Inhaltsverzeichnis

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: --
MODEL: --
STUDY: BO42863
Demographic and Baseline Characteristics

	Treatment Group
	400 mg QD (N=29)
Age (years)	
n	29
Mean (SD)	60.2 (14.12)
Median	65
Min - Max	30 - 87
Age Group (years) (n (%))	
n	29
<65	14 (48.3%)
>=65	15 (51.7%)
Gender (n (%))	
n	29
Female	15 (51.7%)
Male	14 (48.3%)
ECOG Performance Status	
n	29
0	11 (37.9%)
1	17 (58.6%)
2	1 (3.4%)
Geographic region (n (%))	
n	29

USA	7 (24.1%)
Europe	14 (48.3%)
Asia	8 (27.6%)
Race (n (%))	
n	29
American Indian or Alaska Native	0
Asian	10 (34.5%)
Black or African American	0
Native Hawaiian or Other Pacific Islander	1 (3.4%)
White	17 (58.6%)
Unknown	1 (3.4%)
Other	0
CNS Metastases at Baseline	
n	29
Yes	12 (41.4%)
No	17 (58.6%)
Radiotherapy/Radiosurgery to Brain within 2 Months Prior to Baseline	
n	12
Yes	0
No	12 (100%)
Smoking History	
n	29
Never Smoked	15 (51.7%)
Former	10 (34.5%)
Current	3 (10.3%)
Unknown	1 (3.4%)
NSCLC Histology Type	
n	29
Adenocarcinoma	29 (100%)
Squamous	0
Other	0

Number of Prior Antineoplastic Systemic Therapy Lines	
n	29
0	29 (100%)
1	0
>=2	0
Tumor Stadium at Screening	
n	29
Stage IIB	0
Stage III	0
Stage IV	29 (100%)
Unknown	0
RET-fusion	
n	29
KIF5B	20 (69.0%)
CCDC6	3 (10.3%)
NCOA4	0
Other	6 (20.7%)
Follow-up time [Days]	
Median	190
Mean (SD)	222.5 (132.51)
Min - Max	54 - 693
Prior Antineoplastic Therapies	
Chemotherapy	0
Platinum-based Chemotherapy	0
PD-(L)1 Inhibitors	0
MKI	0

Clinical cut-off: 18NOV2019

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/oth_dm.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_NDA/prod/output/oth_dm_B63_18NOV2019_EF_TN.xls
07MAY2021 9:49

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: --
MODEL: --
STUDY: BO42863
Demographic and Baseline Characteristics

	Treatment Group
	400 mg QD (N=75)
Age (years)	
n	75
Mean (SD)	60.6 (13.74)
Median	63
Min - Max	30 - 87
Age Group (years) (n (%))	
n	75
<65	41 (54.7%)
>=65	34 (45.3%)
Gender (n (%))	
n	75
Female	36 (48.0%)
Male	39 (52.0%)
ECOG Performance Status	
n	75
0	31 (41.3%)
1	43 (57.3%)
2	1 (1.3%)
Geographic region (n (%))	
n	75
USA	22 (29.3%)
Europe	40 (53.3%)
Asia	13 (17.3%)

Race (n (%))	
n	75
American Indian or Alaska Native	0
Asian	17 (22.7%)
Black or African American	0
Native Hawaiian or Other Pacific Islander	1 (1.3%)
White	52 (69.3%)
Unknown	5 (6.7%)
Other	0
CNS Metastases at Baseline	
n	75
Yes	25 (33.3%)
No	50 (66.7%)
Radiotherapy/Radiosurgery to Brain within 2 Months Prior to Baseline	
n	25
Yes	0
No	25 (100%)
Smoking History	
n	75
Never Smoked	41 (54.7%)
Former	28 (37.3%)
Current	4 (5.3%)
Unknown	2 (2.7%)
NSCLC Histology Type	
n	75
Adenocarcinoma	74 (98.7%)
Squamous	1 (1.3%)
Other	0
Number of Prior Antineoplastic Systemic Therapy Lines	
n	75
0	75 (100%)
1	0
>=2	0

Tumor Stadium at Screening	
n	75
Stage IIB	1 (1.3%)
Stage III	1 (1.3%)
Stage IV	73 (97.3%)
Unknown	0
RET-fusion	
n	75
KIF5B	50 (66.7%)
CCDC6	13 (17.3%)
NCOA4	1 (1.3%)
Other	11 (14.7%)
Follow-up time [Days]	
Median	318
Mean (SD)	339.4 (179.83)
Min - Max	48 - 1047
Prior Antineoplastic Therapies	
Chemotherapy	0
Platinum-based Chemotherapy	0
PD-(L)1 Inhibitors	0
MKI	0

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/oth_dm.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/oth_dm_B63_06NOV2020_EF_TN.xls
07MAY2021 10:17

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: --
MODEL: --
STUDY: BO42863
Disposition of Patients

	Treatment Group
	400 mg QD (N=75)
Treatment Status	
n	75
Discontinued	37 (49.3%)
Ongoing	38 (50.7%)
Reason for Treatment Discontinuations	
n	37
Adverse Event	8 (10.7%)
Other	1 (1.3%)
Physician Decision	1 (1.3%)
Progressive Disease	23 (30.7%)
Withdrawal By Subject	4 (5.3%)
Study Status	
n	75
Discontinued	28 (37.3%)
Ongoing	47 (62.7%)
Reason for Study Discontinuations	
n	28
Death	12 (16.0%)
Lost To Follow-Up	1 (1.3%)
Progressive Disease	11 (14.7%)
Withdrawal By Subject	4 (5.3%)

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/oth_disp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/oth_disp_B63_06NOV2020_EF_TN.xls
26FEB2021 15:35

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: --
MODEL: --
STUDY: BO42863
Demographic and Baseline Characteristics

	Treatment Group
	400 mg QD (N=103)
Age (years)	
n	103
Mean (SD)	59.5 (10.39)
Median	60
Min - Max	28 - 85
Age Group (years) (n (%))	
n	103
<65	67 (65.0%)
>=65	36 (35.0%)
Gender (n (%))	
n	103
Female	54 (52.4%)
Male	49 (47.6%)
ECOG Performance Status	
n	103
0	39 (37.9%)
1	59 (57.3%)
2	5 (4.9%)
Geographic region (n (%))	
n	103

USA	37 (35.9%)
Europe	35 (34.0%)
Asia	31 (30.1%)
Race (n (%))	
n	103
American Indian or Alaska Native	0
Asian	33 (32.0%)
Black or African American	0
Native Hawaiian or Other Pacific Islander	0
White	58 (56.3%)
Unknown	10 (9.7%)
Other	2 (1.9%)
CNS Metastases at Baseline	
n	103
Yes	43 (41.7%)
No	60 (58.3%)
Radiotherapy/Radiosurgery to Brain within 2 Months Prior to Baseline	
n	43
Yes	0
No	43 (100%)
Smoking History	
n	103
Never Smoked	67 (65.0%)
Former	33 (32.0%)
Current	1 (1.0%)
Unknown	2 (1.9%)
NSCLC Histology Type	
n	103
Adenocarcinoma	97 (94.2%)
Squamous	2 (1.9%)
Undifferentiated	1 (1.0%)
Other	3 (2.9%)

Number of Prior Antineoplastic Systemic Therapy Lines	
n	103
0	0
1	43 (41.7%)
>=2	60 (58.3%)
Tumor Stadium at Screening	
n	103
Stage IIB	0
Stage III	3 (2.9%)
Stage IV	100 (97.1%)
Unknown	0
RET-fusion	
n	103
KIF5B	74 (71.8%)
CCDC6	19 (18.4%)
NCOA4	0
Other	10 (9.7%)
Follow-up time [Days]	
Median	259
Mean (SD)	276.9 (144.25)
Min - Max	29 - 565
Prior Antineoplastic Therapies	
Chemotherapy	93 (90.3%)
Platinum-based Chemotherapy	92 (89.3%)
PD-(L)1 Inhibitors	48 (46.6%)
MKI	27 (26.2%)

Clinical cut-off: 18NOV2019

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/oth_dm.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_NDA/prod/output/oth_dm_B63_18NOV2019_EF_TP.xls

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: --
MODEL: --
STUDY: BO42863
Demographic and Baseline Characteristics

	Treatment Group
	400 mg QD (N=158)
Age (years)	
n	158
Mean (SD)	58.6 (11.39)
Median	59,5
Min - Max	26 - 85
Age Group (years) (n (%))	
n	158
<65	104 (65.8%)
>=65	54 (34.2%)
Gender (n (%))	
n	158
Female	86 (54.4%)
Male	72 (45.6%)
ECOG Performance Status	
n	158
0	47 (29.7%)
1	106 (67.1%)
2	5 (3.2%)
Geographic region (n (%))	
n	158
USA	40 (25.3%)
Europe	45 (28.5%)
Asia	73 (46.2%)

Race (n (%))	
n	158
American Indian or Alaska Native	0
Asian	75 (47.5%)
Black or African American	0
Native Hawaiian or Other Pacific Islander	1 (0.6%)
White	69 (43.7%)
Unknown	11 (7.0%)
Other	2 (1.3%)
CNS Metastases at Baseline	
n	158
Yes	62 (39.2%)
No	96 (60.8%)
Radiotherapy/Radiosurgery to Brain within 2 Months Prior to Baseline	
n	62
Yes	0
No	62 (100%)
Smoking History	
n	158
Never Smoked	104 (65.8%)
Former	50 (31.6%)
Current	2 (1.3%)
Unknown	2 (1.3%)
NSCLC Histology Type	
n	158
Adenocarcinoma	150 (94.9%)
Squamous	2 (1.3%)
Undifferentiated	1 (0.6%)
Other	5 (3.2%)
Number of Prior Antineoplastic Systemic Therapy Lines	
n	158
0	0
1	73 (46.2%)
>=2	85 (53.8%)

Tumor Stadium at Screening	
n	158
Stage IIB	0
Stage III	4 (2.5%)
Stage IV	154 (97.5%)
Unknown	0
RET-fusion	
n	158
KIF5B	114 (72.2%)
CCDC6	28 (17.7%)
NCOA4	0
Other	16 (10.1%)
Follow-up time [Days]	
Median	363
Mean (SD)	403.1 (247.31)
Min - Max	29 - 919
Prior Antineoplastic Therapies	
Chemotherapy	138 (87.3%)
Platinum-based Chemotherapy	136 (86.1%)
PD-(L)1 Inhibitors	69 (43.7%)
MKI	44 (27.8%)

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/oth_dm.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/oth_dm_B63_06NOV2020_EF_TP.xls
07MAY2021 10:16

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: --
MODEL: --
STUDY: BO42863
Disposition of Patients

	Treatment Group
	400 mg QD (N=158)
Treatment Status	
n	158
Discontinued	86 (54.4%)
Ongoing	72 (45.6%)
Reason for Treatment Discontinuations	
n	86
Adverse Event	26 (16.5%)
Other	1 (0.6%)
Physician Decision	2 (1.3%)
Progressive Disease	51 (32.3%)
Withdrawal By Subject	6 (3.8%)
Study Status	
n	158
Discontinued	74 (46.8%)
Ongoing	84 (53.2%)
Reason for Study Discontinuations	
n	74
Adverse Event	2 (1.3%)
Death	43 (27.2%)
Initiation Of Another Therapy	2 (1.3%)
Lost To Follow-Up	1 (0.6%)
Progressive Disease	14 (8.9%)
Withdrawal By Subject	12 (7.6%)

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/oth_disp.sas

Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/oth_disp_B63_06NOV2020_EF_TP.xls
26FEB2021 15:34

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: --
MODEL: --
STUDY: BO42863
Demographic and Baseline Characteristics

	Treatment Group
	400 mg QD (N=132)
Age (years)	
n	132
Mean (SD)	59.7 (11.26)
Median	60
Min - Max	28 - 87
Age Group (years) (n (%))	
n	132
<65	81 (61.4%)
>=65	51 (38.6%)
Gender (n (%))	
n	132
Female	69 (52.3%)
Male	63 (47.7%)
ECOG Performance Status	
n	132
0	50 (37.9%)
1	76 (57.6%)
2	6 (4.5%)
Geographic region (n (%))	
n	132

USA	44 (33.3%)
Europe	49 (37.1%)
Asia	39 (29.5%)
Race (n (%))	
n	132
American Indian or Alaska Native	0
Asian	43 (32.6%)
Black or African American	0
Native Hawaiian or Other Pacific Islander	1 (0.8%)
White	75 (56.8%)
Unknown	11 (8.3%)
Other	2 (1.5%)
CNS Metastases at Baseline	
n	132
Yes	55 (41.7%)
No	77 (58.3%)
Radiotherapy/Radiosurgery to Brain within 2 Months Prior to Baseline	
n	55
Yes	0
No	55 (100%)
Smoking History	
n	132
Never Smoked	82 (62.1%)
Former	43 (32.6%)
Current	4 (3.0%)
Unknown	3 (2.3%)
NSCLC Histology Type	
n	132
Adenocarcinoma	126 (95.5%)
Squamous	2 (1.5%)
Undifferentiated	1 (0.8%)
Other	3 (2.3%)

Number of Prior Antineoplastic Systemic Therapy Lines	
n	132
0	29 (22.0%)
1	43 (32.6%)
>=2	60 (45.5%)
Tumor Stadium at Screening	
n	132
Stage IIB	0
Stage III	3 (2.3%)
Stage IV	129 (97.7%)
Unknown	0
RET-fusion	
n	132
KIF5B	94 (71.2%)
CCDC6	22 (16.7%)
NCOA4	0
Other	16 (12.1%)
Follow-up time [Days]	
Median	249,5
Mean (SD)	265.0 (143.06)
Min - Max	29 - 693
Prior Antineoplastic Therapies	
Chemotherapy	93 (70.5%)
Platinum-based Chemotherapy	92 (69.7%)
PD-(L)1 Inhibitors	48 (36.4%)
MKI	27 (20.5%)

Clinical cut-off: 18NOV2019

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/oth_dm.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_NDA/prod/output/oth_dm_B63_18NOV2019_EF_TO.xls

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: --
MODEL: --
STUDY: BO42863
Demographic and Baseline Characteristics

	Treatment Group
	400 mg QD (N=233)
Age (years)	
n	233
Mean (SD)	59.2 (12.20)
Median	60
Min - Max	26 - 87
Age Group (years) (n (%))	
n	233
<65	145 (62.2%)
>=65	88 (37.8%)
Gender (n (%))	
n	233
Female	122 (52.4%)
Male	111 (47.6%)
ECOG Performance Status	
n	233
0	78 (33.5%)
1	149 (63.9%)
2	6 (2.6%)
Geographic region (n (%))	
n	233
USA	62 (26.6%)
Europe	85 (36.5%)
Asia	86 (36.9%)

Race (n (%))	
n	233
American Indian or Alaska Native	0
Asian	92 (39.5%)
Black or African American	0
Native Hawaiian or Other Pacific Islander	2 (0.9%)
White	121 (51.9%)
Unknown	16 (6.9%)
Other	2 (0.9%)
CNS Metastases at Baseline	
n	233
Yes	87 (37.3%)
No	146 (62.7%)
Radiotherapy/Radiosurgery to Brain within 2 Months Prior to Baseline	
n	87
Yes	0
No	87 (100%)
Smoking History	
n	233
Never Smoked	145 (62.2%)
Former	78 (33.5%)
Current	6 (2.6%)
Unknown	4 (1.7%)
NSCLC Histology Type	
n	233
Adenocarcinoma	224 (96.1%)
Squamous	3 (1.3%)
Undifferentiated	1 (0.4%)
Other	5 (2.1%)
Number of Prior Antineoplastic Systemic Therapy Lines	
n	233
0	75 (32.2%)
1	73 (31.3%)
>=2	85 (36.5%)

Tumor Stadium at Screening	
n	233
Stage IIB	1 (0.4%)
Stage III	5 (2.1%)
Stage IV	227 (97.4%)
Unknown	0
RET-fusion	
n	233
KIF5B	164 (70.4%)
CCDC6	41 (17.6%)
NCOA4	1 (0.4%)
Other	27 (11.6%)
Follow-up time [Days]	
Median	345
Mean (SD)	382.6 (229.34)
Min - Max	29 - 1047
Prior Antineoplastic Therapies	
Chemotherapy	138 (59.2%)
Platinum-based Chemotherapy	136 (58.4%)
PD-(L)1 Inhibitors	69 (29.6%)
MKI	44 (18.9%)

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/oth_dm.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/oth_dm_B63_06NOV2020_EF_TO.xls
07MAY2021 10:14

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: --
MODEL: --
STUDY: BO42863
Demographic and Baseline Characteristics

	Treatment Group
	400 mg QD (N=221)
Age (years)	
n	221
Mean (SD)	59.2 (12.33)
Median	60
Min - Max	26 - 87
Age Group (years) (n (%))	
n	221
<65	141 (63.8%)
>=65	80 (36.2%)
Gender (n (%))	
n	221
Female	128 (57.9%)
Male	93 (42.1%)
ECOG Performance Status	
n	220
0	63 (28.6%)
1	157 (71.4%)
2	0
Geographic region (n (%))	
n	221
USA	43 (19.5%)
Europe	74 (33.5%)
Asia	104 (47.1%)

Race (n (%))	
n	221
American Indian or Alaska Native	0
Asian	109 (49.3%)
Black or African American	1 (0.5%)
Native Hawaiian or Other Pacific Islander	2 (0.9%)
White	94 (42.5%)
Unknown	13 (5.9%)
Other	2 (0.9%)
CNS Metastases at Baseline	
n	221
Yes	72 (32.6%)
No	149 (67.4%)
Radiotherapy/Radiosurgery to Brain within 2 Months Prior to Baseline	
n	72
Yes	0
No	72 (100%)
Smoking History	
n	221
Never Smoked	136 (61.5%)
Former	74 (33.5%)
Current	6 (2.7%)
Unknown	5 (2.3%)
NSCLC Histology Type	
n	221
Adenocarcinoma	215 (97.3%)
Squamous	2 (0.9%)
Other	4 (1.8%)
Number of Prior Antineoplastic Systemic Therapy Lines	
n	221
0	108 (48.9%)
1	60 (27.1%)
>=2	53 (24.0%)

Tumor Stadium at Screening	
n	221
Stage IIB	1 (0.5%)
Stage III	5 (2.3%)
Stage IV	215 (97.3%)
Unknown	0
RET-fusion	
n	221
KIF5B	155 (70.1%)
CCDC6	38 (17.2%)
NCOA4	2 (0.9%)
Other	26 (11.8%)
Follow-up time [Days]	
Median	286
Mean (SD)	311.6 (200.00)
Min - Max	34 - 793
Prior Antineoplastic Therapies	
Chemotherapy	95 (43.0%)
Platinum-based Chemotherapy	94 (42.5%)
PD-(L)1 Inhibitors	47 (21.3%)
MKI	31 (14.0%)

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/oth_dm.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/oth_dm_B63_06NOV2020_SAF_P41_TO.xls
15OCT2021 11:23

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: --
MODEL: --
STUDY: BO42863
Demographic and Baseline Characteristics

	Treatment Group
	400 mg QD (N=281)
Age (years)	
n	281
Mean (SD)	59.3 (11.94)
Median	60
Min - Max	26 - 87
Age Group (years) (n (%))	
n	281
<65	176 (62.6%)
>=65	105 (37.4%)
Gender (n (%))	
n	281
Female	152 (54.1%)
Male	129 (45.9%)
ECOG Performance Status	
n	280
0	84 (30.0%)
1	190 (67.9%)
2	6 (2.1%)
Geographic region (n (%))	
n	281
USA	64 (22.8%)
Europe	95 (33.8%)
Asia	122 (43.4%)

Race (n (%))	
n	281
American Indian or Alaska Native	0
Asian	128 (45.6%)
Black or African American	1 (0.4%)
Native Hawaiian or Other Pacific Islander	2 (0.7%)
White	130 (46.3%)
Unknown	18 (6.4%)
Other	2 (0.7%)
CNS Metastases at Baseline	
n	281
Yes	97 (34.5%)
No	184 (65.5%)
Radiotherapy/Radiosurgery to Brain within 2 Months Prior to Baseline	
n	97
Yes	0
No	97 (100%)
Smoking History	
n	281
Never Smoked	176 (62.6%)
Former	93 (33.1%)
Current	7 (2.5%)
Unknown	5 (1.8%)
NSCLC Histology Type	
n	281
Adenocarcinoma	272 (96.8%)
Squamous	3 (1.1%)
Undifferentiated	1 (0.4%)
Other	5 (1.8%)
Number of Prior Antineoplastic Systemic Therapy Lines	
n	281
0	116 (41.3%)
1	77 (27.4%)
>=2	88 (31.3%)

Tumor Stadium at Screening	
n	281
Stage IIB	1 (0.4%)
Stage III	7 (2.5%)
Stage IV	273 (97.2%)
Unknown	0
RET-fusion	
n	281
KIF5B	197 (70.1%)
CCDC6	50 (17.8%)
NCOA4	2 (0.7%)
Other	32 (11.4%)
Follow-up time [Days]	
Median	283
Mean (SD)	334.8 (234.63)
Min - Max	29 - 1047
Prior Antineoplastic Therapies	
Chemotherapy	143 (50.9%)
Platinum-based Chemotherapy	141 (50.2%)
PD-(L)1 Inhibitors	73 (26.0%)
MKI	45 (16.0%)

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/oth_dm.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/oth_dm_B63_06NOV2020_SE_TO.xls
07MAY2021 10:13

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: --
MODEL: --
STUDY: BO42863
Disposition of Patients

	Treatment Group
	400 mg QD (N=233)
Treatment Status	
n	233
Discontinued	123 (52.8%)
Ongoing	110 (47.2%)
Reason for Treatment Discontinuations	
n	123
Adverse Event	34 (14.6%)
Other	2 (0.9%)
Physician Decision	3 (1.3%)
Progressive Disease	74 (31.8%)
Withdrawal By Subject	10 (4.3%)
Study Status	
n	233
Discontinued	102 (43.8%)
Ongoing	131 (56.2%)
Reason for Study Discontinuations	
n	102
Adverse Event	2 (0.9%)
Death	55 (23.6%)
Initiation Of Another Therapy	2 (0.9%)
Lost To Follow-Up	2 (0.9%)
Progressive Disease	25 (10.7%)
Withdrawal By Subject	16 (6.9%)

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/oth_disp.sas

Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/oth_disp_B63_06NOV2020_EF_TO.xls
26FEB2021 15:34

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: --
MODEL: --
STUDY: BO42863
Disposition of Patients

	Treatment Group
	400 mg QD (N=281)
Treatment Status	
n	281
Discontinued	130 (46.3%)
Ongoing	151 (53.7%)
Reason for Treatment Discontinuations	
n	130
Adverse Event	39 (13.9%)
Other	2 (0.7%)
Physician Decision	3 (1.1%)
Progressive Disease	75 (26.7%)
Withdrawal By Subject	11 (3.9%)
Study Status	
n	281
Discontinued	106 (37.7%)
Ongoing	175 (62.3%)
Reason for Study Discontinuations	
n	106
Adverse Event	2 (0.7%)
Death	59 (21.0%)
Initiation Of Another Therapy	2 (0.7%)
Lost To Follow-Up	2 (0.7%)
Progressive Disease	25 (8.9%)
Withdrawal By Subject	16 (5.7%)

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/oth_disp.sas

Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/oth_disp_B63_06NOV2020_SE_TO.xls
26FEB2021 15:33

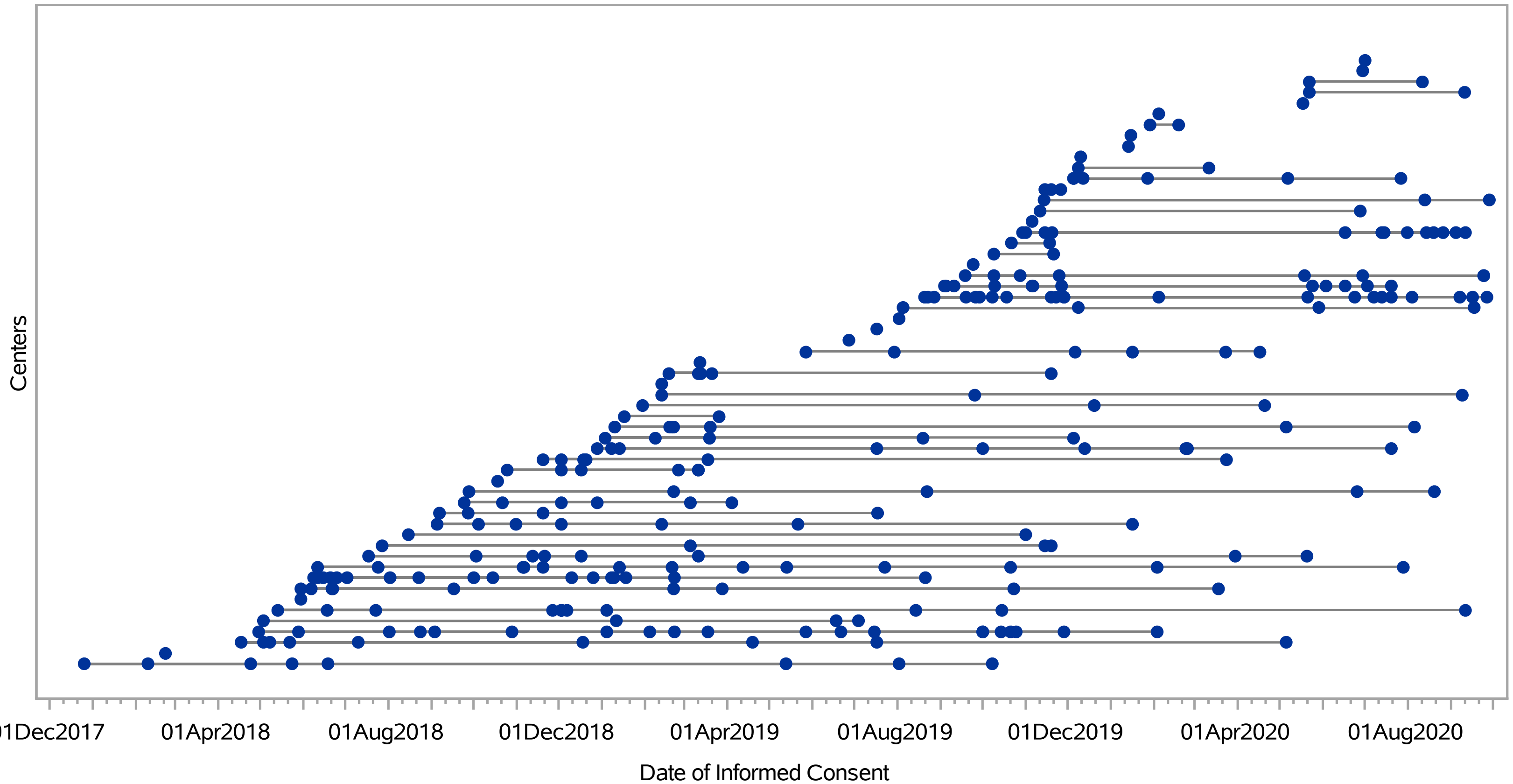
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: --
MODEL: --
STUDY: BO42863
Number of centers/countries/geographical regions with <10, >=10 patients per arm

	Center				Country				Geographical region (3)			
Category	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)
Overall	52	100	233	100	11	100	233	100	3	100	233	100
with <10 patients per arm (1)	47	90,4	161	69,1	3	27,3	14	6	0	0	0	0
with >=10 patients per arm (2)	5	9,6	72	30,9	8	72,7	219	94	3	100	233	100

(1): "<10 patients" category if at least one treatment arm has <10 patients. (2): ">=10 patients" category if all treatment arms have >=10 patients.
(3): Geographical regions: Asia-Pacific, Europe, Other. (4): Number of centers/countries/geographical regions. (5): % of centers/countries/geographical regions compared to overall number.
(6): Number of patients randomized in the corresponding category (e.g. number of patients randomized in centers with <10 patients per arm).
(7): % of randomized patients compared to overall number of randomized patients (e.g. % of randomized patients in centers with <10 patients per arm compared to overall number of randomized patients).
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/oth_center.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/oth_center_B63_06NOV2020_EF_TO.xls
26FEB2021 15:26

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: --
MODEL: --
STUDY: BO42863
Time of patient inclusion per center



Clinical cut-off: 06NOV2020
Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/oth_g_pat_incl.sas.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/oth_g_pat_incl.sas_B63_06NOV2020_SE_TO.pdf
10MAY2021 12:34

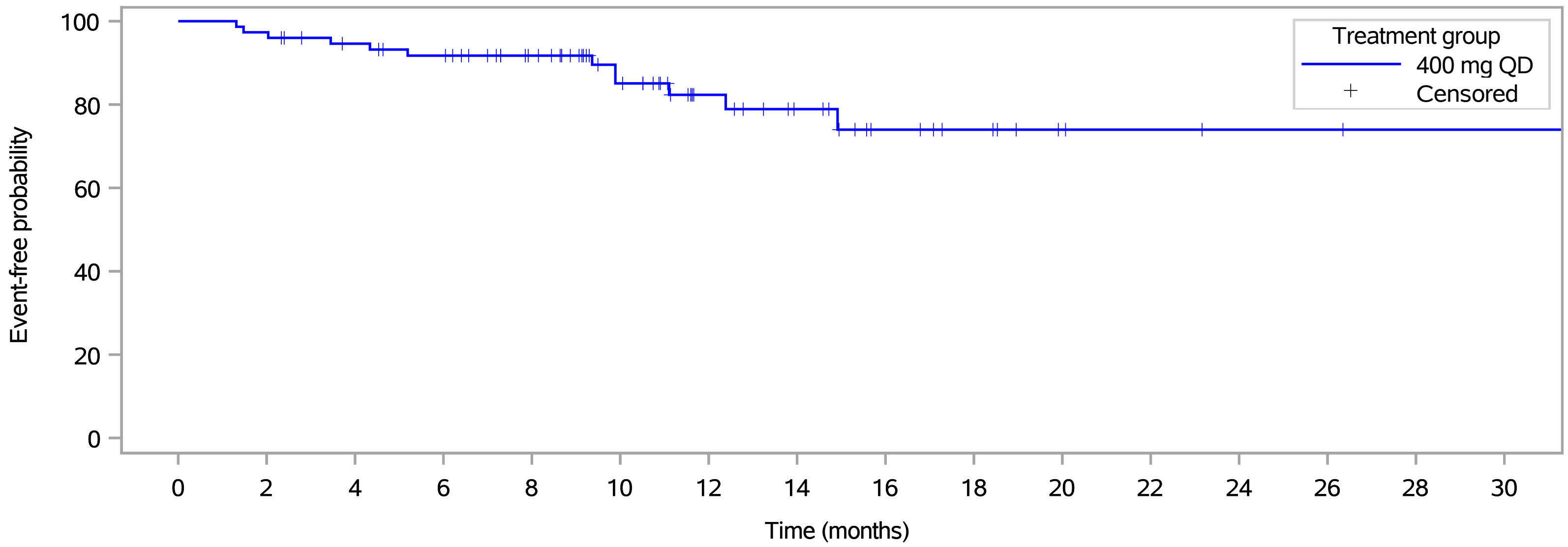
POPULATION: All Screened Patients
ENDPOINT: --
MODEL: --
STUDY: BO42863
Screening Information

	Screened Patients
	(N=644)
Patients who were Screening Failures	65 (10.1%)
Reason for Screening Failure	
n	65
Consent Withdrawn	4 (0.6%)
Does Not Meet Inclusion Criteria	28 (4.3%)
Meets Exclusion Criteria	31 (4.8%)
Other	2 (0.3%)
Patients Not Assigned to Treatment	1 (0.2%)
Patients who Received at least one Pralsetinib Dose	578 (89.8%)
Patients who Received at least one Pralsetinib 400mg Dose	528 (82.0%)
Patients with RET fusion NSCLC	295 (45.8%)
Patients with RET fusion NSCLC and Prior Selective RET-inhibitor	14 (2.2%)
Patients with RET fusion NSCLC and No Prior Selective RET-inhibitor	281 (43.6%)
Patients with Other RET-altered Solid Tumors	49 (7.6%)

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/oth_scr.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/oth_scr_B63_06NOV2020.xls
26FEB2021 15:33

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Overall Survival
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

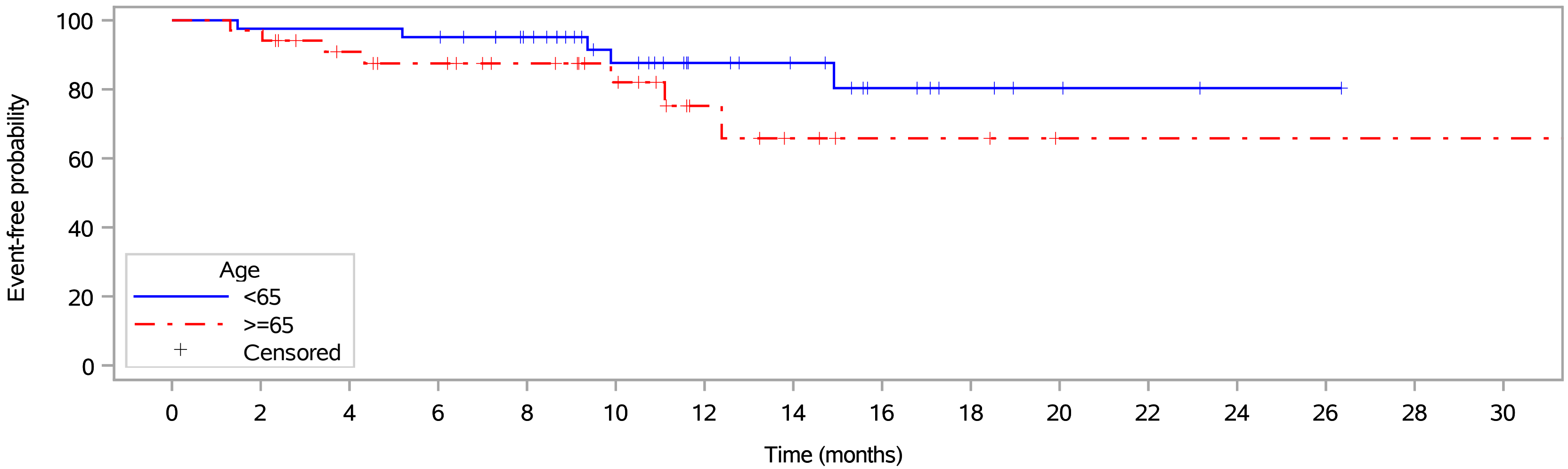


Patients at risk																
400 mg QD	75	73	67	63	53	38	24	18	11	8	4	3	2	2	1	1
Patients censored																
400 mg QD	0	0	4	6	16	28	41	46	52	55	59	60	61	61	62	62

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_OS.pdf
23MAR2021 9:43

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Overall Survival
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

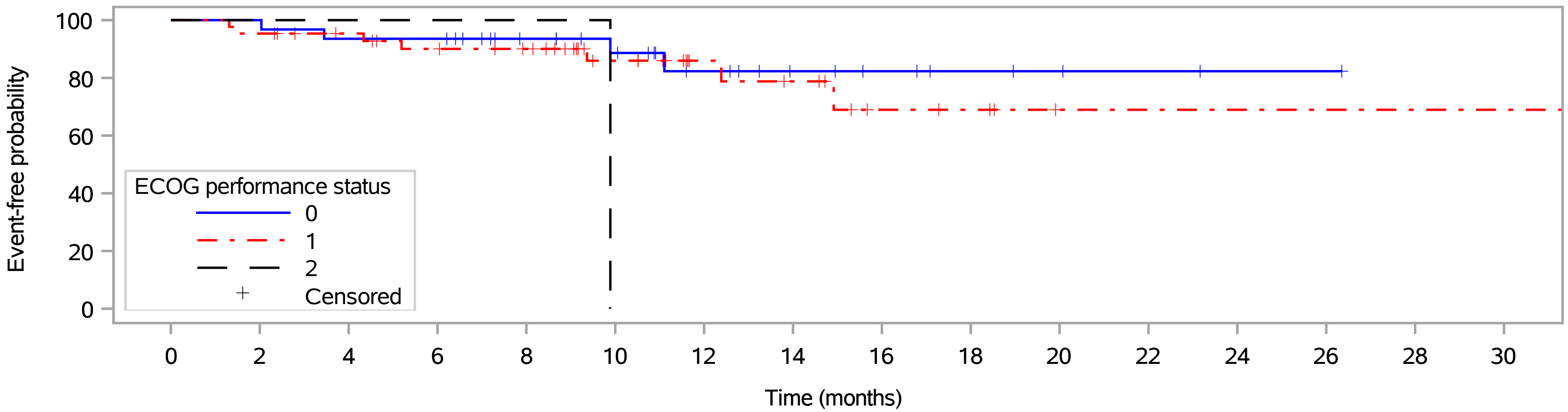


Patients at risk															
<65	41	40	40	39	33	23	16	13	8	5	3	2	1	1	NE	NE
>=65	34	33	27	24	20	15	8	5	3	3	1	1	1	1	1	1
Patients censored															
<65	0	0	0	0	6	14	21	24	28	31	33	34	35	35	NE	NE
>=65	0	0	4	6	10	14	20	22	24	24	26	26	26	26	26	26

