDIAN	33.33	0.00
Q1, Q3	16.67, 50.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 26		
N	4	2
MEAN	25.00	-16.67
SD	16.667	23.570
MEDIAN	33.33	-16.67
Q1, Q3	16.67, 33.33	-33.33, 0.00
MIN, MAX	0.0, 33.3	-33.3, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 27		
N	6	4
MEAN	16.67	8.33
SD	27.889	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 27		
N	6	4
MEAN	11.11	0.00
SD	17.213	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CYCLE 28		
N	9	4
MEAN	18.52	0.00
SD	29.397	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 28		
N	9	4
MEAN	14.81	0.00
SD	24.216	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CYCLE 29		
N	5	2
MEAN	26.67	16.67
SD	36.515	23.570
MEDIAN	0.00	16.67
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 29		
N	5	2
MEAN	20.00	0.00
SD	29.814	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 30		
N	2	3
MEAN	33.33	11.11
SD	47.140	19.245
MEDIAN	33.33	0.00
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 30		
N	2	3
MEAN	16.67	0.00
SD	23.570	0.000
MEDIAN	16.67	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CYCLE 31		
N	7	2
MEAN	19.05	0.00
SD	32.530	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 66.67	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 31		
N	7	2
MEAN	14.29	0.00
SD	26.227	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CYCLE 32		
N	3	1
MEAN	33.33	0.00
SD	33.333	N.A.
MEDIAN	33.33	0.00
Q1, Q3	0.00, 66.67	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 32		
N	3	1
MEAN	22.22	0.00
SD	19.245	N.A.
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0

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EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;
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Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 33		
N	1	2
MEAN	33.33	0.00
SD	N.A.	0.000
MEDIAN	33.33	0.00
Q1, Q3	33.33, 33.33	0.00, 0.00
MIN, MAX	33.3, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 33		
N	1	2
MEAN	33.33	0.00
SD	N.A.	0.000
MEDIAN	33.33	0.00
Q1, Q3	33.33, 33.33	0.00, 0.00
MIN, MAX	33.3, 33.3	0.0, 0.0
CYCLE 34		
N	5	1
MEAN	13.33	0.00
SD	18.257	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 34		
N	5	1
MEAN	13.33	0.00
SD	18.257	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CYCLE 36		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 36		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 37		
N	3	0
MEAN	33.33	
SD	33.333	
MEDIAN	33.33	
Q1, Q3	0.00, 66.67	
MIN, MAX	0.0, 66.7	
CHANGE FROM BASELINE AT CYCLE 37		
N	3	0
MEAN	33.33	
SD	33.333	
MEDIAN	33.33	
Q1, Q3	0.00, 66.67	
MIN, MAX	0.0, 66.7	
CYCLE 38		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 38		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CYCLE 40		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 40		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 41		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 41		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CYCLE 43		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 43		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
END OF TREATMENT		
N	14	22
MEAN	28.57	18.18
SD	31.642	33.692
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	14	22
MEAN	11.90	-1.52
SD	21.111	26.181
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	-33.33, 0.00
MIN, MAX	0.0, 66.7	-33.3, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CONSTIPATION		
BASELINE		
N	52	81
MEAN	16.03	13.58
SD	23.329	25.154
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CYCLE 2		
N	46	74
MEAN	34.78	21.17
SD	32.928	27.902
MEDIAN	33.33	0.00
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	45	73
MEAN	20.74	7.76
SD	34.296	30.692
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-33.3, 100.0	-100.0, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 3		
N	41	58
MEAN	30.89	14.94
SD	31.964	23.506
MEDIAN	33.33	0.00
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	40	57
MEAN	18.33	2.92
SD	31.981	31.673
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-33.3, 100.0	-100.0, 100.0
CYCLE 4		
N	39	53
MEAN	27.35	16.98
SD	28.482	25.839
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 4		
N	38	52
MEAN	14.91	4.49
SD	35.257	29.542
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-66.7, 100.0	-66.7, 100.0
CYCLE 5		
N	39	45
MEAN	25.64	16.30
SD	29.081	26.230
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	38	44
MEAN	12.28	6.82
SD	35.869	28.375
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-66.7, 100.0	-66.7, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 6		
N	37	38
MEAN	34.23	15.79
SD	33.781	27.658
MEDIAN	33.33	0.00
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	36	38
MEAN	21.30	5.26
SD	33.949	32.444
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-33.3, 100.0	-66.7, 100.0
CYCLE 7		
N	35	38
MEAN	25.71	9.65
SD	29.245	25.595
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 7		
N	34	38
MEAN	12.75	0.88
SD	31.798	28.461
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-33.3, 100.0	-66.7, 100.0
CYCLE 8		
N	34	37
MEAN	31.37	14.41
SD	33.776	25.508
MEDIAN	33.33	0.00
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	33	37
MEAN	18.18	5.41
SD	37.352	31.927
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-66.7, 100.0	-66.7, 100.0

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 9		
N	32	32
MEAN	31.25	18.75
SD	30.454	30.454
MEDIAN	33.33	0.00
Q1, Q3	0.00, 50.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	31	32
MEAN	19.35	9.38
SD	35.250	27.086
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-66.7, 100.0	-33.3, 100.0
CYCLE 10		
N	31	30
MEAN	30.11	15.56
SD	34.806	24.343
MEDIAN	33.33	0.00
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 10		
N	30	30
MEAN	17.78	4.44
SD	35.808	27.310
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-66.7, 100.0	-66.7, 100.0
CYCLE 11		
N	30	27
MEAN	18.89	19.75
SD	25.795	28.132
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	29	27
MEAN	6.90	7.41
SD	24.200	31.123
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 66.7	-66.7, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 12		
N	27	23
MEAN	23.46	17.39
SD	28.963	26.342
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	26	23
MEAN	14.10	2.90
SD	30.071	33.201
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-33.3, 100.0	-66.7, 100.0
CYCLE 13		
N	28	21
MEAN	22.62	15.87
SD	28.766	27.119
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 13		
N	27	21
MEAN	12.35	4.76
SD	29.451	26.427
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-33.3, 100.0	-33.3, 100.0
CYCLE 14		
N	21	13
MEAN	20.63	25.64
SD	28.822	30.894
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	20	13
MEAN	8.33	20.51
SD	28.357	32.026
MEDIAN	0.00	33.33
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	-33.3, 100.0	-33.3, 100.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 15		
N	28	16
MEAN	23.81	25.00
SD	32.530	35.486
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	27	16
MEAN	13.58	20.83
SD	28.132	36.260
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-33.3, 100.0	-33.3, 100.0
CYCLE 16		
N	21	13
MEAN	30.16	17.95
SD	37.866	32.247
MEDIAN	0.00	0.00
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 16		
N	21	13
MEAN	15.87	12.82
SD	30.946	34.797
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 100.0
CYCLE 17		
N	24	13
MEAN	26.39	10.26
SD	32.570	16.013
MEDIAN	16.67	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 17		
N	23	13
MEAN	14.49	5.13
SD	26.258	18.490
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 18		
N	11	8
MEAN	24.24	20.83
SD	36.790	24.801
MEDIAN	0.00	16.67
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 18		
N	11	8
MEAN	12.12	16.67
SD	26.968	25.198
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-33.3, 66.7	0.0, 66.7
CYCLE 19		
N	21	12
MEAN	31.75	11.11
SD	37.232	16.412
MEDIAN	33.33	0.00
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 19		
N	21	12
MEAN	20.63	5.56
SD	30.689	19.245
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	-33.3, 66.7	-33.3, 33.3
CYCLE 20		
N	10	5
MEAN	30.00	26.67
SD	33.148	27.889
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 20		
N	10	5
MEAN	16.67	20.00
SD	28.328	29.814
MEDIAN	16.67	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-33.3, 66.7	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 21		
N	13	8
MEAN	17.95	20.83
SD	22.008	24.801
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 21		
N	13	8
MEAN	10.26	12.50
SD	28.495	30.538
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-33.3, 66.7	-33.3, 66.7
CYCLE 22		
N	18	7
MEAN	29.63	14.29
SD	30.008	26.227
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 22		
N	18	7
MEAN	20.37	4.76
SD	28.328	29.991
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 66.7
CYCLE 23		
N	7	4
MEAN	14.29	33.33
SD	17.817	27.217
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	16.67, 50.00
MIN, MAX	0.0, 33.3	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 23		
N	7	4
MEAN	9.52	25.00
SD	25.198	31.914
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 50.00
MIN, MAX	-33.3, 33.3	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 24		
N	11	4
MEAN	24.24	0.00
SD	21.556	0.000
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 24		
N	11	4
MEAN	21.21	-16.67
SD	26.968	19.245
MEDIAN	33.33	-16.67
Q1, Q3	0.00, 33.33	-33.33, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 0.0
CYCLE 25		
N	12	4
MEAN	25.00	0.00
SD	25.126	0.000
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 25		
N	12	4
MEAN	19.44	-16.67
SD	26.432	19.245
MEDIAN	33.33	-16.67
Q1, Q3	0.00, 33.33	-33.33, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 0.0
CYCLE 26		
N	4	2
MEAN	50.00	16.67
SD	19.245	23.570
MEDIAN	50.00	16.67
Q1, Q3	33.33, 66.67	0.00, 33.33
MIN, MAX	33.3, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 26		
N	4	2
MEAN	50.00	0.00
SD	19.245	0.000
MEDIAN	50.00	0.00
Q1, Q3	33.33, 66.67	0.00, 0.00
MIN, MAX	33.3, 66.7	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 27		
N	6	4
MEAN	22.22	8.33
SD	27.217	16.667
MEDIAN	16.67	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 27		
N	6	4
MEAN	16.67	-8.33
SD	34.960	16.667
MEDIAN	16.67	0.00
Q1, Q3	0.00, 33.33	-16.67, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 0.0
CYCLE 28		
N	9	4
MEAN	22.22	0.00
SD	28.868	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 28		
N	9	4
MEAN	18.52	-8.33
SD	33.793	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	-16.67, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 0.0
CYCLE 29		
N	5	2
MEAN	33.33	0.00
SD	33.333	0.000
MEDIAN	33.33	0.00
Q1, Q3	0.00, 66.67	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 29		
N	5	2
MEAN	33.33	-16.67
SD	33.333	23.570
MEDIAN	33.33	-16.67
Q1, Q3	0.00, 66.67	-33.33, 0.00
MIN, MAX	0.0, 66.7	-33.3, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 30		
N	2	3
MEAN	50.00	0.00
SD	23.570	0.000
MEDIAN	50.00	0.00
Q1, Q3	33.33, 66.67	0.00, 0.00
MIN, MAX	33.3, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 30		
N	2	3
MEAN	50.00	-11.11
SD	23.570	19.245
MEDIAN	50.00	0.00
Q1, Q3	33.33, 66.67	-33.33, 0.00
MIN, MAX	33.3, 66.7	-33.3, 0.0
CYCLE 31		
N	7	2
MEAN	33.33	0.00
SD	27.217	0.000
MEDIAN	33.33	0.00
Q1, Q3	0.00, 66.67	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 31		
N	7	2
MEAN	33.33	0.00
SD	27.217	0.000
MEDIAN	33.33	0.00
Q1, Q3	0.00, 66.67	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CYCLE 32		
N	3	1
MEAN	44.44	0.00
SD	19.245	N.A.
MEDIAN	33.33	0.00
Q1, Q3	33.33, 66.67	0.00, 0.00
MIN, MAX	33.3, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 32		
N	3	1
MEAN	44.44	0.00
SD	19.245	N.A.
MEDIAN	33.33	0.00
Q1, Q3	33.33, 66.67	0.00, 0.00
MIN, MAX	33.3, 66.7	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 33		
N	1	2
MEAN	33.33	0.00
SD	N.A.	0.000
MEDIAN	33.33	0.00
Q1, Q3	33.33, 33.33	0.00, 0.00
MIN, MAX	33.3, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 33		
N	1	2
MEAN	33.33	0.00
SD	N.A.	0.000
MEDIAN	33.33	0.00
Q1, Q3	33.33, 33.33	0.00, 0.00
MIN, MAX	33.3, 33.3	0.0, 0.0
CYCLE 34		
N	5	1
MEAN	13.33	0.00
SD	18.257	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 34		
N	5	1
MEAN	13.33	0.00
SD	18.257	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CYCLE 36		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 36		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 37		
N	3	0
MEAN	22.22	
SD	19.245	
MEDIAN	33.33	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 37		
N	3	0
MEAN	22.22	
SD	19.245	
MEDIAN	33.33	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CYCLE 38		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 38		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	
CYCLE 40		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	
CHANGE FROM BASELINE AT CYCLE 40		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 41		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 41		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CYCLE 43		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 43		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
END OF TREATMENT		
N	14	22
MEAN	16.67	21.21
SD	25.318	28.257
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	14	22
MEAN	0.00	3.03
SD	18.490	22.792
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
DIARRHEA		
BASELINE		
N	52	81
MEAN	6.41	7.41
SD	14.817	15.811
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CYCLE 2		
N	46	73
MEAN	7.97	6.39
SD	20.104	15.373
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 2		
N	45	72
MEAN	0.74	-1.85
SD	20.706	15.713
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 33.3

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Table P.2.2
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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 3		
N	40	58
MEAN	7.50	8.05
SD	19.226	18.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	39	57
MEAN	0.85	0.58
SD	20.925	22.264
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 100.0
CYCLE 4		
N	39	53
MEAN	7.69	11.95
SD	16.153	19.714
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 4		
N	38	52
MEAN	0.88	2.56
SD	19.738	21.739
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 66.7
CYCLE 5		
N	39	44
MEAN	6.84	7.58
SD	17.404	15.854
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 5		
N	38	43
MEAN	0.00	-0.78
SD	20.504	18.528
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 6		
N	37	38
MEAN	5.41	15.79
SD	12.456	26.550
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	36	38
MEAN	-0.93	7.89
SD	18.663	30.446
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-66.7, 33.3	-66.7, 100.0
CYCLE 7		
N	35	38
MEAN	8.57	14.04
SD	18.687	28.613
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 7		
N	34	38
MEAN	1.96	6.14
SD	21.620	29.870
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 100.0
CYCLE 8		
N	34	38
MEAN	6.86	12.28
SD	21.366	25.018
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	33	38
MEAN	1.01	5.26
SD	24.274	23.920
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-33.3, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 9		
N	32	32
MEAN	6.25	15.63
SD	19.743	30.509
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	31	32
MEAN	1.08	8.33
SD	25.069	29.329
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-33.3, 100.0
CYCLE 10		
N	31	30
MEAN	4.30	12.22
SD	18.742	20.498
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 10		
N	30	30
MEAN	-1.11	6.67
SD	23.947	18.362
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-33.3, 66.7
CYCLE 11		
N	30	27
MEAN	3.33	7.41
SD	10.171	16.879
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 11		
N	29	27
MEAN	-2.30	3.70
SD	17.663	16.879
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 12		
N	27	23
MEAN	6.17	13.04
SD	16.111	26.091
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	26	23
MEAN	0.00	8.70
SD	21.082	25.060
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	0.0, 100.0
CYCLE 13		
N	28	21
MEAN	5.95	11.11
SD	13.001	21.943
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 13		
N	27	21
MEAN	0.00	7.94
SD	16.013	23.345
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 66.7
CYCLE 14		
N	21	13
MEAN	6.35	10.26
SD	17.059	21.014
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 14		
N	20	13
MEAN	-1.67	5.13
SD	25.305	22.958
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-33.3, 66.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 15		
N	28	16
MEAN	5.95	12.50
SD	15.853	23.960
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 15		
N	27	16
MEAN	0.00	10.42
SD	20.672	26.440
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	-66.7, 66.7	-33.3, 66.7
CYCLE 16		
N	21	13
MEAN	4.76	12.82
SD	15.936	28.991
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 100.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 16		
N	21	13
MEAN	0.00	7.69
SD	18.257	30.894
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 100.0
CYCLE 17		
N	24	13
MEAN	11.11	10.26
SD	18.822	21.014
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 17		
N	23	13
MEAN	4.35	5.13
SD	23.147	22.958
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 18		
N	11	8
MEAN	12.12	12.50
SD	26.968	24.801
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 18		
N	11	8
MEAN	6.06	4.17
SD	25.025	27.817
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 66.7
CYCLE 19		
N	21	12
MEAN	7.94	19.44
SD	25.614	38.817
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 100.0	0.0, 100.0