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_OS_SGAGE65.pdf
23MAR2021 9:44

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Overall Survival
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

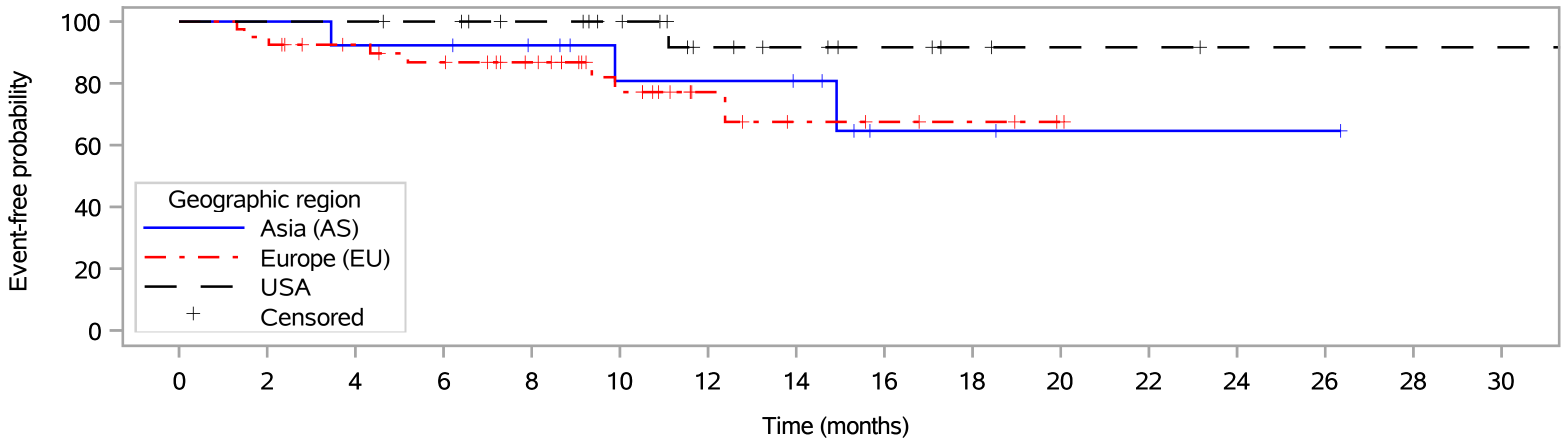


Patients at risk																
0	31	31	29	29	22	18	12	8	6	4	3	2	1	1	NE	NE
1	43	41	37	33	30	20	12	10	5	4	1	1	1	1	1	1
2	1	1	1	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
0	0	0	0	0	7	10	15	19	21	23	24	25	26	26	NE	NE
1	0	0	4	6	9	18	26	27	31	32	35	35	35	35	35	35
2	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_OS_SGECOG.pdf
23MAR2021 9:45

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Overall Survival
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

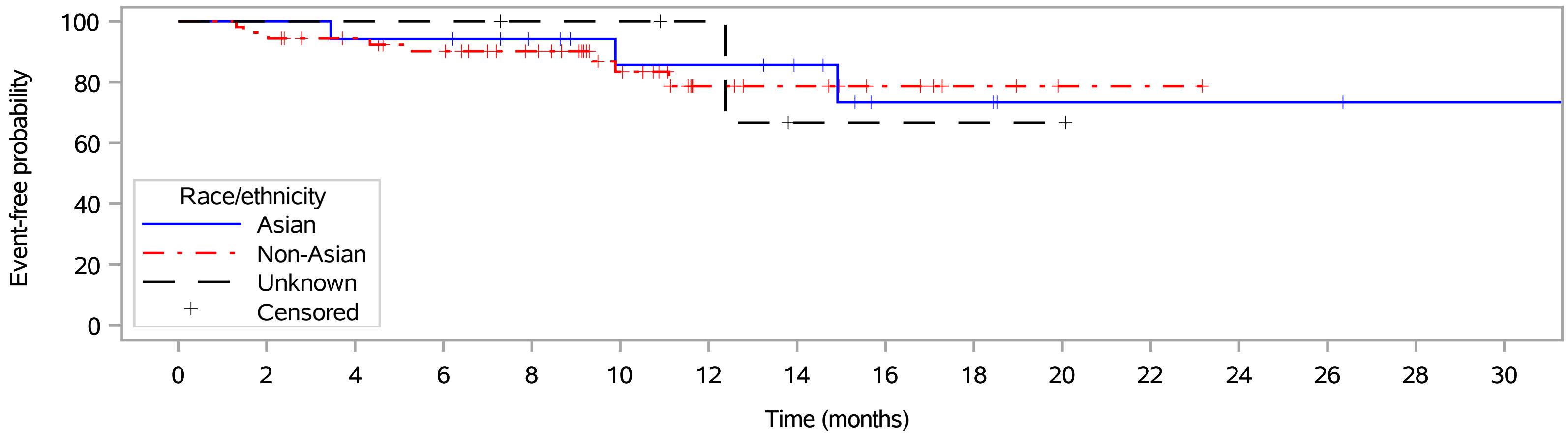


Patients at risk																
Asia (AS)	13	13	12	12	10	7	7	6	2	2	1	1	1	1	NE	NE
Europe (EU)	40	38	33	30	25	16	8	5	4	3	1	NE	NE	NE	NE	NE
USA	22	22	22	21	18	15	9	7	5	3	2	2	1	1	1	1
Patients censored																
Asia (AS)	0	0	0	0	2	4	4	5	8	8	9	9	9	9	NE	NE
Europe (EU)	0	0	4	5	10	17	25	27	28	29	31	NE	NE	NE	NE	NE
USA	0	0	0	1	4	7	12	14	16	18	19	19	20	20	20	20

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_OS_SGGEO.pdf
23MAR2021 9:45

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Overall Survival
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

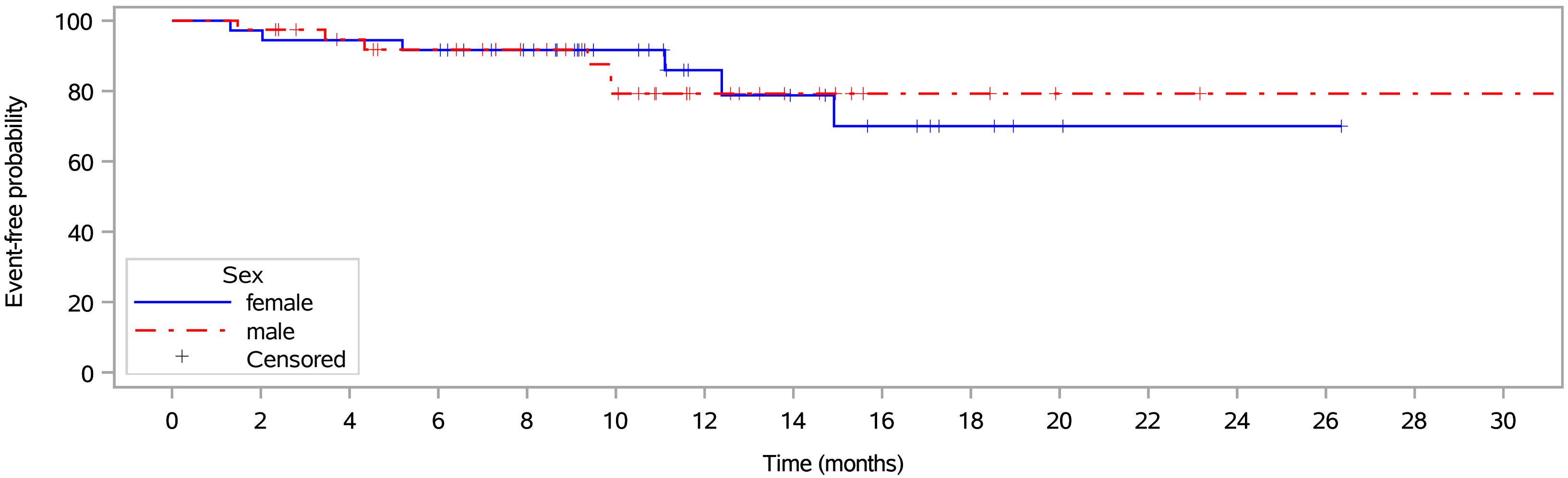


Patients at risk																
Asian	17	17	16	16	13	10	10	8	4	4	2	2	2	2	1	1
Non-Asian	53	51	46	42	36	24	11	9	6	3	1	1	NE	NE	NE	NE
Unknown	5	5	5	5	4	4	3	1	1	1	1	NE	NE	NE	NE	NE
Patients censored																
Asian	0	0	0	0	3	5	5	7	10	10	12	12	12	12	13	13
Non-Asian	0	0	4	6	12	22	34	36	39	42	44	44	NE	NE	NE	NE
Unknown	0	0	0	0	1	1	2	3	3	3	3	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_OS_SGRE.pdf
23MAR2021 9:46

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Overall Survival
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)



Patients at risk																
female	36	35	34	33	28	19	12	10	7	4	2	1	1	1	NE	NE
male	39	38	33	30	25	19	12	8	4	4	2	2	1	1	1	1
Patients censored																
female	0	0	0	0	5	14	20	21	23	26	28	29	29	29	NE	NE
male	0	0	4	6	11	14	21	25	29	29	31	31	32	32	32	32

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_OS_SGSEX.pdf
23MAR2021 9:44

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Overall Survival
MODEL: --
STUDY: BO42863
Time to Event Landmark Analysis

Time to Overall Survival

	400 mg QD (N=75)
Patients with event (%)	12 (16.0%)
Patients without event (%)	63 (84.0%)
Time to event (months)	
Median	NE
95% CI	NE
25% and 75%-ile	14.9 - NE
Range	1.3 - 32.6*
Time point analysis	
3 months	
Patients remaining at risk	69
Event Free Rate (%)	96
95% CI	(91.57, 100.00)
6 months	
Patients remaining at risk	63
Event Free Rate (%)	91,74
95% CI	(85.40, 98.08)
9 months	
Patients remaining at risk	47
Event Free Rate (%)	91,74
95% CI	(85.40, 98.08)
12 months	
Patients remaining at risk	24

Event Free Rate (%)	82,33
95% CI	(71.86, 92.81)
15 months	
Patients remaining at risk	14
Event Free Rate (%)	73,97
95% CI	(59.33, 88.61)
18 months	
Patients remaining at risk	8
Event Free Rate (%)	73,97
95% CI	(59.33, 88.61)
21 months	
Patients remaining at risk	3
Event Free Rate (%)	73,97
95% CI	(59.33, 88.61)
24 months	
Patients remaining at risk	2
Event Free Rate (%)	73,97
95% CI	(59.33, 88.61)

* Censored values.
Summaries of time to event (median, percentiles) are based on Kaplan Meier estimates.
95% CI for median was computed using the method of Brookmeyer and Crowley.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_lm.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/eff_lm_B63_06NOV2020_EF_TN_OS.xls
07MAY2021 7:56

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, No Prior Systemic Treatment, Safety Population
ENDPOINT: Overall Survival
STUDY: BO42863
Time to Event Landmark Analysis

	400 mg QD (N=116)
Deaths, n(%)	
Death	16 (13.8%)
Censored, n (%)	
n (Total Patients)	100 (86.2%)
Alive	95 (81.9%)
Lost to Follow-up	1 (0.9%)
Withdrawal of Consent	4 (3.4%)
Overall Follow-Up Time Kaplan-Meier Estimates (Months) [1]	
Median	9.5
95% CI	(7.9, 11.1)
25% and 75%-ile	4.1 - 14.7
Overall Survival Kaplan-Meier Estimates (Months) [2]	
Median	NE
95% CI	NE
25% and 75%-ile	14.9 - NE
Overall Survival Rate	
3-months	
Events	7
Censored	21
Patients remaining at risk	88
Event free proportion (%)	93.51
95% CI	(88.84, 98.17)
6-months	
Events	10
Censored	43
Patients remaining at risk	63
Event free proportion (%)	89.73
95% CI	(83.60, 95.87)
9-months	
Events	10
Censored	59

Patients remaining at risk	47
Event free proportion (%)	89.73
95% CI	(83.60, 95.87)
12-months	
Events	14
Censored	78
Patients remaining at risk	24
Event free proportion (%)	80.53
95% CI	(70.32, 90.75)
18-months	
Events	16
Censored	92
Patients remaining at risk	8
Event free proportion (%)	72.35
95% CI	(58.05, 86.65)
24-months	
Events	16
Censored	98
Patients remaining at risk	2
Event free proportion (%)	72.35
95% CI	(58.05, 86.65)
30-months	
Events	16
Censored	99
Patients remaining at risk	1
Event free proportion (%)	72.35
95% CI	(58.05, 86.65)

[1] Overall follow-up time is based on reverse Kaplan-Meier method, with censoring at date of study discontinuation.
[2] The 95% CI is based on Greenwood formula.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_lma.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_lma_BO42863_SAF_NSCLCNPS_OS.xls
12MAR2021 12:02

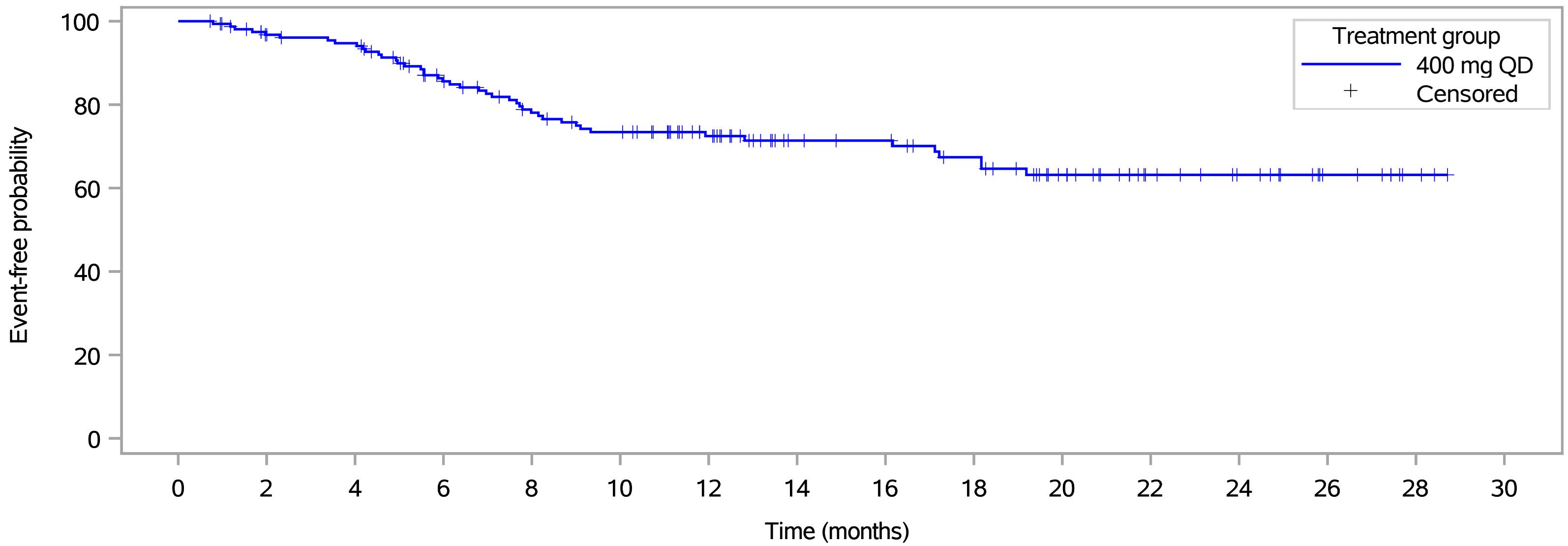
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Subgroup analysis, Overall Survival
MODEL: Unstratified analysis
STUDY: BO42863
Time to event analysis

		(N=75)								
		Patients		Patients with Event		Censored		Time To Event		
Name	Level	n	%	n	%	n	%	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	75	100.0	12	16.0	63	84.0	NE	NE	NE
Sex	Female	36	48.0	6	16.7	30	83.3	NE	14.9	NE
	Male	39	52.0	6	15.4	33	84.6	NE	NE	NE
Age	< 65	41	54.7	5	12.2	36	87.8	NE	NE	NE
	>= 65	34	45.3	7	20.6	27	79.4	NE	12.4	NE
ECOG performance status	0	31	41.3	4	12.9	27	87.1	NE	NE	NE
	1	43	57.3	7	16.3	36	83.7	NE	14.9	NE
	2	1	1.3	1	100.0	0	0.0	-	-	-
Geographic region	USA	22	29.3	1	4.5	21	95.5	NE	NE	NE
	Europe (EU)	40	53.3	8	20.0	32	80.0	NE	12.4	NE
	Asia (AS)	13	17.3	3	23.1	10	76.9	NE	14.9	NE
Race/ethnicity	Asian	17	22.7	3	17.6	14	82.4	NE	14.9	NE
	Non-Asian	53	70.7	8	15.1	45	84.9	NE	NE	NE
	Unknown	5	6.7	1	20.0	4	80.0	-	-	-

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_tte2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_tte2_B63_06NOV2020_EF_TN_OS_SG.xls
25FEB2021 20:56

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Overall Survival
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

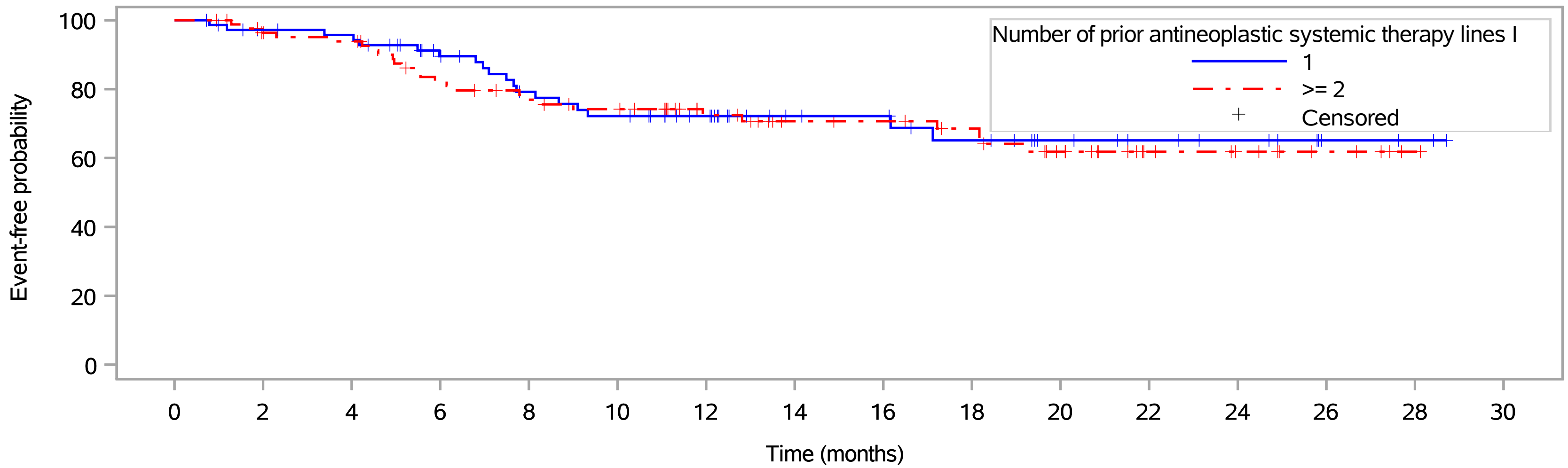


Patients at risk															
400 mg QD	158	145	140	117	102	94	76	58	56	49	36	23	18	9	3	NE
Patients censored															
400 mg QD	0	8	10	20	25	27	44	61	63	67	77	90	95	104	110	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_OS.pdf
23MAR2021 9:14

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Overall Survival
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

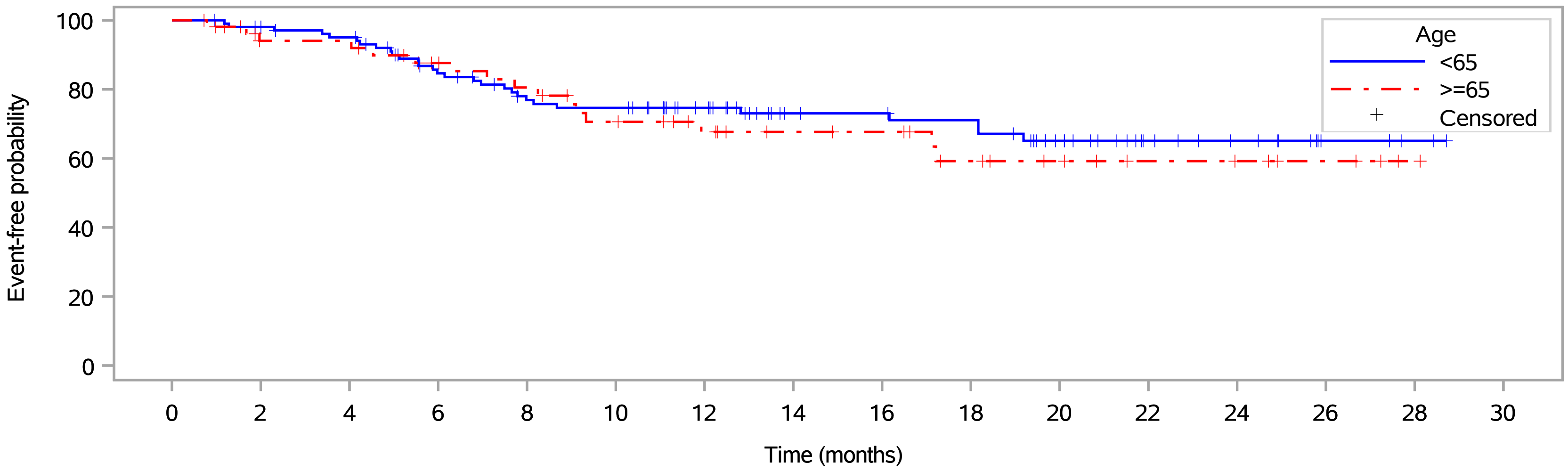


Patients at risk																
1	73	67	65	54	45	41	34	23	22	18	13	10	8	3	2	NE
>= 2	85	78	75	63	57	53	42	35	34	31	23	13	10	6	1	NE
Patients censored																
1	0	4	5	12	15	15	22	33	34	36	41	44	46	51	52	NE
>= 2	0	4	5	8	10	12	22	28	29	31	36	46	49	53	58	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_OS_PRTHL1.pdf
23MAR2021 9:17

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Overall Survival
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

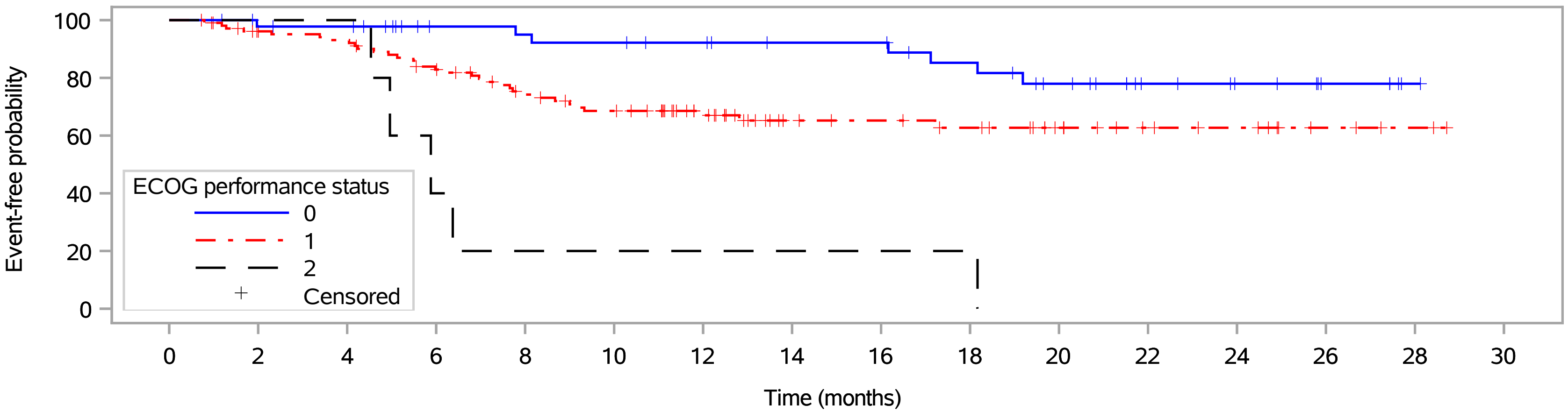


Patients at risk																
<65	104	100	95	79	68	66	53	39	38	36	26	16	12	5	2	NE
>=65	54	45	45	38	34	28	23	19	18	13	10	7	6	4	1	NE
Patients censored																
<65	0	2	4	10	14	14	27	40	41	42	49	59	63	70	73	NE
>=65	0	6	6	10	11	13	17	21	22	25	28	31	32	34	37	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_OS_SGAGE65.pdf
23MAR2021 9:14

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Overall Survival
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

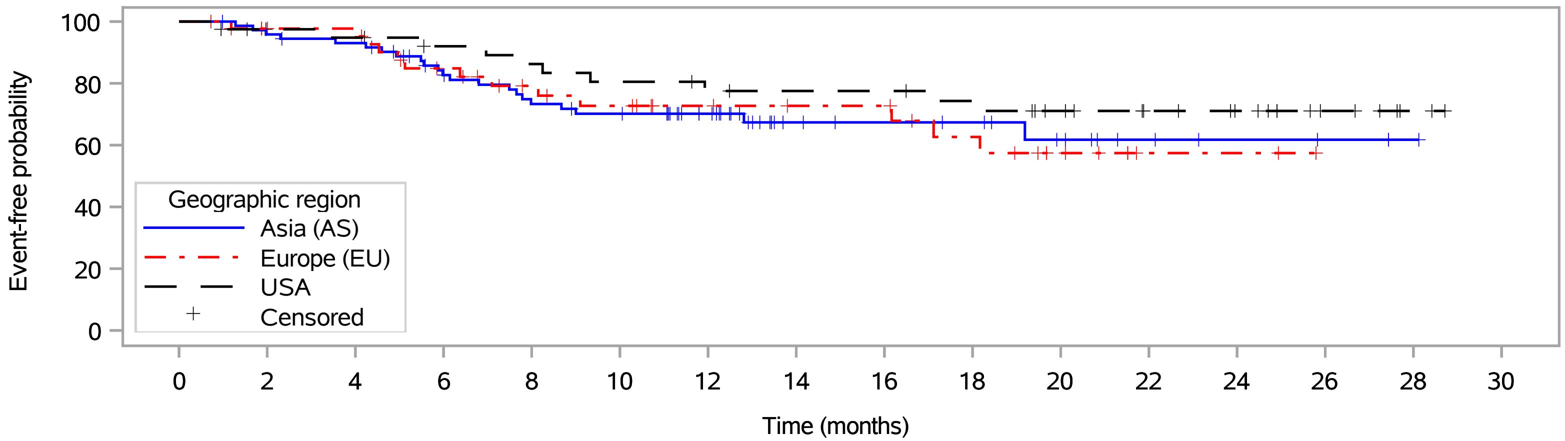


Patients at risk																
0	47	44	43	35	34	33	31	28	28	24	19	12	9	5	1	NE
1	106	96	92	80	67	60	44	29	27	24	17	11	9	4	2	NE
2	5	5	5	2	1	1	1	1	1	1	NE	NE	NE	NE	NE	NE
Patients censored																
0	0	2	3	11	11	11	13	16	16	18	21	28	31	35	39	NE
1	0	6	7	9	14	16	31	45	47	49	56	62	64	69	71	NE
2	0	0	0	0	0	0	0	0	0	0	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_OS_SGECOG.pdf
23MAR2021 9:15

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Overall Survival
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

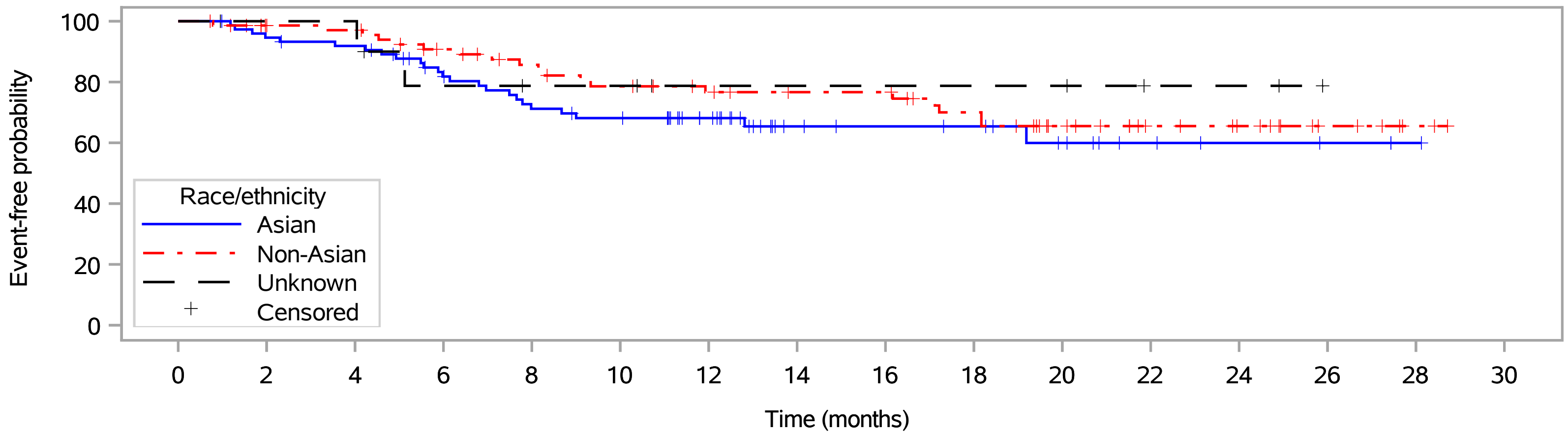


	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Patients at risk																
Asia (AS)	73	69	66	54	47	44	32	17	15	14	10	6	4	3	1	NE
Europe (EU)	45	40	39	31	25	22	18	16	16	12	7	2	2	NE	NE	NE
USA	40	36	35	32	30	28	26	25	25	23	19	15	12	6	2	NE
Patients censored																
Asia (AS)	0	1	2	7	8	9	21	35	37	38	41	45	47	48	50	NE
Europe (EU)	0	4	5	8	12	13	17	19	19	21	25	30	30	NE	NE	NE
USA	0	3	3	5	5	5	6	7	7	8	11	15	18	24	28	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_OS_SGGEO.pdf
23MAR2021 9:16

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Overall Survival
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

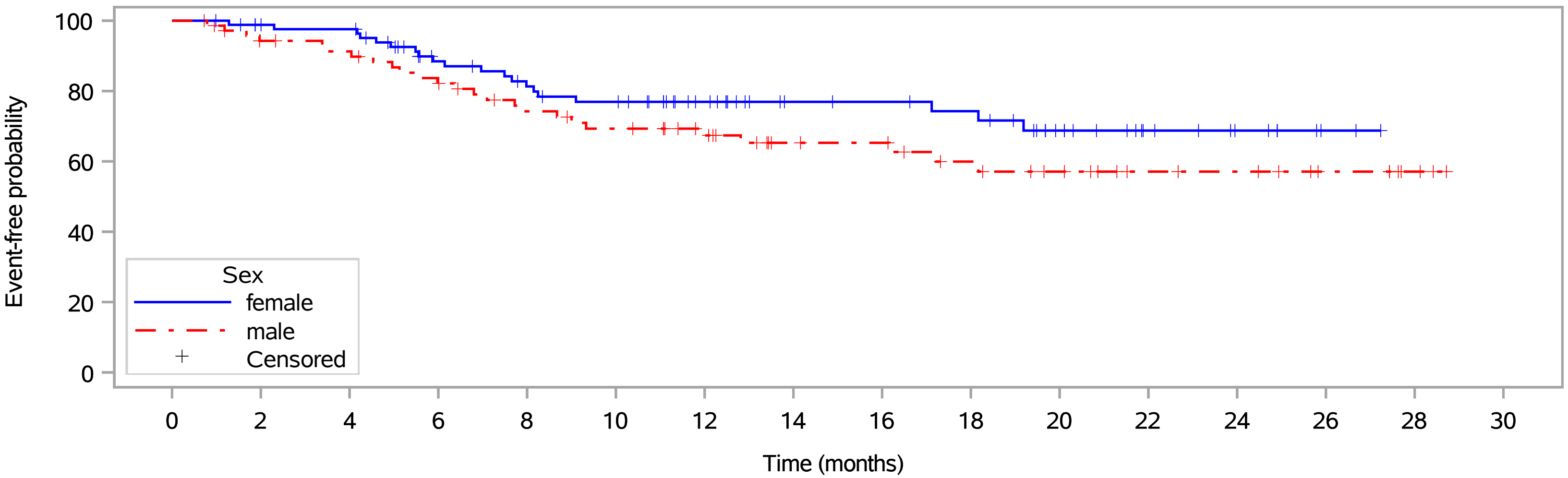


	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Patients at risk																
Asian	75	70	67	55	47	44	32	17	15	14	10	6	4	3	1	NE
Non-Asian	72	65	63	55	49	44	40	37	37	31	22	15	12	6	2	NE
Unknown	11	10	10	7	6	6	4	4	4	4	4	2	2	NE	NE	NE
Patients censored																
Asian	0	1	2	7	8	9	21	35	37	38	41	45	47	48	50	NE
Non-Asian	0	6	7	11	14	15	18	21	21	24	31	38	41	47	51	NE
Unknown	0	1	1	2	3	3	5	5	5	5	5	7	7	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_OS_SGRE.pdf
23MAR2021 9:16

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Overall Survival
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)



Patients at risk															
female	86	81	79	63	56	52	41	31	30	28	19	11	7	2	NE	NE
male	72	64	61	54	46	42	35	27	26	21	17	12	11	7	3	NE
Patients censored																
female	0	4	5	14	16	17	28	38	39	40	47	55	59	64	NE	NE
male	0	4	5	6	9	10	16	23	24	27	30	35	36	40	44	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_OS_SGSEX.pdf
23MAR2021 9:15

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Overall Survival
MODEL: --
STUDY: BO42863
Time to Event Landmark Analysis

Time to Overall Survival

	400 mg QD (N=158)
Patients with event (%)	45 (28.5%)
Patients without event (%)	113 (71.5%)
Time to event (months)	
Median	NE
95% CI	NE
25% and 75%-ile	9.0 - NE
Range	0.7* - 28.7*
Time point analysis	
3 months	
Patients remaining at risk	142
Event Free Rate (%)	96,08
95% CI	(93.00, 99.16)
6 months	
Patients remaining at risk	117
Event Free Rate (%)	85,59
95% CI	(79.88, 91.31)
9 months	
Patients remaining at risk	97
Event Free Rate (%)	75,76
95% CI	(68.63, 82.90)
12 months	
Patients remaining at risk	76

Event Free Rate (%)	72,47
95% CI	(64.94, 79.99)
15 months	
Patients remaining at risk	56
Event Free Rate (%)	71,38
95% CI	(63.68, 79.09)
18 months	
Patients remaining at risk	49
Event Free Rate (%)	67,39
95% CI	(58.89, 75.89)
21 months	
Patients remaining at risk	29
Event Free Rate (%)	63,17
95% CI	(53.96, 72.38)
24 months	
Patients remaining at risk	18
Event Free Rate (%)	63,17
95% CI	(53.96, 72.38)

* Censored values.
Summaries of time to event (median, percentiles) are based on Kaplan Meier estimates.
95% CI for median was computed using the method of Brookmeyer and Crowley.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_lm.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/eff_lm_B63_06NOV2020_EF_TP_OS.xls
07MAY2021 7:57

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Prior Systemic Treatment, Safety Population
ENDPOINT: Overall Survival
STUDY: BO42863
Time to Event Landmark Analysis

	400 mg QD (N=165)
Deaths, n(%)	
Death	45 (27.3%)
Censored, n (%)	
n (Total Patients)	120 (72.7%)
Alive	107 (64.8%)
Lost to Follow-up	1 (0.6%)
Withdrawal of Consent	12 (7.3%)
Overall Follow-Up Time Kaplan-Meier Estimates (Months) [1]	
Median	19.7
95% CI	(14.9, 21.3)
25% and 75%-ile	12.1 - 23.9
Overall Survival Kaplan-Meier Estimates (Months) [2]	
Median	NE
95% CI	NE
25% and 75%-ile	9.1 - NE
Overall Survival Rate	
3-months	
Events	6
Censored	12
Patients remaining at risk	147
Event free proportion (%)	96.24
95% CI	(93.29, 99.19)
6-months	
Events	21
Censored	27
Patients remaining at risk	117
Event free proportion (%)	85.82
95% CI	(80.17, 91.46)
9-months	
Events	34
Censored	34

Patients remaining at risk	97
Event free proportion (%)	75.96
95% CI	(68.86, 83.06)
12-months	
Events	38
Censored	51
Patients remaining at risk	76
Event free proportion (%)	72.66
95% CI	(65.16, 80.15)
18-months	
Events	42
Censored	74
Patients remaining at risk	49
Event free proportion (%)	67.57
95% CI	(59.08, 76.05)
24-months	
Events	45
Censored	102
Patients remaining at risk	18
Event free proportion (%)	63.34
95% CI	(54.13, 72.54)
30-months	
Events	NE
Censored	NE
Patients remaining at risk	NE
Event free proportion (%)	NE
95% CI	NE

[1] Overall follow-up time is based on reverse Kaplan-Meier method, with censoring at date of study discontinuation.
[2] The 95% CI is based on Greenwood formula.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_lma.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_lma_BO42863_SAF_NSCLCPS_OS.xls
12MAR2021 12:01

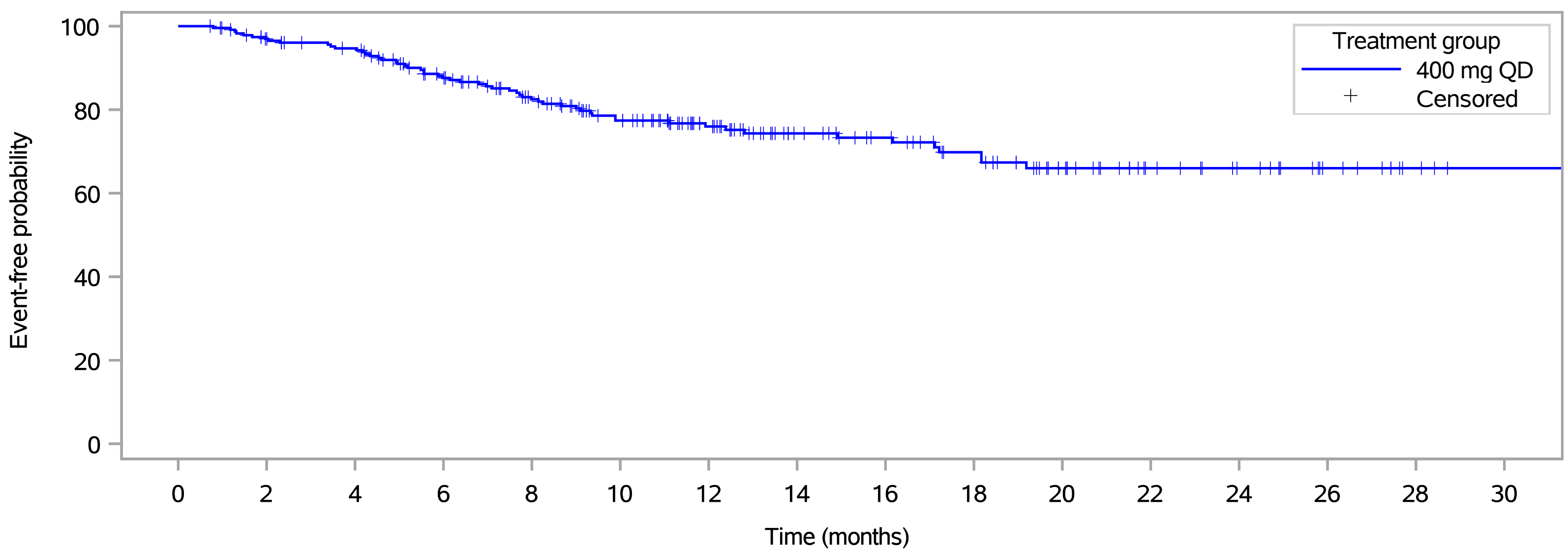
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Subgroup analysis, Overall Survival
MODEL: Unstratified analysis
STUDY: BO42863
Time to event analysis

		(N=158)								
		Patients		Patients with Event		Censored		Time To Event		
Name	Level	n	%	n	%	n	%	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	158	100,0	45	28,5	113	71,5	NE	NE	NE
Sex	Female	86	54,4	20	23,3	66	76,7	NE	NE	NE
	Male	72	45,6	25	34,7	47	65,3	NE	17,2	NE
Age	< 65	104	65,8	29	27,9	75	72,1	NE	NE	NE
	>= 65	54	34,2	16	29,6	38	70,4	NE	17,1	NE
ECOG performance status	0	47	29,7	7	14,9	40	85,1	NE	NE	NE
	1	106	67,1	33	31,1	73	68,9	NE	NE	NE
	2	5	3,2	5	100,0	0	0,0	-	-	-
Geographic region	USA	40	25,3	10	25,0	30	75,0	NE	NE	NE
	Europe (EU)	45	28,5	13	28,9	32	71,1	NE	17,1	NE
	Asia (AS)	73	46,2	22	30,1	51	69,9	NE	19,2	NE
Race/ethnicity	Asian	75	47,5	24	32,0	51	68,0	NE	19,2	NE
	Non-Asian	72	45,6	19	26,4	53	73,6	NE	NE	NE
	Unknown	11	7,0	2	18,2	9	81,8	NE	NE	NE
Number of prior antineoplastic systemic therapy lines I	1	73	46,2	19	26,0	54	74,0	NE	NE	NE
	>= 2	85	53,8	26	30,6	59	69,4	NE	19,2	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_tte2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_tte2_B63_06NOV2020_EF_TP_OS_SG.xls
25FEB2021 20:56

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Overall Survival
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

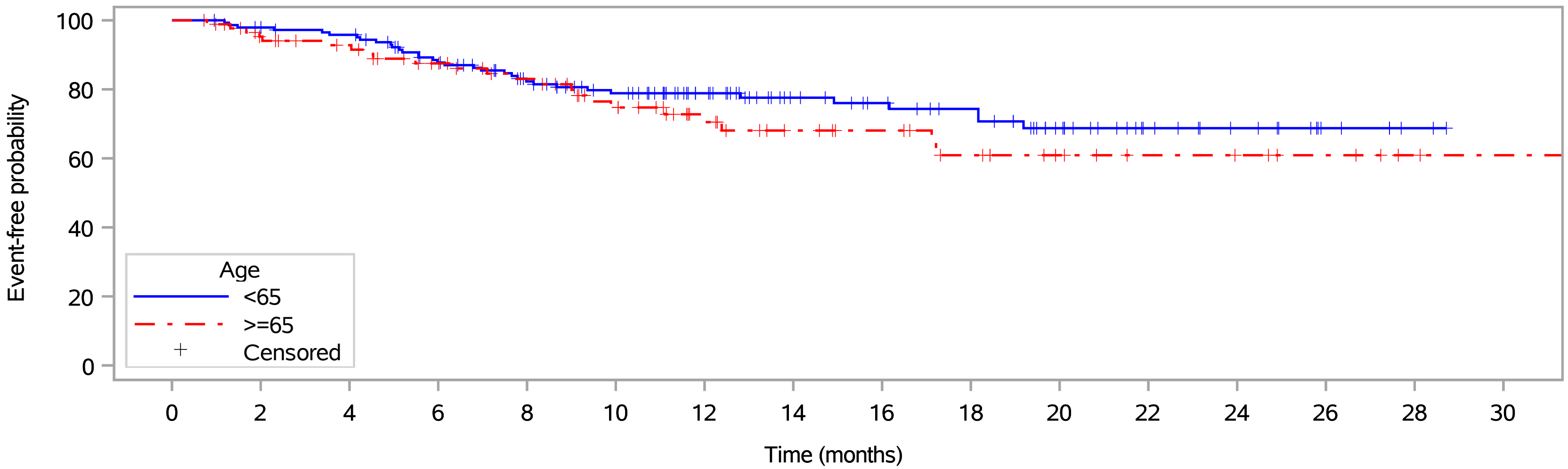


Patients at risk																
400 mg QD	233	218	207	180	155	132	100	76	67	57	40	26	20	11	4	1
Patients censored																
400 mg QD	0	8	14	26	41	55	85	107	115	122	136	150	156	165	172	175

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_OS.pdf
23MAR2021 8:41

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Overall Survival
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

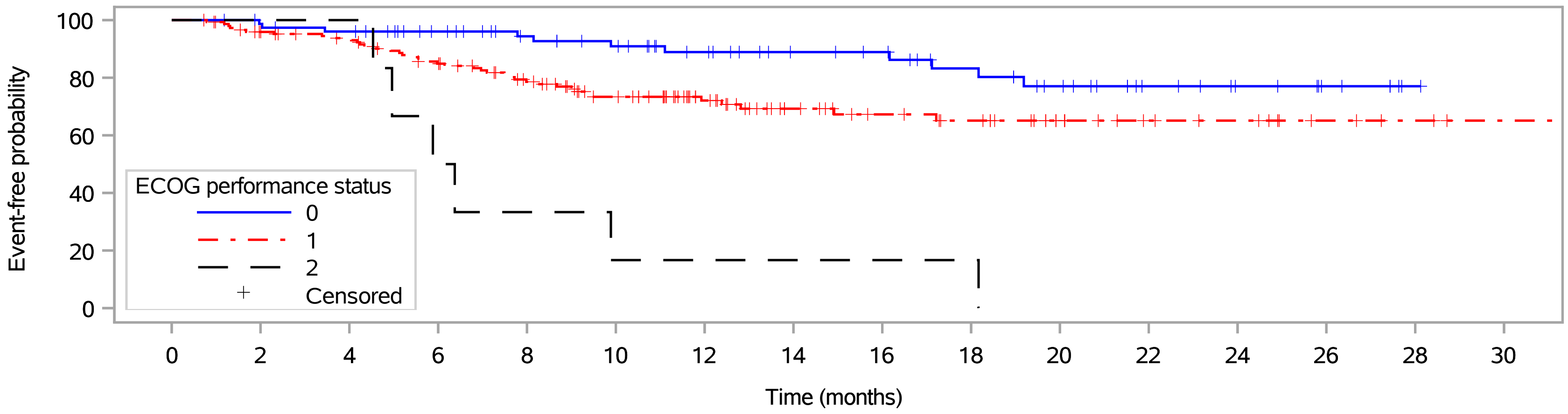


Patients at risk															
<65	145	140	135	118	101	89	69	52	46	41	29	18	13	6	2	NE
>=65	88	78	72	62	54	43	31	24	21	16	11	8	7	5	2	1
Patients censored																
<65	0	2	4	10	20	28	48	64	69	73	82	93	98	105	109	NE
>=65	0	6	10	16	21	27	37	43	46	49	54	57	58	60	63	64

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_OS_SGAGE65.pdf
23MAR2021 8:41

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Overall Survival
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

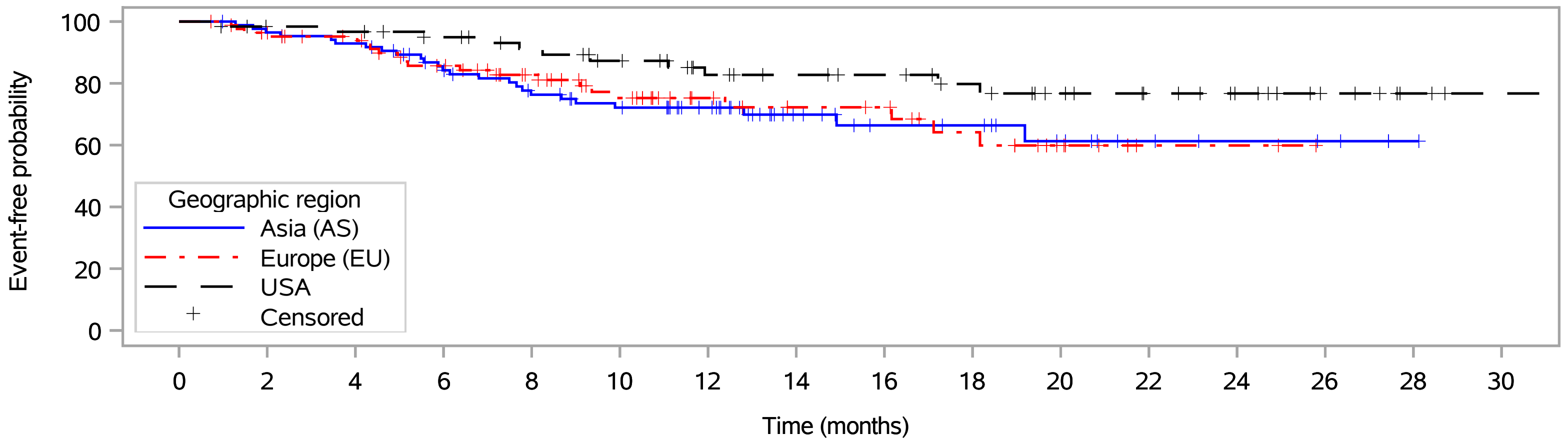


Patients at risk																
0	78	75	72	64	56	51	43	36	34	28	22	14	10	6	1	NE
1	149	137	129	113	97	80	56	39	32	28	18	12	10	5	3	1
2	6	6	6	3	2	1	1	1	1	1	NE	NE	NE	NE	NE	NE
Patients censored																
0	0	2	3	11	18	21	28	35	37	41	45	53	57	61	66	NE
1	0	6	11	15	23	34	57	72	78	81	91	97	99	104	106	108
2	0	0	0	0	0	0	0	0	0	0	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_OS_SGECOG.pdf
23MAR2021 8:42

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Overall Survival
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

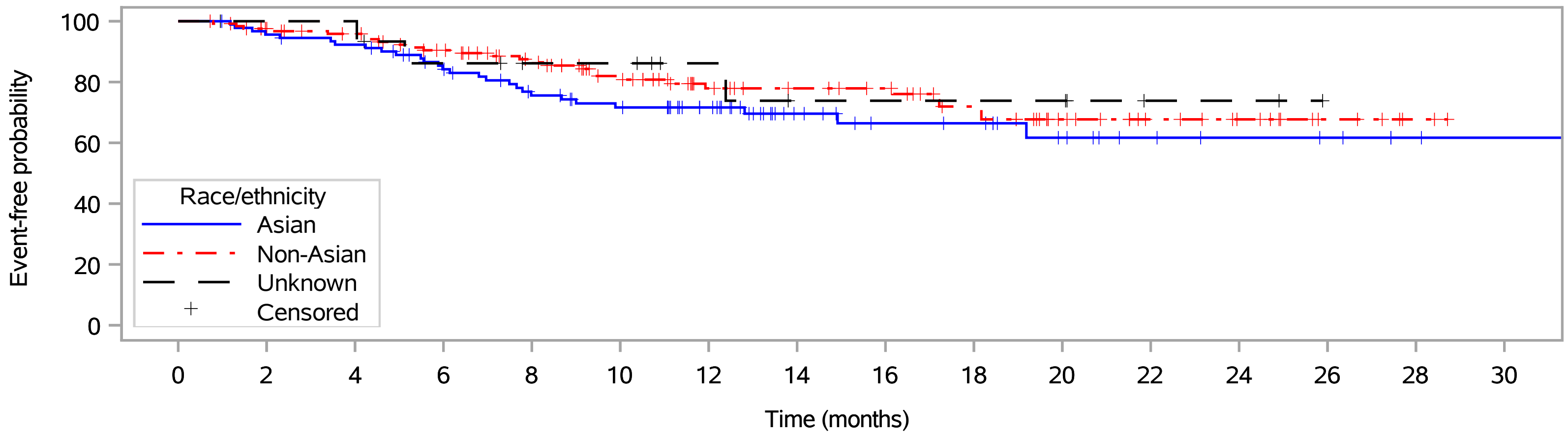


Patients at risk															
Asia (AS)	86	82	78	66	57	51	39	23	17	16	11	7	5	4	1	NE
Europe (EU)	85	78	72	61	50	38	26	21	20	15	8	2	2	NE	NE	NE
USA	62	58	57	53	48	43	35	32	30	26	21	17	13	7	3	1
Patients censored															
Asia (AS)	0	1	2	7	10	13	25	40	45	46	50	54	56	57	60	NE
Europe (EU)	0	4	9	13	22	30	42	46	47	50	56	62	62	NE	NE	NE
USA	0	3	3	6	9	12	18	21	23	26	30	34	38	44	48	50

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_OS_SGGEO.pdf
23MAR2021 8:43

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Overall Survival
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

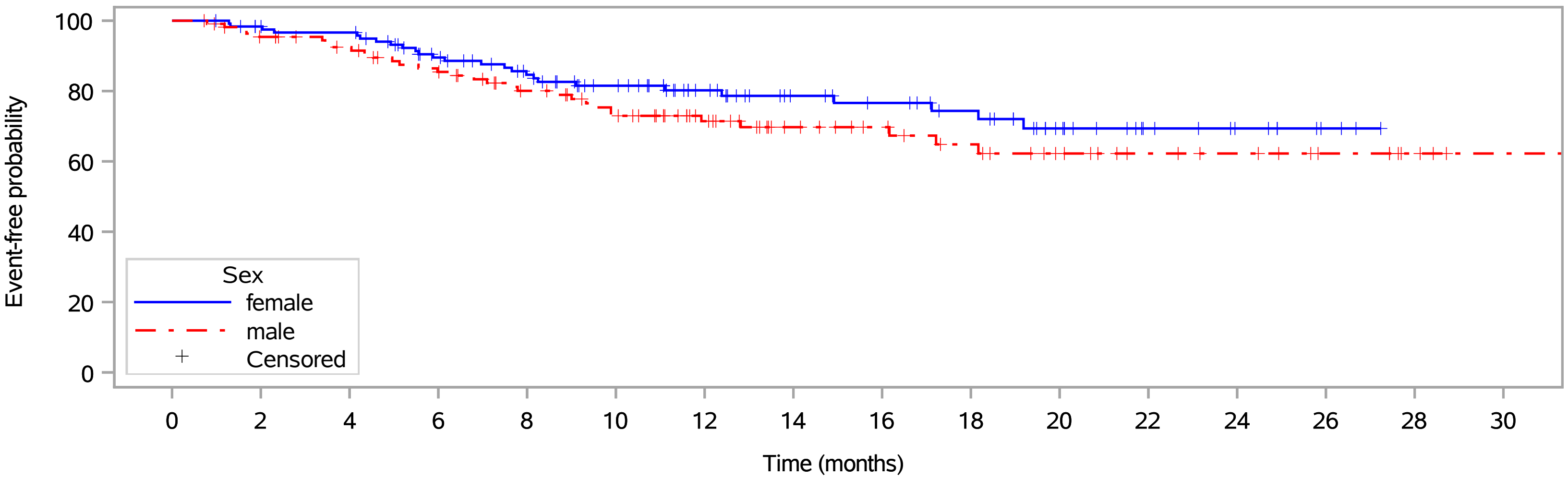


	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Patients at risk																
Asian	92	87	83	71	60	54	42	25	19	18	12	8	6	5	2	1
Non-Asian	125	116	109	97	85	68	51	46	43	34	23	16	12	6	2	NE
Unknown	16	15	15	12	10	10	7	5	5	5	5	2	2	NE	NE	NE
Patients censored																
Asian	0	1	2	7	11	14	26	42	47	48	53	57	59	60	63	64
Non-Asian	0	6	11	17	26	37	52	57	60	66	75	82	86	92	96	NE
Unknown	0	1	1	2	4	4	7	8	8	8	8	11	11	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_OS_SGRE.pdf
23MAR2021 8:43

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Overall Survival
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)



Patients at risk																
female	122	116	113	96	84	71	53	41	37	32	21	12	8	3	NE	NE
male	111	102	94	84	71	61	47	35	30	25	19	14	12	8	4	1
Patients censored																
female	0	4	5	14	21	31	48	59	62	66	75	84	88	93	NE	NE
male	0	4	9	12	20	24	37	48	53	56	61	66	68	72	76	79

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_OS_SGSEX.pdf
23MAR2021 8:42

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Overall Survival
STUDY: BO42863
Time to Event Landmark Analysis

	400 mg QD (N=281)
Deaths, n(%)	
Death	61 (21.7%)
Censored, n (%)	
n (Total Patients)	220 (78.3%)
Alive	202 (71.9%)
Lost to Follow-up	2 (0.7%)
Withdrawal of Consent	16 (5.7%)
Overall Follow-Up Time Kaplan-Meier Estimates (Months) [1]	
Median	13.2
95% CI	(12.1, 15.5)
25% and 75%-ile	9.1 - 21.3
Overall Survival Kaplan-Meier Estimates (Months) [2]	
Median	NE
95% CI	NE
25% and 75%-ile	12.4 - NE
Overall Survival Rate	
3-months	
Events	13
Censored	33
Patients remaining at risk	235
Event free proportion (%)	95.15
95% CI	(92.57, 97.72)
6-months	

Events	31
Censored	70
Patients remaining at risk	180
Event free proportion (%)	87.01
95% CI	(82.71, 91.32)
9-months	
Events	44
Censored	93
Patients remaining at risk	144
Event free proportion (%)	80.32
95% CI	(75.02, 85.61)
12-months	
Events	52
Censored	129
Patients remaining at risk	100
Event free proportion (%)	75.46
95% CI	(69.50, 81.42)
18-months	
Events	58
Censored	166
Patients remaining at risk	57
Event free proportion (%)	69.34
95% CI	(62.08, 76.59)
24-months	
Events	61
Censored	200
Patients remaining at risk	20
Event free proportion (%)	65.54
95% CI	(57.50, 73.58)
30-months	
Events	61
Censored	219

Patients remaining at risk	1
Event free proportion (%)	65.54
95% CI	(57.50, 73.58)

[1] Overall follow-up time is based on reverse Kaplan-Meier method, with censoring at date of study discontinuation.
[2] The 95% CI is based on Greenwood formula.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_lma.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_lma_BO42863_SAF_NSCLCO_OS.xls
12MAR2021 12:00

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Overall Survival
MODEL: --
STUDY: BO42863
Time to Event Landmark Analysis

Time to Overall Survival

	400 mg QD (N=233)
Patients with event (%)	57 (24.5%)
Patients without event (%)	176 (75.5%)
Time to event (months)	
Median	NE
95% CI	NE
25% and 75%-ile	12.8 - NE
Range	0.7* - 32.6*
Time point analysis	
3 months	
Patients remaining at risk	211
Event Free Rate (%)	96,05
95% CI	(93.52, 98.58)
6 months	
Patients remaining at risk	180
Event Free Rate (%)	87,61
95% CI	(83.22, 91.99)
9 months	
Patients remaining at risk	144
Event Free Rate (%)	80,86
95% CI	(75.50, 86.23)
12 months	
Patients remaining at risk	100

Event Free Rate (%)	75,97
95% CI	(69.94, 82.00)
15 months	
Patients remaining at risk	70
Event Free Rate (%)	73,29
95% CI	(66.74, 79.83)
18 months	
Patients remaining at risk	57
Event Free Rate (%)	69,81
95% CI	(62.48, 77.14)
21 months	
Patients remaining at risk	32
Event Free Rate (%)	65,98
95% CI	(57.88, 74.09)
24 months	
Patients remaining at risk	20
Event Free Rate (%)	65,98
95% CI	(57.88, 74.09)

* Censored values.
Summaries of time to event (median, percentiles) are based on Kaplan Meier estimates.
95% CI for median was computed using the method of Brookmeyer and Crowley.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_lm.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/eff_lm_B63_06NOV2020_EF_TO_OS.xls
07MAY2021 7:55

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Subgroup analysis, Overall Survival
MODEL: Unstratified analysis
STUDY: BO42863
Time to event analysis

		(N=233)								
		Patients		Patients with Event		Censored		Time To Event		
Name	Level	n	%	n	%	n	%	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	233	100,0	57	24,5	176	75,5	NE	NE	NE
Sex	Female	122	52,4	26	21,3	96	78,7	NE	NE	NE
	Male	111	47,6	31	27,9	80	72,1	NE	NE	NE
Age	< 65	145	62,2	34	23,4	111	76,6	NE	NE	NE
	>= 65	88	37,8	23	26,1	65	73,9	NE	17,2	NE
ECOG performance status	0	78	33,5	11	14,1	67	85,9	NE	NE	NE
	1	149	63,9	40	26,8	109	73,2	NE	NE	NE
	2	6	2,6	6	100,0	0	0,0	-	-	-
Geographic region	USA	62	26,6	11	17,7	51	82,3	NE	NE	NE
	Europe (EU)	85	36,5	21	24,7	64	75,3	NE	17,1	NE
	Asia (AS)	86	36,9	25	29,1	61	70,9	NE	19,2	NE
Race/ethnicity	Asian	92	39,5	27	29,3	65	70,7	NE	19,2	NE
	Non-Asian	125	53,6	27	21,6	98	78,4	NE	NE	NE
	Unknown	16	6,9	3	18,8	13	81,3	NE	12,4	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_tte2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_tte2_B63_06NOV2020_EF_TO_OS_SG.xls
25FEB2021 20:55

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Subjects with Objective Response (BICR),
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (efficacy)

		(N=29)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	29	100.0	19	65.5	47.3	80.1
Sex	Female	15	51.7	11	73.3	48.0	89.1
	Male	14	48.3	8	57.1	32.6	78.6
Age	< 65	14	48.3	12	85.7	60.1	96.0
	>= 65	15	51.7	7	46.7	24.8	69.9
ECOG performance status	0	11	37.9	10	90.9	62.3	98.4
	1	17	58.6	8	47.1	26.2	69.0
	2	1	3.4	1	100.0	20.7	100.0
Geographic region	USA	7	24.1	7	100.0	64.6	100.0
	Europe (EU)	14	48.3	7	50.0	26.8	73.2
	Asia (AS)	8	27.6	5	62.5	30.6	86.3
Race/ethnicity	Asian	10	34.5	7	70.0	39.7	89.2
	Non-Asian	18	62.1	11	61.1	38.6	79.7
	Unknown	1	3.4	1	100.0	20.7	100.0

Clinical cut-off: 18NOV2019

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_resp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_NDA_import/prod/output/eff_resp_B63_18NOV2019_EF_TN_OBRESPRR_SG.xls
26FEB2021 13:37

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Subjects with Objective Response (Investigator-assessed),
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (efficacy)

		(N=29)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	29	100.0	17	58.6	40.7	74.5
Sex	Female	15	51.7	9	60.0	35.7	80.2
	Male	14	48.3	8	57.1	32.6	78.6
Age	< 65	14	48.3	10	71.4	45.4	88.3
	>= 65	15	51.7	7	46.7	24.8	69.9
ECOG performance status	0	11	37.9	7	63.6	35.4	84.8
	1	17	58.6	9	52.9	31.0	73.8
	2	1	3.4	1	100.0	20.7	100.0
Geographic region	USA	7	24.1	5	71.4	35.9	91.8
	Europe (EU)	14	48.3	6	42.9	21.4	67.4
	Asia (AS)	8	27.6	6	75.0	40.9	92.9
Race/ethnicity	Asian	10	34.5	8	80.0	49.0	94.3
	Non-Asian	18	62.1	9	50.0	29.0	71.0
	Unknown	1	3.4	0	0.0	0.0	79.3

Clinical cut-off: 18NOV2019

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_resp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_NDA_import/prod/output/eff_resp_B63_18NOV2019_EF_TN_OBRESP_SG.xls
26FEB2021 13:39

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Subjects with Objective Response (BICR),
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (efficacy)

		(N=75)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	75	100.0	54	72.0	61.0	80.9
Sex	Female	36	48.0	27	75.0	58.9	86.2
	Male	39	52.0	27	69.2	53.6	81.4
Age	< 65	41	54.7	35	85.4	71.6	93.1
	>= 65	34	45.3	19	55.9	39.5	71.1
ECOG performance status	0	31	41.3	26	83.9	67.4	92.9
	1	43	57.3	27	62.8	47.9	75.6
	2	1	1.3	1	100.0	20.7	100.0
Geographic region	USA	22	29.3	19	86.4	66.7	95.3
	Europe (EU)	40	53.3	26	65.0	49.5	77.9
	Asia (AS)	13	17.3	9	69.2	42.4	87.3
Race/ethnicity	Asian	17	22.7	12	70.6	46.9	86.7
	Non-Asian	53	70.7	38	71.7	58.4	82.0
	Unknown	5	6.7	4	80.0	37.6	96.4

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_resp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_resp_B63_06NOV2020_EF_TN_OBRESPRR_SG.xls
26FEB2021 13:23

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Subjects with Objective Response (Investigator-assessed),
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (efficacy)

		(N=75)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	75	100.0	57	76.0	65.2	84.2
Sex	Female	36	48.0	29	80.6	65.0	90.2
	Male	39	52.0	28	71.8	56.2	83.5
Age	< 65	41	54.7	33	80.5	66.0	89.8
	>= 65	34	45.3	24	70.6	53.8	83.2
ECOG performance status	0	31	41.3	25	80.6	63.7	90.8
	1	43	57.3	31	72.1	57.3	83.3
	2	1	1.3	1	100.0	20.7	100.0
Geographic region	USA	22	29.3	20	90.9	72.2	97.5
	Europe (EU)	40	53.3	26	65.0	49.5	77.9
	Asia (AS)	13	17.3	11	84.6	57.8	95.7
Race/ethnicity	Asian	17	22.7	15	88.2	65.7	96.7
	Non-Asian	53	70.7	37	69.8	56.5	80.5
	Unknown	5	6.7	5	100.0	56.6	100.0

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_resp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_resp_B63_06NOV2020_EF_TN_OBRESP_SG.xls
26FEB2021 13:25

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Subgroup analysis, Best Overall Response (BICR)
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (efficacy)

			400 mg QD (N=75)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	ORR*	n/a	75	100.0	54	72.0	61.0	80.9
	CR	n/a	75	100.0	4	5.3	2.1	12.9
	PR	n/a	75	100.0	50	66.7	55.4	76.3
	SD	n/a	75	100.0	14	18.7	11.5	28.9
	PD	n/a	75	100.0	5	6.7	2.9	14.7
	NE	n/a	75	100.0	2	2.7	0.7	9.2
Sex	ORR*	Female	36	48.0	27	75.0	58.9	86.2
		Male	39	52.0	27	69.2	53.6	81.4
	CR	Female	36	48.0	3	8.3	2.9	21.8
		Male	39	52.0	1	2.6	0.5	13.2
	PR	Female	36	48.0	24	66.7	50.3	79.8
		Male	39	52.0	26	66.7	51.0	79.4
	SD	Female	36	48.0	5	13.9	6.1	28.7
		Male	39	52.0	9	23.1	12.6	38.3
	PD	Female	36	48.0	3	8.3	2.9	21.8
		Male	39	52.0	2	5.1	1.4	16.9
	NE	Female	36	48.0	1	2.8	0.5	14.2
		Male	39	52.0	1	2.6	0.5	13.2
Age	ORR*	< 65	41	54.7	35	85.4	71.6	93.1
		>= 65	34	45.3	19	55.9	39.5	71.1
	CR	< 65	41	54.7	3	7.3	2.5	19.4
		>= 65	34	45.3	1	2.9	0.5	14.9
	PR	< 65	41	54.7	32	78.0	63.3	88.0
		>= 65	34	45.3	18	52.9	36.7	68.5
	SD	< 65	41	54.7	3	7.3	2.5	19.4
		>= 65	34	45.3	11	32.4	19.1	49.2
	PD	< 65	41	54.7	2	4.9	1.3	16.1
		>= 65	34	45.3	3	8.8	3.0	23.0
	NE	< 65	41	54.7	1	2.4	0.4	12.6
		>= 65	34	45.3	1	2.9	0.5	14.9
ECOG performance status	ORR*	0	31	41.3	26	83.9	67.4	92.9

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Subgroup analysis, Duration of Response per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
MODEL: Unstratified analysis
STUDY: BO42863
Time to event analysis

		(N=75)								
		Patients		Patients with Event		Censored		Time To Event		
Name	Level	n	%	n	%	n	%	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	54	72.0	14	25.9	40	74.1	NE	9.0	NE
Sex	Female	27	36.0	7	25.9	20	74.1	NE	7.3	NE
	Male	27	36.0	7	25.9	20	74.1	NE	7.4	NE
Age	< 65	35	46.7	8	22.9	27	77.1	NE	7.4	NE
	>= 65	19	25.3	6	31.6	13	68.4	9.2	6.3	NE
ECOG performance status	0	26	34.7	5	19.2	21	80.8	NE	7.4	NE
	1	27	36.0	8	29.6	19	70.4	11.0	9.0	NE
	2	1	1.3	1	100.0	0	0.0	-	-	-
Geographic region	USA	19	25.3	6	31.6	13	68.4	9.2	7.3	NE
	Europe (EU)	26	34.7	4	15.4	22	84.6	NE	NE	NE
	Asia (AS)	9	12.0	4	44.4	5	55.6	-	-	-
Race/ethnicity	Asian	12	16.0	6	50.0	6	50.0	9.2	7.4	NE
	Non-Asian	38	50.7	8	21.1	30	78.9	NE	NE	NE
	Unknown	4	5.3	0	0.0	4	100.0	-	-	-

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_tte2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_tte2_B63_06NOV2020_EF_TN_DORRREMA_SG.xls
25FEB2021 21:00

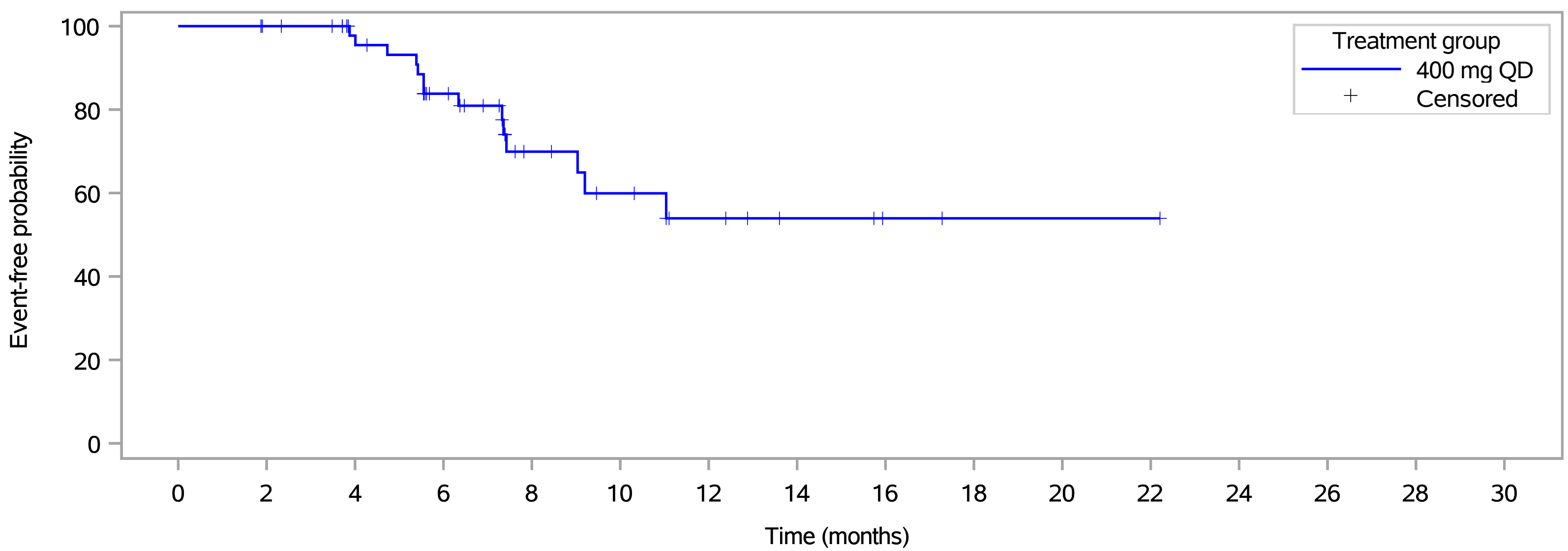
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Subgroup analysis, Time to Response (BICR)
MODEL: Unstratified analysis
STUDY: BO42863
Time to event analysis

		(N=75)								
		Patients		Patients with Event		Censored		Time To Event		
Name	Level	n	%	n	%	n	%	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	54	72.0	54	100.0	0	0.0	1.8	1.8	1.9
Sex	Female	27	36.0	27	100.0	0	0.0	1.8	1.8	2.2
	Male	27	36.0	27	100.0	0	0.0	1.8	1.7	1.9
Age	< 65	35	46.7	35	100.0	0	0.0	1.8	1.8	1.9
	>= 65	19	25.3	19	100.0	0	0.0	1.8	1.8	2.0
ECOG performance status	0	26	34.7	26	100.0	0	0.0	1.8	1.8	2.2
	1	27	36.0	27	100.0	0	0.0	1.8	1.8	1.9
	2	1	1.3	1	100.0	0	0.0	-	-	-
Geographic region	USA	19	25.3	19	100.0	0	0.0	1.8	1.8	2.0
	Europe (EU)	26	34.7	26	100.0	0	0.0	1.8	1.8	1.9
	Asia (AS)	9	12.0	9	100.0	0	0.0	-	-	-
Race/ethnicity	Asian	12	16.0	12	100.0	0	0.0	1.8	1.7	2.0
	Non-Asian	38	50.7	38	100.0	0	0.0	1.8	1.8	1.9
	Unknown	4	5.3	4	100.0	0	0.0	-	-	-