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 19		
N	21	12
MEAN	4.76	13.89
SD	24.234	41.337
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 100.0	-33.3, 100.0
CYCLE 20		
N	10	5
MEAN	10.00	6.67
SD	22.498	14.907
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 20		
N	10	5
MEAN	3.33	0.00
SD	24.595	23.570
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 33.3

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 21		
N	13	8
MEAN	7.69	12.50
SD	19.971	24.801
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 21		
N	13	8
MEAN	5.13	8.33
SD	18.490	29.547
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 66.7	-33.3, 66.7
CYCLE 22		
N	18	7
MEAN	3.70	9.52
SD	10.779	25.198
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 66.7

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 22		
N	18	7
MEAN	1.85	4.76
SD	7.857	29.991
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	-33.3, 66.7
CYCLE 23		
N	7	4
MEAN	4.76	8.33
SD	12.599	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 23		
N	7	4
MEAN	4.76	0.00
SD	12.599	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;
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Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 24		
N	11	4
MEAN	0.00	16.67
SD	0.000	33.333
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 0.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 24		
N	11	4
MEAN	0.00	8.33
SD	0.000	41.944
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 33.33
MIN, MAX	0.0, 0.0	-33.3, 66.7
CYCLE 25		
N	12	4
MEAN	2.78	0.00
SD	9.623	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 25		
N	12	4
MEAN	2.78	-8.33
SD	9.623	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	0.0, 33.3	-33.3, 0.0
CYCLE 26		
N	4	2
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 26		
N	4	2
MEAN	0.00	-16.67
SD	0.000	23.570
MEDIAN	0.00	-16.67
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	0.0, 0.0	-33.3, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 27		
N	6	4
MEAN	0.00	25.00
SD	0.000	31.914
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	0.00, 50.00
MIN, MAX	0.0, 0.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 27		
N	6	4
MEAN	0.00	16.67
SD	0.000	33.333
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 0.0	0.0, 66.7
CYCLE 28		
N	9	4
MEAN	0.00	16.67
SD	0.000	33.333
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 0.0	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 28		
N	9	4
MEAN	0.00	16.67
SD	0.000	33.333
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 0.0	0.0, 66.7
CYCLE 29		
N	5	2
MEAN	0.00	33.33
SD	0.000	47.140
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	0.00, 66.67
MIN, MAX	0.0, 0.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 29		
N	5	2
MEAN	0.00	16.67
SD	0.000	23.570
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 0.0	0.0, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 30		
N	2	3
MEAN	0.00	44.44
SD	0.000	38.490
MEDIAN	0.00	66.67
Q1, Q3	0.00, 0.00	0.00, 66.67
MIN, MAX	0.0, 0.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 30		
N	2	3
MEAN	0.00	33.33
SD	0.000	33.333
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	0.00, 66.67
MIN, MAX	0.0, 0.0	0.0, 66.7
CYCLE 31		
N	7	2
MEAN	4.76	33.33
SD	12.599	47.140
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	0.00, 66.67
MIN, MAX	0.0, 33.3	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 31		
N	7	2
MEAN	4.76	33.33
SD	12.599	47.140
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	0.00, 66.67
MIN, MAX	0.0, 33.3	0.0, 66.7
CYCLE 32		
N	3	1
MEAN	0.00	0.00
SD	0.000	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 32		
N	3	1
MEAN	0.00	0.00
SD	0.000	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 33		
N	1	2
MEAN	0.00	33.33
SD	N.A.	47.140
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	0.00, 66.67
MIN, MAX	0.0, 0.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 33		
N	1	2
MEAN	0.00	33.33
SD	N.A.	47.140
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	0.00, 66.67
MIN, MAX	0.0, 0.0	0.0, 66.7
CYCLE 34		
N	5	1
MEAN	6.67	33.33
SD	14.907	N.A.
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	33.33, 33.33
MIN, MAX	0.0, 33.3	33.3, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 34		
N	5	1
MEAN	6.67	33.33
SD	14.907	N.A.
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	33.33, 33.33
MIN, MAX	0.0, 33.3	33.3, 33.3
CYCLE 36		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 36		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 37		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 37		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 38		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 38		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 40		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 40		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 41		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 41		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 43		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 43		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
END OF TREATMENT		
N	14	22
MEAN	19.05	16.67
SD	21.540	19.920
MEDIAN	16.67	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT END OF TREATMENT		
N	14	22
MEAN	9.52	10.61
SD	15.627	15.891
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
FINANCIAL DIFFICULTIES		
BASELINE		
N	52	81
MEAN	20.51	16.87
SD	29.634	25.886
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	46	73
MEAN	21.01	17.35
SD	28.422	25.525
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	45	72
MEAN	-1.48	1.85
SD	18.743	22.300
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 3		
N	39	58
MEAN	19.66	14.94
SD	26.177	24.321
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	38	57
MEAN	-1.75	-1.17
SD	18.900	25.170
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 100.0
CYCLE 4		
N	39	53
MEAN	21.37	11.95
SD	25.918	19.714
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 4		
N	38	52
MEAN	0.00	-4.49
SD	23.250	23.827
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 33.3
CYCLE 5		
N	39	43
MEAN	20.51	11.63
SD	27.161	19.084
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 5		
N	38	43
MEAN	0.00	-3.88
SD	26.846	25.416
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 6		
N	37	37
MEAN	21.62	9.91
SD	30.648	15.446
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 6		
N	36	37
MEAN	2.78	-6.31
SD	23.060	24.643
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 33.3
CYCLE 7		
N	35	37
MEAN	20.00	7.21
SD	28.238	17.804
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 7		
N	34	37
MEAN	0.98	-9.01
SD	22.451	26.815
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 66.7
CYCLE 8		
N	34	38
MEAN	19.61	10.53
SD	27.362	17.511
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 8		
N	33	38
MEAN	0.00	-5.26
SD	26.352	23.920
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 66.7

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 9		
N	32	32
MEAN	20.83	16.67
SD	29.022	28.081
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	31	32
MEAN	1.08	-1.04
SD	26.505	29.916
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 66.7
CYCLE 10		
N	31	30
MEAN	18.28	14.44
SD	26.996	18.944
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 10		
N	30	30
MEAN	-1.11	-4.44
SD	26.957	22.715
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 33.3
CYCLE 11		
N	30	27
MEAN	22.22	13.58
SD	28.139	21.202
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 11		
N	29	27
MEAN	2.30	-2.47
SD	28.074	29.127
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 33.3

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Table P.2.2
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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 12		
N	27	23
MEAN	16.05	14.49
SD	26.747	19.659
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 12		
N	26	23
MEAN	-5.13	-1.45
SD	27.797	30.942
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 33.3
CYCLE 13		
N	28	21
MEAN	14.29	15.87
SD	24.727	20.053
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 13		
N	27	21
MEAN	-6.17	1.59
SD	22.715	26.825
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 66.7
CYCLE 14		
N	21	13
MEAN	14.29	12.82
SD	22.537	21.681
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 14		
N	20	13
MEAN	-5.00	-7.69
SD	16.312	38.858
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-100.0, 33.3

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 15		
N	28	16
MEAN	15.48	18.75
SD	24.816	24.248
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 15		
N	27	16
MEAN	-6.17	0.00
SD	26.209	34.427
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 33.33
MIN, MAX	-66.7, 33.3	-100.0, 33.3
CYCLE 16		
N	21	13
MEAN	15.87	10.26
SD	22.655	21.014
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 16		
N	21	13
MEAN	-3.17	-10.26
SD	17.965	34.385
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-100.0, 33.3
CYCLE 17		
N	24	13
MEAN	9.72	17.95
SD	18.334	32.247
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 17		
N	23	13
MEAN	-5.80	2.56
SD	21.678	31.802
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 18		
N	11	8
MEAN	15.15	29.17
SD	22.918	37.533
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 50.00
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 18		
N	11	8
MEAN	0.00	0.00
SD	14.907	30.861
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 66.7
CYCLE 19		
N	21	12
MEAN	14.29	19.44
SD	22.537	26.432
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 19		
N	21	12
MEAN	0.00	2.78
SD	18.257	30.011
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 33.3	-66.7, 33.3
CYCLE 20		
N	10	5
MEAN	16.67	13.33
SD	23.570	29.814
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 20		
N	10	5
MEAN	0.00	6.67
SD	15.713	14.907
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	0.0, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 21		
N	13	8
MEAN	20.51	4.17
SD	28.991	11.785
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 21		
N	13	8
MEAN	0.00	-4.17
SD	19.245	21.362
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 33.3
CYCLE 22		
N	18	7
MEAN	16.67	14.29
SD	28.583	17.817
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 22		
N	18	7
MEAN	1.85	4.76
SD	17.977	23.002
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 33.3	-33.3, 33.3
CYCLE 23		
N	7	4
MEAN	28.57	0.00
SD	35.635	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 66.67	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 23		
N	7	4
MEAN	4.76	-8.33
SD	12.599	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	0.0, 33.3	-33.3, 0.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 24		
N	11	4
MEAN	15.15	16.67
SD	27.340	33.333
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 24		
N	11	4
MEAN	-3.03	8.33
SD	23.355	16.667
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 16.67
MIN, MAX	-33.3, 33.3	0.0, 33.3
CYCLE 25		
N	12	4
MEAN	13.89	8.33
SD	26.432	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 33.3

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 25		
N	12	4
MEAN	0.00	8.33
SD	20.101	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	-33.3, 33.3	0.0, 33.3
CYCLE 26		
N	4	2
MEAN	33.33	16.67
SD	38.490	23.570
MEDIAN	33.33	16.67
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 26		
N	4	2
MEAN	8.33	16.67
SD	16.667	23.570
MEDIAN	0.00	16.67
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 27		
N	6	4
MEAN	22.22	16.67
SD	34.427	33.333
MEDIAN	0.00	0.00
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 27		
N	6	4
MEAN	0.00	8.33
SD	21.082	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	-33.3, 33.3	0.0, 33.3
CYCLE 28		
N	9	4
MEAN	18.52	8.33
SD	29.397	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 33.3

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Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 28		
N	9	4
MEAN	3.70	0.00
SD	20.031	27.217
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 16.67
MIN, MAX	-33.3, 33.3	-33.3, 33.3
CYCLE 29		
N	5	2
MEAN	26.67	0.00
SD	36.515	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 66.67	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 29		
N	5	2
MEAN	6.67	0.00
SD	14.907	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0

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Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 30		
N	2	3
MEAN	33.33	22.22
SD	47.140	38.490
MEDIAN	33.33	0.00
Q1, Q3	0.00, 66.67	0.00, 66.67
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 30		
N	2	3
MEAN	0.00	11.11
SD	0.000	19.245
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 0.0	0.0, 33.3
CYCLE 31		
N	6	2
MEAN	22.22	33.33
SD	27.217	47.140
MEDIAN	16.67	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;
QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas 17JUL2024:09:53:51

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 31		
N	6	2
MEAN	0.00	16.67
SD	21.082	23.570
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 33.3	0.0, 33.3
CYCLE 32		
N	3	1
MEAN	22.22	0.00
SD	38.490	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 66.67	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 32		
N	3	1
MEAN	0.00	0.00
SD	0.000	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;
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Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas 17JUL2024:09:53:51

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 33		
N	1	2
MEAN	66.67	0.00
SD	N.A.	0.000
MEDIAN	66.67	0.00
Q1, Q3	66.67, 66.67	0.00, 0.00
MIN, MAX	66.7, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 33		
N	1	2
MEAN	33.33	-16.67
SD	N.A.	23.570
MEDIAN	33.33	-16.67
Q1, Q3	33.33, 33.33	-33.33, 0.00
MIN, MAX	33.3, 33.3	-33.3, 0.0
CYCLE 34		
N	5	1
MEAN	20.00	0.00
SD	29.814	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
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Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas 17JUL2024:09:53:51

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 34		
N	5	1
MEAN	13.33	-33.33
SD	18.257	N.A.
MEDIAN	0.00	-33.33
Q1, Q3	0.00, 33.33	-33.33, -33.33
MIN, MAX	0.0, 33.3	-33.3, -33.3
CYCLE 36		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	
CHANGE FROM BASELINE AT CYCLE 36		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;
QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas 17JUL2024:09:53:51

Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 37		
N	3	0
MEAN	33.33	
SD	33.333	
MEDIAN	33.33	
Q1, Q3	0.00, 66.67	
MIN, MAX	0.0, 66.7	
CHANGE FROM BASELINE AT CYCLE 37		
N	3	0
MEAN	22.22	
SD	19.245	
MEDIAN	33.33	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CYCLE 38		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;
QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas 17JUL2024:09:53:51

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 38		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 40		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	
CHANGE FROM BASELINE AT CYCLE 40		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;
QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas 17JUL2024:09:53:51

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CYCLE 41		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	
CHANGE FROM BASELINE AT CYCLE 41		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CYCLE 43		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;
QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas 17JUL2024:09:53:51

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Table P.2.2
Summary of EORTC QLQ-C30 by Cycle
Safety Set for NTRK+
Subjects from Phase 2 Portion of the Trial

	EXP-5 TKI-naive subjects N = 53	EXP-6 TKI-pretreated subjects N = 82
CHANGE FROM BASELINE AT CYCLE 43		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
END OF TREATMENT		
N	14	22
MEAN	28.57	10.61
SD	38.911	15.891
MEDIAN	0.00	0.00
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 33.3
CHANGE FROM BASELINE AT END OF TREATMENT		
N	14	22
MEAN	0.00	-4.55
SD	26.149	15.585
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;
QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas 17JUL2024:09:53:51

Anhang 4-G 3: Endpunkte Verträglichkeit: Weitere Analysen

Anhang 4-G 3.1: Unerwünschte Ereignisse von besonderem Interesse (UESI)

Anhang 4-G 3.1.1: Jegliche UESI

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Table S.2.2
Treatment-Emergent Adverse Events of Special Interest by Medical Concept
Safety Set for NTRK+

Medical Concept	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
SUBJECTS WITH ANY AESI	57 (100.0)	76 (91.6)
Ataxia	29 (50.9)	18 (21.7)
Cognitive Disorders	19 (33.3)	16 (19.3)
Dizziness	44 (77.2)	49 (59.0)
Dysgeusia	42 (73.7)	45 (54.2)
Hepatic Enzyme Elevation	15 (26.3)	20 (24.1)
Mood Disorders	3 (5.3)	4 (4.8)
Muscular Weakness	13 (22.8)	14 (16.9)
Paraesthesia	25 (43.9)	30 (36.1)
Peripheral Sensory Neuropathy	12 (21.1)	15 (18.1)
Pneumonitis	2 (3.5)	2 (2.4)
QT Prolongation	0	1 (1.2)
Skeletal Fractures	1 (1.8)	3 (3.6)
Sleep Disorders	15 (26.3)	16 (19.3)
Vision Disorders	13 (22.8)	13 (15.7)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: AESI = Treatment-Emergent Adverse Event of Special Interest.
Percentages are based on the total number of subjects in the corresponding cohort.
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.
All Medical Concepts are included, irrespective of their frequency, and sorted alphabetically.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-summc-ebr2365.sas 28MAY2024:10:41:57