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_tte2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_tte2_B63_06NOV2020_EF_TN_TTRESPRR_SG.xls
25FEB2021 21:01

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Duration of Response per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

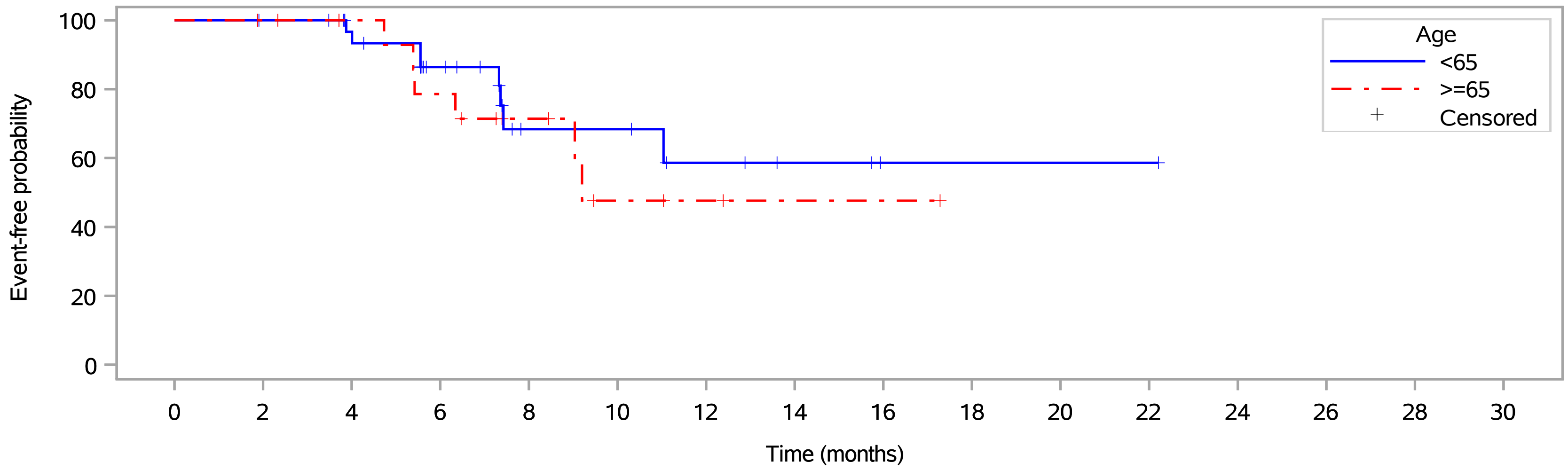


Patients at risk															
400 mg QD	54	51	43	30	15	11	7	4	2	1	1	1	NE	NE	NE	NE
Patients censored															
400 mg QD	0	3	10	17	28	30	33	36	38	39	39	39	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_DORRREMA.pdf
23MAR2021 9:17

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Duration of Response per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

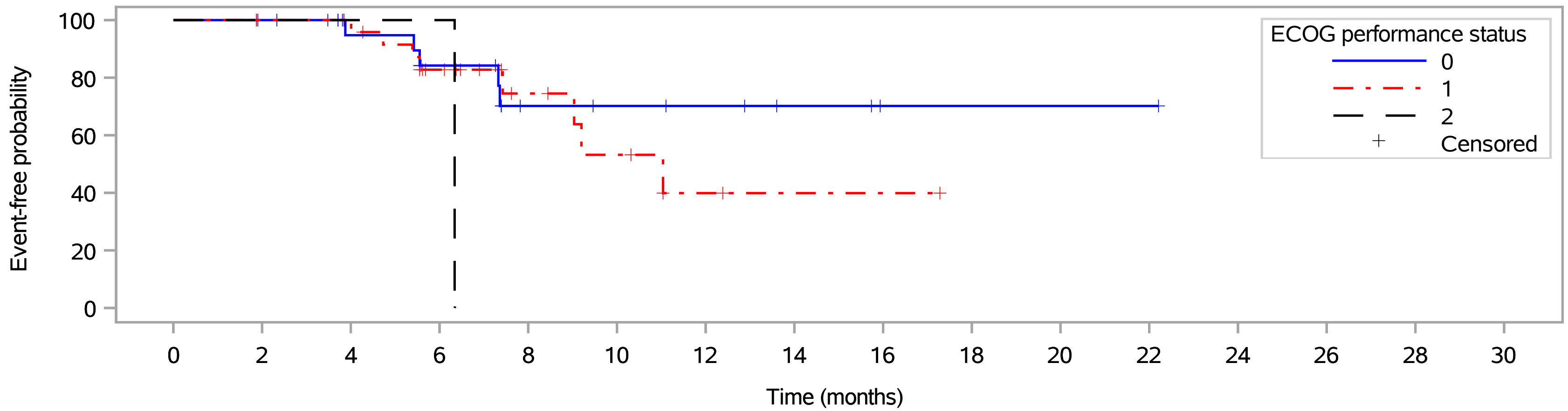


	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Patients at risk																
<65	35	34	29	19	8	8	5	3	1	1	1	1	NE	NE	NE	NE
>=65	19	17	14	11	7	3	2	1	1	NE	NE	NE	NE	NE	NE	NE
Patients censored																
<65	0	1	5	12	20	20	22	24	26	26	26	26	NE	NE	NE	NE
>=65	0	2	5	5	8	10	11	12	12	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_DORRREMA_SGAGE65.pdf
23MAR2021 9:18

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Duration of Response per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

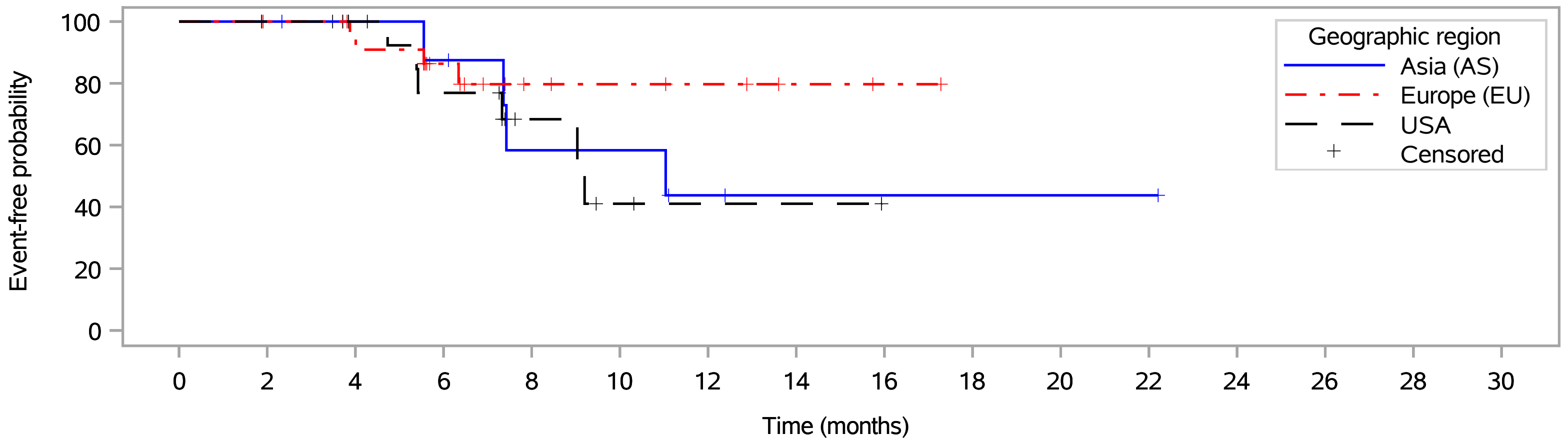


Patients at risk																
0	26	25	18	13	7	6	5	3	1	1	1	1	NE	NE	NE	NE
1	27	25	24	16	8	5	2	1	1	NE	NE	NE	NE	NE	NE	NE
2	1	1	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
0	0	1	7	10	14	15	16	18	20	20	20	20	NE	NE	NE	NE
1	0	2	3	7	14	15	17	18	18	NE	NE	NE	NE	NE	NE	NE
2	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_DORRREMA_SGECOG.pdf
23MAR2021 9:19

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Duration of Response per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

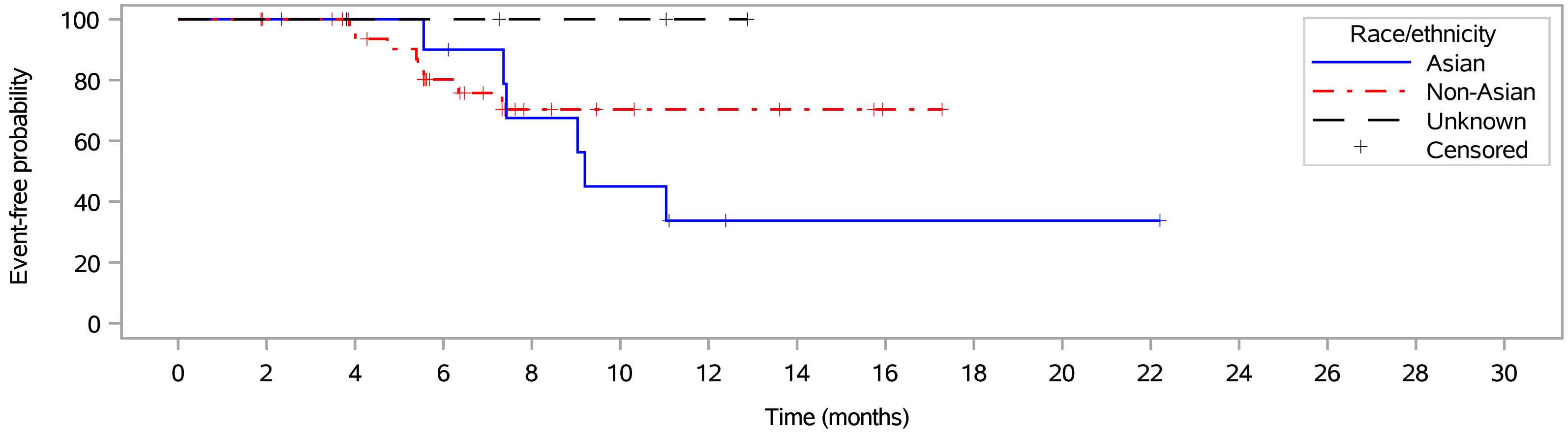


	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Patients at risk																
Asia (AS)	9	9	8	7	4	4	2	1	1	1	1	1	NE	NE	NE	NE
Europe (EU)	26	24	21	13	6	5	4	2	1	NE	NE	NE	NE	NE	NE	NE
USA	19	18	14	10	5	2	1	1	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
Asia (AS)	0	0	1	1	2	2	3	4	4	4	4	4	NE	NE	NE	NE
Europe (EU)	0	2	4	10	16	17	18	20	21	NE	NE	NE	NE	NE	NE	NE
USA	0	1	5	6	10	11	12	12	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_DORRREMA_SGGEO.pdf
23MAR2021 9:19

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Duration of Response per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

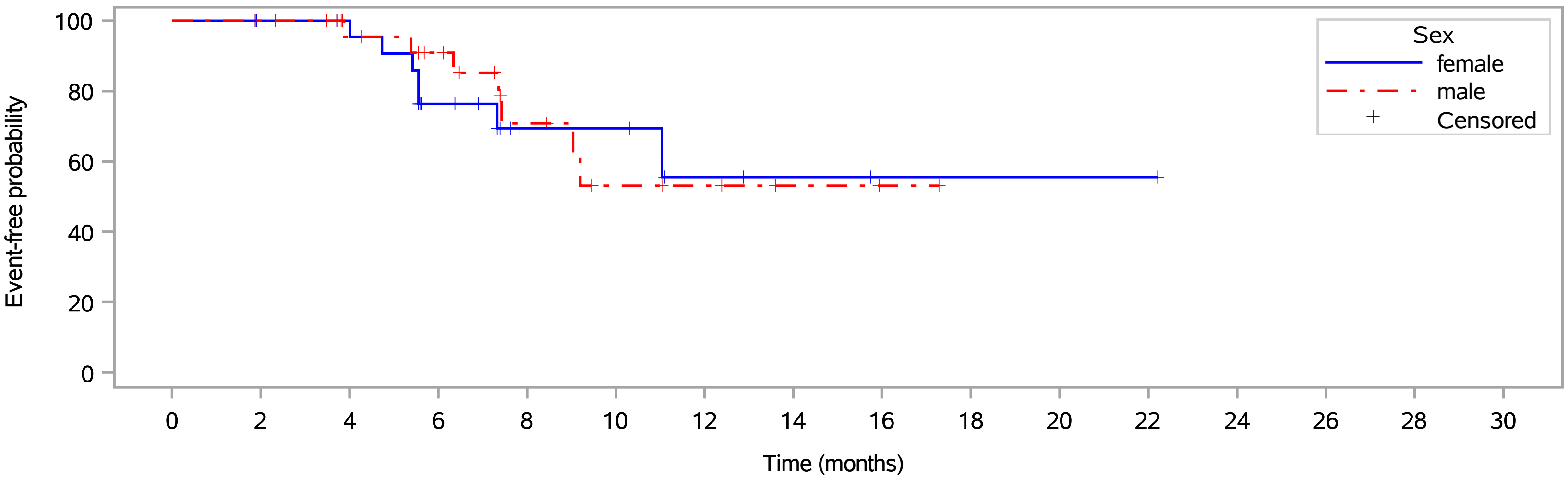


	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Patients at risk																
Asian	12	12	10	9	6	4	2	1	1	1	1	1	NE	NE	NE	NE
Non-Asian	38	35	30	18	7	5	4	3	1	NE	NE	NE	NE	NE	NE	NE
Unknown	4	4	3	3	2	2	1	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
Asian	0	0	2	2	3	3	4	5	5	5	5	5	NE	NE	NE	NE
Non-Asian	0	3	7	14	23	25	26	27	29	NE	NE	NE	NE	NE	NE	NE
Unknown	0	0	1	1	2	2	3	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_DORRREMA_SGRE.pdf
23MAR2021 9:20

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Duration of Response per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

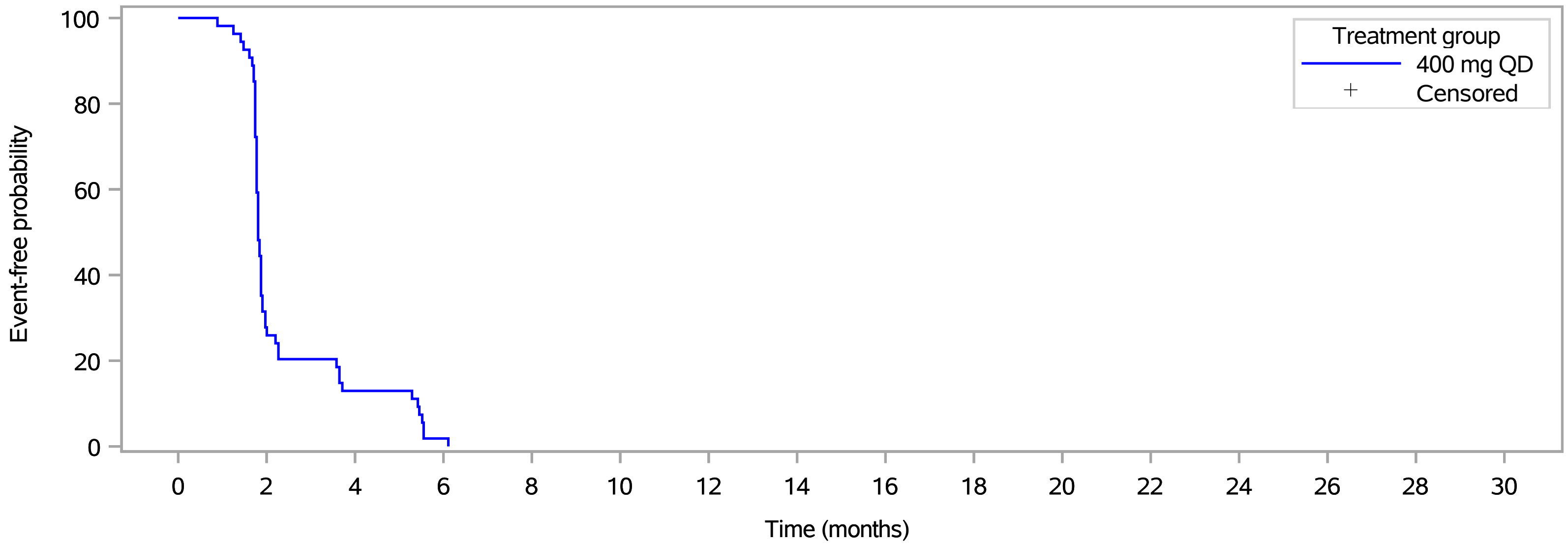


Patients at risk																
female	27	25	22	13	6	6	3	2	1	1	1	1	NE	NE	NE	NE
male	27	26	21	17	9	5	4	2	1	NE	NE	NE	NE	NE	NE	NE
Patients censored																
female	0	2	5	9	15	15	17	18	19	19	19	19	NE	NE	NE	NE
male	0	1	5	8	13	15	16	18	19	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_DORRREMA_SGSEX.pdf
23MAR2021 9:18

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Time to Response (BICR)
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

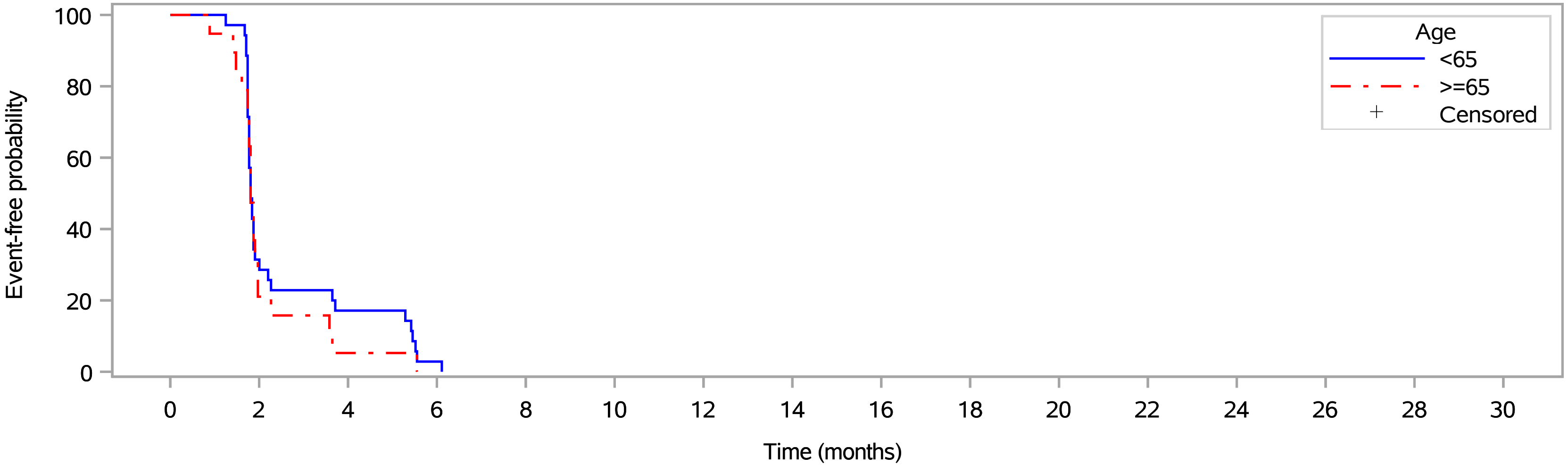


Patients at risk																
400 mg QD	54	15	7	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
400 mg QD	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_TTRESPRR.pdf
23MAR2021 9:24

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Time to Response (BICR)
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

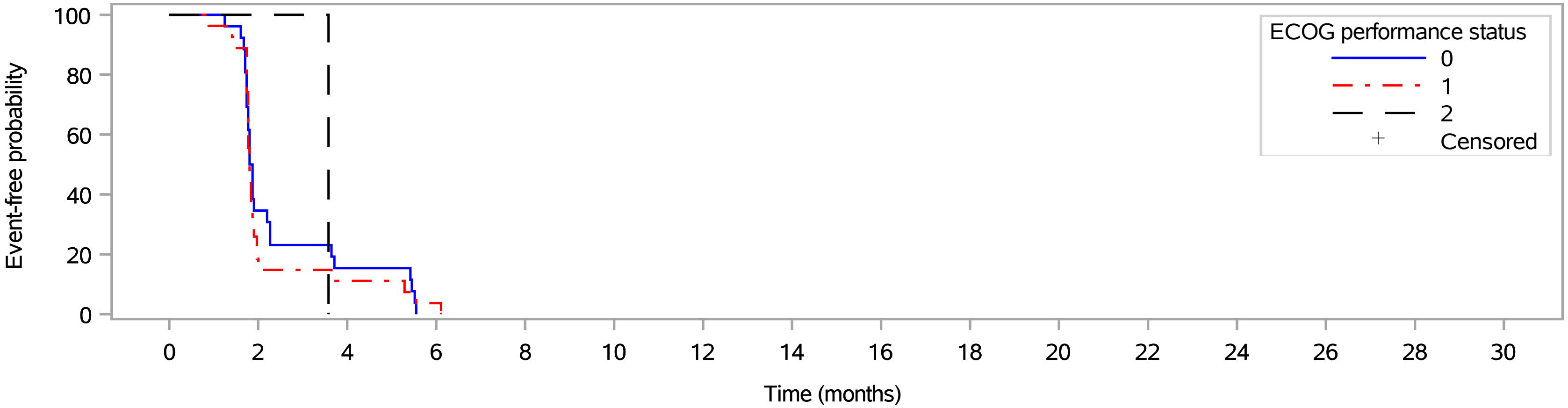


Patients at risk																
<65	35	11	6	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
>=65	19	4	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
<65	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
>=65	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_TTRESPRR_SGAGE65.pdf
23MAR2021 9:24

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Time to Response (BICR)
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

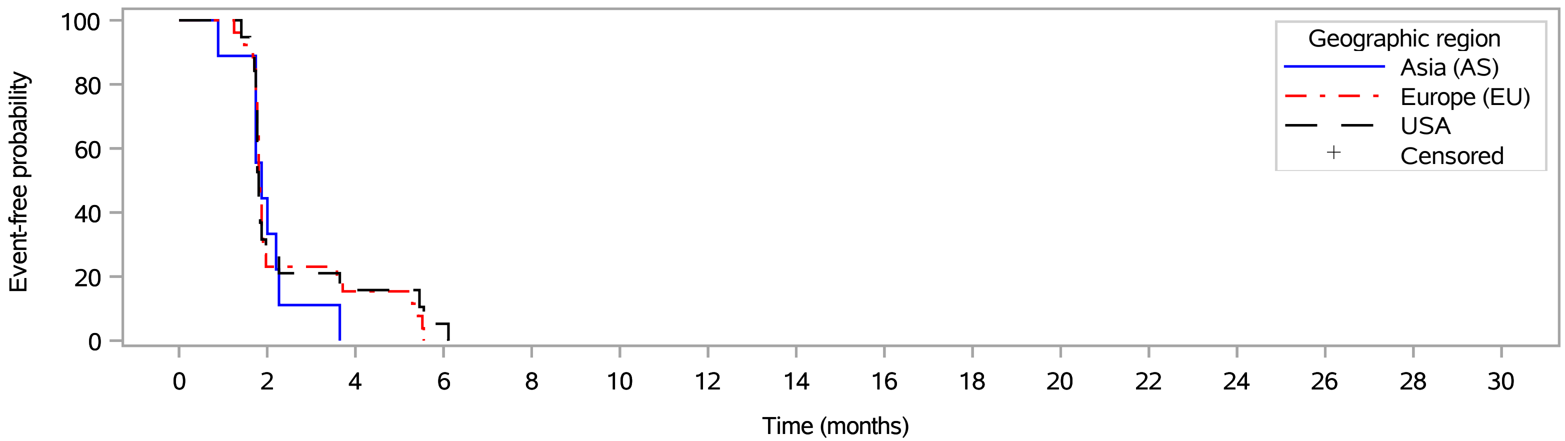


Patients at risk																
0	26	9	4	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
1	27	5	3	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
2	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
1	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
2	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_TTRESPRR_SGECOG.pdf
23MAR2021 9:25

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Time to Response (BICR)
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

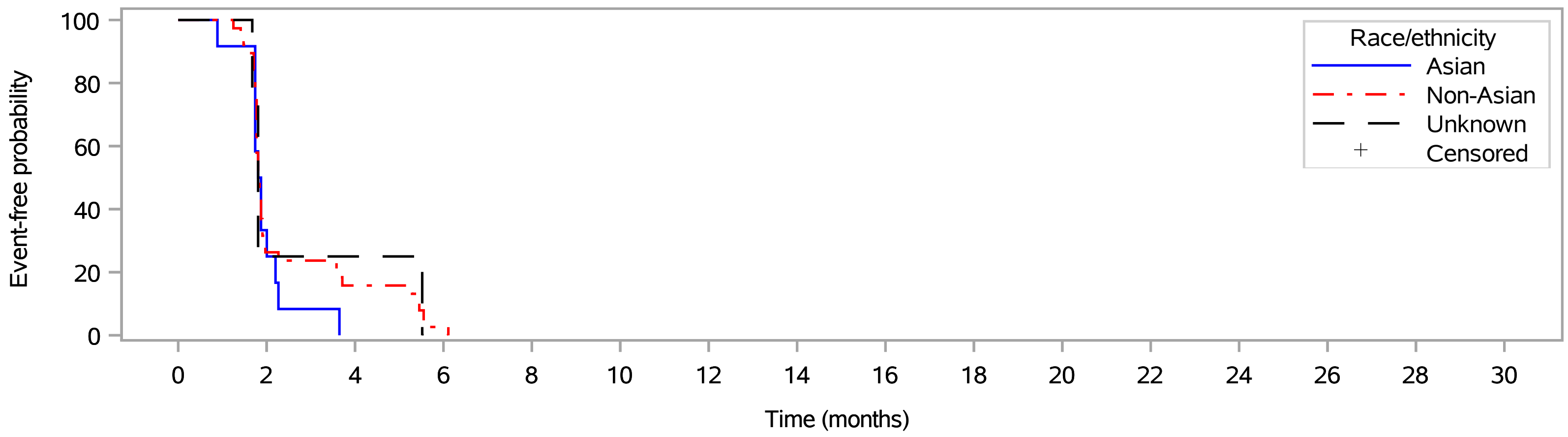


Patients at risk																
Asia (AS)	9	4	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Europe (EU)	26	6	4	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
USA	19	5	3	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
Asia (AS)	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Europe (EU)	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
USA	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_TTRESPRR_SGGEO.pdf
23MAR2021 9:26

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Time to Response (BICR)
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

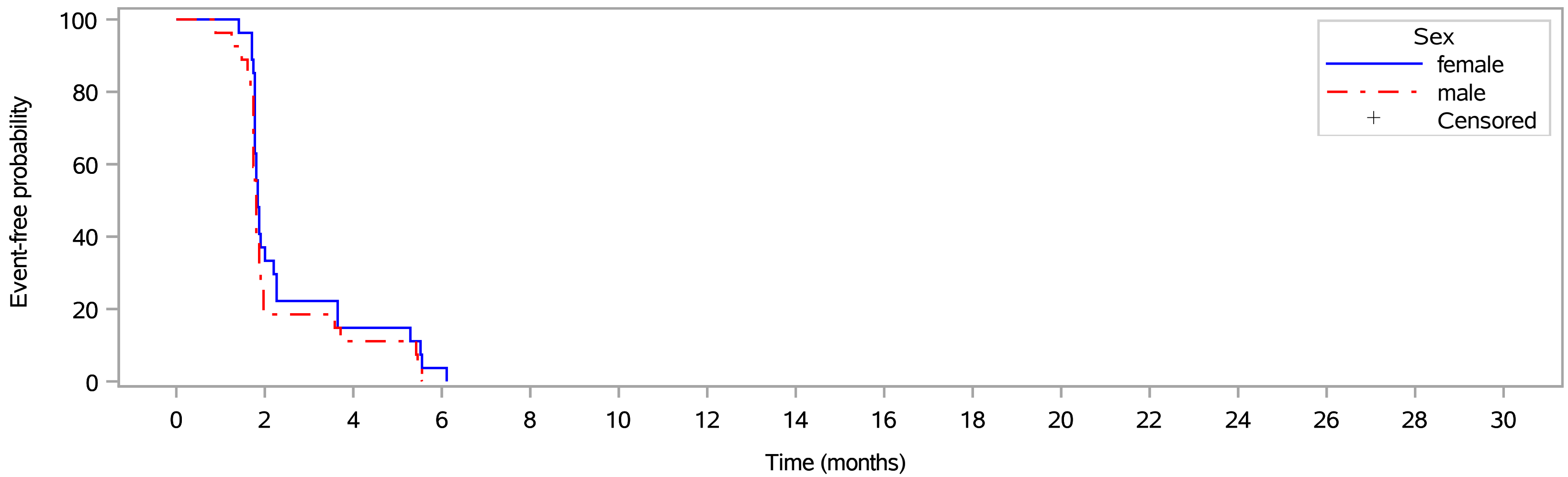


Patients at risk																
Asian	12	4	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Non-Asian	38	10	6	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Unknown	4	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
Asian	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Non-Asian	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Unknown	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_TTRESPRR_SGRE.pdf
23MAR2021 9:26

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Time to Response (BICR)
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)



Patients at risk																
female	27	10	4	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
male	27	5	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
female	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
male	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_TTRESPRR_SGSEX.pdf
23MAR2021 9:25

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Subjects with Objective Response (BICR),
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (efficacy)

		(N=103)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	103	100.0	56	54.4	44.8	63.7
Sex	Female	54	52.4	34	63.0	49.6	74.6
	Male	49	47.6	22	44.9	31.9	58.7
Age	< 65	67	65.0	39	58.2	46.3	69.3
	>= 65	36	35.0	17	47.2	32.0	63.0
ECOG performance status	0	39	37.9	24	61.5	45.9	75.1
	1	59	57.3	30	50.8	38.4	63.2
	2	5	4.9	2	40.0	11.8	76.9
Geographic region	USA	37	35.9	24	64.9	48.8	78.2
	Europe (EU)	35	34.0	18	51.4	35.6	67.0
	Asia (AS)	31	30.1	14	45.2	29.2	62.2
Race/ethnicity	Asian	33	32.0	15	45.5	29.8	62.0
	Non-Asian	60	58.3	36	60.0	47.4	71.4
	Unknown	10	9.7	5	50.0	23.7	76.3
Number of prior antineoplastic systemic therapy lines I	1	43	41.7	23	53.5	38.9	67.5
	>= 2	60	58.3	33	55.0	42.5	66.9

Clinical cut-off: 18NOV2019

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_resp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_NDA_import/prod/output/eff_resp_B63_18NOV2019_EF_TP_OBRESPRR_SG.xls
26FEB2021 13:38

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Subjects with Objective Response (Investigator-assessed),
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (efficacy)

		(N=103)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	103	100.0	52	50.5	41.0	59.9
Sex	Female	54	52.4	30	55.6	42.4	68.0
	Male	49	47.6	22	44.9	31.9	58.7
Age	< 65	67	65.0	37	55.2	43.4	66.5
	>= 65	36	35.0	15	41.7	27.1	57.8
ECOG performance status	0	39	37.9	21	53.8	38.6	68.4
	1	59	57.3	29	49.2	36.8	61.6
	2	5	4.9	2	40.0	11.8	76.9
Geographic region	USA	37	35.9	22	59.5	43.5	73.7
	Europe (EU)	35	34.0	17	48.6	33.0	64.4
	Asia (AS)	31	30.1	13	41.9	26.4	59.2
Race/ethnicity	Asian	33	32.0	14	42.4	27.2	59.2
	Non-Asian	60	58.3	34	56.7	44.1	68.4
	Unknown	10	9.7	4	40.0	16.8	68.7
Number of prior antineoplastic systemic therapy lines I	1	43	41.7	22	51.2	36.8	65.4
	>= 2	60	58.3	30	50.0	37.7	62.3

Clinical cut-off: 18NOV2019

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_resp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_NDA_import/prod/output/eff_resp_B63_18NOV2019_EF_TP_OBRESP_SG.xls
26FEB2021 13:39

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Subjects with Objective Response (Investigator-assessed),
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (efficacy)

		(N=158)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	158	100.0	88	55.7	47.9	63.2
Sex	Female	86	54.4	50	58.1	47.6	68.0
	Male	72	45.6	38	52.8	41.4	63.9
Age	< 65	104	65.8	60	57.7	48.1	66.7
	>= 65	54	34.2	28	51.9	38.9	64.6
ECOG performance status	0	47	29.7	29	61.7	47.4	74.2
	1	106	67.1	57	53.8	44.3	63.0
	2	5	3.2	2	40.0	11.8	76.9
Geographic region	USA	40	25.3	25	62.5	47.0	75.8
	Europe (EU)	45	28.5	26	57.8	43.3	71.0
	Asia (AS)	73	46.2	37	50.7	39.5	61.8
Race/ethnicity	Asian	75	47.5	38	50.7	39.6	61.7
	Non-Asian	72	45.6	45	62.5	51.0	72.8
	Unknown	11	7.0	5	45.5	21.3	72.0
Number of prior antineoplastic systemic therapy lines I	1	73	46.2	45	61.6	50.2	71.9
	>= 2	85	53.8	43	50.6	40.2	61.0

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_resp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_resp_B63_06NOV2020_EF_TP_OBRESP_SG.xls
26FEB2021 13:25

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Subjects with Objective Response (BICR),
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (efficacy)

		(N=158)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	158	100.0	96	60.8	53.0	68.0
Sex	Female	86	54.4	56	65.1	54.6	74.3
	Male	72	45.6	40	55.6	44.1	66.5
Age	< 65	104	65.8	65	62.5	52.9	71.2
	>= 65	54	34.2	31	57.4	44.2	69.7
ECOG performance status	0	47	29.7	32	68.1	53.8	79.6
	1	106	67.1	62	58.5	49.0	67.4
	2	5	3.2	2	40.0	11.8	76.9
Geographic region	USA	40	25.3	24	60.0	44.6	73.7
	Europe (EU)	45	28.5	29	64.4	49.8	76.8
	Asia (AS)	73	46.2	43	58.9	47.4	69.5
Race/ethnicity	Asian	75	47.5	44	58.7	47.4	69.1
	Non-Asian	72	45.6	46	63.9	52.4	74.0
	Unknown	11	7.0	6	54.5	28.0	78.7
Number of prior antineoplastic systemic therapy lines I	1	73	46.2	44	60.3	48.8	70.7
	>= 2	85	53.8	52	61.2	50.5	70.8

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_resp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_resp_B63_06NOV2020_EF_TP_OBRESPRR_SG.xls
26FEB2021 13:24

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Subgroup analysis, Best Overall Response (BICR)
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (efficacy)

			400 mg QD (N=158)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	ORR*	n/a	158	100.0	96	60.8	53.0	68.0
	CR	n/a	158	100.0	7	4.4	2.2	8.9
	PR	n/a	158	100.0	89	56.3	48.5	63.8
	SD	n/a	158	100.0	47	29.7	23.2	37.3
	PD	n/a	158	100.0	8	5.1	2.6	9.7
	NE	n/a	158	100.0	7	4.4	2.2	8.9
Sex	ORR*	Female	86	54.4	56	65.1	54.6	74.3
		Male	72	45.6	40	55.6	44.1	66.5
	CR	Female	86	54.4	5	5.8	2.5	12.9
		Male	72	45.6	2	2.8	0.8	9.6
	PR	Female	86	54.4	51	59.3	48.7	69.1
		Male	72	45.6	38	52.8	41.4	63.9
	SD	Female	86	54.4	23	26.7	18.5	36.9
		Male	72	45.6	24	33.3	23.5	44.8
	PD	Female	86	54.4	6	7.0	3.2	14.4
		Male	72	45.6	2	2.8	0.8	9.6
	NE	Female	86	54.4	1	1.2	0.2	6.3
		Male	72	45.6	6	8.3	3.9	17.0
Age	ORR*	< 65	104	65.8	65	62.5	52.9	71.2
		>= 65	54	34.2	31	57.4	44.2	69.7
	CR	< 65	104	65.8	7	6.7	3.3	13.2
		>= 65	54	34.2	0	0.0	0.0	6.6
	PR	< 65	104	65.8	58	55.8	46.2	64.9
		>= 65	54	34.2	31	57.4	44.2	69.7
	SD	< 65	104	65.8	30	28.8	21.0	38.2
		>= 65	54	34.2	17	31.5	20.7	44.7
	PD	< 65	104	65.8	6	5.8	2.7	12.0
		>= 65	54	34.2	2	3.7	1.0	12.5

	NE	< 65	104	65.8	3	2.9	1.0	8.1
		>= 65	54	34.2	4	7.4	2.9	17.6
ECOG performance status	ORR*	0	47	29.7	32	68.1	53.8	79.6
		1	106	67.1	62	58.5	49.0	67.4
		2	5	3.2	2	40.0	11.8	76.9
	CR	0	47	29.7	3	6.4	2.2	17.2
		1	106	67.1	4	3.8	1.5	9.3
		2	5	3.2	0	0.0	0.0	43.4
	PR	0	47	29.7	29	61.7	47.4	74.2
		1	106	67.1	58	54.7	45.2	63.9
		2	5	3.2	2	40.0	11.8	76.9
	SD	0	47	29.7	12	25.5	15.3	39.5
		1	106	67.1	32	30.2	22.3	39.5
		2	5	3.2	3	60.0	23.1	88.2
	PD	0	47	29.7	2	4.3	1.2	14.2
		1	106	67.1	6	5.7	2.6	11.8
		2	5	3.2	0	0.0	0.0	43.4
	NE	0	47	29.7	1	2.1	0.4	11.1
		1	106	67.1	6	5.7	2.6	11.8
		2	5	3.2	0	0.0	0.0	43.4
Geographic region	ORR*	USA	40	25.3	24	60.0	44.6	73.7
		Europe (EU)	45	28.5	29	64.4	49.8	76.8
		Asia (AS)	73	46.2	43	58.9	47.4	69.5
	CR	USA	40	25.3	3	7.5	2.6	19.9
		Europe (EU)	45	28.5	3	6.7	2.3	17.9
		Asia (AS)	73	46.2	1	1.4	0.2	7.4
	PR	USA	40	25.3	21	52.5	37.5	67.1
		Europe (EU)	45	28.5	26	57.8	43.3	71.0
		Asia (AS)	73	46.2	42	57.5	46.1	68.2
	SD	USA	40	25.3	12	30.0	18.1	45.4
		Europe (EU)	45	28.5	12	26.7	16.0	41.0
		Asia (AS)	73	46.2	23	31.5	22.0	42.9
	PD	USA	40	25.3	2	5.0	1.4	16.5
		Europe (EU)	45	28.5	1	2.2	0.4	11.6
		Asia (AS)	73	46.2	5	6.8	3.0	15.1
	NE	USA	40	25.3	2	5.0	1.4	16.5
		Europe (EU)	45	28.5	3	6.7	2.3	17.9
		Asia (AS)	73	46.2	2	2.7	0.8	9.5
Race/ethnicity	ORR*	Asian	75	47.5	44	58.7	47.4	69.1

		Non-Asian	72	45.6	46	63.9	52.4	74.0
		Unknown	11	7.0	6	54.5	28.0	78.7
	CR	Asian	75	47.5	1	1.3	0.2	7.2
		Non-Asian	72	45.6	6	8.3	3.9	17.0
		Unknown	11	7.0	0	0.0	0.0	25.9
	PR	Asian	75	47.5	43	57.3	46.1	67.9
		Non-Asian	72	45.6	40	55.6	44.1	66.5
		Unknown	11	7.0	6	54.5	28.0	78.7
	SD	Asian	75	47.5	23	30.7	21.4	41.8
		Non-Asian	72	45.6	20	27.8	18.8	39.0
		Unknown	11	7.0	4	36.4	15.2	64.6
	PD	Asian	75	47.5	5	6.7	2.9	14.7
		Non-Asian	72	45.6	3	4.2	1.4	11.5
		Unknown	11	7.0	0	0.0	0.0	25.9
	NE	Asian	75	47.5	3	4.0	1.4	11.1
		Non-Asian	72	45.6	3	4.2	1.4	11.5
		Unknown	11	7.0	1	9.1	1.6	37.7
Number of prior antineoplastic systemic therapy lines I	ORR*	1	73	46.2	44	60.3	48.8	70.7
		>= 2	85	53.8	52	61.2	50.5	70.8
	CR	1	73	46.2	4	5.5	2.2	13.3
		>= 2	85	53.8	3	3.5	1.2	9.9
	PR	1	73	46.2	40	54.8	43.4	65.7
		>= 2	85	53.8	49	57.6	47.0	67.6
	SD	1	73	46.2	22	30.1	20.8	41.4
		>= 2	85	53.8	25	29.4	20.8	39.8
	PD	1	73	46.2	4	5.5	2.2	13.3
		>= 2	85	53.8	4	4.7	1.8	11.5
	NE	1	73	46.2	3	4.1	1.4	11.4
		>= 2	85	53.8	4	4.7	1.8	11.5

95% CI based on Wilson Scores.
*Event is defined as having either complete response (CR) or partial response (PR).
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_resp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/eff_resp_B63_06NOV2020_EF_TP_BORR_SG.xls
27MAY2021 12:28

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Subgroup analysis, Duration of Response per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
MODEL: Unstratified analysis
STUDY: BO42863
Time to event analysis

		(N=158)								
		Patients		Patients with Event		Censored		Time To Event		
Name	Level	n	%	n	%	n	%	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	96	60.8	35	36.5	61	63.5	22.3	15.1	NE
Sex	Female	56	35.4	17	30.4	39	69.6	NE	16.4	NE
	Male	40	25.3	18	45.0	22	55.0	14.5	8.8	NE
Age	< 65	65	41.1	21	32.3	44	67.7	22.3	15.1	NE
	>= 65	31	19.6	14	45.2	17	54.8	15.2	8.8	NE
ECOG performance status	0	32	20.3	11	34.4	21	65.6	NE	16.4	NE
	1	62	39.2	22	35.5	40	64.5	22.3	10.6	NE
	2	2	1.3	2	100.0	0	0.0	-	-	-
Geographic region	USA	24	15.2	9	37.5	15	62.5	22.3	13.1	NE
	Europe (EU)	29	18.4	12	41.4	17	58.6	16.4	9.2	NE
	Asia (AS)	43	27.2	14	32.6	29	67.4	NE	10.6	NE
Race/ethnicity	Asian	44	27.8	15	34.1	29	65.9	NE	10.6	NE
	Non-Asian	46	29.1	18	39.1	28	60.9	22.3	14.7	NE
	Unknown	6	3.8	2	33.3	4	66.7	-	-	-
Number of prior antineoplastic systemic therapy lines I	1	44	27.8	15	34.1	29	65.9	NE	11.1	NE
	>= 2	52	32.9	20	38.5	32	61.5	22.3	14.7	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_tte2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_tte2_B63_06NOV2020_EF_TP_DORRREMA_SG.xls
25FEB2021 20:57

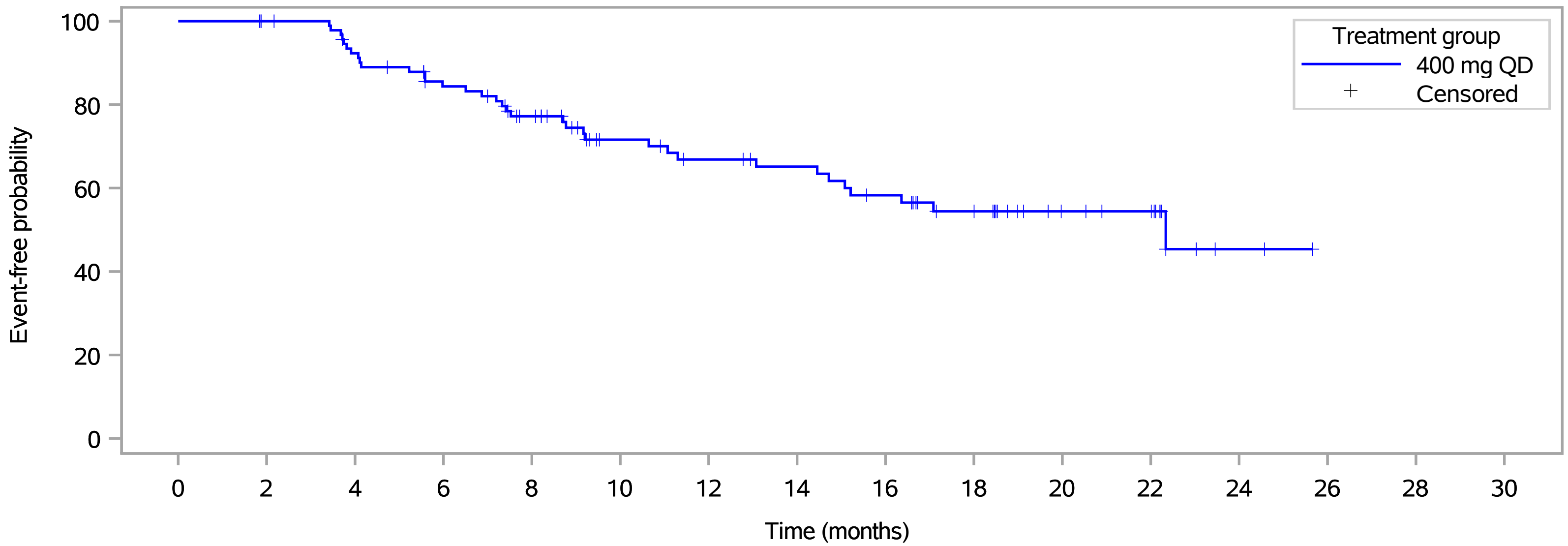
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Subgroup analysis, Time to Response (BICR)
MODEL: Unstratified analysis
STUDY: BO42863
Time to event analysis

		(N=158)								
		Patients		Patients with Event		Censored		Time To Event		
Name	Level	n	%	n	%	n	%	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	96	60.8	96	100.0	0	0.0	1.8	1.8	1.9
Sex	Female	56	35.4	56	100.0	0	0.0	1.8	1.8	1.9
	Male	40	25.3	40	100.0	0	0.0	1.8	1.8	1.9
Age	< 65	65	41.1	65	100.0	0	0.0	1.8	1.8	1.8
	>= 65	31	19.6	31	100.0	0	0.0	1.9	1.8	1.9
ECOG performance status	0	32	20.3	32	100.0	0	0.0	1.8	1.8	1.8
	1	62	39.2	62	100.0	0	0.0	1.8	1.8	1.9
	2	2	1.3	2	100.0	0	0.0	-	-	-
Geographic region	USA	24	15.2	24	100.0	0	0.0	1.8	1.8	2.2
	Europe (EU)	29	18.4	29	100.0	0	0.0	1.8	1.7	1.9
	Asia (AS)	43	27.2	43	100.0	0	0.0	1.8	1.8	1.9
Race/ethnicity	Asian	44	27.8	44	100.0	0	0.0	1.8	1.8	1.9
	Non-Asian	46	29.1	46	100.0	0	0.0	1.8	1.8	1.9
	Unknown	6	3.8	6	100.0	0	0.0	-	-	-
Number of prior antineoplastic systemic therapy lines I	1	44	27.8	44	100.0	0	0.0	1.8	1.8	1.9
	>= 2	52	32.9	52	100.0	0	0.0	1.8	1.8	1.9

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_tte2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_tte2_B63_06NOV2020_EF_TP_TTRESPRR_SG.xls
25FEB2021 20:58

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Duration of Response per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

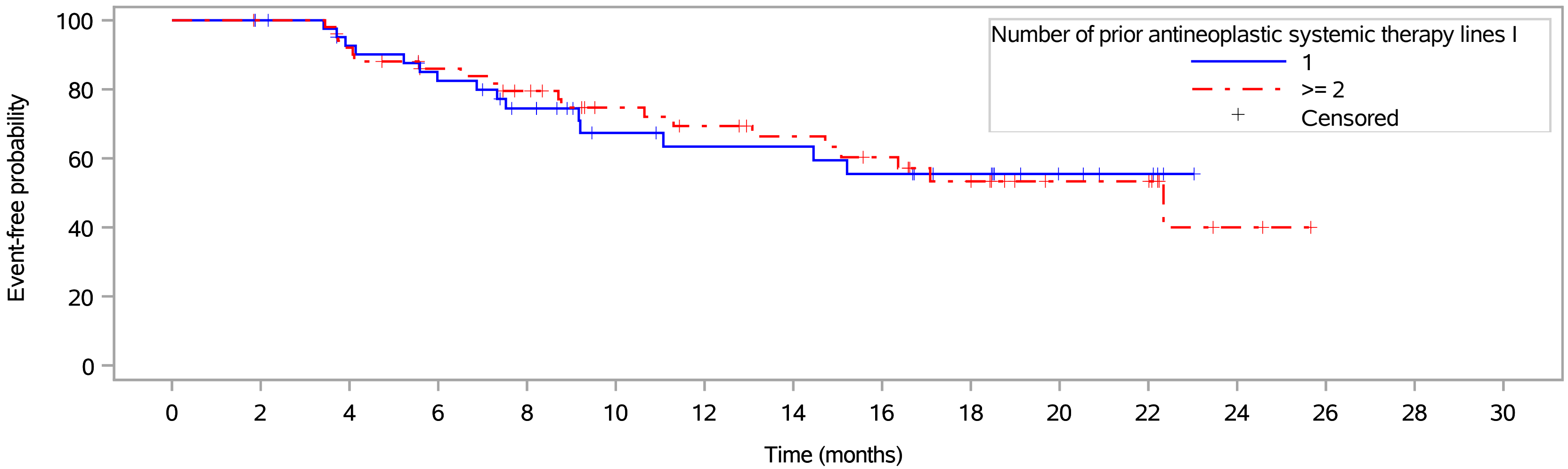


Patients at risk															
400 mg QD	96	93	83	72	61	46	41	38	33	25	14	12	2	NE	NE	NE
Patients censored																
400 mg QD	0	3	6	10	15	26	28	30	31	37	48	50	59	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_DORRREMA.pdf
23MAR2021 8:44

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Duration of Response per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

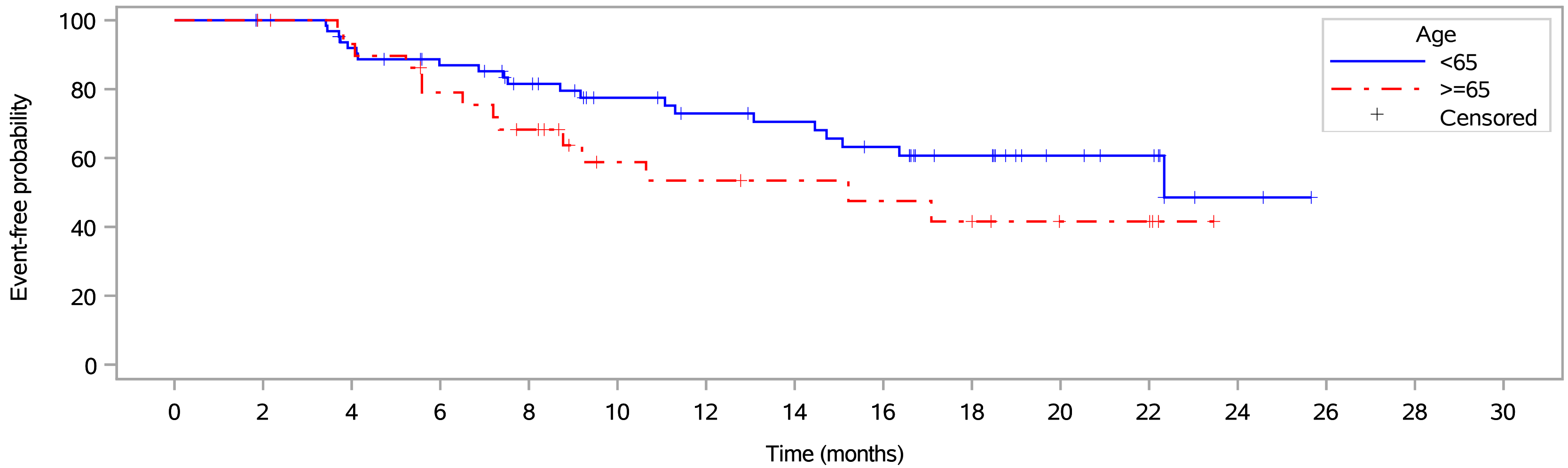


Patients at risk																
1	44	42	37	32	26	18	16	16	14	11	6	4	NE	NE	NE	NE
>= 2	52	51	46	40	35	28	25	22	19	14	8	8	2	NE	NE	NE
Patients censored																
1	0	2	4	5	8	14	15	15	15	18	23	25	NE	NE	NE	NE
>= 2	0	1	2	5	7	12	13	15	16	19	25	25	30	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_DORRREMA_PRTHL1.pdf
23MAR2021 8:47

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Duration of Response per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

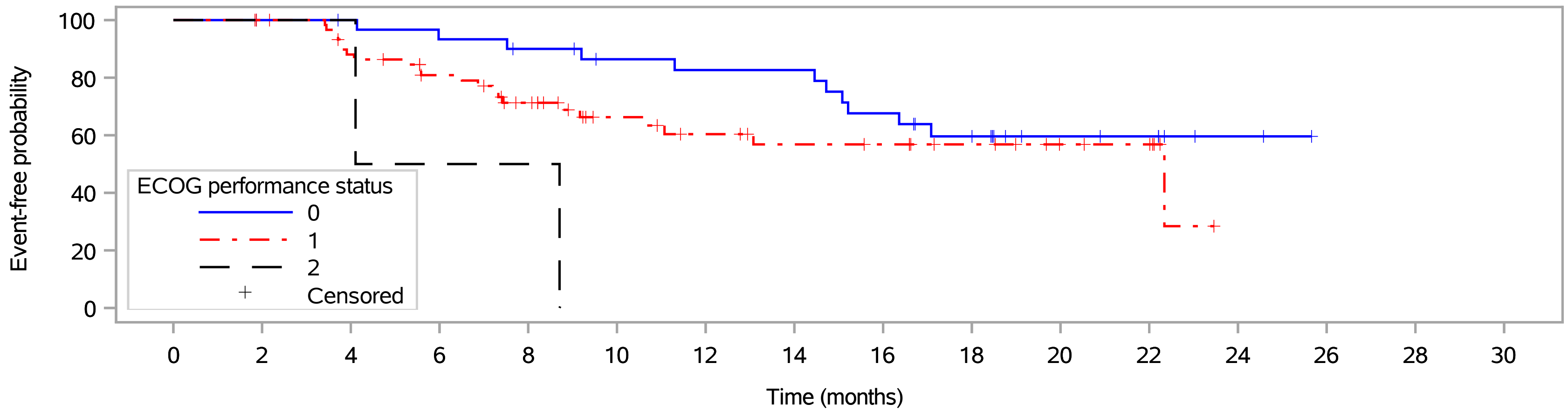


Patients at risk															
<65	65	63	56	50	43	35	31	29	25	18	10	8	2	NE	NE	NE
>=65	31	30	27	22	18	11	10	9	8	7	4	4	NE	NE	NE	NE
Patients censored																
<65	0	2	4	7	11	17	19	20	21	27	35	37	42	NE	NE	NE
>=65	0	1	2	3	4	9	9	10	10	10	13	13	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_DORRREMA_SGAGE65.pdf
23MAR2021 8:44

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Duration of Response per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

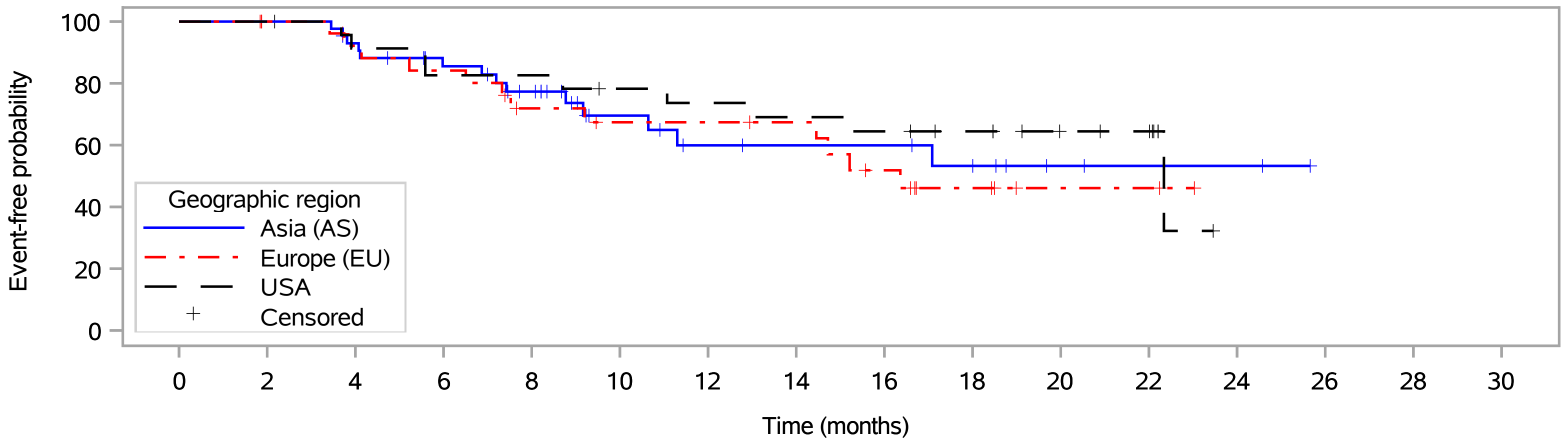


Patients at risk																
0	32	31	30	28	26	23	22	22	18	14	7	6	2	NE	NE	NE
1	62	60	51	43	34	23	19	16	15	11	7	6	NE	NE	NE	NE
2	2	2	2	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
0	0	1	2	2	3	5	5	5	5	7	14	15	19	NE	NE	NE
1	0	2	4	8	12	21	23	25	26	30	34	35	NE	NE	NE	NE
2	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_DORRREMA_SGECOG.pdf
23MAR2021 8:45

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Duration of Response per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

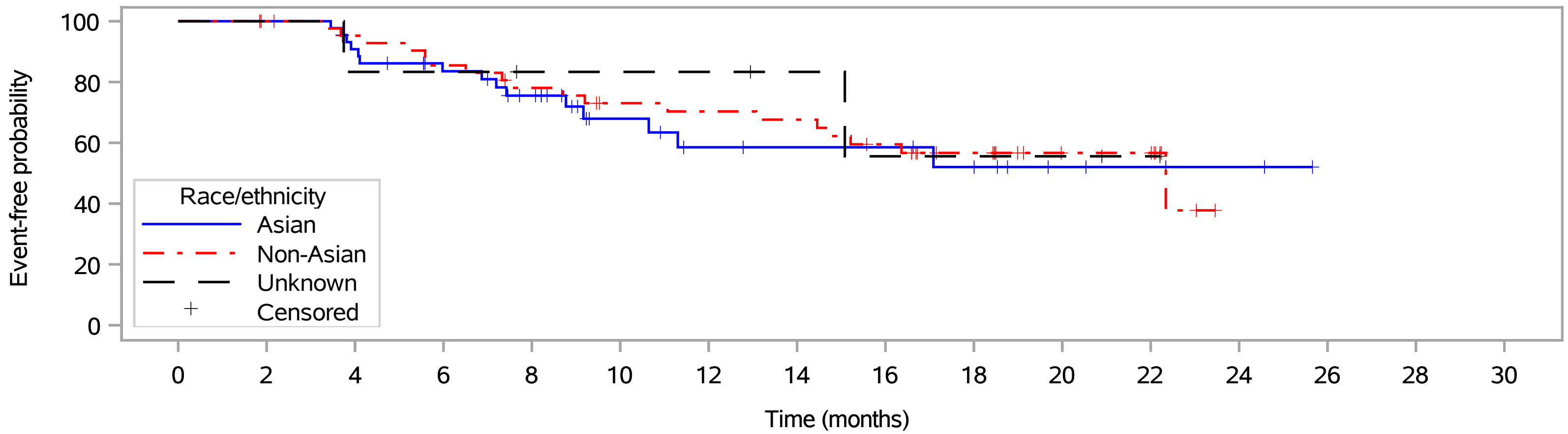


Patients at risk																
Asia (AS)	43	43	39	32	26	15	11	10	10	8	4	3	2	NE	NE	NE
Europe (EU)	29	26	23	21	16	14	14	13	9	5	2	2	NE	NE	NE	NE
USA	24	24	21	19	19	17	16	15	14	12	8	7	NE	NE	NE	NE
Patients censored																
Asia (AS)	0	0	1	5	8	17	19	20	20	21	25	26	27	NE	NE	NE
Europe (EU)	0	3	4	4	6	7	7	8	9	12	15	15	NE	NE	NE	NE
USA	0	0	1	1	1	2	2	2	2	4	8	9	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_DORRREMA_SGGEO.pdf
23MAR2021 8:46

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Duration of Response per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

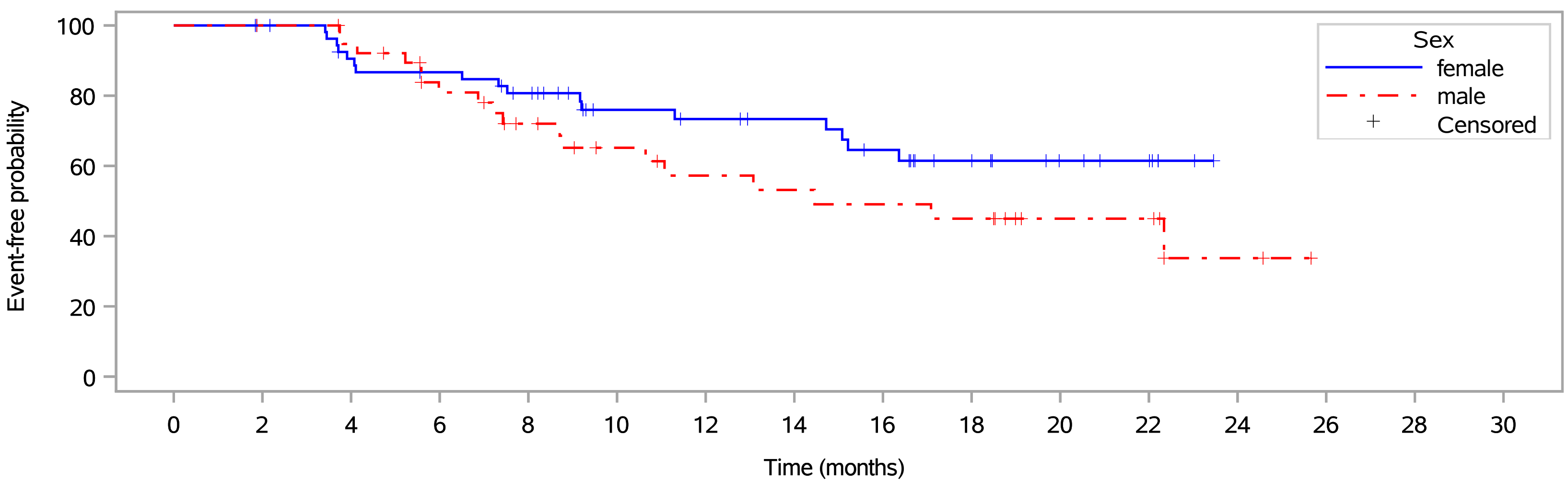


Patients at risk																
Asian	44	44	39	32	26	15	11	10	10	8	4	3	2	NE	NE	NE
Non-Asian	46	43	39	35	31	27	26	25	21	15	8	8	NE	NE	NE	NE
Unknown	6	6	5	5	4	4	4	3	2	2	2	1	NE	NE	NE	NE
Patients censored																
Asian	0	0	1	5	8	17	19	20	20	21	25	26	27	NE	NE	NE
Non-Asian	0	3	5	5	6	8	8	8	9	14	21	21	NE	NE	NE	NE
Unknown	0	0	0	0	1	1	1	2	2	2	2	3	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_DORRREMA_SGRE.pdf
23MAR2021 8:46

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Duration of Response per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

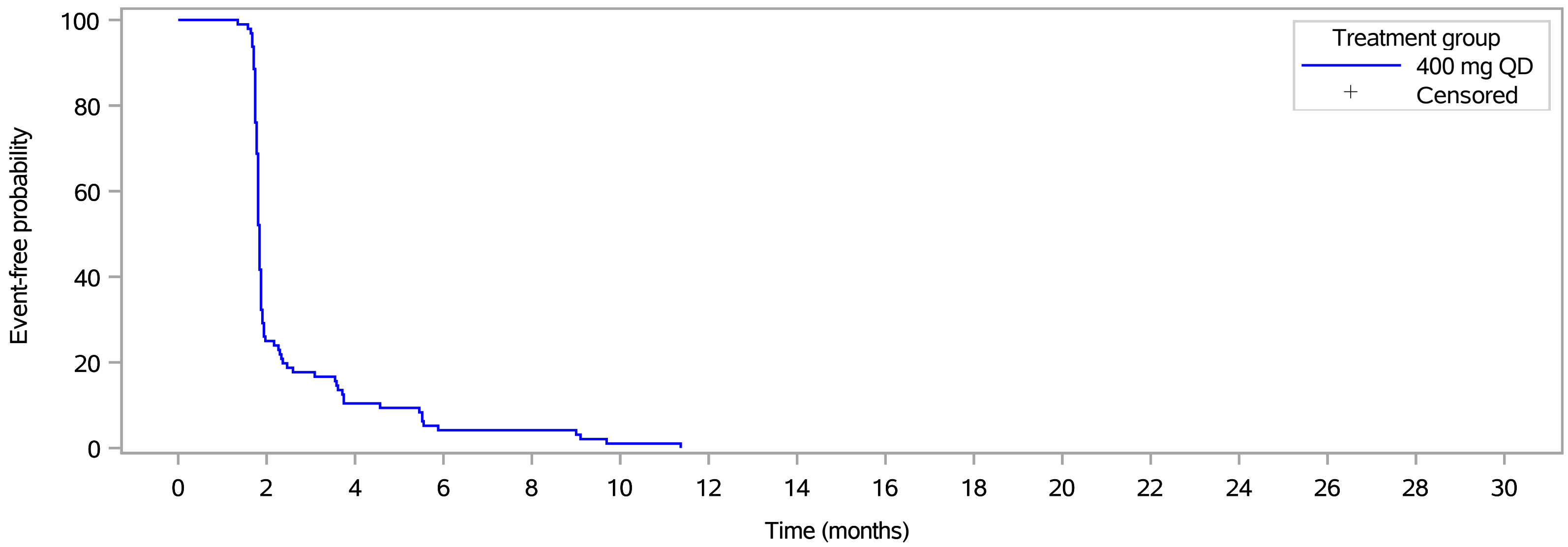


Patients at risk																
female	56	54	47	44	39	29	27	25	21	14	8	6	NE	NE	NE	NE
male	40	39	36	28	22	17	14	13	12	11	6	6	2	NE	NE	NE
Patients censored																
female	0	2	4	5	7	15	16	18	19	25	31	33	NE	NE	NE	NE
male	0	1	2	5	8	11	12	12	12	12	17	17	20	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_DORRREMA_SGSEX.pdf
23MAR2021 8:45

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Time to Response (BICR)
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

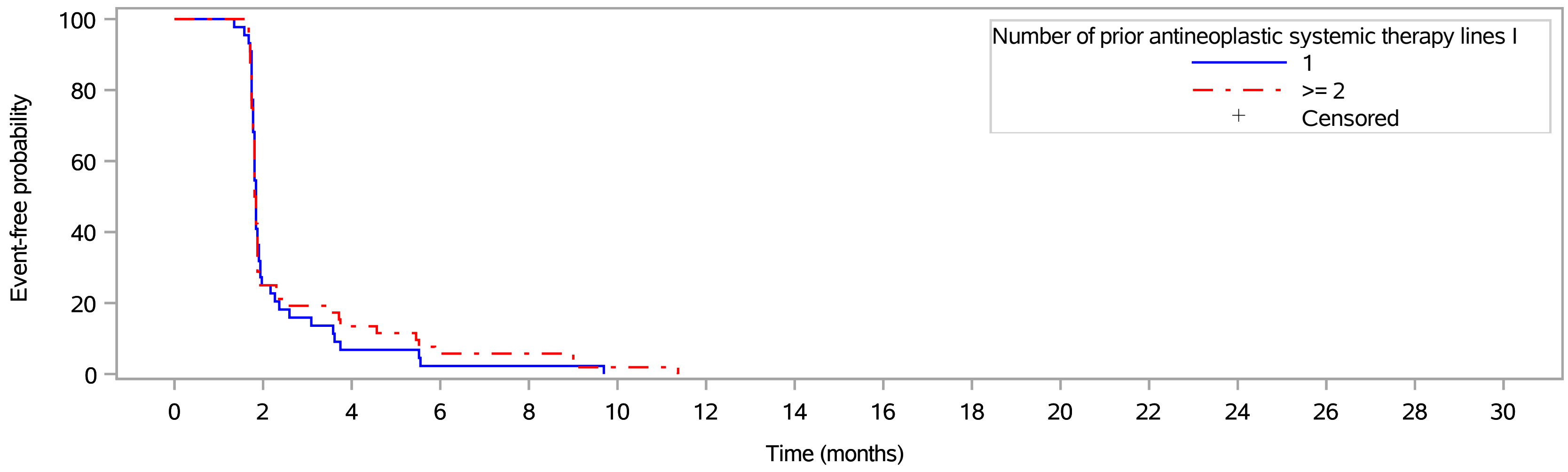


Patients at risk																
400 mg QD	96	24	10	4	4	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
400 mg QD	0	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_TTRESPRR.pdf
23MAR2021 8:51

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Time to Response (BICR)
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

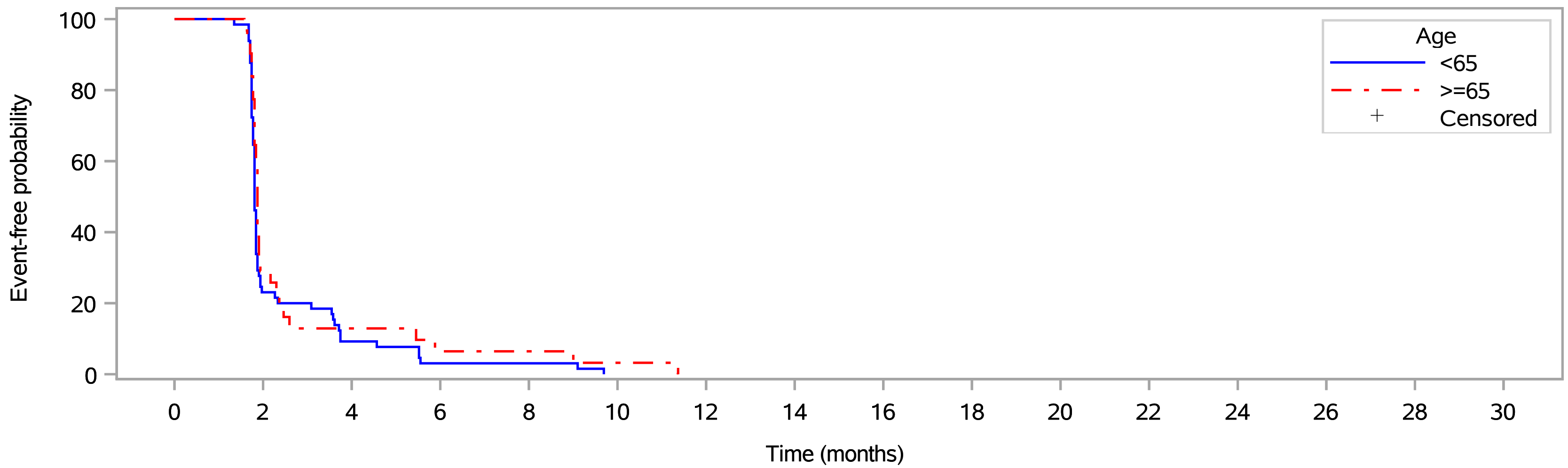


Patients at risk																
1	44	11	3	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
>= 2	52	13	7	3	3	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
1	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
>= 2	0	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_TTRESPRR_PRTHL1.pdf
23MAR2021 8:54

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Time to Response (BICR)
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

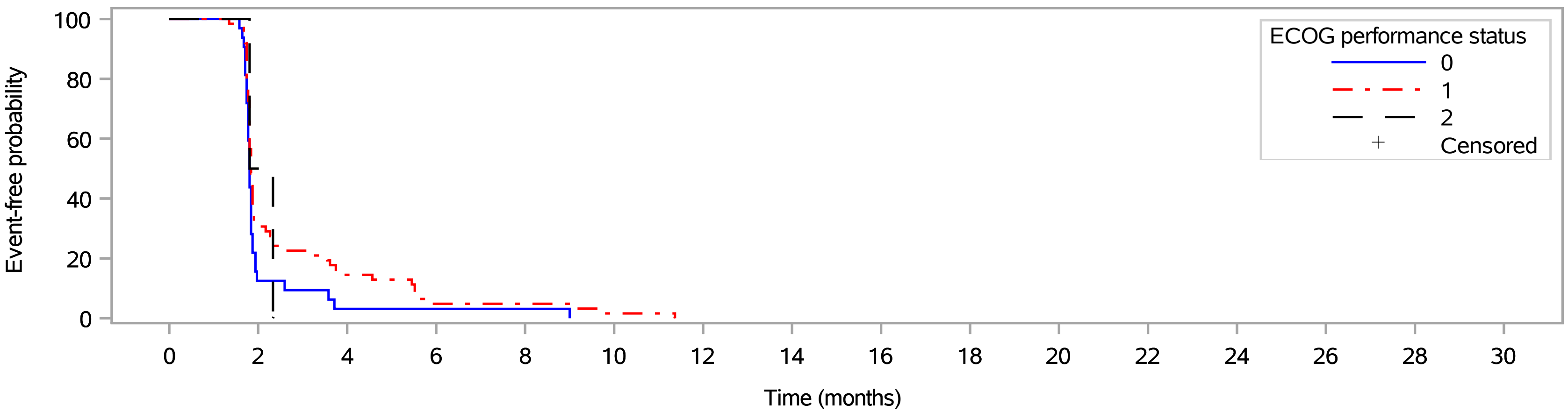


Patients at risk																
<65	65	15	6	2	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
>=65	31	9	4	2	2	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
<65	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
>=65	0	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_TTRESPRR_SGAGE65.pdf
23MAR2021 8:52