Anhang 4-G 3.1.2: Schwere UESI (UESI mit einem Schweregrad von ≥ 3 nach CTCAE)

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Table S.3.2
Severe Treatment-Emergent Adverse Events of Special Interest by Medical Concept
Safety Set for NTRK+

Medical Concept	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
SUBJECTS WITH ANY SEVERE AESI	13 (22.8)	7 (8.4)
Cognitive Disorders	3 (5.3)	0
Dizziness	5 (8.8)	2 (2.4)
Hepatic Enzyme Elevation	5 (8.8)	2 (2.4)
Muscular Weakness	1 (1.8)	2 (2.4)
Paraesthesia	1 (1.8)	0
Peripheral Sensory Neuropathy	1 (1.8)	0
Pneumonitis	0	1 (1.2)
Vision Disorders	1 (1.8)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: AESI = Treatment-Emergent Adverse Event of Special Interest.
Percentages are based on the total number of subjects in the corresponding cohort.
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.
All Medical Concepts are included, irrespective of their frequency, and sorted alphabetically.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-summc-ebr2365.sas 28MAY2024:10:42:03

Anhang 4-G 3.1.3: Schwerwiegende UESI

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Table S.4.2
Serious Treatment-Emergent Adverse Events of Special Interest by Medical Concept
Safety Set for NTRK+

Medical Concept	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
SUBJECTS WITH ANY SERIOUS AESI	4 (7.0)	5 (6.0)
Cognitive Disorders	2 (3.5)	1 (1.2)
Dizziness	0	2 (2.4)
Muscular Weakness	1 (1.8)	1 (1.2)
Pneumonitis	0	1 (1.2)
Skeletal Fractures	0	1 (1.2)
Vision Disorders	1 (1.8)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: AESI = Treatment-Emergent Adverse Event of Special Interest.
Percentages are based on the total number of subjects in the corresponding cohort.
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.
All Medical Concepts are included, irrespective of their frequency, and sorted alphabetically.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-summc-ebr2365.sas 28MAY2024:10:42:10

Anhang 4-G 3.2: UE auf SOC/PT-Ebene

Anhang 4-G 3.2.1: Jegliche UE auf SOC/PT-Ebene

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Table S.5.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
SUBJECTS WITH ANY TEAE	57 (100.0)	82 (98.8)
Blood and lymphatic system disorders	27 (47.4)	34 (41.0)
Anaemia	26 (45.6)	32 (38.6)
Blood loss anaemia	1 (1.8)	0
Eosinophilia	1 (1.8)	0
Hyperleukocytosis	1 (1.8)	0
Iron deficiency anaemia	1 (1.8)	0
Leukopenia	1 (1.8)	2 (2.4)
Lymphopenia	1 (1.8)	2 (2.4)
Neutropenia	1 (1.8)	3 (3.6)
Pancytopenia	0	1 (1.2)
Thrombocytopenia	1 (1.8)	0
Cardiac disorders	8 (14.0)	11 (13.3)
Cardiac arrest	0	1 (1.2)
Cardiac failure congestive	0	1 (1.2)
Cardio-respiratory arrest	0	1 (1.2)
Cardiomyopathy	0	1 (1.2)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent
Adverse Event.
Percentages are based on the total number of subjects in the corresponding cohort.
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
are considered treatment emergent.
System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms
are sorted alphabetically as well.
All System Organ Classes and Preferred Terms are included, irrespective of their frequency.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sumsocptsaf-ebr2365.sas 29MAY2024:01:07:47

Table S.5.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Coronary artery disease	0	1 (1.2)
Mitral valve incompetence	1 (1.8)	0
Palpitations	5 (8.8)	0
Pericardial effusion	1 (1.8)	0
Sinus bradycardia	0	1 (1.2)
Sinus tachycardia	1 (1.8)	4 (4.8)
Supraventricular tachycardia	0	1 (1.2)
Tachycardia	1 (1.8)	1 (1.2)
Tricuspid valve incompetence	2 (3.5)	0
Ear and labyrinth disorders	3 (5.3)	6 (7.2)
Ear haemorrhage	1 (1.8)	0
Ear pain	0	1 (1.2)
Tinnitus	0	2 (2.4)
Vertigo	2 (3.5)	2 (2.4)
Vertigo positional	0	1 (1.2)
Endocrine disorders	2 (3.5)	2 (2.4)
Androgen deficiency	1 (1.8)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent
Adverse Event.
Percentages are based on the total number of subjects in the corresponding cohort.
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
are considered treatment emergent.
System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms
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All System Organ Classes and Preferred Terms are included, irrespective of their frequency.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sumsocptsaf-ebr2365.sas 29MAY2024:01:07:47

Table S.5.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Hypoparathyroidism	0	1 (1.2)
Hypothyroidism	1 (1.8)	1 (1.2)
Eye disorders	12 (21.1)	12 (14.5)
Asthenopia	0	1 (1.2)
Cataract	1 (1.8)	0
Diplopia	1 (1.8)	0
Dry eye	0	3 (3.6)
Eye haematoma	0	1 (1.2)
Eye pain	0	1 (1.2)
Night blindness	1 (1.8)	1 (1.2)
Periorbital oedema	1 (1.8)	0
Photophobia	0	3 (3.6)
Vision blurred	5 (8.8)	1 (1.2)
Visual impairment	2 (3.5)	2 (2.4)
Xerophthalmia	1 (1.8)	0
Gastrointestinal disorders	45 (78.9)	53 (63.9)
Abdominal distension	3 (5.3)	2 (2.4)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent Adverse Event.
Percentages are based on the total number of subjects in the corresponding cohort.
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.
System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.
All System Organ Classes and Preferred Terms are included, irrespective of their frequency.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sumsocptsaf-ebr2365.sas 29MAY2024:01:07:47

Table S.5.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Abdominal pain	2 (3.5)	8 (9.6)
Abdominal pain upper	1 (1.8)	1 (1.2)
Anal incontinence	1 (1.8)	3 (3.6)
Ascites	1 (1.8)	0
Colitis	0	1 (1.2)
Constipation	27 (47.4)	31 (37.3)
Dental caries	0	1 (1.2)
Diarrhoea	13 (22.8)	20 (24.1)
Dry mouth	3 (5.3)	4 (4.8)
Dyspepsia	1 (1.8)	3 (3.6)
Dysphagia	8 (14.0)	3 (3.6)
Gastritis	0	1 (1.2)
Gastrointestinal pain	0	1 (1.2)
Gastrooesophageal reflux disease	2 (3.5)	2 (2.4)
Haemorrhoids	1 (1.8)	0
Hypoaesthesia oral	0	2 (2.4)
Melaena	1 (1.8)	0
Mouth ulceration	1 (1.8)	0
Nausea	12 (21.1)	18 (21.7)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent
Adverse Event.
Percentages are based on the total number of subjects in the corresponding cohort.
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Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
are considered treatment emergent.
System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms
are sorted alphabetically as well.
All System Organ Classes and Preferred Terms are included, irrespective of their frequency.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sumsocptsaf-ebr2365.sas 29MAY2024:01:07:47

Table S.5.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Oesophageal pain	1 (1.8)	0
Paraesthesia oral	7 (12.3)	3 (3.6)
Salivary gland pain	1 (1.8)	0
Toothache	0	1 (1.2)
Upper gastrointestinal haemorrhage	1 (1.8)	0
Vomiting	12 (21.1)	17 (20.5)
General disorders and administration site conditions	40 (70.2)	50 (60.2)
Asthenia	12 (21.1)	6 (7.2)
Axillary pain	1 (1.8)	0
Catheter site bruise	1 (1.8)	0
Chest pain	3 (5.3)	0
Chills	1 (1.8)	1 (1.2)
Device related thrombosis	0	1 (1.2)
Fatigue	14 (24.6)	27 (32.5)
Feeling cold	0	1 (1.2)
Gait disturbance	6 (10.5)	4 (4.8)
General physical health deterioration	1 (1.8)	1 (1.2)
Impaired healing	0	1 (1.2)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent
Adverse Event.
Percentages are based on the total number of subjects in the corresponding cohort.
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
are considered treatment emergent.
System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms
are sorted alphabetically as well.
All System Organ Classes and Preferred Terms are included, irrespective of their frequency.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sumsocptsaf-ebr2365.sas 29MAY2024:01:07:47

Table S.5.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Malaise	1 (1.8)	1 (1.2)
Mucosal inflammation	1 (1.8)	0
Non-cardiac chest pain	0	3 (3.6)
Oedema	0	1 (1.2)
Oedema peripheral	12 (21.1)	12 (14.5)
Pain	4 (7.0)	4 (4.8)
Peripheral swelling	3 (5.3)	0
Pyrexia	13 (22.8)	10 (12.0)
Sensation of foreign body	1 (1.8)	0
Sudden cardiac death	0	1 (1.2)
Withdrawal syndrome	0	2 (2.4)
Hepatobiliary disorders	2 (3.5)	5 (6.0)
Cholangitis	0	1 (1.2)
Cholecystitis	0	1 (1.2)
Cholelithiasis	0	2 (2.4)
Cholestasis	1 (1.8)	1 (1.2)
Hepatic cytolysis	1 (1.8)	0
Hepatic function abnormal	1 (1.8)	0

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Table S.5.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Hyperbilirubinaemia	0	1 (1.2)
Hypertransaminasaemia	0	1 (1.2)
Immune system disorders	0	2 (2.4)
Contrast media allergy	0	1 (1.2)
Hypersensitivity	0	1 (1.2)
Infections and infestations	29 (50.9)	35 (42.2)
Abscess	0	1 (1.2)
Bacteraemia	0	1 (1.2)
Bacterial diarrhoea	0	1 (1.2)
Bacteriuria	0	1 (1.2)
Biliary tract infection bacterial	0	1 (1.2)
Body tinea	1 (1.8)	0
Bronchitis	2 (3.5)	1 (1.2)
COVID-19	8 (14.0)	7 (8.4)
COVID-19 pneumonia	0	2 (2.4)
Cellulitis	0	2 (2.4)
Chronic sinusitis	0	1 (1.2)

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Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Clostridium difficile infection	0	1 (1.2)
Conjunctivitis	0	1 (1.2)
Ear infection	0	1 (1.2)
Erysipelas	1 (1.8)	0
Escherichia sepsis	0	1 (1.2)
Folliculitis	0	1 (1.2)
Gastroenteritis	2 (3.5)	0
Gastroenteritis viral	0	1 (1.2)
Gingivitis	0	1 (1.2)
Herpes virus infection	1 (1.8)	0
Herpes zoster	2 (3.5)	0
Laryngopharyngitis	1 (1.8)	0
Lower respiratory tract infection	1 (1.8)	0
Mucosal infection	1 (1.8)	0
Nail infection	0	1 (1.2)
Nasopharyngitis	2 (3.5)	3 (3.6)
Onychomycosis	1 (1.8)	0
Ophthalmic herpes zoster	1 (1.8)	0
Pharyngitis	1 (1.8)	0

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Table S.5.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Pneumonia	7 (12.3)	7 (8.4)
Pneumonia adenoviral	0	1 (1.2)
Pyelonephritis	1 (1.8)	0
Rash pustular	0	1 (1.2)
Respiratory tract infection	0	1 (1.2)
Rhinitis	0	1 (1.2)
Sepsis	0	2 (2.4)
Sinusitis	1 (1.8)	1 (1.2)
Upper respiratory tract infection	3 (5.3)	3 (3.6)
Urinary tract infection	6 (10.5)	11 (13.3)
Urinary tract infection bacterial	0	1 (1.2)
Vaginal infection	1 (1.8)	0
Wound infection	0	2 (2.4)
Injury, poisoning and procedural complications	9 (15.8)	14 (16.9)
Contusion	1 (1.8)	1 (1.2)
Eyelid injury	1 (1.8)	0
Fall	3 (5.3)	7 (8.4)
Febrile nonhaemolytic transfusion reaction	1 (1.8)	0

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Table S.5.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Fibula fracture	0	1 (1.2)
Foot fracture	0	2 (2.4)
Fracture	1 (1.8)	0
Head injury	1 (1.8)	1 (1.2)
Joint dislocation	0	1 (1.2)
Muscle injury	1 (1.8)	0
Post procedural inflammation	0	1 (1.2)
Procedural haemorrhage	0	1 (1.2)
Procedural pain	0	1 (1.2)
Skin laceration	1 (1.8)	0
Stoma site erythema	0	1 (1.2)
Thermal burn	0	1 (1.2)
Toxicity to various agents	1 (1.8)	0
Urinary tract stoma complication	0	1 (1.2)
Investigations	37 (64.9)	41 (49.4)
Activated partial thromboplastin time prolonged	0	1 (1.2)
Adenovirus test positive	0	1 (1.2)
Alanine aminotransferase increased	13 (22.8)	14 (16.9)

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Table S.5.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Alpha hydroxybutyrate dehydrogenase increased	1 (1.8)	0
Amylase increased	2 (3.5)	0
Aspartate aminotransferase increased	11 (19.3)	16 (19.3)
Bacterial test positive	0	1 (1.2)
Bile acids increased	1 (1.8)	0
Blood alkaline phosphatase increased	8 (14.0)	6 (7.2)
Blood bicarbonate increased	1 (1.8)	0
Blood bilirubin increased	4 (7.0)	2 (2.4)
Blood chloride increased	1 (1.8)	0
Blood cholesterol increased	1 (1.8)	0
Blood cholinesterase increased	1 (1.8)	1 (1.2)
Blood creatine decreased	1 (1.8)	0
Blood creatine phosphokinase increased	13 (22.8)	16 (19.3)
Blood creatinine increased	5 (8.8)	4 (4.8)
Blood follicle stimulating hormone	1 (1.8)	0
Blood follicle stimulating hormone increased	1 (1.8)	0
Blood gases abnormal	1 (1.8)	0
Blood glucose increased	2 (3.5)	0
Blood lactate dehydrogenase increased	6 (10.5)	4 (4.8)

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Table S.5.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Blood luteinising hormone increased	1 (1.8)	0
Blood magnesium increased	1 (1.8)	0
Blood phosphorus decreased	1 (1.8)	0
Blood prolactin increased	1 (1.8)	1 (1.2)
Blood testosterone decreased	1 (1.8)	1 (1.2)
Blood urea increased	3 (5.3)	0
Blood uric acid increased	2 (3.5)	0
Blood urine present	1 (1.8)	1 (1.2)
C-reactive protein increased	0	1 (1.2)
Creatinine renal clearance decreased	1 (1.8)	0
Ejection fraction decreased	0	1 (1.2)
Electrocardiogram QRS complex abnormal	1 (1.8)	0
Electrocardiogram QT prolonged	0	1 (1.2)
Electrocardiogram low voltage	1 (1.8)	0
Gamma-glutamyltransferase increased	6 (10.5)	6 (7.2)
Glomerular filtration rate increased	1 (1.8)	0
Haematocrit decreased	0	1 (1.2)
Head lag abnormal	1 (1.8)	0
Lipase increased	5 (8.8)	0

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Table S.5.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Lipoprotein increased	1 (1.8)	0
Lymphocyte count decreased	7 (12.3)	4 (4.8)
Mean cell volume increased	0	1 (1.2)
Neutrophil count decreased	4 (7.0)	3 (3.6)
Neutrophil count increased	1 (1.8)	0
PCO2 increased	1 (1.8)	0
Platelet count decreased	0	1 (1.2)
Platelet count increased	5 (8.8)	1 (1.2)
Protein urine present	1 (1.8)	0
Pulmonary function test decreased	1 (1.8)	0
Red blood cell count decreased	0	1 (1.2)
SARS-CoV-2 test positive	0	1 (1.2)
Sex hormone binding globulin decreased	0	1 (1.2)
Sex hormone binding globulin increased	1 (1.8)	0
Transaminases increased	0	2 (2.4)
Troponin I increased	2 (3.5)	0
Troponin T increased	0	1 (1.2)
Urinary occult blood	1 (1.8)	0
Urinary occult blood positive	1 (1.8)	0