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Time to Response (BICR)
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

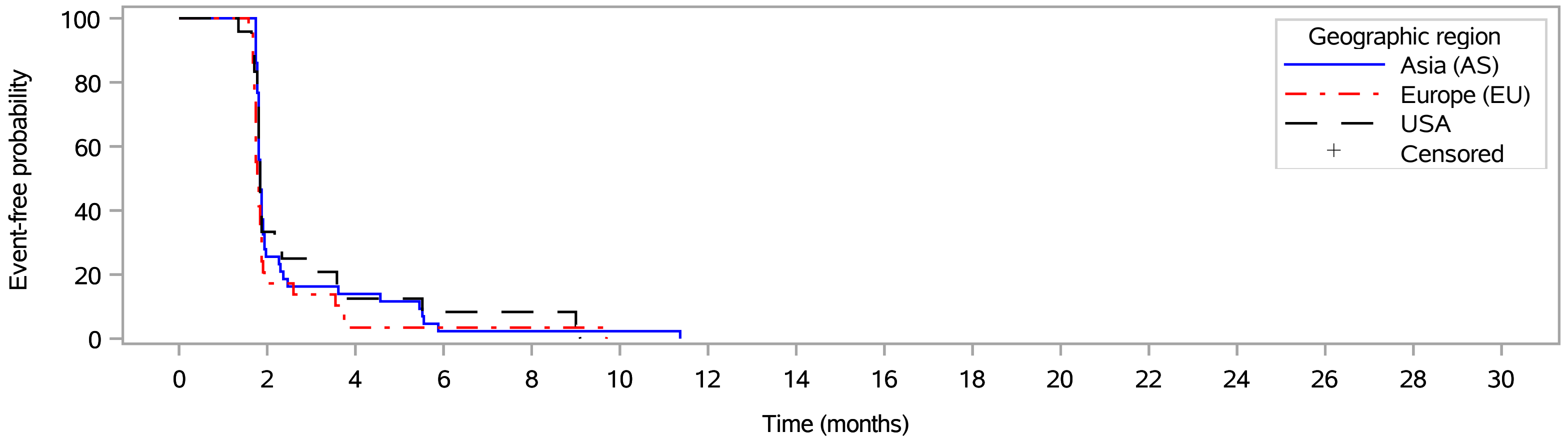


Patients at risk																
0	32	4	1	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
1	62	19	9	3	3	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
2	2	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
0	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
1	0	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
2	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_TTRESPRR_SGECOG.pdf
23MAR2021 8:53

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Time to Response (BICR)
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

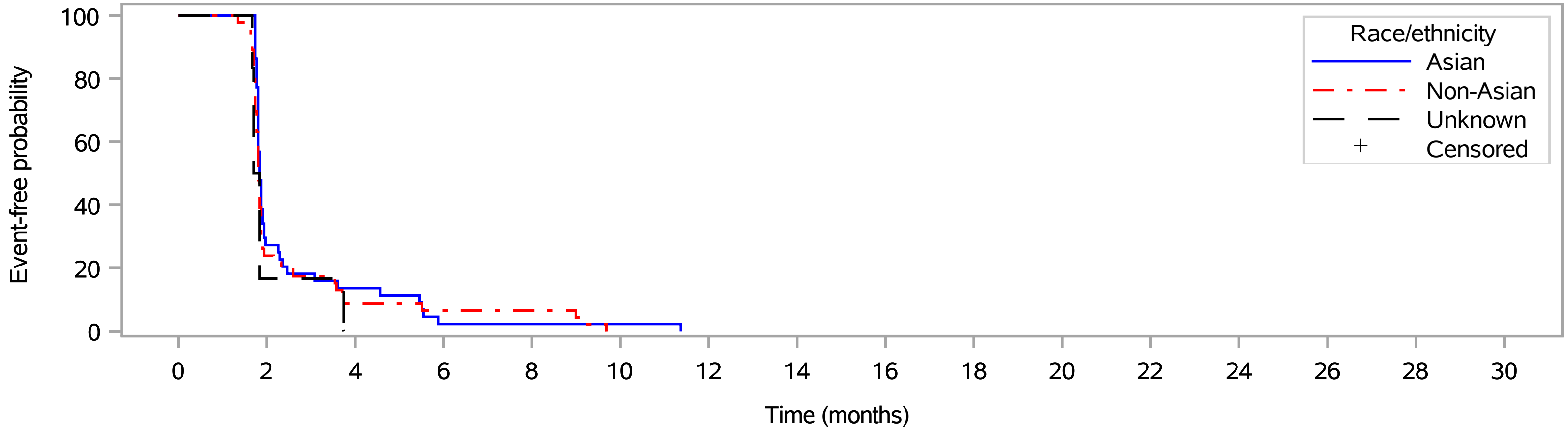


Patients at risk																
Asia (AS)	43	11	6	1	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Europe (EU)	29	5	1	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
USA	24	8	3	2	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
Asia (AS)	0	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Europe (EU)	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
USA	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_TTRESPRR_SGGEO.pdf
23MAR2021 8:53

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Time to Response (BICR)
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

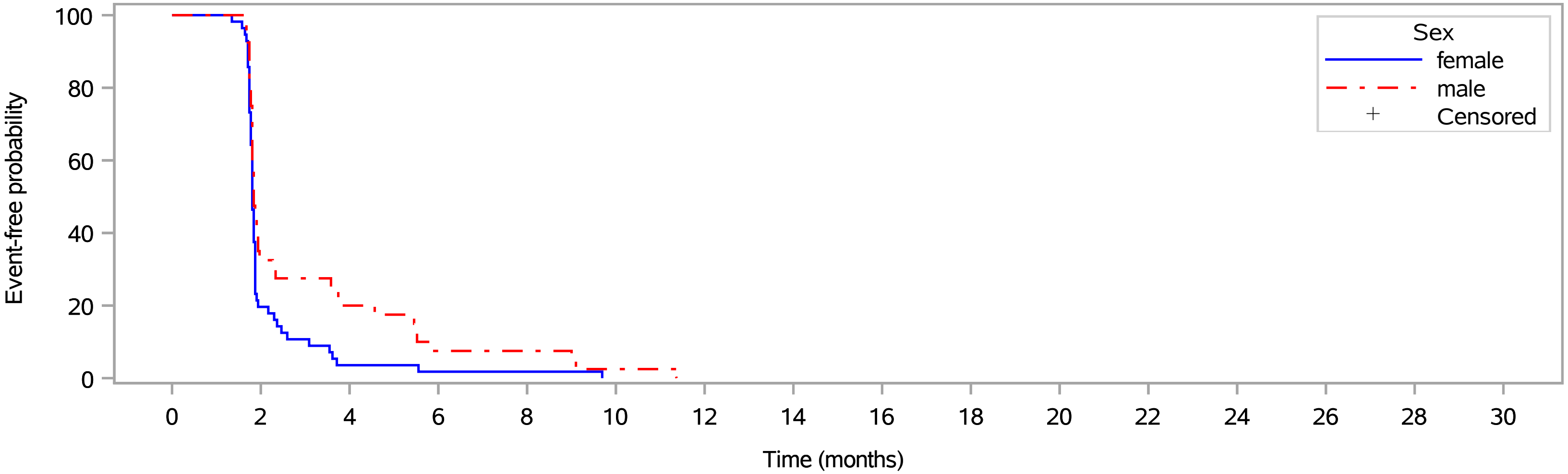


Patients at risk																
Asian	44	12	6	1	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Non-Asian	46	11	4	3	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Unknown	6	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
Asian	0	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Non-Asian	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Unknown	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_TTRESPRR_SGRE.pdf
23MAR2021 8:54

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Time to Response (BICR)
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)



Patients at risk																
female	56	11	2	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
male	40	13	8	3	3	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
female	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
male	0	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_TTRESPRR_SGSEX.pdf
23MAR2021 8:52

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Subgroup analysis, Best Overall Response (BICR)
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (efficacy)

			400 mg QD (N=132)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	ORR*	n/a	132	100.0	75	56.8	48.3	65.0
	CR	n/a	132	100.0	8	6.1	3.1	11.5
	PR	n/a	132	100.0	67	50.8	42.3	59.1
	SD	n/a	132	100.0	41	31.1	23.8	39.4
	PD	n/a	132	100.0	10	7.6	4.2	13.4
	NE	n/a	132	100.0	6	4.5	2.1	9.6
Sex	ORR*	Female	69	52.3	45	65.2	53.4	75.4
		Male	63	47.7	30	47.6	35.8	59.7
	CR	Female	69	52.3	7	10.1	5.0	19.5
		Male	63	47.7	1	1.6	0.3	8.5
	PR	Female	69	52.3	38	55.1	43.4	66.2
		Male	63	47.7	29	46.0	34.3	58.2
	SD	Female	69	52.3	16	23.2	14.8	34.4
		Male	63	47.7	25	39.7	28.5	52.0
	PD	Female	69	52.3	6	8.7	4.0	17.7
		Male	63	47.7	4	6.3	2.5	15.2
	NE	Female	69	52.3	2	2.9	0.8	10.0
		Male	63	47.7	4	6.3	2.5	15.2
Age	ORR*	< 65	81	61.4	51	63.0	52.1	72.7
		>= 65	51	38.6	24	47.1	34.1	60.5
	CR	< 65	81	61.4	8	9.9	5.1	18.3
		>= 65	51	38.6	0	0.0	0.0	7.0
	PR	< 65	81	61.4	43	53.1	42.3	63.6
		>= 65	51	38.6	24	47.1	34.1	60.5
	SD	< 65	81	61.4	20	24.7	16.6	35.1
		>= 65	51	38.6	21	41.2	28.8	54.8
	PD	< 65	81	61.4	7	8.6	4.2	16.8

		>= 65	51	38.6	3	5.9	2.0	15.9
	NE	< 65	81	61.4	3	3.7	1.3	10.3
		>= 65	51	38.6	3	5.9	2.0	15.9
ECOG performance status	ORR*	0	50	37.9	34	68.0	54.2	79.2
		1	76	57.6	38	50.0	39.0	61.0
		2	6	4.5	3	50.0	18.8	81.2
	CR	0	50	37.9	4	8.0	3.2	18.8
		1	76	57.6	4	5.3	2.1	12.8
		2	6	4.5	0	0.0	0.0	39.0
	PR	0	50	37.9	30	60.0	46.2	72.4
		1	76	57.6	34	44.7	34.1	55.9
		2	6	4.5	3	50.0	18.8	81.2
	SD	0	50	37.9	12	24.0	14.3	37.4
		1	76	57.6	26	34.2	24.5	45.4
		2	6	4.5	3	50.0	18.8	81.2
	PD	0	50	37.9	3	6.0	2.1	16.2
		1	76	57.6	7	9.2	4.5	17.8
		2	6	4.5	0	0.0	0.0	39.0
	NE	0	50	37.9	1	2.0	0.4	10.5
		1	76	57.6	5	6.6	2.8	14.5
		2	6	4.5	0	0.0	0.0	39.0
Geographic region	ORR*	USA	44	33.3	31	70.5	55.8	81.8
		Europe (EU)	49	37.1	25	51.0	37.5	64.4
		Asia (AS)	39	29.5	19	48.7	33.9	63.8
	CR	USA	44	33.3	2	4.5	1.3	15.1
		Europe (EU)	49	37.1	4	8.2	3.2	19.2
		Asia (AS)	39	29.5	2	5.1	1.4	16.9
	PR	USA	44	33.3	29	65.9	51.1	78.1
		Europe (EU)	49	37.1	21	42.9	30.0	56.7
		Asia (AS)	39	29.5	17	43.6	29.3	59.0
	SD	USA	44	33.3	10	22.7	12.8	37.0
		Europe (EU)	49	37.1	18	36.7	24.7	50.7
		Asia (AS)	39	29.5	13	33.3	20.6	49.0
	PD	USA	44	33.3	1	2.3	0.4	11.8
		Europe (EU)	49	37.1	3	6.1	2.1	16.5
		Asia (AS)	39	29.5	6	15.4	7.2	29.7
	NE	USA	44	33.3	2	4.5	1.3	15.1
		Europe (EU)	49	37.1	3	6.1	2.1	16.5
		Asia (AS)	39	29.5	1	2.6	0.5	13.2

Race/ethnicity	ORR*	Asian	43	32.6	22	51.2	36.8	65.4
		Non-Asian	78	59.1	47	60.3	49.2	70.4
		Unknown	11	8.3	6	54.5	28.0	78.7
	CR	Asian	43	32.6	2	4.7	1.3	15.5
		Non-Asian	78	59.1	6	7.7	3.6	15.8
		Unknown	11	8.3	0	0.0	0.0	25.9
	PR	Asian	43	32.6	20	46.5	32.5	61.1
		Non-Asian	78	59.1	41	52.6	41.6	63.3
		Unknown	11	8.3	6	54.5	28.0	78.7
	SD	Asian	43	32.6	13	30.2	18.6	45.1
		Non-Asian	78	59.1	24	30.8	21.6	41.7
		Unknown	11	8.3	4	36.4	15.2	64.6
	PD	Asian	43	32.6	6	14.0	6.6	27.3
		Non-Asian	78	59.1	4	5.1	2.0	12.5
		Unknown	11	8.3	0	0.0	0.0	25.9
	NE	Asian	43	32.6	2	4.7	1.3	15.5
		Non-Asian	78	59.1	3	3.8	1.3	10.7
		Unknown	11	8.3	1	9.1	1.6	37.7

95% CI based on Wilson Scores.
*Event is defined as having either complete response (CR) or partial response (PR).
Clinical cut-off: 18NOV2019

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_resp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_NDA/prod/output/eff_resp_B63_18NOV2019_EF_TO_BORR_SG.xls
28MAY2021 16:53

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Subjects with Objective Response (Investigator-assessed),
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (efficacy)

		(N=132)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	132	100.0	69	52.3	43.8	60.6
Sex	Female	69	52.3	39	56.5	44.8	67.6
	Male	63	47.7	30	47.6	35.8	59.7
Age	< 65	81	61.4	47	58.0	47.2	68.2
	>= 65	51	38.6	22	43.1	30.5	56.7
ECOG performance status	0	50	37.9	28	56.0	42.3	68.8
	1	76	57.6	38	50.0	39.0	61.0
	2	6	4.5	3	50.0	18.8	81.2
Geographic region	USA	44	33.3	27	61.4	46.6	74.3
	Europe (EU)	49	37.1	23	46.9	33.7	60.6
	Asia (AS)	39	29.5	19	48.7	33.9	63.8
Race/ethnicity	Asian	43	32.6	22	51.2	36.8	65.4
	Non-Asian	78	59.1	43	55.1	44.1	65.7
	Unknown	11	8.3	4	36.4	15.2	64.6

Clinical cut-off: 18NOV2019

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_resp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_NDA_import/prod/output/eff_resp_B63_18NOV2019_EF_TO_OBRESP_SG.xls
26FEB2021 13:38

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Subjects with Objective Response (BICR),
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (efficacy)

		(N=233)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	233	100.0	150	64.4	58.0	70.2
Sex	Female	122	52.4	83	68.0	59.3	75.6
	Male	111	47.6	67	60.4	51.1	69.0
Age	< 65	145	62.2	100	69.0	61.0	75.9
	>= 65	88	37.8	50	56.8	46.4	66.7
ECOG performance status	0	78	33.5	58	74.4	63.7	82.7
	1	149	63.9	89	59.7	51.7	67.3
	2	6	2.6	3	50.0	18.8	81.2
Geographic region	USA	62	26.6	43	69.4	57.0	79.4
	Europe (EU)	85	36.5	55	64.7	54.1	74.0
	Asia (AS)	86	36.9	52	60.5	49.9	70.1
Race/ethnicity	Asian	92	39.5	56	60.9	50.7	70.2
	Non-Asian	125	53.6	84	67.2	58.6	74.8
	Unknown	16	6.9	10	62.5	38.6	81.5

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_resp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_resp_B63_06NOV2020_EF_TO_OBRESPRR_SG.xls
26FEB2021 13:23

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Subjects with Objective Response (Investigator-assessed),
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (efficacy)

		(N=233)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	233	100.0	145	62.2	55.9	68.2
Sex	Female	122	52.4	79	64.8	55.9	72.7
	Male	111	47.6	66	59.5	50.2	68.1
Age	< 65	145	62.2	93	64.1	56.1	71.5
	>= 65	88	37.8	52	59.1	48.6	68.8
ECOG performance status	0	78	33.5	54	69.2	58.3	78.4
	1	149	63.9	88	59.1	51.0	66.6
	2	6	2.6	3	50.0	18.8	81.2
Geographic region	USA	62	26.6	45	72.6	60.4	82.1
	Europe (EU)	85	36.5	52	61.2	50.5	70.8
	Asia (AS)	86	36.9	48	55.8	45.3	65.8
Race/ethnicity	Asian	92	39.5	53	57.6	47.4	67.2
	Non-Asian	125	53.6	82	65.6	56.9	73.4
	Unknown	16	6.9	10	62.5	38.6	81.5

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_resp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_resp_B63_06NOV2020_EF_TO_OBRESP_SG.xls
26FEB2021 13:24

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Subgroup analysis, Best Overall Response (BICR)
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (efficacy)

			400 mg QD (N=233)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	ORR*	n/a	233	100.0	150	64.4	58.0	70.2
	CR	n/a	233	100.0	11	4.7	2.7	8.3
	PR	n/a	233	100.0	139	59.7	53.3	65.7
	SD	n/a	233	100.0	61	26.2	21.0	32.2
	PD	n/a	233	100.0	13	5.6	3.3	9.3
	NE	n/a	233	100.0	9	3.9	2.0	7.2
Sex	ORR*	Female	122	52.4	83	68.0	59.3	75.6
		Male	111	47.6	67	60.4	51.1	69.0
	CR	Female	122	52.4	8	6.6	3.4	12.4
		Male	111	47.6	3	2.7	0.9	7.6
	PR	Female	122	52.4	75	61.5	52.6	69.6
		Male	111	47.6	64	57.7	48.4	66.4
	SD	Female	122	52.4	28	23.0	16.4	31.2
		Male	111	47.6	33	29.7	22.0	38.8
	PD	Female	122	52.4	9	7.4	3.9	13.4
		Male	111	47.6	4	3.6	1.4	8.9
	NE	Female	122	52.4	2	1.6	0.5	5.8
		Male	111	47.6	7	6.3	3.1	12.4
Age	ORR*	< 65	145	62.2	100	69.0	61.0	75.9
		>= 65	88	37.8	50	56.8	46.4	66.7
	CR	< 65	145	62.2	10	6.9	3.8	12.2
		>= 65	88	37.8	1	1.1	0.2	6.2
	PR	< 65	145	62.2	90	62.1	54.0	69.6
		>= 65	88	37.8	49	55.7	45.3	65.6
	SD	< 65	145	62.2	33	22.8	16.7	30.2
		>= 65	88	37.8	28	31.8	23.0	42.1
	PD	< 65	145	62.2	8	5.5	2.8	10.5
		>= 65	88	37.8	5	5.7	2.5	12.6

	NE	< 65	145	62.2	4	2.8	1.1	6.9
		>= 65	88	37.8	5	5.7	2.5	12.6
ECOG performance status	ORR*	0	78	33.5	58	74.4	63.7	82.7
		1	149	63.9	89	59.7	51.7	67.3
		2	6	2.6	3	50.0	18.8	81.2
	CR	0	78	33.5	5	6.4	2.8	14.1
		1	149	63.9	6	4.0	1.9	8.5
		2	6	2.6	0	0.0	0.0	39.0
	PR	0	78	33.5	53	67.9	57.0	77.3
		1	149	63.9	83	55.7	47.7	63.4
		2	6	2.6	3	50.0	18.8	81.2
	SD	0	78	33.5	16	20.5	13.0	30.8
		1	149	63.9	42	28.2	21.6	35.9
		2	6	2.6	3	50.0	18.8	81.2
	PD	0	78	33.5	3	3.8	1.3	10.7
		1	149	63.9	10	6.7	3.7	11.9
		2	6	2.6	0	0.0	0.0	39.0
	NE	0	78	33.5	1	1.3	0.2	6.9
		1	149	63.9	8	5.4	2.7	10.2
		2	6	2.6	0	0.0	0.0	39.0
Geographic region	ORR*	USA	62	26.6	43	69.4	57.0	79.4
		Europe (EU)	85	36.5	55	64.7	54.1	74.0
		Asia (AS)	86	36.9	52	60.5	49.9	70.1
	CR	USA	62	26.6	3	4.8	1.7	13.3
		Europe (EU)	85	36.5	4	4.7	1.8	11.5
		Asia (AS)	86	36.9	4	4.7	1.8	11.4
	PR	USA	62	26.6	40	64.5	52.1	75.3
		Europe (EU)	85	36.5	51	60.0	49.4	69.8
		Asia (AS)	86	36.9	48	55.8	45.3	65.8
	SD	USA	62	26.6	15	24.2	15.2	36.2
		Europe (EU)	85	36.5	22	25.9	17.8	36.1
		Asia (AS)	86	36.9	24	27.9	19.5	38.2
	PD	USA	62	26.6	2	3.2	0.9	11.0
		Europe (EU)	85	36.5	3	3.5	1.2	9.9
		Asia (AS)	86	36.9	8	9.3	4.8	17.3
	NE	USA	62	26.6	2	3.2	0.9	11.0
		Europe (EU)	85	36.5	5	5.9	2.5	13.0
		Asia (AS)	86	36.9	2	2.3	0.6	8.1
Race/ethnicity	ORR*	Asian	92	39.5	56	60.9	50.7	70.2

		Non-Asian	125	53.6	84	67.2	58.6	74.8
		Unknown	16	6.9	10	62.5	38.6	81.5
	CR	Asian	92	39.5	4	4.3	1.7	10.7
		Non-Asian	125	53.6	7	5.6	2.7	11.1
		Unknown	16	6.9	0	0.0	0.0	19.4
	PR	Asian	92	39.5	52	56.5	46.3	66.2
		Non-Asian	125	53.6	77	61.6	52.8	69.7
		Unknown	16	6.9	10	62.5	38.6	81.5
	SD	Asian	92	39.5	25	27.2	19.1	37.0
		Non-Asian	125	53.6	31	24.8	18.1	33.0
		Unknown	16	6.9	5	31.3	14.2	55.6
	PD	Asian	92	39.5	8	8.7	4.5	16.2
		Non-Asian	125	53.6	5	4.0	1.7	9.0
		Unknown	16	6.9	0	0.0	0.0	19.4
	NE	Asian	92	39.5	3	3.3	1.1	9.2
		Non-Asian	125	53.6	5	4.0	1.7	9.0
		Unknown	16	6.9	1	6.3	1.1	28.3

95% CI based on Wilson Scores.
*Event is defined as having either complete response (CR) or partial response (PR).
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_resp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/eff_resp_B63_06NOV2020_EF_TO_BORR_SG.xls
27MAY2021 12:30

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Subgroup analysis, Duration of Response per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
MODEL: Unstratified analysis
STUDY: BO42863
Time to event analysis

		(N=233)								
		Patients		Patients with Event		Censored		Time To Event		
Name	Level	n	%	n	%	n	%	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	150	64.4	49	32.7	101	67.3	22.3	14.7	NE
Sex	Female	83	35.6	24	28.9	59	71.1	NE	15.2	NE
	Male	67	28.8	25	37.3	42	62.7	14.5	9.2	NE
Age	< 65	100	42.9	29	29.0	71	71.0	22.3	15.1	NE
	>= 65	50	21.5	20	40.0	30	60.0	15.2	9.0	NE
ECOG performance status	0	58	24.9	16	27.6	42	72.4	NE	15.2	NE
	1	89	38.2	30	33.7	59	66.3	22.3	10.6	NE
	2	3	1.3	3	100.0	0	0.0	-	-	-
Geographic region	USA	43	18.5	15	34.9	28	65.1	22.3	11.1	NE
	Europe (EU)	55	23.6	16	29.1	39	70.9	NE	14.5	NE
	Asia (AS)	52	22.3	18	34.6	34	65.4	NE	10.6	NE
Race/ethnicity	Asian	56	24.0	21	37.5	35	62.5	17.1	9.2	NE
	Non-Asian	84	36.1	26	31.0	58	69.0	22.3	14.7	NE
	Unknown	10	4.3	2	20.0	8	80.0	NE	15.1	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_tte2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_tte2_B63_06NOV2020_EF_TO_DORREMA_SG.xls
25FEB2021 20:52

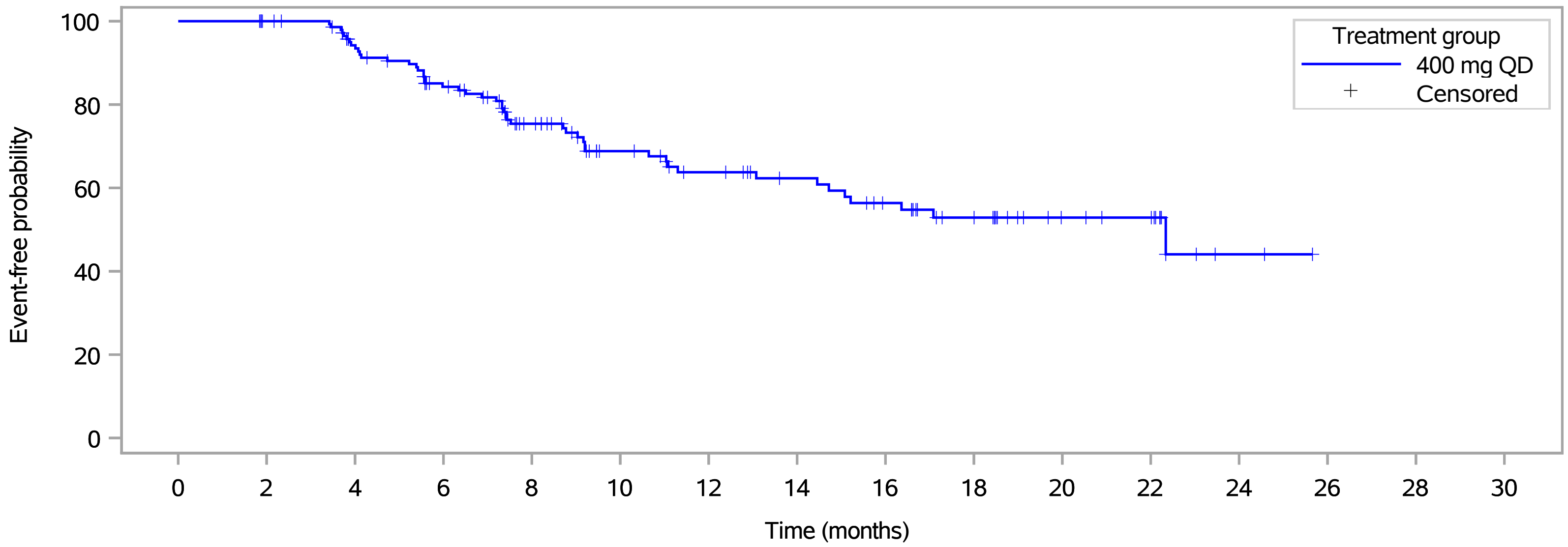
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Subgroup analysis, Time to Response (BICR)
MODEL: Unstratified analysis
STUDY: BO42863
Time to event analysis

		(N=233)								
		Patients		Patients with Event		Censored		Time To Event		
Name	Level	n	%	n	%	n	%	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	150	64.4	150	100.0	0	0.0	1.8	1.8	1.9
Sex	Female	83	35.6	83	100.0	0	0.0	1.8	1.8	1.9
	Male	67	28.8	67	100.0	0	0.0	1.8	1.8	1.9
Age	< 65	100	42.9	100	100.0	0	0.0	1.8	1.8	1.8
	>= 65	50	21.5	50	100.0	0	0.0	1.9	1.8	1.9
ECOG performance status	0	58	24.9	58	100.0	0	0.0	1.8	1.8	1.9
	1	89	38.2	89	100.0	0	0.0	1.8	1.8	1.9
	2	3	1.3	3	100.0	0	0.0	-	-	-
Geographic region	USA	43	18.5	43	100.0	0	0.0	1.8	1.8	1.9
	Europe (EU)	55	23.6	55	100.0	0	0.0	1.8	1.8	1.9
	Asia (AS)	52	22.3	52	100.0	0	0.0	1.8	1.8	1.9
Race/ethnicity	Asian	56	24.0	56	100.0	0	0.0	1.8	1.8	1.9
	Non-Asian	84	36.1	84	100.0	0	0.0	1.8	1.8	1.9
	Unknown	10	4.3	10	100.0	0	0.0	1.8	1.7	1.8

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_tte2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_tte2_B63_06NOV2020_EF_TO_TTRESPRR_SG.xls
25FEB2021 20:53

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Duration of Response per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

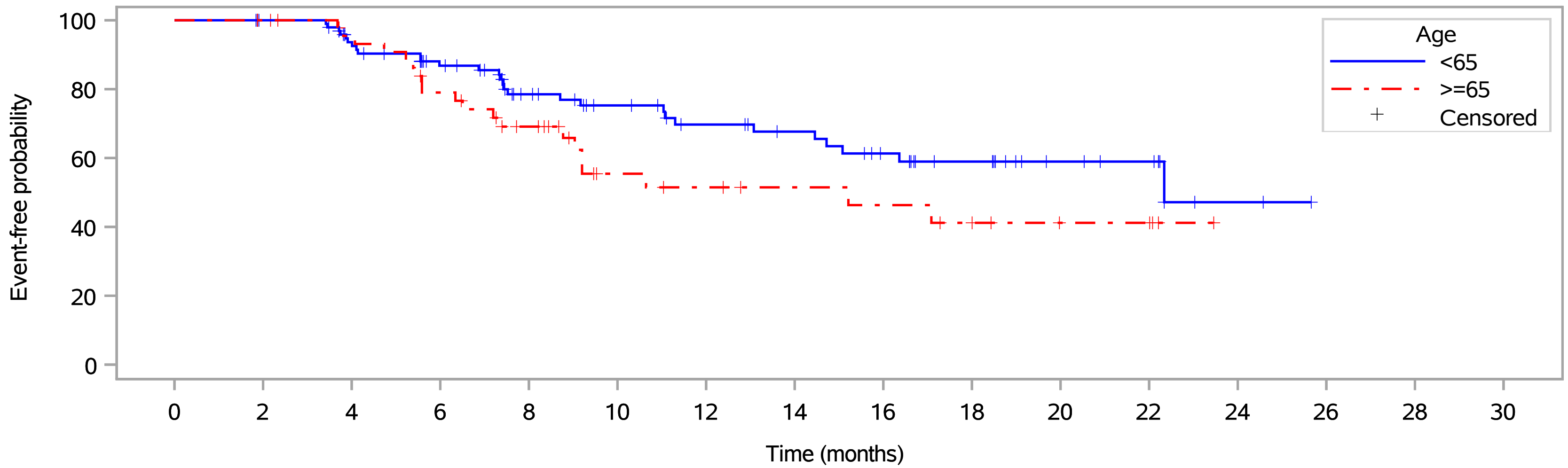


Patients at risk															
400 mg QD	150	144	126	102	76	57	48	42	35	26	15	13	2	NE	NE	NE
Patients censored															
400 mg QD	0	6	16	27	43	56	61	66	69	76	87	89	99	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_DORRREMA.pdf
23MAR2021 8:14

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Duration of Response per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

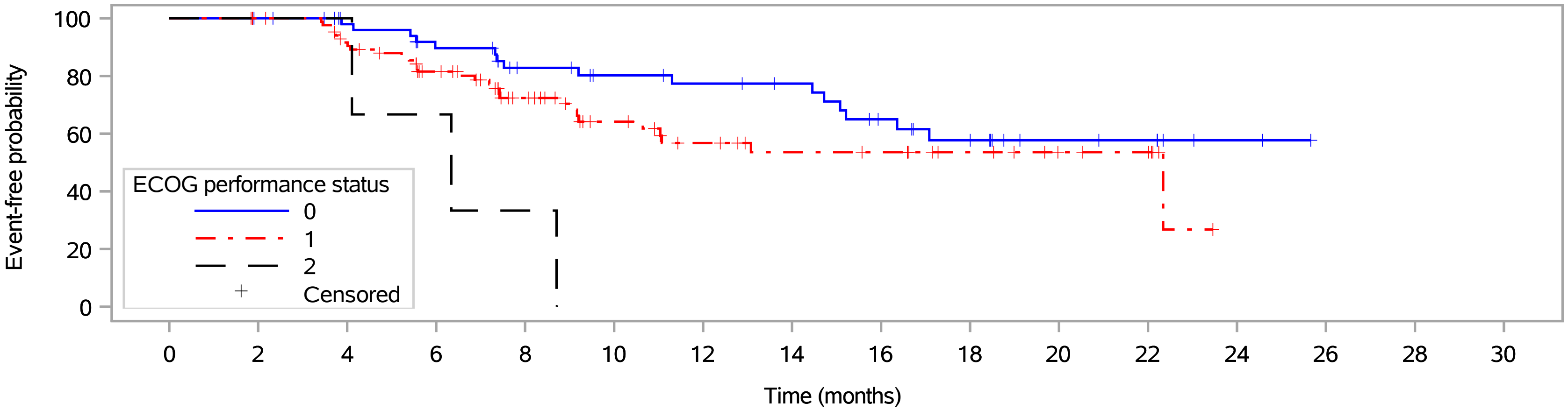


Patients at risk																
<65	100	97	85	69	51	43	36	32	26	19	11	9	2	NE	NE	NE
>=65	50	47	41	33	25	14	12	10	9	7	4	4	NE	NE	NE	NE
Patients censored																
<65	0	3	9	19	31	37	41	44	47	53	61	63	69	NE	NE	NE
>=65	0	3	7	8	12	19	20	22	22	23	26	26	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_DORRREMA_SGAGE65.pdf
23MAR2021 8:15

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Duration of Response per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

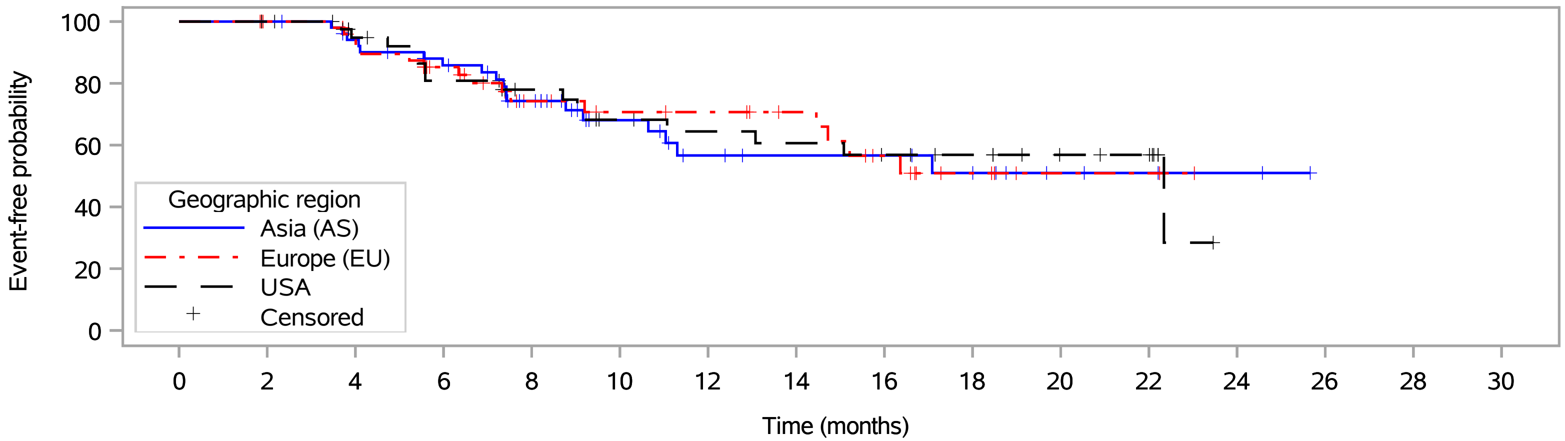


Patients at risk															
0	58	56	48	41	33	29	27	25	19	15	8	7	2	NE	NE	NE
1	89	85	75	59	42	28	21	17	16	11	7	6	NE	NE	NE	NE
2	3	3	3	2	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
0	0	2	9	12	17	20	21	23	25	27	34	35	40	NE	NE	NE
1	0	4	7	15	26	36	40	43	44	49	53	54	NE	NE	NE	NE
2	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_DORRREMA_SGECOG.pdf
23MAR2021 8:16

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Duration of Response per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