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Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Urine ketone body present	0	2 (2.4)
Urobilinogen urine increased	1 (1.8)	0
Weight decreased	1 (1.8)	2 (2.4)
Weight increased	11 (19.3)	10 (12.0)
White blood cell count decreased	5 (8.8)	7 (8.4)
White blood cell count increased	0	1 (1.2)
White blood cells urine positive	1 (1.8)	0
Metabolism and nutrition disorders	25 (43.9)	34 (41.0)
Cachexia	1 (1.8)	0
Cell death	0	1 (1.2)
Decreased appetite	13 (22.8)	12 (14.5)
Dehydration	2 (3.5)	1 (1.2)
Dyslipidaemia	0	1 (1.2)
Fluid retention	0	1 (1.2)
Hypercalcaemia	2 (3.5)	2 (2.4)
Hyperchloraemia	1 (1.8)	0
Hypercholesterolaemia	1 (1.8)	1 (1.2)
Hyperglycaemia	3 (5.3)	4 (4.8)

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Table S.5.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Hyperkalaemia	1 (1.8)	1 (1.2)
Hyperlipidaemia	1 (1.8)	1 (1.2)
Hypermagnesaemia	2 (3.5)	1 (1.2)
Hypernatraemia	1 (1.8)	1 (1.2)
Hyperphosphataemia	1 (1.8)	0
Hypertriglyceridaemia	3 (5.3)	0
Hyperuricaemia	3 (5.3)	5 (6.0)
Hypoalbuminaemia	5 (8.8)	1 (1.2)
Hypocalcaemia	3 (5.3)	5 (6.0)
Hypochloraemia	1 (1.8)	1 (1.2)
Hypokalaemia	3 (5.3)	6 (7.2)
Hypomagnesaemia	1 (1.8)	2 (2.4)
Hyponatraemia	5 (8.8)	4 (4.8)
Hypophosphataemia	3 (5.3)	6 (7.2)
Hypoproteinaemia	0	1 (1.2)
Hypovolaemia	0	1 (1.2)
Iron deficiency	1 (1.8)	0
Vitamin D deficiency	0	1 (1.2)

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Table S.5.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Musculoskeletal and connective tissue disorders	37 (64.9)	40 (48.2)
Arthralgia	10 (17.5)	8 (9.6)
Arthritis	1 (1.8)	1 (1.2)
Back pain	9 (15.8)	8 (9.6)
Bone pain	1 (1.8)	2 (2.4)
Flank pain	1 (1.8)	1 (1.2)
Hypercreatinaemia	1 (1.8)	0
Hypertrophic osteoarthropathy	0	1 (1.2)
Intervertebral disc protrusion	1 (1.8)	0
Joint range of motion decreased	1 (1.8)	0
Muscle spasms	1 (1.8)	0
Muscular weakness	13 (22.8)	14 (16.9)
Musculoskeletal chest pain	1 (1.8)	1 (1.2)
Musculoskeletal pain	1 (1.8)	1 (1.2)
Myalgia	12 (21.1)	9 (10.8)
Myopathy	1 (1.8)	0
Neck pain	3 (5.3)	0
Osteonecrosis	0	1 (1.2)
Osteonecrosis of jaw	0	1 (1.2)

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Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Pain in extremity	6 (10.5)	6 (7.2)
Spinal osteoarthritis	0	1 (1.2)
Spinal pain	1 (1.8)	0
Trismus	1 (1.8)	0
Neoplasms benign, malignant and unspecified (incl cysts andolyps)	1 (1.8)	3 (3.6)
Basal cell carcinoma	1 (1.8)	0
Large cell lung cancer	0	1 (1.2)
Pericardial effusion malignant	0	1 (1.2)
Squamous cell carcinoma of skin	1 (1.8)	0
Tumour obstruction	0	1 (1.2)
Nervous system disorders	56 (98.2)	74 (89.2)
Ageusia	1 (1.8)	1 (1.2)
Allodynia	1 (1.8)	0
Aphasia	2 (3.5)	0
Ataxia	21 (36.8)	13 (15.7)
Balance disorder	6 (10.5)	2 (2.4)

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Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Brain oedema	0	1 (1.2)
Cerebellar ataxia	1 (1.8)	0
Cerebrovascular accident	1 (1.8)	0
Cognitive disorder	8 (14.0)	2 (2.4)
Depressed level of consciousness	1 (1.8)	0
Disturbance in attention	11 (19.3)	8 (9.6)
Dizziness	44 (77.2)	45 (54.2)
Dizziness postural	0	1 (1.2)
Dysaesthesia	1 (1.8)	1 (1.2)
Dysarthria	5 (8.8)	0
Dysgeusia	39 (68.4)	42 (50.6)
Dyskinesia	1 (1.8)	0
Extrapyramidal disorder	1 (1.8)	3 (3.6)
Facial paralysis	1 (1.8)	0
Headache	12 (21.1)	16 (19.3)
Hemiparesis	1 (1.8)	0
Hyperaesthesia	2 (3.5)	1 (1.2)
Hypersomnia	2 (3.5)	0
Hypoaesthesia	0	3 (3.6)

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System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Hypokinesia	1 (1.8)	0
Ischaemic cerebral infarction	1 (1.8)	0
Lethargy	0	1 (1.2)
Memory impairment	13 (22.8)	11 (13.3)
Migraine	1 (1.8)	0
Mononeuritis	0	1 (1.2)
Motor dysfunction	1 (1.8)	0
Movement disorder	0	1 (1.2)
Myoclonus	0	1 (1.2)
Narcolepsy	0	1 (1.2)
Neuralgia	6 (10.5)	10 (12.0)
Neurological decompensation	2 (3.5)	0
Neuropathy peripheral	3 (5.3)	3 (3.6)
Paraesthesia	24 (42.1)	27 (32.5)
Partial seizures	0	1 (1.2)
Peripheral motor neuropathy	2 (3.5)	0
Peripheral sensory neuropathy	3 (5.3)	3 (3.6)
Presyncope	1 (1.8)	3 (3.6)
Sciatica	1 (1.8)	0

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Percentages are based on the total number of subjects in the corresponding cohort.
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
are considered treatment emergent.
System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms
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All System Organ Classes and Preferred Terms are included, irrespective of their frequency.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sumsocptsaf-ebr2365.sas 29MAY2024:01:07:47

Table S.5.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Somnolence	9 (15.8)	10 (12.0)
Spinal cord compression	1 (1.8)	1 (1.2)
Subarachnoid haemorrhage	1 (1.8)	0
Syncope	4 (7.0)	5 (6.0)
Taste disorder	3 (5.3)	2 (2.4)
Tonic convulsion	0	1 (1.2)
Tremor	1 (1.8)	2 (2.4)
Product issues	0	1
(1.2) Device occlusion	0	
1 (1.2)		
Psychiatric disorders	9 (15.8)	14 (16.9)
Affective disorder	1 (1.8)	0
Anxiety	1 (1.8)	1 (1.2)
Confusional state	1 (1.8)	1 (1.2)
Delirium	0	1 (1.2)
Depressed mood	0	1 (1.2)
Depression	1 (1.8)	2 (2.4)
Initial insomnia	1 (1.8)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent
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Program Name: rt-ae-sumsocptsaf-ebr2365.sas 29MAY2024:01:07:47

Table S.5.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Insomnia	5 (8.8)	5 (6.0)
Irritability	0	2 (2.4)
Orgasm abnormal	0	1 (1.2)
Personality change	0	1 (1.2)
Restlessness	0	1 (1.2)
Sleep disorder	0	1 (1.2)
Renal and urinary disorders	15 (26.3)	19 (22.9)
Acute kidney injury	0	1 (1.2)
Albuminuria	0	1 (1.2)
Bladder hypertrophy	1 (1.8)	0
Chronic kidney disease	0	1 (1.2)
Cystitis noninfective	1 (1.8)	0
Dysuria	2 (3.5)	3 (3.6)
Haematuria	2 (3.5)	2 (2.4)
Pollakiuria	0	3 (3.6)
Proteinuria	4 (7.0)	6 (7.2)
Urinary incontinence	3 (5.3)	4 (4.8)
Urinary retention	4 (7.0)	1 (1.2)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent
Adverse Event.
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Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sumsocptsaf-ebr2365.sas 29MAY2024:01:07:47

Table S.5.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Urinary tract disorder	1 (1.8)	0
Reproductive system and breast disorders	3 (5.3)	3 (3.6)
Erectile dysfunction	1 (1.8)	0
Intermenstrual bleeding	0	1 (1.2)
Menstruation irregular	0	1 (1.2)
Pelvic pain	1 (1.8)	0
Testicular pain	1 (1.8)	1 (1.2)
Respiratory, thoracic and mediastinal disorders	28 (49.1)	42 (50.6)
Acute respiratory failure	0	1 (1.2)
Aspiration	1 (1.8)	0
Atelectasis	0	1 (1.2)
Bronchitis chronic	0	1 (1.2)
Chronic obstructive pulmonary disease	1 (1.8)	0
Cough	13 (22.8)	14 (16.9)
Dysphonia	3 (5.3)	1 (1.2)
Dyspnoea	16 (28.1)	28 (33.7)
Dyspnoea exertional	3 (5.3)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent
Adverse Event.
Percentages are based on the total number of subjects in the corresponding cohort.
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
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Table S.5.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Epistaxis	0	1 (1.2)
Haemoptysis	1 (1.8)	2 (2.4)
Haemothorax	0	1 (1.2)
Hypoxia	3 (5.3)	1 (1.2)
Interstitial lung disease	1 (1.8)	0
Lower respiratory tract congestion	0	1 (1.2)
Nasal congestion	1 (1.8)	0
Oropharyngeal pain	3 (5.3)	3 (3.6)
Pharyngeal paraesthesia	1 (1.8)	0
Pleural effusion	0	3 (3.6)
Pneumonitis	1 (1.8)	2 (2.4)
Productive cough	4 (7.0)	4 (4.8)
Pulmonary embolism	1 (1.8)	2 (2.4)
Pulmonary hypertension	1 (1.8)	0
Respiratory failure	1 (1.8)	1 (1.2)
Rhinorrhoea	1 (1.8)	1 (1.2)
Snoring	0	1 (1.2)
Tachypnoea	2 (3.5)	3 (3.6)
Throat tightness	1 (1.8)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
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Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
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All System Organ Classes and Preferred Terms are included, irrespective of their frequency.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sumsocptsaf-ebr2365.sas 29MAY2024:01:07:47

Table S.5.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Upper-airway cough syndrome	1 (1.8)	0
Wheezing	1 (1.8)	0
Skin and subcutaneous tissue disorders	14 (24.6)	19 (22.9)
Alopecia	4 (7.0)	2 (2.4)
Dermatitis acneiform	2 (3.5)	1 (1.2)
Dry skin	4 (7.0)	2 (2.4)
Erythema	2 (3.5)	0
Neurodermatitis	0	1 (1.2)
Night sweats	0	1 (1.2)
Pain of skin	3 (5.3)	3 (3.6)
Photosensitivity reaction	0	1 (1.2)
Pruritus	0	3 (3.6)
Pruritus allergic	0	1 (1.2)
Rash	1 (1.8)	5 (6.0)
Rash maculo-papular	2 (3.5)	0
Scab	1 (1.8)	0
Sensitive skin	0	2 (2.4)
Skin burning sensation	0	1 (1.2)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent Adverse Event.
Percentages are based on the total number of subjects in the corresponding cohort.
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.
System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.
All System Organ Classes and Preferred Terms are included, irrespective of their frequency.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sumsocptsaf-ebr2365.sas 29MAY2024:01:07:47

Table S.5.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

System Organ Class (%) Preferred Term (%)	TKI-naive subjects (N = 57)	TKI-pretreated subjects (N = 83)
Skin ulcer	1 (1.8)	1 (1.2)
Urticaria	0	1 (1.2)
Surgical and medical procedures	1 (1.8)	0
Tooth extraction	1 (1.8)	0
Vascular disorders	10 (17.5)	15 (18.1)
Deep vein thrombosis	0	1 (1.2)
Embolism	1 (1.8)	1 (1.2)
Flushing	1 (1.8)	3 (3.6)
Hot flush	0	4 (4.8)
Hypertension	5 (8.8)	0
Hypotension	3 (5.3)	3 (3.6)
Lymphoedema	0	3 (3.6)
Orthostatic hypotension	0	1 (1.2)
Pelvic venous thrombosis	0	1 (1.2)
Venous thrombosis limb	0	1 (1.2)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent Adverse Event.
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Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.
System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.
All System Organ Classes and Preferred Terms are included, irrespective of their frequency.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sumsocptsaf-ebr2365.sas 29MAY2024:01:07:47

Anhang 4-G 3.2.2: Schwere UE (UE mit einem Schweregrad von ≥ 3 nach CTCAE) auf SOC/PT-Ebene

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Table S.7.2
Severe Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

SOC PT	EXP-5 TKI-naive subjects N = 57	EXP-6 TKI-pretreated subjects N = 83
SUBJECTS WITH ANY SEVERE TEAE	35 (61.4)	45 (54.2)
Blood and lymphatic system disorders	7 (12.3)	11 (13.3)
Anaemia	5 (8.8)	10 (12.0)
Blood loss anaemia	1 (1.8)	0
Lymphopenia	0	1 (1.2)
Neutropenia	1 (1.8)	1 (1.2)
Cardiac disorders	0	3 (3.6)
Cardiac arrest	0	1 (1.2)
Cardio-respiratory arrest	0	1 (1.2)
Supraventricular tachycardia	0	1 (1.2)
Gastrointestinal disorders	4 (7.0)	7 (8.4)
Abdominal pain	1 (1.8)	1 (1.2)
Colitis	0	1 (1.2)
Constipation	1 (1.8)	0
Diarrhoea	2 (3.5)	2 (2.4)
Gastritis	0	1 (1.2)
Nausea	0	2 (2.4)
Upper gastrointestinal haemorrhage	1 (1.8)	0
Vomiting	1 (1.8)	2 (2.4)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent
Adverse Event.
Percentages are based on the total number of subjects in the corresponding cohort.
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
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System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms
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All System Organ Classes and Preferred Terms are included, irrespective of their frequency.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sumsocpt-ebr2365-b2.sas 20JUN2024:04:33:35

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Table S.7.2
Severe Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

SOC PT	EXP-5 TKI-naive subjects N = 57	EXP-6 TKI-pretreated subjects N = 83
General disorders and administration site conditions	3 (5.3)	8 (9.6)
Fatigue	1 (1.8)	2 (2.4)
General physical health deterioration	1 (1.8)	1 (1.2)
Impaired healing	0	1 (1.2)
Pain	0	2 (2.4)
Pyrexia	1 (1.8)	0
Sudden cardiac death	0	1 (1.2)
Withdrawal syndrome	0	1 (1.2)
Hepatobiliary disorders	1 (1.8)	1 (1.2)
Cholestasis	0	1 (1.2)
Hepatic function abnormal	1 (1.8)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent
Adverse Event.
Percentages are based on the total number of subjects in the corresponding cohort.
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Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
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Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sumsocpt-ebr2365-b2.sas 20JUN2024:04:33:35