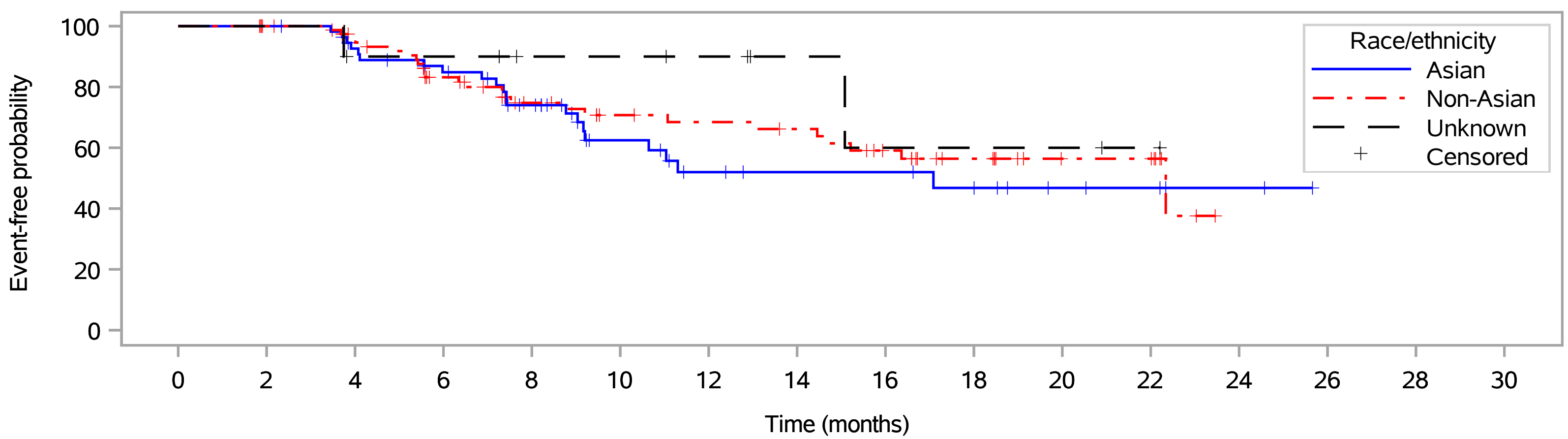


Patients at risk																
Asia (AS)	52	52	47	39	30	19	13	11	11	9	5	4	2	NE	NE	NE
Europe (EU)	55	50	44	34	22	19	18	15	10	5	2	2	NE	NE	NE	NE
USA	43	42	35	29	24	19	17	16	14	12	8	7	NE	NE	NE	NE
Patients censored																
Asia (AS)	0	0	2	6	10	19	22	24	24	25	29	30	32	NE	NE	NE
Europe (EU)	0	5	8	14	22	24	25	28	30	34	37	37	NE	NE	NE	NE
USA	0	1	6	7	11	13	14	14	15	17	21	22	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_DORRREMA_SGGEO.pdf
23MAR2021 8:16

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Duration of Response per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

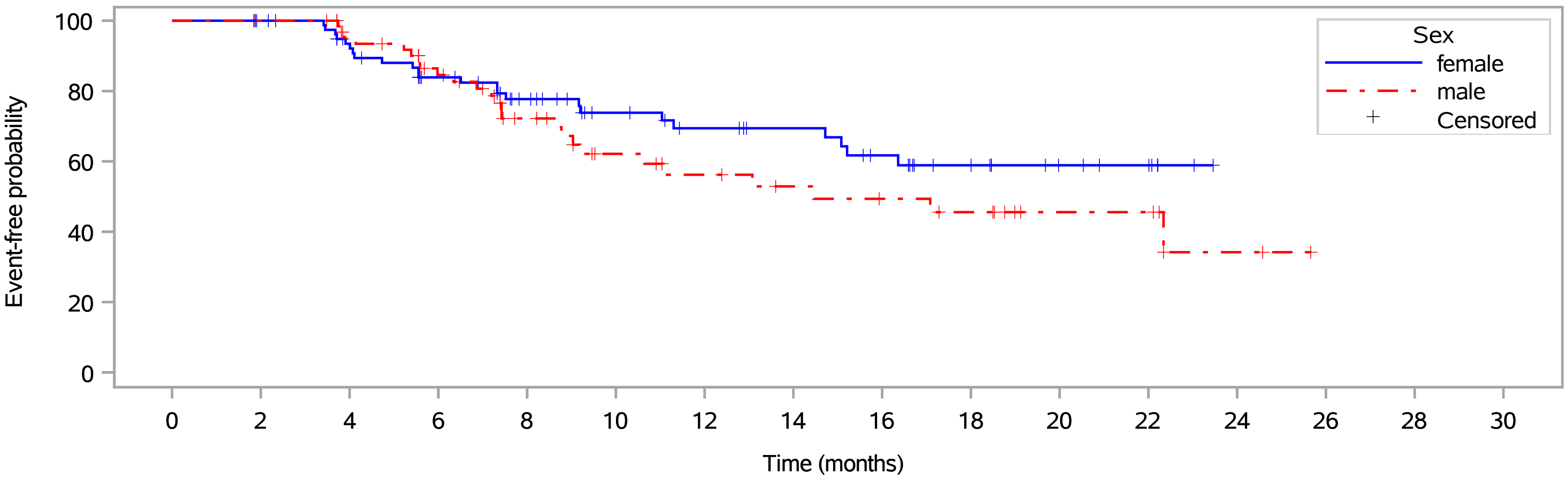


Patients at risk																
Asian	56	56	49	41	32	19	13	11	11	9	5	4	2	NE	NE	NE
Non-Asian	84	78	69	53	38	32	30	28	22	15	8	8	NE	NE	NE	NE
Unknown	10	10	8	8	6	6	5	3	2	2	2	1	NE	NE	NE	NE
Patients censored																
Asian	0	0	3	7	11	20	23	25	25	26	30	31	33	NE	NE	NE
Non-Asian	0	6	12	19	29	33	34	35	38	44	51	51	NE	NE	NE	NE
Unknown	0	0	1	1	3	3	4	6	6	6	6	7	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_DORRREMA_SGRE.pdf
23MAR2021 8:17

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Duration of Response per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

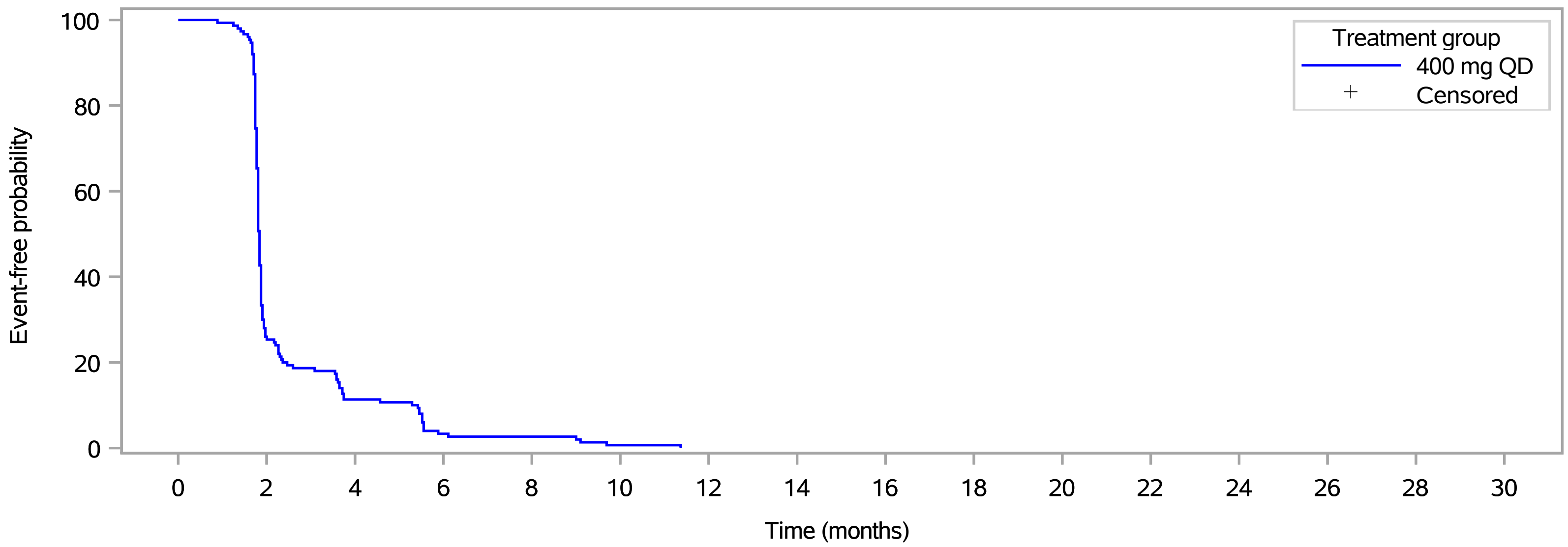


Patients at risk																
female	83	79	69	57	45	35	30	27	22	15	9	7	NE	NE	NE	NE
male	67	65	57	45	31	22	18	15	13	11	6	6	2	NE	NE	NE
Patients censored																
female	0	4	9	14	22	30	33	36	38	44	50	52	NE	NE	NE	NE
male	0	2	7	13	21	26	28	30	31	32	37	37	40	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_DORRREMA_SGSEX.pdf
23MAR2021 8:15

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Time to Response (BICR)
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

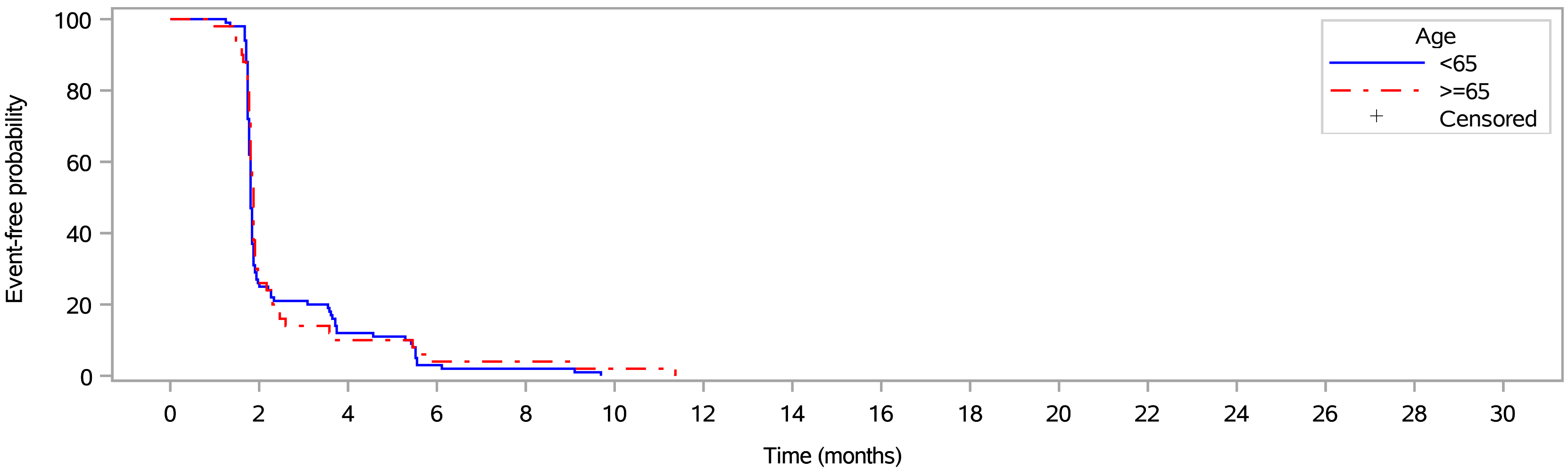


Patients at risk															
400 mg QD	150	39	17	5	4	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored															
400 mg QD	0	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_TTRESPRR.pdf
23MAR2021 8:21

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Time to Response (BICR)
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

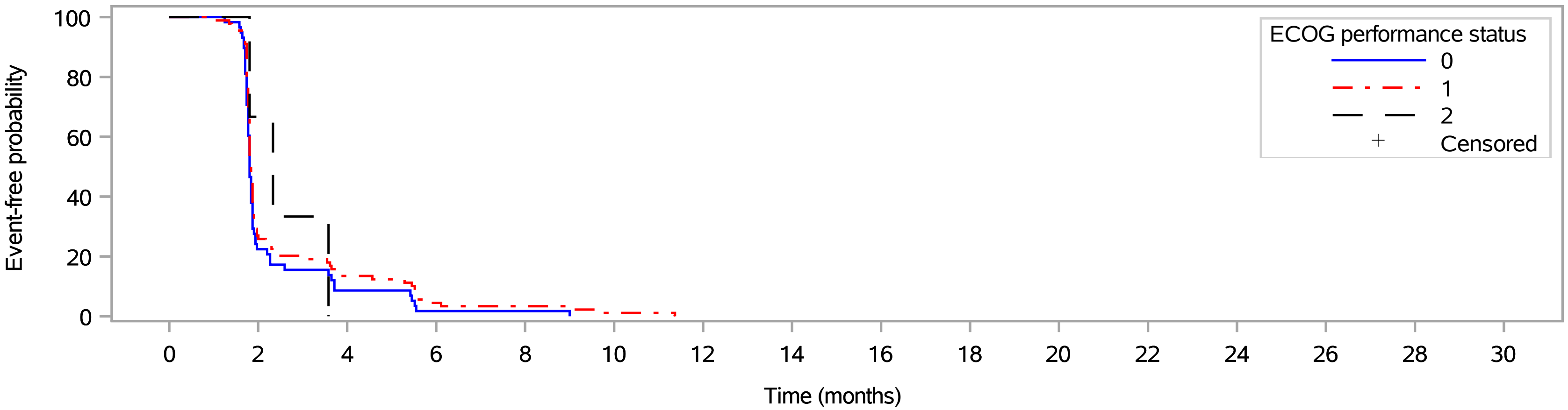


Patients at risk																
<65	100	26	12	3	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
>=65	50	13	5	2	2	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
<65	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
>=65	0	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_TTRESPRR_SGAGE65.pdf
23MAR2021 8:21

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Time to Response (BICR)
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)



Patients at risk

0	58	13	5	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
1	89	24	12	4	3	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
2	3	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

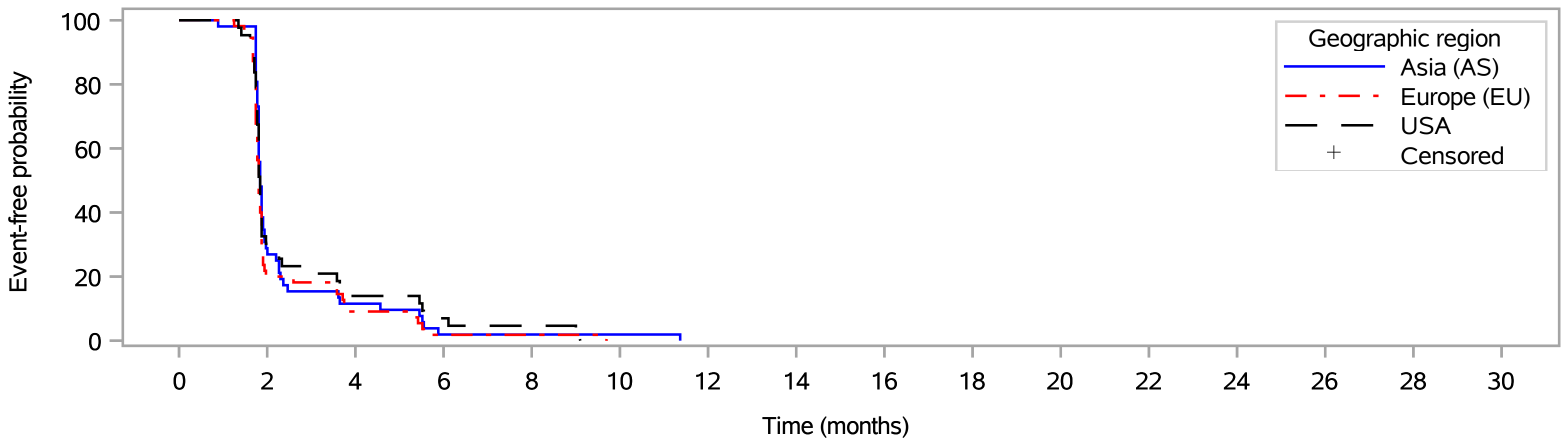
Patients censored

0	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
1	0	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
2	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_TTRESPRR_SGECOG.pdf
23MAR2021 8:22

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Time to Response (BICR)
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

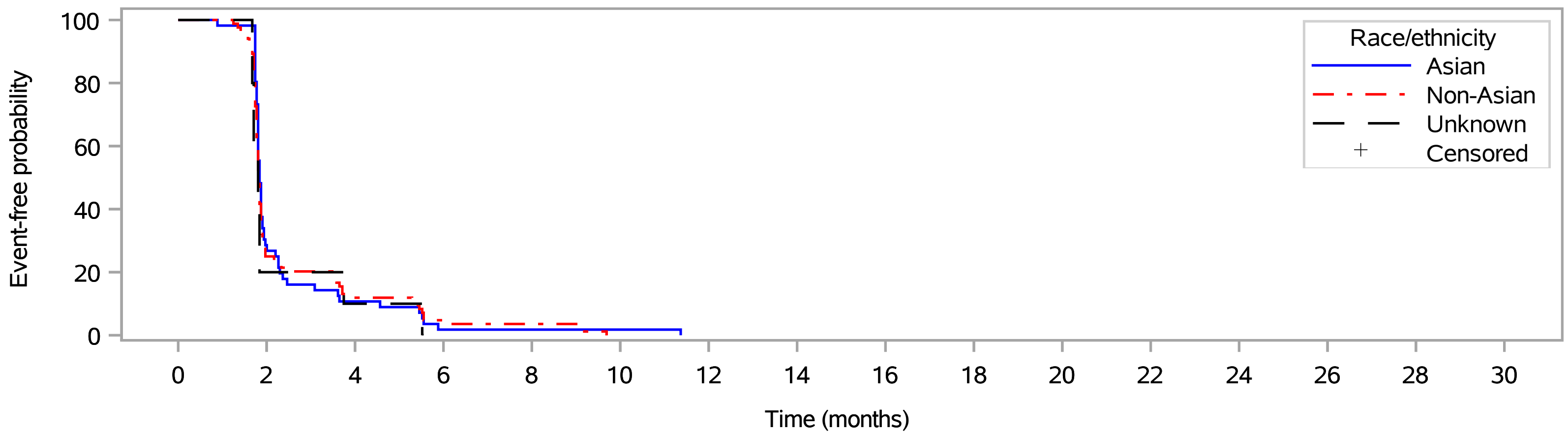


Patients at risk																
Asia (AS)	52	15	6	1	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Europe (EU)	55	11	5	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
USA	43	13	6	3	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
Asia (AS)	0	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Europe (EU)	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
USA	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_TTRESPRR_SGGEO.pdf
23MAR2021 8:23

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Time to Response (BICR)
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

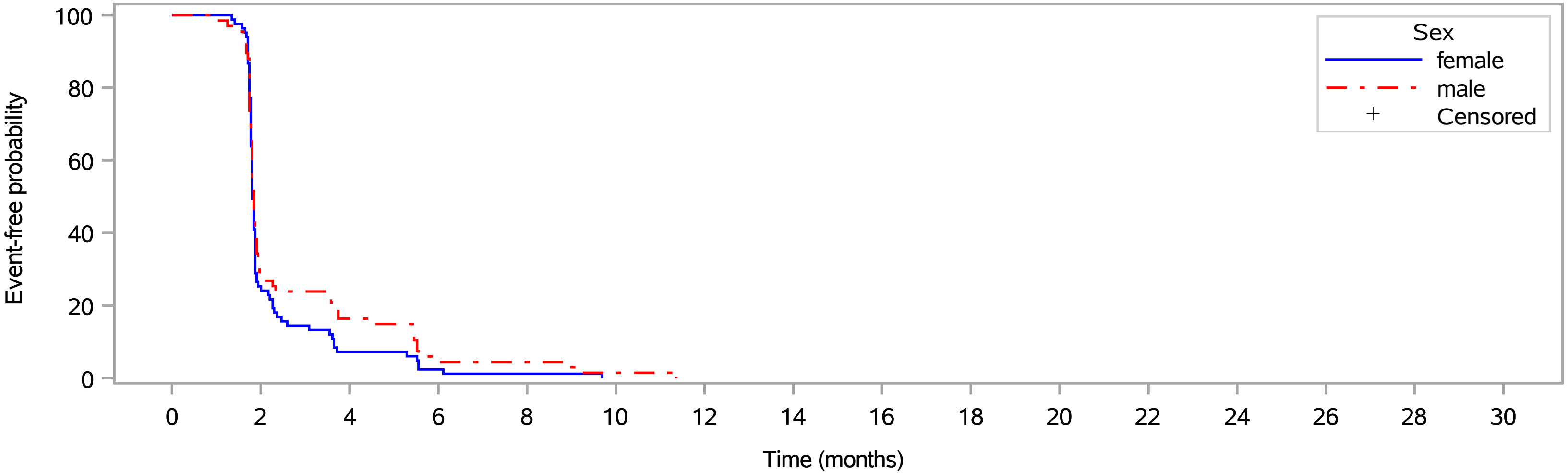


Patients at risk																
Asian	56	16	6	1	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Non-Asian	84	21	10	4	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Unknown	10	2	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
Asian	0	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Non-Asian	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Unknown	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_TTRESPRR_SGRE.pdf
23MAR2021 8:23

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Time to Response (BICR)
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

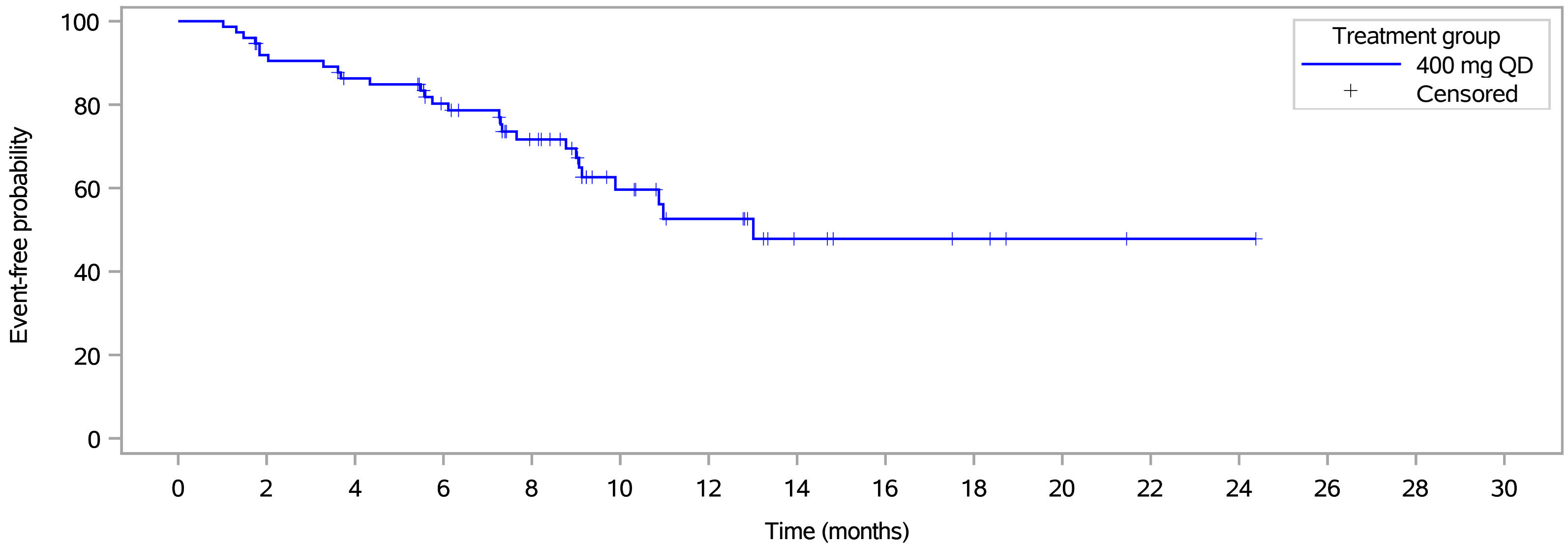


Patients at risk																
female	83	21	6	2	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
male	67	18	11	3	3	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
female	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
male	0	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_TTRESPRR_SGSEX.pdf
23MAR2021 8:22

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

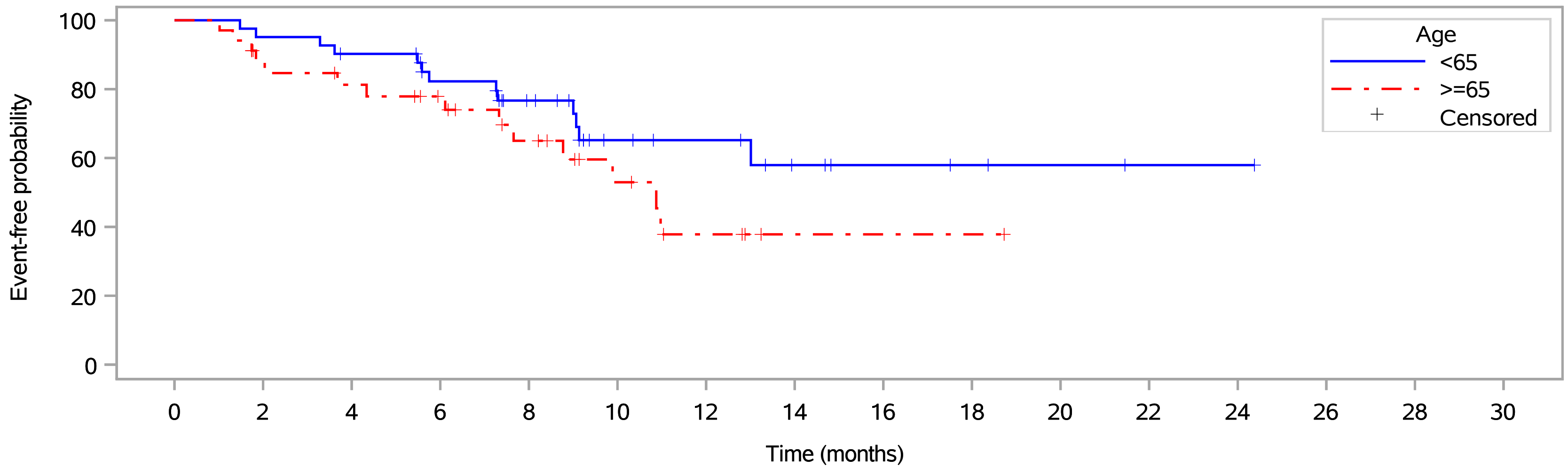


Patients at risk															
400 mg QD	75	66	60	50	37	20	14	7	5	4	2	1	1	NE	NE	NE
Patients censored															
400 mg QD	0	3	5	11	19	31	35	41	43	44	46	47	47	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_PFSEMAR.pdf
23MAR2021 9:40

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

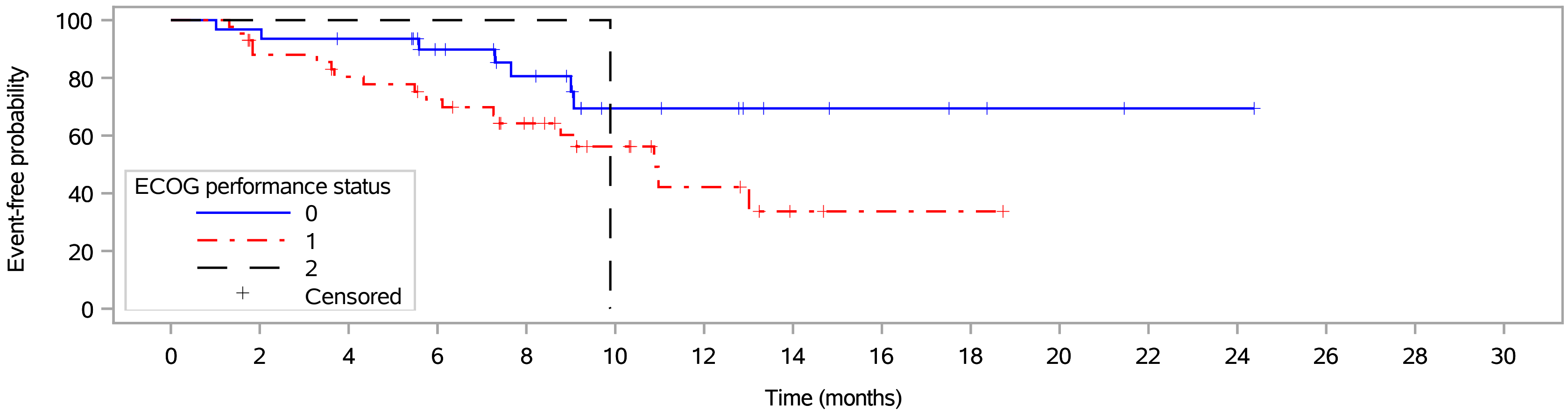


Patients at risk																
<65	41	39	36	30	23	12	10	6	4	3	2	1	1	NE	NE	NE
>=65	34	27	24	20	14	8	4	1	1	1	NE	NE	NE	NE	NE	NE
Patients censored																
<65	0	0	1	4	9	17	19	22	24	25	26	27	27	NE	NE	NE
>=65	0	3	4	7	10	14	16	19	19	19	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_PFSEMAR_SGAGE65.pdf
23MAR2021 9:40

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

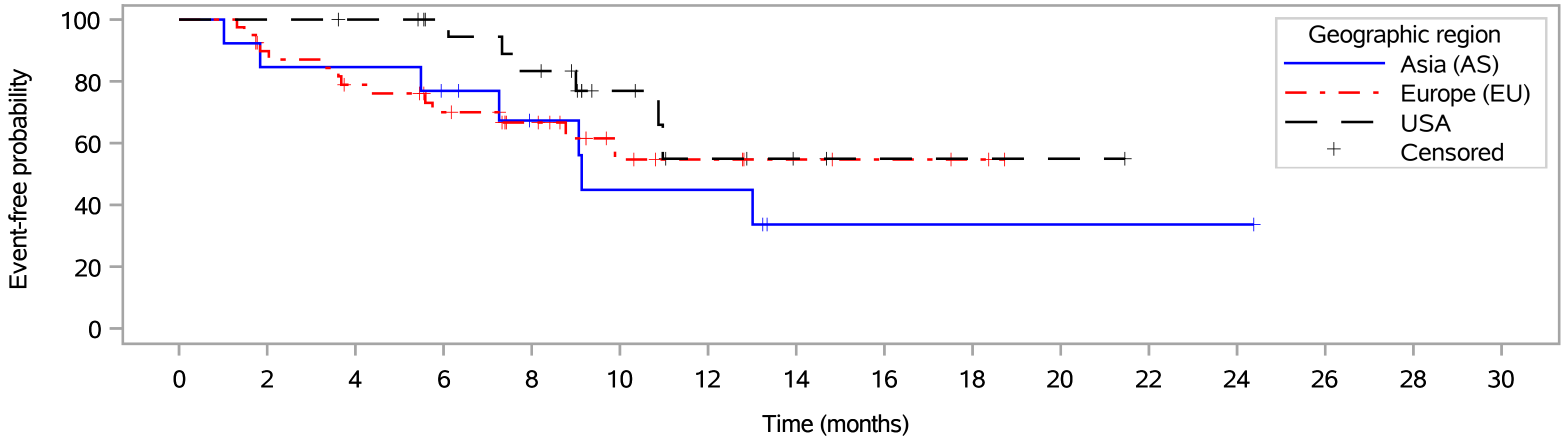


Patients at risk																
0	31	30	28	22	17	9	8	5	4	3	2	1	1	NE	NE	NE
1	43	35	31	27	19	11	6	2	1	1	NE	NE	NE	NE	NE	NE
2	1	1	1	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
0	0	0	1	6	9	15	16	19	20	21	22	23	23	NE	NE	NE
1	0	3	4	5	10	16	19	22	23	23	NE	NE	NE	NE	NE	NE
2	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_PFSEMAR_SGECOG.pdf
23MAR2021 9:41

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

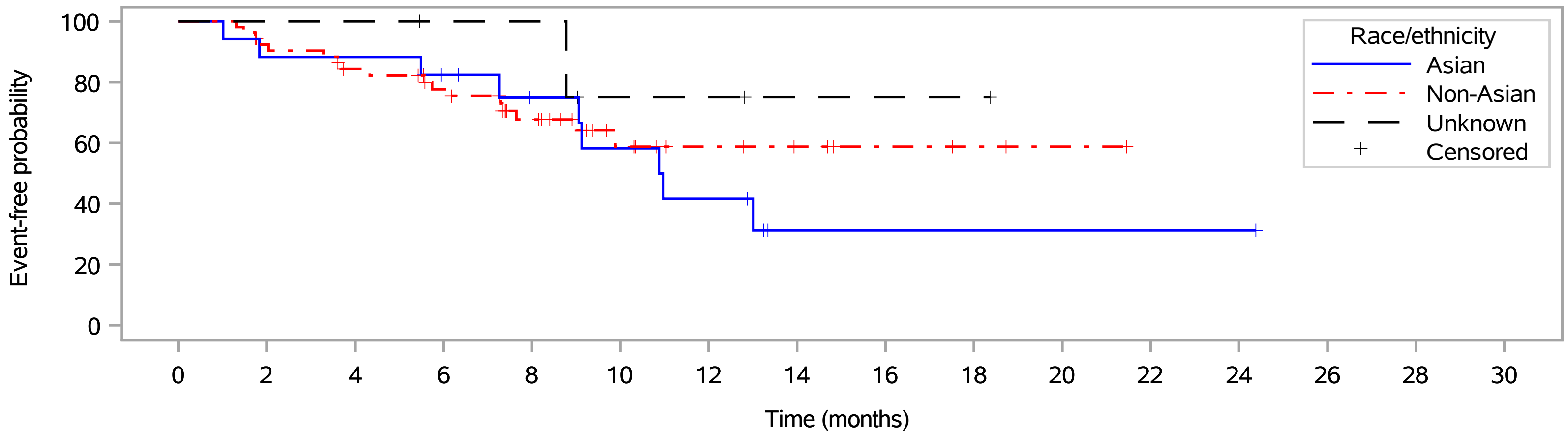


	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Patients at risk																
Asia (AS)	13	11	11	9	6	4	4	1	1	1	1	1	1	NE	NE	NE
Europe (EU)	40	33	28	23	16	8	6	4	3	2	NE	NE	NE	NE	NE	NE
USA	22	22	21	18	15	8	4	2	1	1	1	NE	NE	NE	NE	NE
Patients censored																
Asia (AS)	0	0	0	1	3	3	3	5	5	5	5	5	5	NE	NE	NE
Europe (EU)	0	3	4	6	12	18	20	22	23	24	NE	NE	NE	NE	NE	NE
USA	0	0	1	4	4	10	12	14	15	15	15	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_PFSEMAR_SGGEO.pdf
23MAR2021 9:42

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

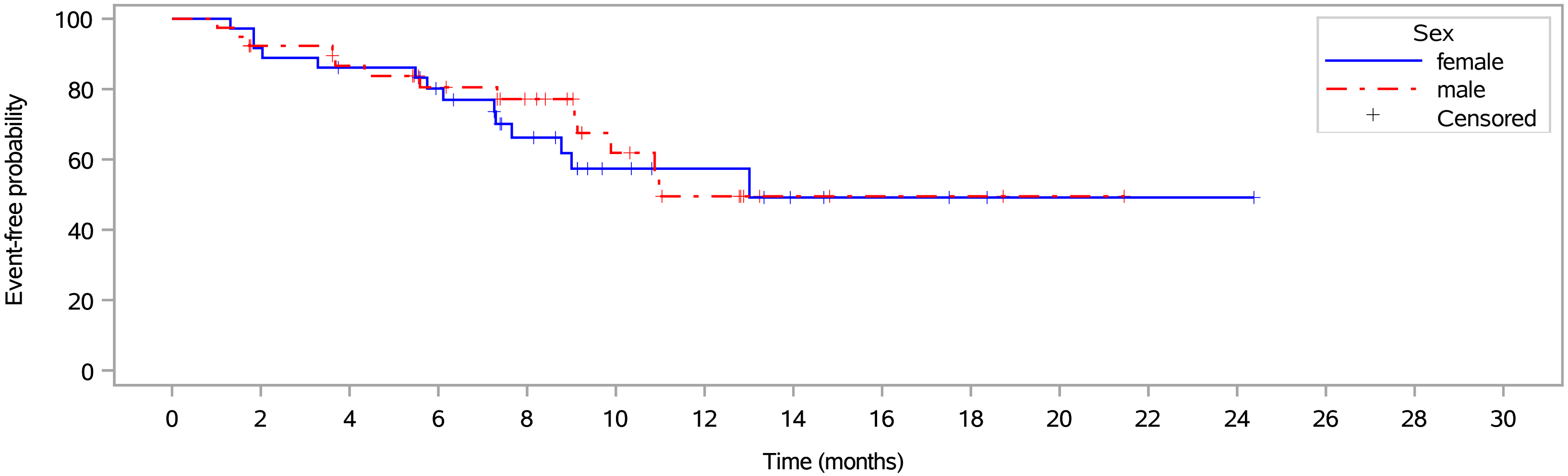


Patients at risk																
Asian	17	15	15	12	9	7	5	1	1	1	1	1	1	NE	NE	NE
Non-Asian	53	46	40	34	24	11	7	5	3	2	1	NE	NE	NE	NE	NE
Unknown	5	5	5	4	4	2	2	1	1	1	NE	NE	NE	NE	NE	NE
Patients censored																
Asian	0	0	0	2	4	4	4	7	7	7	7	7	7	NE	NE	NE
Non-Asian	0	3	5	8	14	25	29	31	33	34	35	NE	NE	NE	NE	NE
Unknown	0	0	0	1	1	2	2	3	3	3	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_PFSEMAR_SGRE.pdf
23MAR2021 9:42