Table S.7.2
Severe Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

SOC PT	EXP-5 TKI-naive subjects N = 57	EXP-6 TKI-pretreated subjects N = 83
Infections and infestations	11 (19.3)	11 (13.3)
Bacteraemia	0	1 (1.2)
Biliary tract infection bacterial	0	1 (1.2)
COVID-19	2 (3.5)	0
COVID-19 pneumonia	0	2 (2.4)
Erysipelas	1 (1.8)	0
Escherichia sepsis	0	1 (1.2)
Lower respiratory tract infection	1 (1.8)	0
Ophthalmic herpes zoster	1 (1.8)	0
Pneumonia	5 (8.8)	5 (6.0)
Pneumonia adenoviral	0	1 (1.2)
Pyelonephritis	1 (1.8)	0
Sepsis	0	1 (1.2)
Urinary tract infection	0	1 (1.2)
Wound infection	0	1 (1.2)
Injury, poisoning and procedural complications	2 (3.5)	1 (1.2)
Fall	1 (1.8)	0
Febrile nonhaemolytic transfusion reaction	1 (1.8)	0
Procedural haemorrhage	0	1 (1.2)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent
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Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
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Table S.7.2
Severe Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

SOC PT	EXP-5 TKI-naive subjects N = 57	EXP-6 TKI-pretreated subjects N = 83
Investigations	13 (22.8)	14 (16.9)
Alanine aminotransferase increased	2 (3.5)	0
Aspartate aminotransferase increased	4 (7.0)	2 (2.4)
Blood alkaline phosphatase increased	0	1 (1.2)
Blood bilirubin increased	1 (1.8)	1 (1.2)
Blood creatine phosphokinase increased	1 (1.8)	3 (3.6)
Gamma-glutamyltransferase increased	2 (3.5)	2 (2.4)
Lipase increased	2 (3.5)	0
Lymphocyte count decreased	4 (7.0)	3 (3.6)
Neutrophil count decreased	0	2 (2.4)
Platelet count decreased	0	1 (1.2)
Platelet count increased	1 (1.8)	0
Weight increased	0	2 (2.4)
White blood cell count decreased	0	1 (1.2)
Metabolism and nutrition disorders	1 (1.8)	9 (10.8)
Decreased appetite	0	1 (1.2)
Hypercalcaemia	0	1 (1.2)
Hyperkalaemia	0	1 (1.2)
Hypokalaemia	0	2 (2.4)
Hyponatraemia	1 (1.8)	1 (1.2)
Hypophosphataemia	0	3 (3.6)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
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Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables
Program Name: rt-ae-sumsocpt-ebr2365-b2.sas 20JUN2024:04:33:35

Table S.7.2
Severe Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

SOC PT	EXP-5 TKI-naive subjects N = 57	EXP-6 TKI-pretreated subjects N = 83
Musculoskeletal and connective tissue disorders	3 (5.3)	4 (4.8)
Back pain	0	1 (1.2)
Bone pain	1 (1.8)	0
Muscular weakness	1 (1.8)	2 (2.4)
Myalgia	0	1 (1.2)
Myopathy	1 (1.8)	0
Pain in extremity	0	1 (1.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	2 (2.4)
Large cell lung cancer	0	1 (1.2)
Pericardial effusion malignant	0	1 (1.2)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent
Adverse Event.
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Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
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Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
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Table S.7.2
Severe Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

SOC PT	EXP-5 TKI-naive subjects N = 57	EXP-6 TKI-pretreated subjects N = 83
Nervous system disorders	10 (17.5)	10 (12.0)
Depressed level of consciousness	1 (1.8)	0
Dizziness	5 (8.8)	2 (2.4)
Headache	0	1 (1.2)
Myoclonus	0	1 (1.2)
Neuralgia	1 (1.8)	0
Neurological decompensation	2 (3.5)	0
Paraesthesia	1 (1.8)	0
Presyncope	0	1 (1.2)
Spinal cord compression	0	1 (1.2)
Syncope	3 (5.3)	3 (3.6)
Tremor	0	1 (1.2)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent
Adverse Event.
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Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
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Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
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Table S.7.2
Severe Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

SOC PT	EXP-5 TKI-naive subjects N = 57	EXP-6 TKI-pretreated subjects N = 83
Respiratory, thoracic and mediastinal disorders	5 (8.8)	12 (14.5)
Acute respiratory failure	0	1 (1.2)
Atelectasis	0	1 (1.2)
Bronchitis chronic	0	1 (1.2)
Cough	1 (1.8)	0
Dyspnoea	1 (1.8)	5 (6.0)
Haemothorax	0	1 (1.2)
Hypoxia	0	1 (1.2)
Pleural effusion	0	1 (1.2)
Pneumonitis	0	1 (1.2)
Productive cough	1 (1.8)	0
Pulmonary embolism	1 (1.8)	2 (2.4)
Pulmonary hypertension	1 (1.8)	0
Respiratory failure	1 (1.8)	1 (1.2)
Skin and subcutaneous tissue disorders	1 (1.8)	
0 Skin ulcer	1 (1.8)	
0		
Vascular disorders	3 (5.3)	1 (1.2)
Embolism	1 (1.8)	0
Hypertension	2 (3.5)	0
Pelvic venous thrombosis	0	1 (1.2)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent
Adverse Event.
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Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
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All System Organ Classes and Preferred Terms are included, irrespective of their
frequency. Program Path:
/projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sumsocpt-ebr2365-b2.sas 20JUN2024:04:33:35

Anhang 4-G 3.2.3: Schwerwiegende UE auf SOC/PT-Ebene

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Table S.8.2
Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

SOC PT	EXP-5 TKI-naive subjects N = 57	EXP-6 TKI-pretreated subjects N = 83
SUBJECTS WITH ANY SERIOUS TEAE	26 (45.6)	29 (34.9)
Blood and lymphatic system disorders	0	2 (2.4)
Anaemia	0	2 (2.4)
Cardiac disorders	0	4 (4.8)
Cardiac arrest	0	1 (1.2)
Cardiac failure congestive	0	1 (1.2)
Cardio-respiratory arrest	0	1 (1.2)
Supraventricular tachycardia	0	1 (1.2)
Gastrointestinal disorders	4 (7.0)	3 (3.6)
Abdominal pain	1 (1.8)	1 (1.2)
Colitis	0	1 (1.2)
Constipation	1 (1.8)	0
Gastritis	0	1 (1.2)
Paraesthesia oral	1 (1.8)	0
Upper gastrointestinal haemorrhage	1 (1.8)	0
Vomiting	1 (1.8)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent Adverse Event.
Percentages are based on the total number of subjects in the corresponding cohort.
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.
System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.
All System Organ Classes and Preferred Terms are included, irrespective of their frequency.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sumsocpt-ebr2365-b2.sas 20JUN2024:04:33:24

Table S.8.2
Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

SOC PT	EXP-5 TKI-naive subjects N = 57	EXP-6 TKI-pretreated subjects N = 83
General disorders and administration site conditions	2 (3.5)	6 (7.2)
Fatigue	0	1 (1.2)
General physical health deterioration	0	1 (1.2)
Impaired healing	0	1 (1.2)
Pain	0	1 (1.2)
Pyrexia	2 (3.5)	1 (1.2)
Sudden cardiac death	0	1 (1.2)
Hepatobiliary disorders	1 (1.8)	0
Hepatic function abnormal	1 (1.8)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent Adverse Event.
Percentages are based on the total number of subjects in the corresponding cohort.
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.
System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.
All System Organ Classes and Preferred Terms are included, irrespective of their frequency.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sumsocpt-ebr2365-b2.sas 20JUN2024:04:33:24

Table S.8.2
Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

SOC PT	EXP-5 TKI-naive subjects N = 57	EXP-6 TKI-pretreated subjects N = 83
Infections and infestations	11 (19.3)	11 (13.3)
Bacteraemia	0	1 (1.2)
Biliary tract infection bacterial	0	1 (1.2)
COVID-19	2 (3.5)	0
COVID-19 pneumonia	0	2 (2.4)
Erysipelas	1 (1.8)	0
Escherichia sepsis	0	1 (1.2)
Gastroenteritis viral	0	1 (1.2)
Ophthalmic herpes zoster	1 (1.8)	0
Pneumonia	6 (10.5)	5 (6.0)
Pneumonia adenoviral	0	1 (1.2)
Pyelonephritis	1 (1.8)	0
Sepsis	0	1 (1.2)
Urinary tract infection	0	1 (1.2)
Wound infection	0	1 (1.2)
Injury, poisoning and procedural complications	1 (1.8)	1 (1.2)
Febrile nonhaemolytic transfusion reaction	1 (1.8)	0
Fibula fracture	0	1 (1.2)
Investigations	1 (1.8)	0
Platelet count increased	1 (1.8)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent Adverse Event.
Percentages are based on the total number of subjects in the corresponding cohort.
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.
System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.
All System Organ Classes and Preferred Terms are included, irrespective of their frequency.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sumsocpt-ebr2365-b2.sas 20JUN2024:04:33:24

Table S.8.2
Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

SOC PT	EXP-5 TKI-naive subjects N = 57	EXP-6 TKI-pretreated subjects N = 83
Metabolism and nutrition disorders	0	1 (1.2)
Hypercalcaemia	0	1 (1.2)
Musculoskeletal and connective tissue disorders	3 (5.3)	2 (2.4)
Back pain	1 (1.8)	0
Bone pain	1 (1.8)	0
Muscular weakness	1 (1.8)	1 (1.2)
Pain in extremity	0	1 (1.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (1.8)	1 (1.2)
Basal cell carcinoma	1 (1.8)	0
Large cell lung cancer	0	1 (1.2)
Squamous cell carcinoma of skin	1 (1.8)	0
Nervous system disorders	3 (5.3)	6 (7.2)
Depressed level of consciousness	1 (1.8)	0
Dizziness	0	2 (2.4)
Neurological decompensation	1 (1.8)	0
Spinal cord compression	0	1 (1.2)
Syncope	1 (1.8)	2 (2.4)
Tremor	0	1 (1.2)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent Adverse Event.
Percentages are based on the total number of subjects in the corresponding cohort.
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.
System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.
All System Organ Classes and Preferred Terms are included, irrespective of their frequency.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sumsocpt-ebr2365-b2.sas 20JUN2024:04:33:24

Table S.8.2
Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for NTRK+

SOC PT	EXP-5 TKI-naive subjects N = 57	EXP-6 TKI-pretreated subjects N = 83
Psychiatric disorders	0	1 (1.2)
Delirium	0	1 (1.2)
Respiratory, thoracic and mediastinal disorders	5 (8.8)	7 (8.4)
Atelectasis	0	1 (1.2)
Bronchitis chronic	0	1 (1.2)
Dyspnoea	1 (1.8)	2 (2.4)
Haemothorax	0	1 (1.2)
Pharyngeal paraesthesia	1 (1.8)	0
Pleural effusion	0	2 (2.4)
Pneumonitis	0	1 (1.2)
Pulmonary embolism	1 (1.8)	1 (1.2)
Pulmonary hypertension	1 (1.8)	0
Respiratory failure	1 (1.8)	1 (1.2)
Vascular disorders	1 (1.8)	1 (1.2)
Embolism	1 (1.8)	0
Pelvic venous thrombosis	0	1 (1.2)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent Adverse Event.
Percentages are based on the total number of subjects in the corresponding cohort.
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.
System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.
All System Organ Classes and Preferred Terms are included, irrespective of their frequency.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sumsocpt-ebr2365-b2.sas 20JUN2024:04:33:24

Anhang 4-G 3.2.4: Zum Therapieabbruch führende UE auf SOC/PT-Ebene

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Table S.9.2
Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by System Organ Class, Preferred Term and Grade
Safety Set for NTRK+

	EXP-5 TKI-naive subjects N = 57			EXP-6 TKI-pretreated subjects N = 83		
SOC PT	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
SUBJECTS WITH ANY EVENT	8 (14.0)	4 (7.0)	1 (1.8)	5 (6.0)	2 (2.4)	2 (2.4)
Cardiac disorders	0	0	0	1 (1.2)	0	1 (1.2)
Cardiac arrest	0	0	0	1 (1.2)	0	1 (1.2)
General disorders and administration site conditions	0	0	0	2 (2.4)	0	1 (1.2)
Fatigue	0	0	0	1 (1.2)	0	0
Sudden cardiac death	0	0	0	1 (1.2)	0	1 (1.2)
Injury, poisoning and procedural complications	2 (3.5)	1 (1.8)	0	0	0	0
Fall	1 (1.8)	0	0	0	0	0
Febrile nonhaemolytic transfusion reaction	1 (1.8)	1 (1.8)	0	0	0	0
Musculoskeletal and connective tissue disorders	1 (1.8)	0	0	0	0	0
Muscular weakness	1 (1.8)	0	0	0	0	0
Nervous system disorders	3 (5.3)	2 (3.5)	0	0	0	0
Neurological decompensation	2 (3.5)	2 (3.5)	0	0	0	0
Spinal cord compression	1 (1.8)	0	0	0	0	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent Adverse Event.
Percentages are based on the total number of subjects in the corresponding cohort.
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent. If a subject reported one or more adverse events, the subject is counted only once at each level reported based on the maximum grade reported for each coded term.
System Organ Classes are sorted alphabetically, and within each System Organ Class, Preferred Terms are sorted alphabetically as well. All System Organ Classes and Preferred Terms are included, irrespective of their frequency.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sumsocptgrl2d-ebr2365-b2.sas 20JUN2024:04:34:17

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Table S.9.2
Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by System Organ Class, Preferred Term and Grade
Safety Set for NTRK+

	EXP-5 TKI-naive subjects N = 57			EXP-6 TKI-pretreated subjects N = 83		
SOC PT	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
Respiratory, thoracic and mediastinal disorders	2 (3.5)	1 (1.8)	1 (1.8)	2 (2.4)	2 (2.4)	0
Dyspnoea	0	0	0	1 (1.2)	1 (1.2)	0
Pneumonitis	0	0	0	1 (1.2)	1 (1.2)	0
Pulmonary hypertension	1 (1.8)	1 (1.8)	0	0	0	0
Respiratory failure	1 (1.8)	0	1 (1.8)	0	0	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent Adverse Event.
Percentages are based on the total number of subjects in the corresponding cohort.
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent. If a subject reported one or more adverse events, the subject is counted only once at each level reported based on the maximum grade reported for each coded term.
System Organ Classes are sorted alphabetically, and within each System Organ Class, Preferred Terms are sorted alphabetically as well. All System Organ Classes and Preferred Terms are included, irrespective of their frequency.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables
Program Name: rt-ae-sumsocptgrl2d-ebr2365-b2.sas 20JUN2024:04:34:17

Anhang 4-G 4: Subgruppenanalysen

Anhang 4-G 4.1: Endpunkt Mortalität – Gesamtüberleben (OS)

Protocol: TPX-0005-01

Table E.10.2
Overall Survival
Subgroup Analysis
Safety Set for NTRK+

Parameter	EXP-5 TKI-naive subjects N	EXP-5 TKI-naive subjects Events n (%)	EXP-5 TKI-naive subjects Median (1) (95% CI) (2) (months)	EXP-6 TKI-pretreated subjects N	EXP-6 TKI-pretreated subjects Events n (%)	EXP-6 TKI-pretreated subjects Median (1) (95% CI) (2) (months)
AGE (YEARS)						
>= 12 TO < 18	0	0	N.M.E.	0	0	N.M.E.
>= 18 TO < 65	35	9 (25.7)	N.M.E.	53	19 (35.8)	19.12 (12.45, 32.46)
>= 65 TO < 75	15	6 (40.0)	N.M.E.	23	14 (60.9)	8.57 (4.50, 22.28)
>= 75	7	2 (28.6)	N.M.E.	7	3 (42.9)	N.M.E.
SEX						
MALE	28	9 (32.1)	N.M.E.	40	15 (37.5)	25.72 (10.78, N.A.)
FEMALE	29	8 (27.6)	N.M.E.	43	21 (48.8)	16.79 (11.60, 19.12)
RACE						
AMERICAN INDIAN OR ALASKAN NATIVE	0	0	N.M.E.	0	0	N.M.E.
ASIAN	25	7 (28.0)	N.M.E.	21	6 (28.6)	N.M.E.
WHITE	20	6 (30.0)	N.M.E.	54	25 (46.3)	12.22 (8.57, 19.32)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	N.M.E.	0	0	N.M.E.
BLACK OR AFRICAN AMERICAN	2	2 (100.0)	N.M.E.	2	1 (50.0)	N.M.E.
OTHER	1	0	N.M.E.	0	0	N.M.E.
NOT REPORTED OR UNKNOWN	9	2 (22.2)	N.M.E.	6	4 (66.7)	N.M.E.
REGION						
US	9	6 (66.7)	N.M.E.	28	12 (42.9)	19.12 (7.36, 25.72)
ASIA	22	6 (27.3)	N.M.E.	15	5 (33.3)	N.M.E.
OTHER	26	5 (19.2)	N.M.E.	40	19 (47.5)	12.22 (10.78, 32.46)
ECOG PERFORMANCE STATUS						
0	23	7 (30.4)	N.M.E.	35	10 (28.6)	22.28 (19.12, N.A.)
1	34	10 (29.4)	27.43 (20.80, N.A.)	48	26 (54.2)	11.60 (8.57, 18.56)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Percentages are based on the total number of subjects in the respective subgroup (within the corresponding cohort).
Overall survival (OS) is defined as the time from the first dose of repotrectinib to the date of death due to any cause + 1 day.
(1) Median computed using Kaplan-Meier method.
(2) 95% CIs are based on Kaplan-Meier methodology using the Greenwood variance estimate.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ef-ossafros-ebr2365-b4.sas 28AUG2024:07:29:02

Protocol: TPX-0005-01

Table E.10.2
Overall Survival
Subgroup Analysis
Safety Set for NTRK+

Parameter	EXP-5 TKI-naive subjects N	EXP-5 TKI-naive subjects Events n (%)	EXP-5 TKI-naive subjects Median (1) (95% CI) (2) (months)	EXP-6 TKI-pretreated subjects N	EXP-6 TKI-pretreated subjects Events n (%)	EXP-6 TKI-pretreated subjects Median (1) (95% CI) (2) (months)
SOLVENT MUTATION STATUS						
YES	0	0	N.M.E.	29	18 (62.1)	12.22 (8.57, 25.26)
NO	57	17 (29.8)	55.59 (25.56, N.A.)	54	18 (33.3)	19.32 (11.60, 25.72)
BRAIN METASTASIS BY INVESTIGATOR						
YES	13	5 (38.5)	N.M.E.	16	9 (56.3)	N.M.E.
NO	44	12 (27.3)	55.59 (N.A., N.A.)	67	27 (40.3)	19.12 (12.19, 25.26)
BRAIN METASTASIS BY BICR						
YES	12	6 (50.0)	N.M.E.	17	9 (52.9)	N.M.E.
NO	45	11 (24.4)	55.59 (N.A., N.A.)	66	27 (40.9)	19.12 (12.19, 25.72)
ANY PRIOR TREATMENT WITH ENTRECTINIB						
YES	0	0	N.M.E.	35	15 (42.9)	19.32 (12.22, 32.46)
NO	57	17 (29.8)	55.59 (25.56, N.A.)	48	21 (43.8)	12.45 (10.18, 25.26)
ANY PRIOR TREATMENT WITH LAROTRECTINIB						
YES	0	0	N.M.E.	48	20 (41.7)	16.92 (10.18, 25.26)
NO	57	17 (29.8)	55.59 (25.56, N.A.)	35	16 (45.7)	19.32 (12.22, 32.46)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Percentages are based on the total number of subjects in the respective subgroup (within the corresponding cohort).
Overall survival (OS) is defined as the time from the first dose of repotrectinib to the date of death due to any cause + 1 day.
(1) Median computed using Kaplan-Meier method.
(2) 95% CIs are based on Kaplan-Meier methodology using the Greenwood variance estimate. Program Path:
/projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ef-ossafros-ebr2365-b4.sas 28AUG2024:07:29:02

Anhang 4-G 4.2: Endpunkte Verträglichkeit

Anhang 4-G 4.2.1: Schwere UE (UE mit einem Schweregrad von ≥ 3 nach CTCAE)

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Table S.11.2
Severe Treatment-Emergent Adverse Events
Subgroup Analysis
Safety Set for NTRK+

Parameter	EXP-5 TKI-naive subjects N	EXP-5 TKI-naive subjects Events n (%)	EXP-5 TKI-naive subjects 95% CI	EXP-6 TKI-pretreated subjects N	EXP-6 TKI-pretreated subjects Events n (%)	EXP-6 TKI-pretreated subjects 95% CI
AGE (YEARS)						
>= 12 TO < 18	0	0	N.M.E.	0	0	N.M.E.
>= 18 TO < 65	35	18 (51.4)	34.0, 68.6	53	26 (49.1)	35.1, 63.2
>= 65 TO < 75	15	11 (73.3)	44.9, 92.2	23	15 (65.2)	42.7, 83.6
>= 75	7	6 (85.7)	N.M.E.	7	4 (57.1)	N.M.E.
SEX						
MALE	28	19 (67.9)	47.6, 84.1	40	24 (60.0)	43.3, 75.1
FEMALE	29	16 (55.2)	35.7, 73.6	43	21 (48.8)	33.3, 64.5
RACE						
AMERICAN INDIAN OR ALASKAN NATIVE	0	0	N.M.E.	0	0	N.M.E.
ASIAN	25	14 (56.0)	34.9, 75.6	21	12 (57.1)	34.0, 78.2
WHITE	20	14 (70.0)	45.7, 88.1	54	29 (53.7)	39.6, 67.4
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	N.M.E.	0	0	N.M.E.
BLACK OR AFRICAN AMERICAN	2	1 (50.0)	N.M.E.	2	1 (50.0)	N.M.E.
OTHER	1	0	N.M.E.	0	0	N.M.E.
NOT REPORTED OR UNKNOWN	9	6 (66.7)	N.M.E.	6	3 (50.0)	N.M.E.
REGION						
US	9	6 (66.7)	N.M.E.	28	16 (57.1)	37.2, 75.5
ASIA	22	12 (54.5)	32.2, 75.6	15	9 (60.0)	N.M.E.
OTHER	26	17 (65.4)	44.3, 82.8	40	20 (50.0)	33.8, 66.2

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent
Adverse Event.
Percentages are based on the total number of subjects in the respective subgroup (within the corresponding cohort).
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of
study drug
are considered treatment emergent. Severe TEAE are TEAE CTCAE Grade >=3.
Program Path: /pic/projects5/blinded/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sum-ebr2365.sas 28AUG2024:08:50:53

Protocol: TPX-0005-01

Table S.11.2
Severe Treatment-Emergent Adverse Events
Subgroup Analysis
Safety Set for NTRK+

Parameter	EXP-5 TKI-naive subjects N	Events n (%)	95% CI	EXP-6 TKI-pretreated subjects N	Events n (%)	95% CI
ECOG PERFORMANCE STATUS						
0	23	13 (56.5)	34.5, 76.8	35	13 (37.1)	21.5, 55.1
1	34	22 (64.7)	46.5, 80.3	48	32 (66.7)	51.6, 79.6
SOLVENT MUTATION STATUS						
YES	0	0	N.M.E.	29	17 (58.6)	38.9, 76.5
NO	57	35 (61.4)	47.6, 74.0	54	28 (51.9)	37.8, 65.7
BRAIN METASTASIS BY INVESTIGATOR						
YES	13	9 (69.2)	N.M.E.	16	9 (56.3)	N.M.E.
NO	44	26 (59.1)	43.2, 73.7	67	36 (53.7)	41.1, 66.0
BRAIN METASTASIS BY BICR						
YES	12	8 (66.7)	N.M.E.	17	9 (52.9)	N.M.E.
NO	45	27 (60.0)	44.3, 74.3	66	36 (54.5)	41.8, 66.9
ANY PRIOR TREATMENT WITH ENTRECTINIB						
YES	0	0	N.M.E.	35	17 (48.6)	31.4, 66.0
NO	57	35 (61.4)	47.6, 74.0	48	28 (58.3)	43.2, 72.4
ANY PRIOR TREATMENT WITH LAROTRECTINIB						
YES	0	0	N.M.E.	48	26 (54.2)	39.2, 68.6
NO	57	35 (61.4)	47.6, 74.0	35	19 (54.3)	36.6, 71.2

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Abbreviations: TEAE = Treatment-Emergent
Adverse Event.
Percentages are based on the total number of subjects in the respective subgroup (within the corresponding cohort).
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of
study drug
are considered treatment emergent. Severe TEAE are TEAE CTCAE Grade >=3.
Program Path: /pic/projects5/blinded/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sum-ebr2365.sas 28AUG2024:08:50:53

Anhang 4-G 4.2.2: Schwerwiegende UE

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Table S.12.2
Serious Treatment-Emergent Adverse Events
Subgroup Analysis
Safety Set for NTRK+

Parameter	EXP-5 TKI-naive subjects N	EXP-5 TKI-naive subjects Events n (%)	EXP-5 TKI-naive subjects 95% CI	EXP-6 TKI-pretreated subjects N	EXP-6 TKI-pretreated subjects Events n (%)	EXP-6 TKI-pretreated subjects 95% CI
AGE (YEARS)						
>= 12 TO < 18	0	0	N.M.E.	0	0	N.M.E.
>= 18 TO < 65	35	12 (34.3)	19.1, 52.2	53	15 (28.3)	16.8, 42.3
>= 65 TO < 75	15	9 (60.0)	N.M.E.	23	11 (47.8)	26.8, 69.4
>= 75	7	5 (71.4)	N.M.E.	7	3 (42.9)	N.M.E.
SEX						
MALE	28	11 (39.3)	21.5, 59.4	40	16 (40.0)	24.9, 56.7
FEMALE	29	15 (51.7)	32.5, 70.6	43	13 (30.2)	17.2, 46.1
RACE						
AMERICAN INDIAN OR ALASKAN NATIVE	0	0	N.M.E.	0	0	N.M.E.
ASIAN	25	10 (40.0)	21.1, 61.3	21	7 (33.3)	N.M.E.
WHITE	20	8 (40.0)	N.M.E.	54	20 (37.0)	24.3, 51.3
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	N.M.E.	0	0	N.M.E.
BLACK OR AFRICAN AMERICAN	2	1 (50.0)	N.M.E.	2	0	N.M.E.
OTHER	1	0	N.M.E.	0	0	N.M.E.
NOT REPORTED OR UNKNOWN	9	7 (77.8)	N.M.E.	6	2 (33.3)	N.M.E.
REGION						
US	9	5 (55.6)	N.M.E.	28	11 (39.3)	21.5, 59.4
ASIA	22	9 (40.9)	N.M.E.	15	6 (40.0)	N.M.E.
OTHER	26	12 (46.2)	26.6, 66.6	40	12 (30.0)	16.6, 46.5

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Percentages are based on the total number of subjects in the respective subgroup (within the corresponding cohort).
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
are considered treatment emergent.
Program Path: /pic/projects5/blinded/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sum-ebr2365.sas 28AUG2024:08:51:00

Protocol: TPX-0005-01

Table S.12.2
Serious Treatment-Emergent Adverse Events
Subgroup Analysis
Safety Set for NTRK+

Parameter	EXP-5 TKI-naive subjects N	Events n (%)	95% CI	EXP-6 TKI-pretreated subjects N	Events n (%)	95% CI
ECOG PERFORMANCE STATUS						
0	23	10 (43.5)	23.2, 65.5	35	6 (17.1)	N.M.E.
1	34	16 (47.1)	29.8, 64.9	48	23 (47.9)	33.3, 62.8
SOLVENT MUTATION STATUS						
YES	0	0	N.M.E.	29	13 (44.8)	26.4, 64.3
NO	57	26 (45.6)	32.4, 59.3	54	16 (29.6)	18.0, 43.6
BRAIN METASTASIS BY INVESTIGATOR						
YES	13	8 (61.5)	N.M.E.	16	6 (37.5)	N.M.E.
NO	44	18 (40.9)	26.3, 56.8	67	23 (34.3)	23.2, 46.9
BRAIN METASTASIS BY BICR						
YES	12	7 (58.3)	N.M.E.	17	5 (29.4)	N.M.E.
NO	45	19 (42.2)	27.7, 57.8	66	24 (36.4)	24.9, 49.1
ANY PRIOR TREATMENT WITH ENTRECTINIB						
YES	0	0	N.M.E.	35	11 (31.4)	16.9, 49.3
NO	57	26 (45.6)	32.4, 59.3	48	18 (37.5)	24.0, 52.6
ANY PRIOR TREATMENT WITH LAROTRECTINIB						
YES	0	0	N.M.E.	48	16 (33.3)	20.4, 48.4
NO	57	26 (45.6)	32.4, 59.3	35	13 (37.1)	21.5, 55.1

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Percentages are based on the total number of subjects in the respective subgroup (within the corresponding cohort).
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
are considered treatment emergent.
Program Path: /pic/projects5/blinded/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sum-ebr2365.sas 28AUG2024:08:51:00

Anhang 4-G 4.2.3: Zum Therapieabbruch führende UE

Protocol: TPX-0005-01

Table S.13.2
Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
Subgroup Analysis
Safety Set for NTRK+

Parameter	EXP-5 TKI-naive subjects N	EXP-5 TKI-naive subjects Events n (%)	EXP-5 TKI-naive subjects 95% CI	EXP-6 TKI-pretreated subjects N	EXP-6 TKI-pretreated subjects Events n (%)	EXP-6 TKI-pretreated subjects 95% CI
AGE (YEARS)						
>= 12 TO < 18	0	0	N.M.E.	0	0	N.M.E.
>= 18 TO < 65	35	2 (5.7)	N.M.E.	53	2 (3.8)	N.M.E.
>= 65 TO < 75	15	4 (26.7)	N.M.E.	23	2 (8.7)	N.M.E.
>= 75	7	2 (28.6)	N.M.E.	7	1 (14.3)	N.M.E.
SEX						
MALE	28	2 (7.1)	N.M.E.	40	5 (12.5)	N.M.E.
FEMALE	29	6 (20.7)	N.M.E.	43	0	N.M.E.
RACE						
AMERICAN INDIAN OR ALASKAN NATIVE	0	0	N.M.E.	0	0	N.M.E.
ASIAN	25	2 (8.0)	N.M.E.	21	1 (4.8)	N.M.E.
WHITE	20	4 (20.0)	N.M.E.	54	4 (7.4)	N.M.E.
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	N.M.E.	0	0	N.M.E.
BLACK OR AFRICAN AMERICAN	2	0	N.M.E.	2	0	N.M.E.
OTHER	1	0	N.M.E.	0	0	N.M.E.
NOT REPORTED OR UNKNOWN	9	2 (22.2)	N.M.E.	6	0	N.M.E.
REGION						
US	9	1 (11.1)	N.M.E.	28	0	N.M.E.
ASIA	22	1 (4.5)	N.M.E.	15	1 (6.7)	N.M.E.
OTHER	26	6 (23.1)	N.M.E.	40	4 (10.0)	N.M.E.

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Percentages are based on the total number of subjects in the respective subgroup (within the corresponding cohort).
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
are considered treatment emergent.
Program Path: /pic/projects5/blinded/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sum-ebr2365.sas 28AUG2024:08:51:07

Protocol: TPX-0005-01

Table S.13.2
Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
Subgroup Analysis
Safety Set for NTRK+

Parameter	EXP-5 TKI-naive subjects N	Events n (%)	95% CI	EXP-6 TKI-pretreated subjects N	Events n (%)	95% CI
ECOG PERFORMANCE STATUS						
0	23	4 (17.4)	N.M.E.	35	2 (5.7)	N.M.E.
1	34	4 (11.8)	N.M.E.	48	3 (6.3)	N.M.E.
SOLVENT MUTATION STATUS						
YES	0	0	N.M.E.	29	1 (3.4)	N.M.E.
NO	57	8 (14.0)	N.M.E.	54	4 (7.4)	N.M.E.
BRAIN METASTASIS BY INVESTIGATOR						
YES	13	2 (15.4)	N.M.E.	16	1 (6.3)	N.M.E.
NO	44	6 (13.6)	N.M.E.	67	4 (6.0)	N.M.E.
BRAIN METASTASIS BY BICR						
YES	12	2 (16.7)	N.M.E.	17	2 (11.8)	N.M.E.
NO	45	6 (13.3)	N.M.E.	66	3 (4.5)	N.M.E.
ANY PRIOR TREATMENT WITH ENTRECTINIB						
YES	0	0	N.M.E.	35	2 (5.7)	N.M.E.
NO	57	8 (14.0)	N.M.E.	48	3 (6.3)	N.M.E.
ANY PRIOR TREATMENT WITH LAROTRECTINIB						
YES	0	0	N.M.E.	48	3 (6.3)	N.M.E.
NO	57	8 (14.0)	N.M.E.	35	2 (5.7)	N.M.E.

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Percentages are based on the total number of subjects in the respective subgroup (within the corresponding cohort).
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
are considered treatment emergent.
Program Path: /pic/projects5/blinded/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sum-ebr2365.sas 28AUG2024:08:51:07

Anhang 4-G 4.2.4: Jegliche UESI

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Table S.14.2
Treatment-Emergent Adverse Events of Special Interest
Subgroup Analysis
Safety Set for NTRK+

Parameter	EXP-5 TKI-naive subjects N	Events n (%)	95% CI	EXP-6 TKI-pretreated subjects N	Events n (%)	95% CI
AGE (YEARS)						
>= 12 TO < 18	0	0	N.M.E.	0	0	N.M.E.
>= 18 TO < 65	35	35 (100.0)	90.0,100.0	53	48 (90.6)	79.3, 96.9
>= 65 TO < 75	15	15 (100.0)	78.2,100.0	23	21 (91.3)	72.0, 98.9
>= 75	7	7 (100.0)	N.M.E.	7	7 (100.0)	N.M.E.
SEX						
MALE	28	28 (100.0)	87.7,100.0	40	37 (92.5)	79.6, 98.4
FEMALE	29	29 (100.0)	88.1,100.0	43	39 (90.7)	77.9, 97.4
RACE						
AMERICAN INDIAN OR ALASKAN NATIVE	0	0	N.M.E.	0	0	N.M.E.
ASIAN	25	25 (100.0)	86.3,100.0	21	20 (95.2)	76.2, 99.9
WHITE	20	20 (100.0)	83.2,100.0	54	48 (88.9)	77.4, 95.8
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	N.M.E.	0	0	N.M.E.
BLACK OR AFRICAN AMERICAN	2	2 (100.0)	N.M.E.	2	2 (100.0)	N.M.E.
OTHER	1	1 (100.0)	N.M.E.	0	0	N.M.E.
NOT REPORTED OR UNKNOWN	9	9 (100.0)	N.M.E.	6	6 (100.0)	N.M.E.
REGION						
US	9	9 (100.0)	N.M.E.	28	25 (89.3)	71.8, 97.7
ASIA	22	22 (100.0)	84.6,100.0	15	15 (100.0)	78.2,100.0
OTHER	26	26 (100.0)	86.8,100.0	40	36 (90.0)	76.3, 97.2

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Percentages are based on the total number of subjects in the respective subgroup (within the corresponding cohort).
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
are considered treatment emergent.
Program Path: /pic/projects5/blinded/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sum-ebr2365.sas 28AUG2024:08:51:14

Protocol: TPX-0005-01

Table S.14.2
Treatment-Emergent Adverse Events of Special Interest
Subgroup Analysis
Safety Set for NTRK+

Parameter	EXP-5 TKI-naive subjects N	Events n (%)	95% CI	EXP-6 TKI-pretreated subjects N	Events n (%)	95% CI
ECOG PERFORMANCE STATUS						
0	23	23 (100.0)	85.2,100.0	35	32 (91.4)	76.9, 98.2
1	34	34 (100.0)	89.7,100.0	48	44 (91.7)	80.0, 97.7
SOLVENT MUTATION STATUS						
YES	0	0	N.M.E.	29	27 (93.1)	77.2, 99.2
NO	57	57 (100.0)	93.7,100.0	54	49 (90.7)	79.7, 96.9
BRAIN METASTASIS BY INVESTIGATOR						
YES	13	13 (100.0)	75.3,100.0	16	14 (87.5)	61.7, 98.4
NO	44	44 (100.0)	92.0,100.0	67	62 (92.5)	83.4, 97.5
BRAIN METASTASIS BY BICR						
YES	12	12 (100.0)	73.5,100.0	17	15 (88.2)	63.6, 98.5
NO	45	45 (100.0)	92.1,100.0	66	61 (92.4)	83.2, 97.5
ANY PRIOR TREATMENT WITH ENTRECTINIB						
YES	0	0	N.M.E.	35	31 (88.6)	73.3, 96.8
NO	57	57 (100.0)	93.7,100.0	48	45 (93.8)	82.8, 98.7
ANY PRIOR TREATMENT WITH LAROTRECTINIB						
YES	0	0	N.M.E.	48	45 (93.8)	82.8, 98.7
NO	57	57 (100.0)	93.7,100.0	35	31 (88.6)	73.3, 96.8

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Percentages are based on the total number of subjects in the respective subgroup (within the corresponding cohort).
Adverse events were coded using the MedDRA dictionary, Version 25.0.
Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
are considered treatment emergent.
Program Path: /pic/projects5/blinded/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-sum-ebr2365.sas 28AUG2024:08:51:14

Anhang 4-G 5: Kaplan-Meier-Kurven

Anhang 4-G 5.1: Kaplan-Meier-Kurven für den Endpunkt Dauer des Ansprechens (DOR) gemäß BICR

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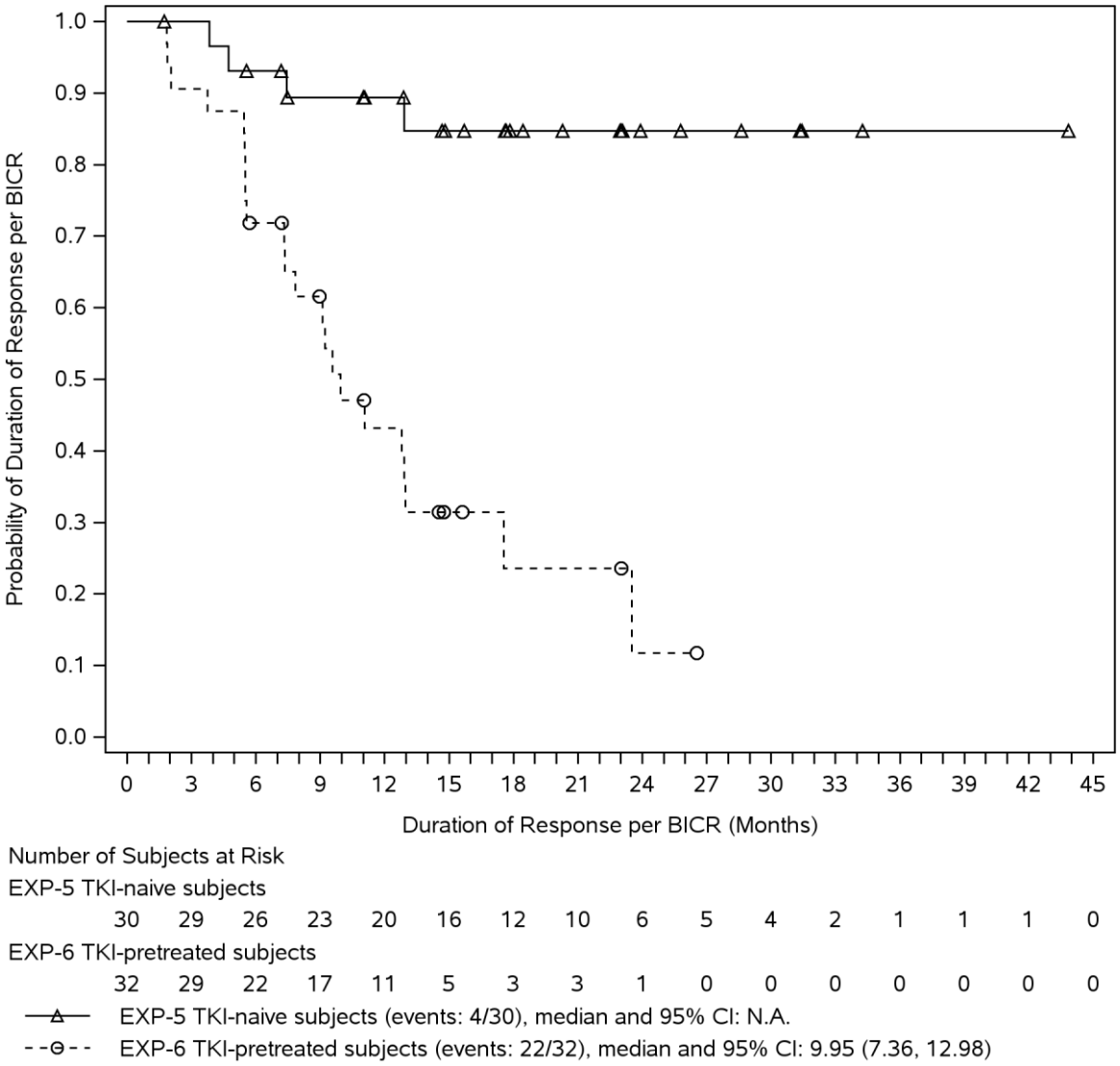
Figure E.3.2
Kaplan-Meier Plot of Duration of Response per BICR , AMNOG definition - Full Analysis Set for NTRK+ - Subjects with Confirmed Objective Tumor Response (PR or CR)



DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Symbols represent censored observations.
Duration of response (DOR) is only calculated for the subgroup of subjects with a confirmed objective tumor response (PR or CR). CR/PR must be confirmed with a repeat radiological assessment >=4 weeks immediately after first reported CR/PR.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/figures
Program Name: rg-ef-kmplot-ebr2365.sas 16JUL2024:13:41:01

Anhang 4-G 5.2: Kaplan-Meier-Kurven für den Endpunkt Dauer des intrakraniellen Ansprechens (IC-DOR) gemäß BICR

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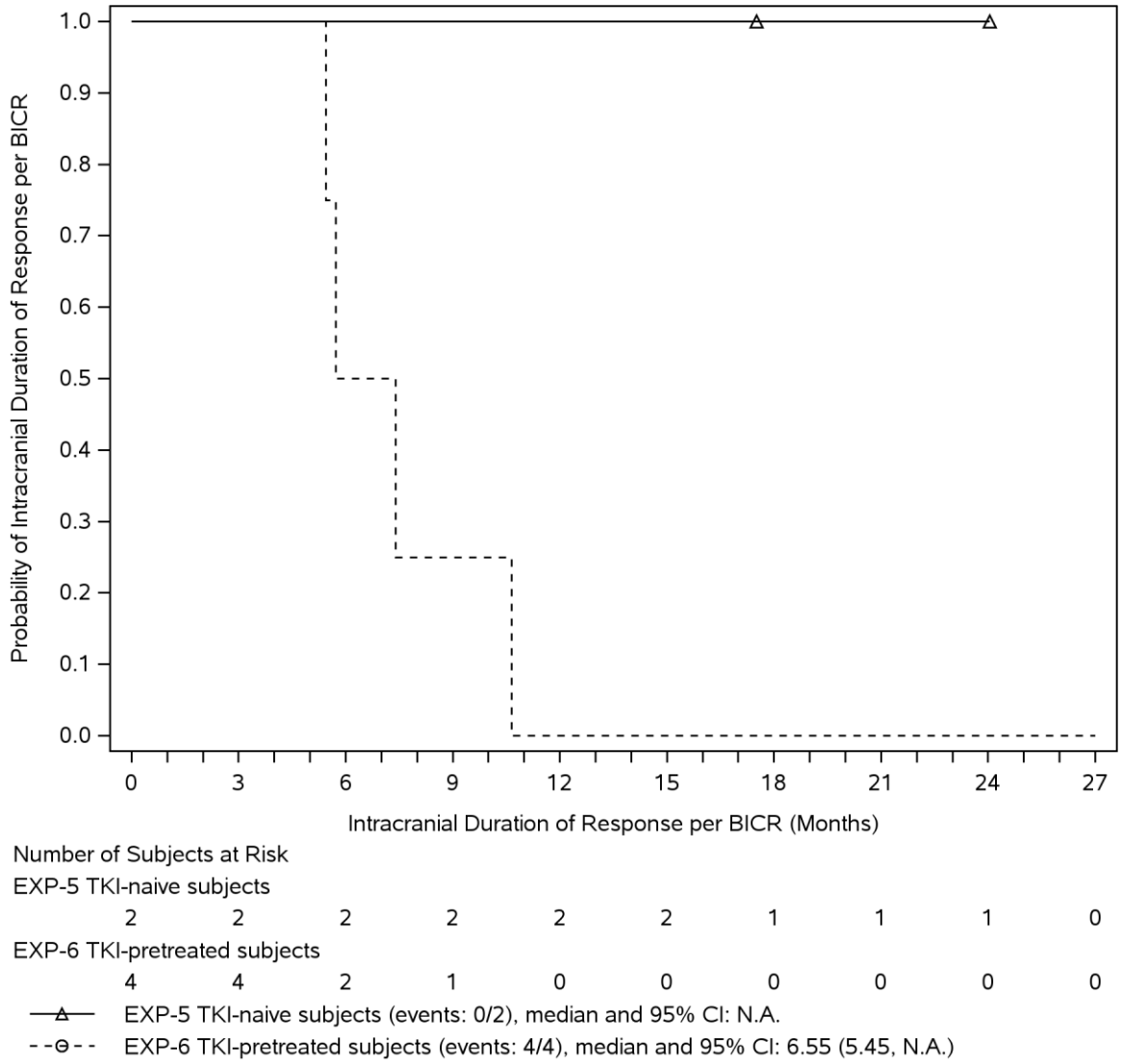
Figure E.4.2
Kaplan-Meier Plot of Intracranial Duration of Response per BICR, AMNOG definition - Full Analysis Set for NTRK+ - Subjects from Phase 2 Portion of the Trial with Measurable Brain Metastasis at Baseline - and Confirmed Objective Tumor Response (PR or CR)



DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Symbols represent censored observations.
Duration of intracranial response (IC-DOR) is only calculated for the subgroup of patients in the corresponding cohort of the Phase 2 portion of the trial with measurable baseline brain metastasis per BICR for tumor assessment per modified RECIST v1.1 criteria.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/figures
Program Name: rg-ef-kmplot-ebr2365.sas 16JUL2024:13:41:24

Anhang 4-G 5.3: Kaplan-Meier-Kurven für den Endpunkt intrakranielles progressionsfreies Überleben (IC-PFS) gemäß BICR

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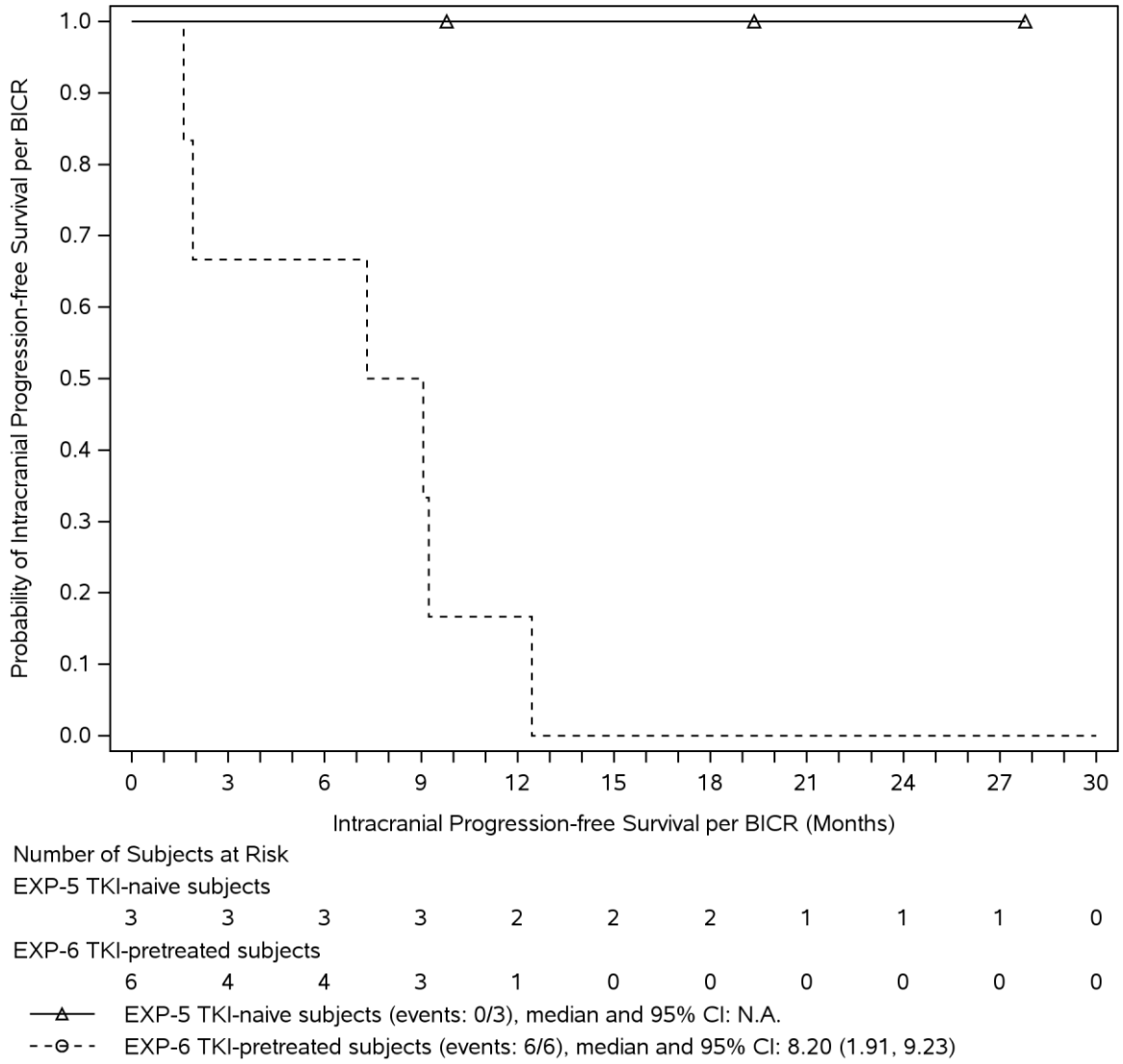
Figure E.5.2
Kaplan-Meier Plot of Intracranial Progression-free Survival per BICR, AMNOG definition - Full Analysis Set for NTRK+ - Subjects from Phase 2 Portion of the Trial with Measurable Brain Metastasis at Baseline



DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Intracranial Progression-free survival (IC-PFS) is only calculated for the subgroup of patients in the corresponding cohort of the Phase 2 portion of the trial with measurable baseline brain metastasis per BICR for tumor assessment per modified RECIST v1.1 criteria.
IC-PFS is defined as the time from the first dose of repotrectinib to first evidence of radiographic intracranial disease progression per modified RECIST v1.1 or death due to any cause (whichever occurs first) + 1 day.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/figures
Program Name: rg-ef-kmplot-ebr2365.sas 25JUL2024:15:47:00

Anhang 4-G 6: Übersicht der den UESI zugrundeliegenden MedDRA-Terme

Table S.6
Summary of MedDRA terms for Treatment-Emergent Adverse Events of Special Interest classification

Medical Concept	MedDRA Terms Included
Ataxia	Higher Level Term: Coordination and balance disturbances Preferred Term: Gait disturbance
Cognitive disorders	Preferred Term: Altered state of consciousness Preferred Term: Amnesia Preferred Term: Aphasia Preferred Term: Attention deficit hyperactivity disorder Preferred Term: Bradyphrenia Preferred Term: Cognitive disorder Preferred Term: Confusional state Preferred Term: Delirium Preferred Term: Delusion Preferred Term: Depressed level of consciousness Preferred Term: Disorientation Preferred Term: Disturbance in attention Preferred Term: Dysgraphia Preferred Term: Hallucination Preferred Term: Hallucination, visual Preferred Term: Intellectual disability Preferred Term: Memory impairment Preferred Term: Mental disorder Preferred Term: Mental status changes Preferred Term: Neurological decompensation

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Based on MedDRA dictionary, Version 25.0.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-summedra.sas 31MAY2024:04:29:42

Table S.6
Summary of MedDRA terms for Treatment-Emergent Adverse Events of Special Interest classification

Medical Concept	MedDRA Terms Included
Dizziness	Preferred Term: Dizziness Preferred Term: Dizziness exertional Preferred Term: Dizziness postural Preferred Term: Vertigo Preferred Term: Vertigo positional
Dysgeusia	Higher Level Term: Sensory abnormalities NEC Remove the Preferred Term: Neuralgia
Hepatic enzyme elevation	Preferred Term: Alanine aminotransferase increased Preferred Term: Aspartate aminotransferase increased Preferred Term: Hepatic cytolysis Preferred Term: Hypertransaminasaemia Preferred Term: Liver function test increased Preferred Term: Transaminases increased
Mood disorders	Preferred Term: Affect lability Preferred Term: Affective disorder Preferred Term: Aggression Preferred Term: Agitated depression Preferred Term: Agitation Preferred Term: Anxiety Preferred Term: Anxiety disorder Preferred Term: Depressed mood

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Based on MedDRA dictionary, Version 25.0.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-summedra.sas 31MAY2024:04:29:42

Table S.6
Summary of MedDRA terms for Treatment-Emergent Adverse Events of Special Interest classification

Medical Concept	MedDRA Terms Included
Mood disorders	Preferred Term: Depression Preferred Term: Euphoric mood Preferred Term: Irritability Preferred Term: Mania Preferred Term: Mood altered Preferred Term: Mood swings Preferred Term: Persistent depressive disorder Preferred Term: Personality change Preferred Term: Personality disorder Preferred Term: Psychomotor retardation Preferred Term: Stress Preferred Term: Suicidal ideation
Muscular weakness	Preferred Term: Muscle fatigue Preferred Term: Muscular weakness
Paraesthesia	Higher Level Term: Paraesthesias and dysaesthesias
Peripheral Sensory Neuropathy	Higher Level Term: Peripheral neuropathies NEC Preferred Term: Neuralgia
Pneumonitis	Preferred Term: Interstitial lung disease Preferred Term: Pneumonitis

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Based on MedDRA dictionary, Version 25.0.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-summedra.sas 31MAY2024:04:29:42

Table S.6
Summary of MedDRA terms for Treatment-Emergent Adverse Events of Special Interest classification

Medical Concept	MedDRA Terms Included
QT prolongation	Preferred Term: Electrocardiogram qt prolonged Preferred Term: Torsade de pointes Preferred Term: Ventricular arrhythmia Preferred Term: Ventricular fibrillation Preferred Term: Ventricular flutter Preferred Term: Ventricular tachycardia
Skeletal fractures	Preferred Term: Acetabulum fracture Preferred Term: Ankle fracture Preferred Term: Atypical femur fracture Preferred Term: Atypical fracture Preferred Term: Avulsion fracture Preferred Term: Bone fragmentation Preferred Term: Cervical vertebral fracture Preferred Term: Chance fracture Preferred Term: Clavicle fracture Preferred Term: Comminuted fracture Preferred Term: Complicated fracture Preferred Term: Compression fracture Preferred Term: Costal cartilage fracture Preferred Term: Craniofacial fracture Preferred Term: Epiphyseal fracture Preferred Term: Facial bones fracture Preferred Term: Femoral neck fracture

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Based on MedDRA dictionary, Version 25.0.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-summedra.sas 31MAY2024:04:29:42

Table S.6
Summary of MedDRA terms for Treatment-Emergent Adverse Events of Special Interest classification

Medical Concept	MedDRA Terms Included
Skeletal fractures	Preferred Term: Femur fracture Preferred Term: Fibula fracture Preferred Term: Flail chest Preferred Term: Foot fracture Preferred Term: Forearm fracture Preferred Term: Fracture Preferred Term: Fracture blisters Preferred Term: Fracture delayed union Preferred Term: Fracture displacement Preferred Term: Fracture malunion Preferred Term: Fracture nonunion Preferred Term: Fractured coccyx Preferred Term: Fractured sacrum Preferred Term: Fractured skull depressed Preferred Term: Greenstick fracture Preferred Term: Hand fracture Preferred Term: Hip fracture Preferred Term: Humerus fracture Preferred Term: Ilium fracture Preferred Term: Impacted fracture Preferred Term: Jaw fracture Preferred Term: Limb fracture Preferred Term: Lisfranc fracture Preferred Term: Lower limb fracture

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Based on MedDRA dictionary, Version 25.0.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-summedra.sas 31MAY2024:04:29:42

Table S.6
Summary of MedDRA terms for Treatment-Emergent Adverse Events of Special Interest classification

Medical Concept	MedDRA Terms Included
Skeletal fractures	Preferred Term: Lumbar vertebral fracture Preferred Term: Maisonneuve fracture Preferred Term: Metaphyseal corner fracture Preferred Term: Multiple fractures Preferred Term: Open fracture Preferred Term: Osteochondral fracture Preferred Term: Osteophyte fracture Preferred Term: Osteoporotic fracture Preferred Term: Patella fracture Preferred Term: Pathological fracture Preferred Term: Pelvic fracture Preferred Term: Periprosthetic fracture Preferred Term: Radius fracture Preferred Term: Rib fracture Preferred Term: Sacroiliac fracture Preferred Term: Scapula fracture Preferred Term: Skull fracture Preferred Term: Skull fractured base Preferred Term: Spinal compression fracture Preferred Term: Spinal fracture Preferred Term: Spinal fusion fracture Preferred Term: Sternal fracture Preferred Term: Stress fracture Preferred Term: Subchondral insufficiency fracture

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Based on MedDRA dictionary, Version 25.0.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-summedra.sas 31MAY2024:04:29:42

Table S.6
Summary of MedDRA terms for Treatment-Emergent Adverse Events of Special Interest classification

Medical Concept	MedDRA Terms Included
Skeletal fractures	Preferred Term: Thoracic vertebral fracture Preferred Term: Tibia fracture Preferred Term: Torus fracture Preferred Term: Traumatic fracture Preferred Term: Ulna fracture Preferred Term: Upper limb fracture Preferred Term: Wrist fracture
Sleep disorders	Preferred Term: Abnormal dreams Preferred Term: Abnormal sleep-related event Preferred Term: Advanced sleep phase Preferred Term: Behavioural induced insufficient sleep syndrome Preferred Term: Behavioural insomnia of childhood Preferred Term: Breathing-related sleep disorder Preferred Term: Cataplexy Preferred Term: Central sleep apnoea syndrome Preferred Term: Circadian rhythm sleep disorder Preferred Term: Confusional arousal Preferred Term: Delayed sleep phase Preferred Term: Dyssomnia Preferred Term: Hypersomnia Preferred Term: Hyposomnia Preferred Term: Initial insomnia Preferred Term: Insomnia

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Based on MedDRA dictionary, Version 25.0.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-summedra.sas 31MAY2024:04:29:42

Table S.6
Summary of MedDRA terms for Treatment-Emergent Adverse Events of Special Interest classification

Medical Concept	MedDRA Terms Included
Sleep disorders	Preferred Term: Irregular sleep phase Preferred Term: Irregular sleep wake rhythm disorder Preferred Term: Loss of dreaming Preferred Term: Middle insomnia Preferred Term: Narcolepsy Preferred Term: Nightmare Preferred Term: Non-24-hour sleep-wake disorder Preferred Term: Obstructive sleep apnoea syndrome Preferred Term: Paradoxical insomnia Preferred Term: Parasomnia Preferred Term: Poor quality sleep Preferred Term: Psychophysiologic insomnia Preferred Term: Rapid eye movement sleep behaviour disorder Preferred Term: Rapid eye movements sleep abnormal Preferred Term: Sleep apnoea syndrome Preferred Term: Sleep attacks Preferred Term: Sleep disorder Preferred Term: Sleep disorder due to a general medical condition Preferred Term: Sleep disorder due to general medical condition, hypersomnia type Preferred Term: Sleep disorder due to general medical condition, insomnia type Preferred Term: Sleep disorder due to general medical condition, mixed type Preferred Term: Sleep disorder due to general medical condition, parasomnia type Preferred Term: Sleep inertia Preferred Term: Sleep paralysis

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Based on MedDRA dictionary, Version 25.0.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-summedra.sas 31MAY2024:04:29:42

Table S.6
Summary of MedDRA terms for Treatment-Emergent Adverse Events of Special Interest classification

Medical Concept	MedDRA Terms Included
Sleep disorders	Preferred Term: Sleep talking Preferred Term: Sleep terror Preferred Term: Snoring Preferred Term: Somnambulism Preferred Term: Somnolence Preferred Term: Sopor Preferred Term: Stupor Preferred Term: Terminal insomnia Preferred Term: Upper airway resistance syndrome
Vision disorders	Preferred Term: Asthenopia Preferred Term: Blepharospasm Preferred Term: Cataract Preferred Term: Cataract nuclear Preferred Term: Colour blindness Preferred Term: Conjunctivitis Preferred Term: Diplopia Preferred Term: Dry eye Preferred Term: Eye haematoma Preferred Term: Eye infection Preferred Term: Eye oedema Preferred Term: Eye pain Preferred Term: Eye swelling Preferred Term: Eyelid disorder

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Based on MedDRA dictionary, Version 25.0.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables
Program Name: rt-ae-summedra.sas 31MAY2024:04:29:42

Table S.6
Summary of MedDRA terms for Treatment-Emergent Adverse Events of Special Interest classification

Medical Concept	MedDRA Terms Included
Vision disorders	Preferred Term: Eyelid injury Preferred Term: Eyelids pruritus Preferred Term: Glaucoma Preferred Term: Hemianopia homonymous Preferred Term: Iridocyclitis Preferred Term: Myopia Preferred Term: Night blindness Preferred Term: Ophthalmic herpes zoster Preferred Term: Orbital oedema Preferred Term: Periorbital oedema Preferred Term: Photophobia Preferred Term: Photosensitivity reaction Preferred Term: Vision blurred Preferred Term: Visual acuity reduced Preferred Term: Visual field defect Preferred Term: Visual impairment Preferred Term: Vitreous floaters

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