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)



Patients at risk																
female	36	33	30	25	17	9	7	4	3	2	1	1	1	NE	NE	NE
male	39	33	30	25	20	11	7	3	2	2	1	NE	NE	NE	NE	NE
Patients censored																
female	0	0	1	4	8	14	16	18	19	20	21	21	21	NE	NE	NE
male	0	3	4	7	11	17	19	23	24	24	25	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TN_PFSEMAR_SGSEX.pdf
23MAR2021 9:41

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, No Prior Systemic Treatment, Safety Population
ENDPOINT: Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Time to Event Landmark Analysis

	400 mg QD (N=116)
Patients with Event, n(%)	
n (Total Patients)	31 (26.7%)
Progressive Disease (PD)	22 (19.0%)
Death without PD before the 1st Scheduled Assessment	6 (5.2%)
Death without PD before the 2nd Scheduled Assessment	7 (6.0%)
Death without PD after 2nd and between Scheduled Assessments	2 (1.7%)
Patients Censored, n (%)	
n (Total Patients)	85 (73.3%)
No Baseline Assessment	7 (6.0%)
No Documented PD	78 (67.2%)
Duration of PFS Follow-up Kaplan-Meier Estimates (Months) [2]	
Median	7.4
95% CI for Median	(5.5, 8.9)
Min - Max	0.0 - 24.4
Progression Free Survival Kaplan-Meier Estimates (Months) [3]	
Median	13
95% CI	(9.1, NE)
25% and 75%-ile	7.3 - NE
Events	31
Censored	75
Patients remaining at risk	10
Progression Free Survival Rate	
3-months	
Events	11
Censored	33
Patients remaining at risk	72
Event free proportion (%)	88.65
95% CI	(82.29, 95.00)
6-months	
Events	18
Censored	48
Patients remaining at risk	50
Event free proportion (%)	78.97

95% CI	(70.11, 87.83)
9-months	
Events	24
Censored	61
Patients remaining at risk	31
Event free proportion (%)	68.38
95% CI	(57.33, 79.44)
12-months	
Events	30
Censored	72
Patients remaining at risk	14
Event free proportion (%)	51.78
95% CI	(37.19, 66.36)
18-months	
Events	31
Censored	81
Patients remaining at risk	4
Event free proportion (%)	47.07
95% CI	(31.16, 62.98)
24-months	
Events	31
Censored	84
Patients remaining at risk	1
Event free proportion (%)	47.07
95% CI	(31.16, 62.98)
30-months	
Events	NE
Censored	NE
Patients remaining at risk	NE
Event free proportion (%)	NE
95% CI	NE

[1] At least 2 consecutively scheduled disease assessment is defined as at least 128 days before end of treatment (EOT) visit or 197 days if the death of progression is after EOT.
[2] Duration of response follow-up is based on reverse Kaplan-Meier method, with censoring at the event date.
[3] The 95% CI is based on Greenwood formula.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_lma.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_lma_BO42863_SAF_NSCLCNPS_PFSEMAR.xls
12MAR2021 12:18

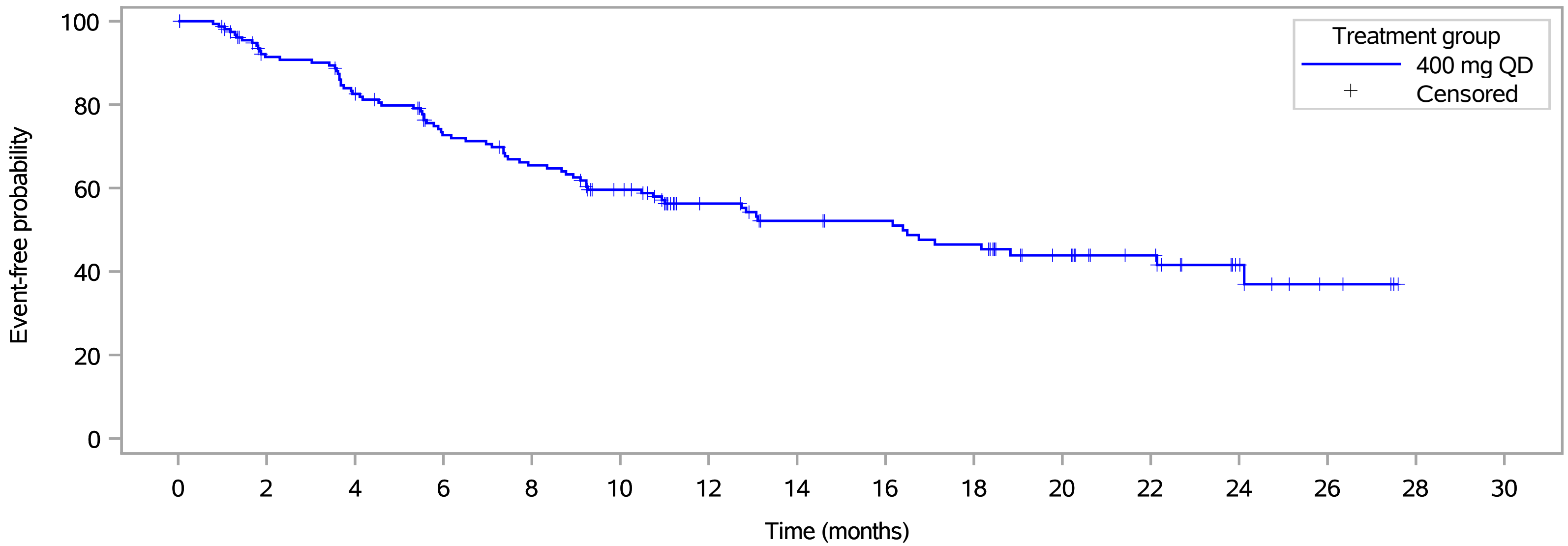
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, Efficacy Population
ENDPOINT: Subgroup analysis, Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
MODEL: Unstratified analysis
STUDY: BO42863
Time to event analysis

		(N=75)								
		Patients		Patients with Event		Censored		Time To Event		
Name	Level	n	%	n	%	n	%	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	75	100,0	27	36,0	48	64,0	13,0	9,1	NE
Sex	Female	36	48,0	14	38,9	22	61,1	13,0	7,7	NE
	Male	39	52,0	13	33,3	26	66,7	11,0	9,1	NE
Age	< 65	41	54,7	13	31,7	28	68,3	NE	9,1	NE
	>= 65	34	45,3	14	41,2	20	58,8	10,9	7,7	NE
ECOG performance status	0	31	41,3	7	22,6	24	77,4	NE	9,1	NE
	1	43	57,3	19	44,2	24	55,8	10,9	7,3	NE
	2	1	1,3	1	100,0	0	0,0	-	-	-
Geographic region	USA	22	29,3	6	27,3	16	72,7	NE	10,9	NE
	Europe (EU)	40	53,3	14	35,0	26	65,0	NE	8,8	NE
	Asia (AS)	13	17,3	7	53,8	6	46,2	9,1	7,3	NE
Race/ethnicity	Asian	17	22,7	9	52,9	8	47,1	10,9	9,1	NE
	Non-Asian	53	70,7	17	32,1	36	67,9	NE	9,0	NE
	Unknown	5	6,7	1	20,0	4	80,0	-	-	-

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_tte2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_tte2_B63_06NOV2020_EF_TN_PFSEMAR_SG.xls
25FEB2021 21:03

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

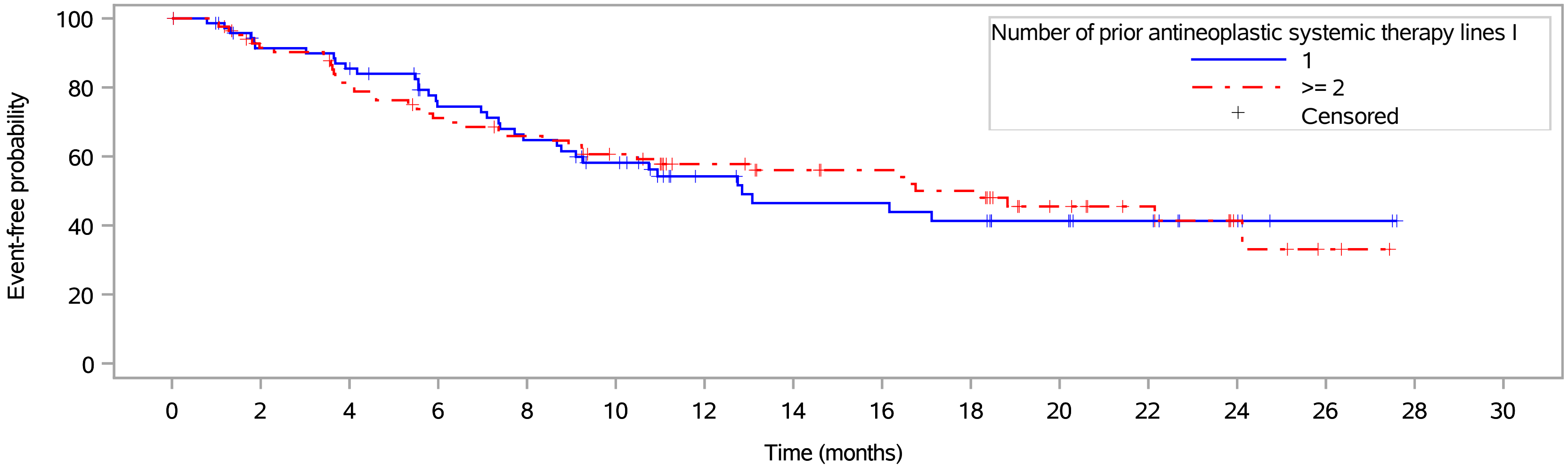


Patients at risk															
400 mg QD	158	135	121	101	90	76	56	48	46	41	27	20	10	4	NE	NE
Patients censored															
400 mg QD	0	10	11	17	18	24	40	44	46	46	58	65	74	79	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_PFSEMAR.pdf
23MAR2021 9:10

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

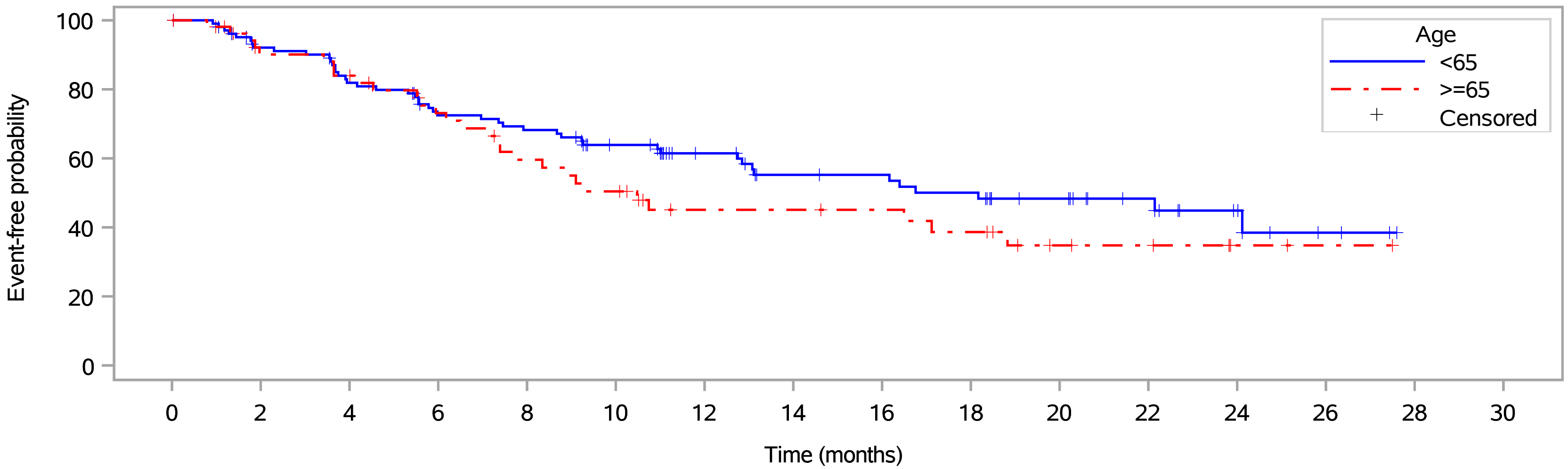


Patients at risk																
1	73	62	58	46	40	33	22	18	18	16	12	9	5	2	NE	NE
>= 2	85	73	63	55	50	43	34	30	28	25	15	11	5	2	NE	NE
Patients censored																
1	0	5	5	10	10	13	22	23	23	23	27	30	34	37	NE	NE
>= 2	0	5	6	7	8	11	18	21	23	23	31	35	40	42	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_PFSEMAR_PRTHL1.pdf
23MAR2021 9:13

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

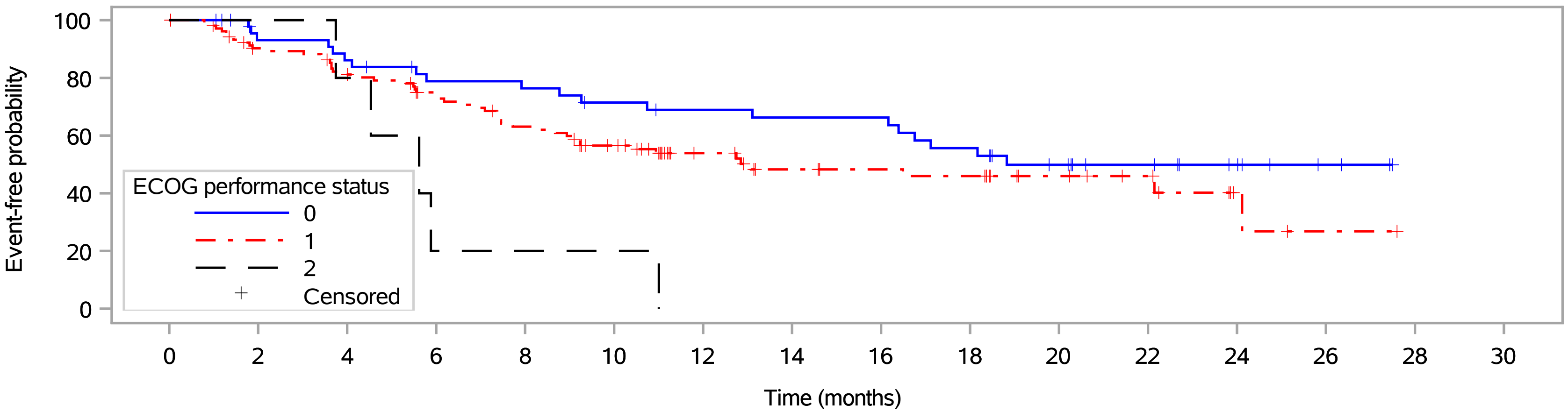


Patients at risk																
<65	104	91	80	68	64	54	41	33	32	29	20	14	8	3	NE	NE
>=65	54	44	41	33	26	22	15	15	14	12	7	6	2	1	NE	NE
Patients censored																
<65	0	5	6	9	9	15	26	30	31	31	39	45	50	54	NE	NE
>=65	0	5	5	8	9	9	14	14	15	15	19	20	24	25	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_PFSEMAR_SGAGE65.pdf
23MAR2021 9:10

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

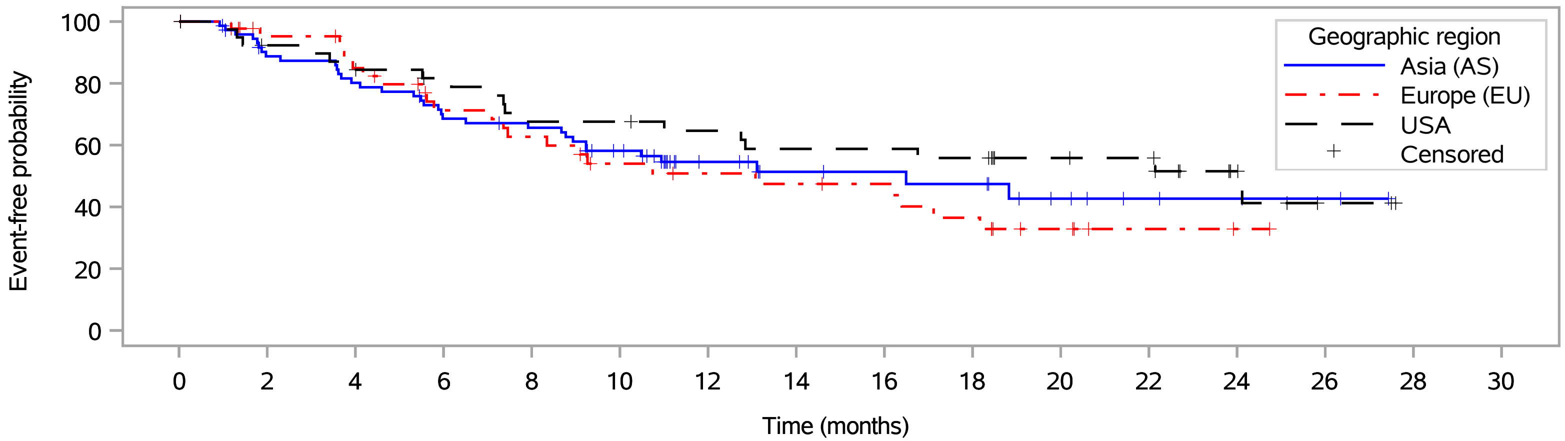


Patients at risk																
0	47	40	37	32	31	28	26	25	25	21	15	11	7	3	NE	NE
1	106	90	80	68	58	47	30	23	21	20	12	9	3	1	NE	NE
2	5	5	4	1	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
0	0	4	4	6	6	7	8	8	8	8	12	16	20	24	NE	NE
1	0	6	7	11	12	17	32	36	38	38	46	49	54	55	NE	NE
2	0	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_PFSEMAR_SGECOG.pdf
23MAR2021 9:11

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

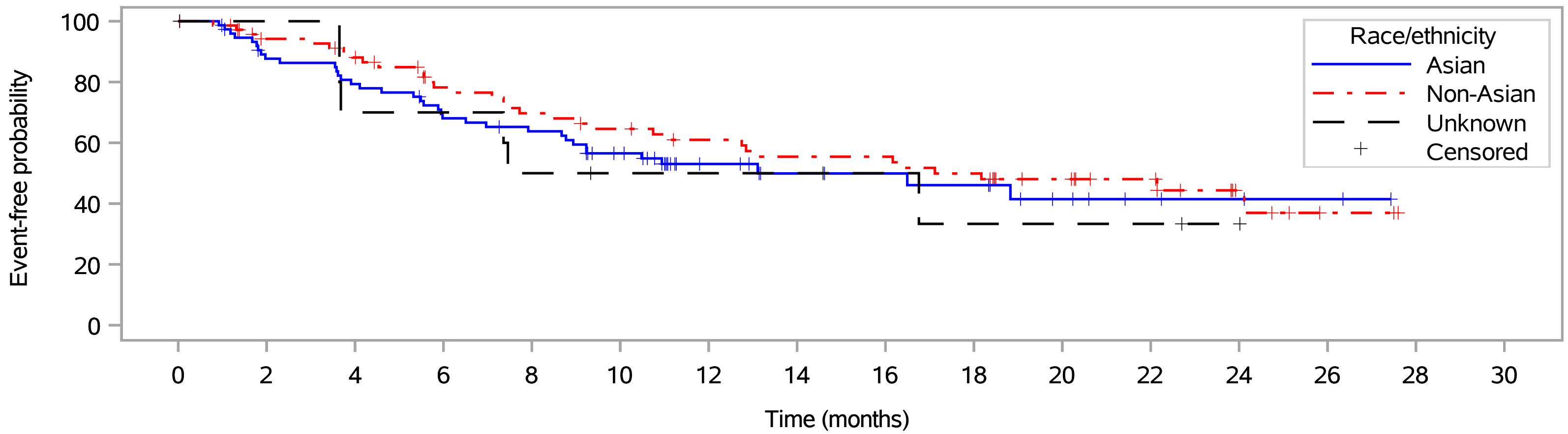


Patients at risk															
Asia (AS)	73	62	56	47	44	35	19	14	13	12	7	4	3	2	NE	NE
Europe (EU)	45	38	33	25	22	17	15	14	13	10	5	2	1	NE	NE	NE
USA	40	35	32	29	24	24	22	20	20	19	15	14	6	2	NE	NE
Patients censored																
Asia (AS)	0	3	3	4	5	9	23	27	28	28	32	35	36	37	NE	NE
Europe (EU)	0	5	6	9	9	11	12	12	13	13	17	20	21	NE	NE	NE
USA	0	2	2	4	4	4	5	5	5	5	9	10	17	20	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_PFSEMAR_SGGEO.pdf
23MAR2021 9:12

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

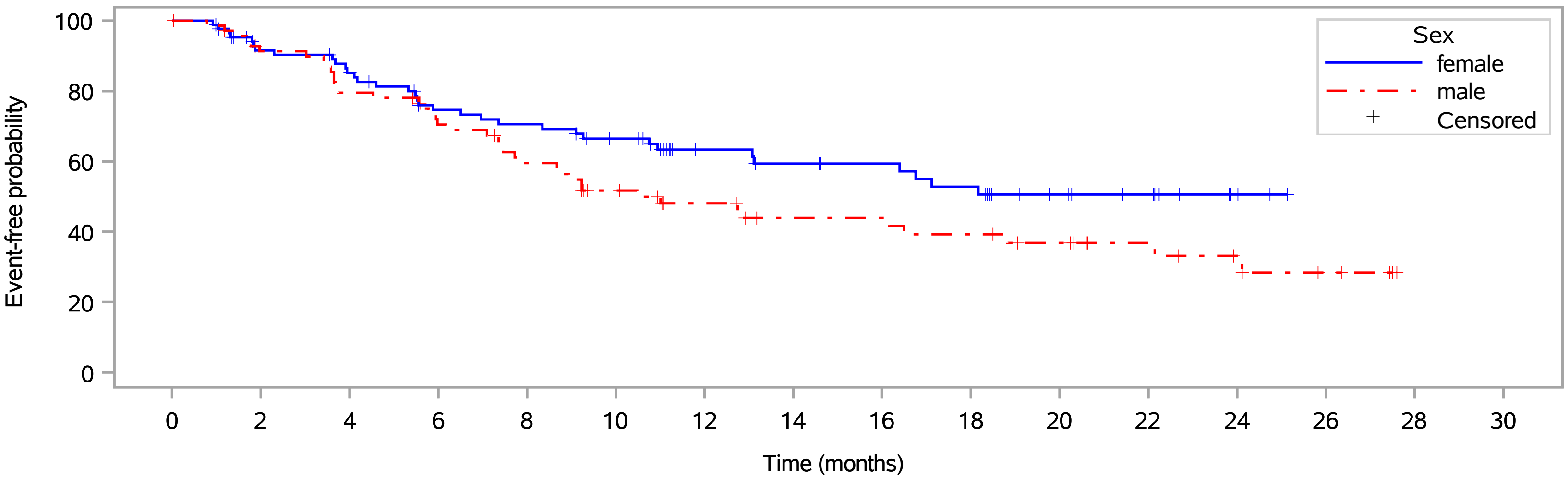


Patients at risk																
Asian	75	63	57	48	44	35	19	14	13	12	7	4	3	2	NE	NE
Non-Asian	72	62	57	46	41	37	33	30	30	27	18	14	6	2	NE	NE
Unknown	11	10	7	7	5	4	4	4	3	2	2	2	1	NE	NE	NE
Patients censored																
Asian	0	3	3	4	5	9	23	27	28	28	32	35	36	37	NE	NE
Non-Asian	0	6	7	12	12	13	15	15	15	15	23	27	34	37	NE	NE
Unknown	0	1	1	1	1	2	2	2	3	3	3	3	4	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_PFSEMAR_SGRE.pdf
23MAR2021 9:13

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population
ENDPOINT: Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)



Patients at risk																
female	86	73	67	55	52	46	32	29	27	24	13	10	3	NE	NE	NE
male	72	62	54	46	38	30	24	19	19	17	14	10	7	4	NE	NE
Patients censored																
female	0	6	7	11	11	14	26	27	29	29	39	42	49	NE	NE	NE
male	0	4	4	6	7	10	14	17	17	17	19	23	25	27	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TP_PFSEMAR_SGSEX.pdf
23MAR2021 9:11

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Prior Systemic Treatment, Safety Population
ENDPOINT: Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Time to Event Landmark Analysis

	400 mg QD (N=165)
Patients with Event, n(%)	
n (Total Patients)	75 (45.5%)
Progressive Disease (PD)	55 (33.3%)
Death without PD before the 1st Scheduled Assessment	5 (3.0%)
Death without PD before the 2nd Scheduled Assessment	8 (4.8%)
Death without PD after 2nd and between Scheduled Assessments	12 (7.3%)
Patients Censored, n (%)	
n (Total Patients)	90 (54.5%)
No Baseline Assessment	1 (0.6%)
No Documented PD	89 (53.9%)
Duration of PFS Follow-up Kaplan-Meier Estimates (Months) [2]	
Median	18.4
95% CI for Median	(12.7, 19.1)
Min - Max	0.0 - 27.6
Progression Free Survival Kaplan-Meier Estimates (Months) [3]	
Median	16.5
95% CI	(10.9, 24.1)
25% and 75%-ile	5.9 - NE
Events	68
Censored	53
Patients remaining at risk	44
Progression Free Survival Rate	
3-months	
Events	14
Censored	15
Patients remaining at risk	136
Event free proportion (%)	91
95% CI	(86.50, 95.50)
6-months	
Events	40
Censored	24
Patients remaining at risk	101
Event free proportion (%)	72.96

95% CI	(65.77, 80.16)
9-months	
Events	54
Censored	25
Patients remaining at risk	86
Event free proportion (%)	62.77
95% CI	(54.85, 70.70)
12-months	
Events	62
Censored	47
Patients remaining at risk	56
Event free proportion (%)	56.48
95% CI	(48.23, 64.73)
18-months	
Events	71
Censored	53
Patients remaining at risk	41
Event free proportion (%)	46.65
95% CI	(37.66, 55.63)
24-months	
Events	74
Censored	81
Patients remaining at risk	10
Event free proportion (%)	41.72
95% CI	(31.95, 51.49)
30-months	
Events	NE
Censored	NE
Patients remaining at risk	NE
Event free proportion (%)	NE
95% CI	NE

[1] At least 2 consecutively scheduled disease assessment is defined as at least 128 days before end of treatment (EOT) visit or 197 days if the death of progression is after EOT.
[2] Duration of response follow-up is based on reverse Kaplan-Meier method, with censoring at the event date.
[3] The 95% CI is based on Greenwood formula.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_lma.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_lma_BO42863_SAF_NSCLCPS_PFSEMAR.xls
12MAR2021 12:17

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, Efficacy Population

ENDPOINT: Subgroup analysis, Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1

MODEL: Unstratified analysis

STUDY: BO42863

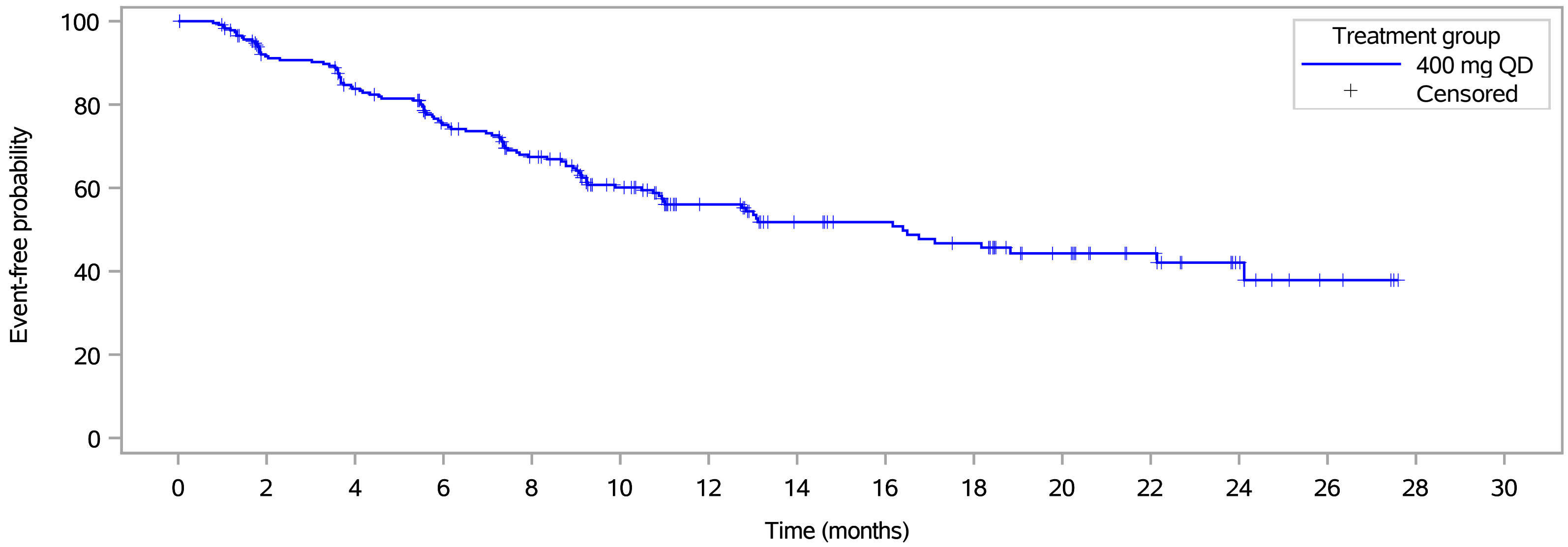
Time to event analysis

		(N=158)								
		Patients		Patients with Event		Censored		Time To Event		
Name	Level	n	%	n	%	n	%	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	158	100,0	75	47,5	83	52,5	16,4	10,7	24,1
Sex	Female	86	54,4	34	39,5	52	60,5	NE	13,1	NE
	Male	72	45,6	41	56,9	31	43,1	10,5	7,7	18,8
Age	< 65	104	65,8	47	45,2	57	54,8	18,2	12,7	NE
	>= 65	54	34,2	28	51,9	26	48,1	10,5	7,4	NE
ECOG performance status	0	47	29,7	20	42,6	27	57,4	18,8	16,2	NE
	1	106	67,1	50	47,2	56	52,8	13,1	9,1	NE
	2	5	3,2	5	100,0	0	0,0	-	-	-
Geographic region	USA	40	25,3	18	45,0	22	55,0	24,1	11,0	NE
	Europe (EU)	45	28,5	23	51,1	22	48,9	13,1	7,5	18,2
	Asia (AS)	73	46,2	34	46,6	39	53,4	16,5	8,9	NE
Race/ethnicity	Asian	75	47,5	36	48,0	39	52,0	13,1	8,8	NE
	Non-Asian	72	45,6	33	45,8	39	54,2	17,1	11,0	NE
	Unknown	11	7,0	6	54,5	5	45,5	12,1	3,7	NE
Number of prior antineoplastic systemic therapy lines I	1	73	46,2	34	46,6	39	53,4	12,8	8,8	NE
	>= 2	85	53,8	41	48,2	44	51,8	18,2	9,2	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_tte2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_tte2_B63_06NOV2020_EF_TP_PFSEMAR_SG.xls
25FEB2021 20:59

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

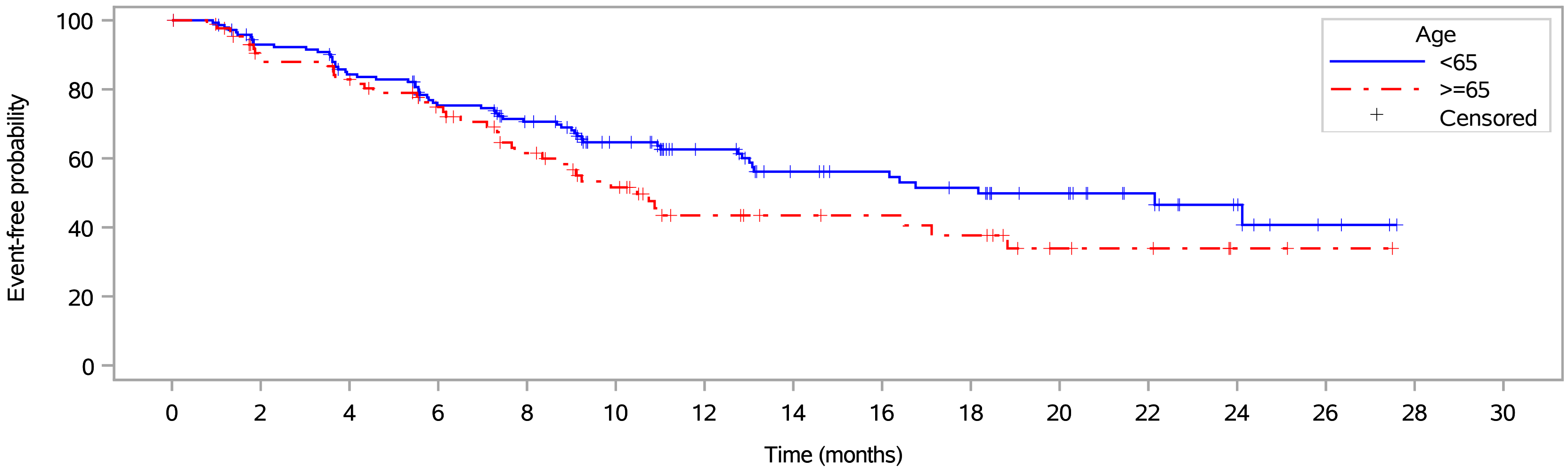


Patients at risk																
400 mg QD	233	201	181	151	127	96	70	55	51	45	29	21	11	4	NE	NE
Patients censored																
400 mg QD	0	13	16	28	37	55	75	85	89	90	104	112	121	127	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_PFSEMAR.pdf
23MAR2021 8:37

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

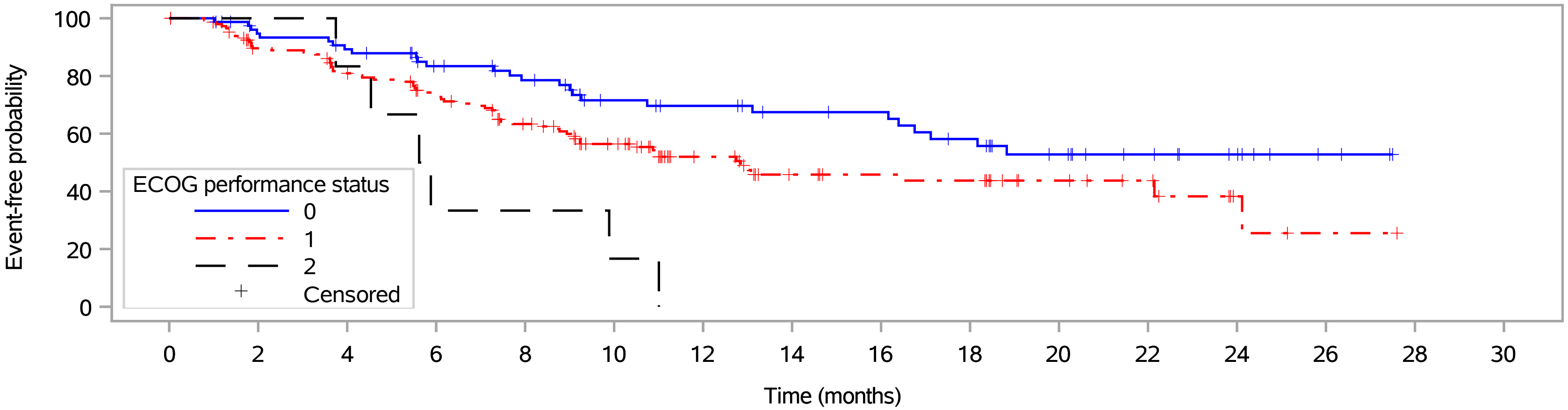


Patients at risk																
<65	145	130	116	98	87	66	51	39	36	32	22	15	9	3	NE	NE
>=65	88	71	65	53	40	30	19	16	15	13	7	6	2	1	NE	NE
Patients censored																
<65	0	5	7	13	18	32	45	52	55	56	65	72	77	82	NE	NE
>=65	0	8	9	15	19	23	30	33	34	34	39	40	44	45	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_PFSEMAR_SGAGE65.pdf
23MAR2021 8:38

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

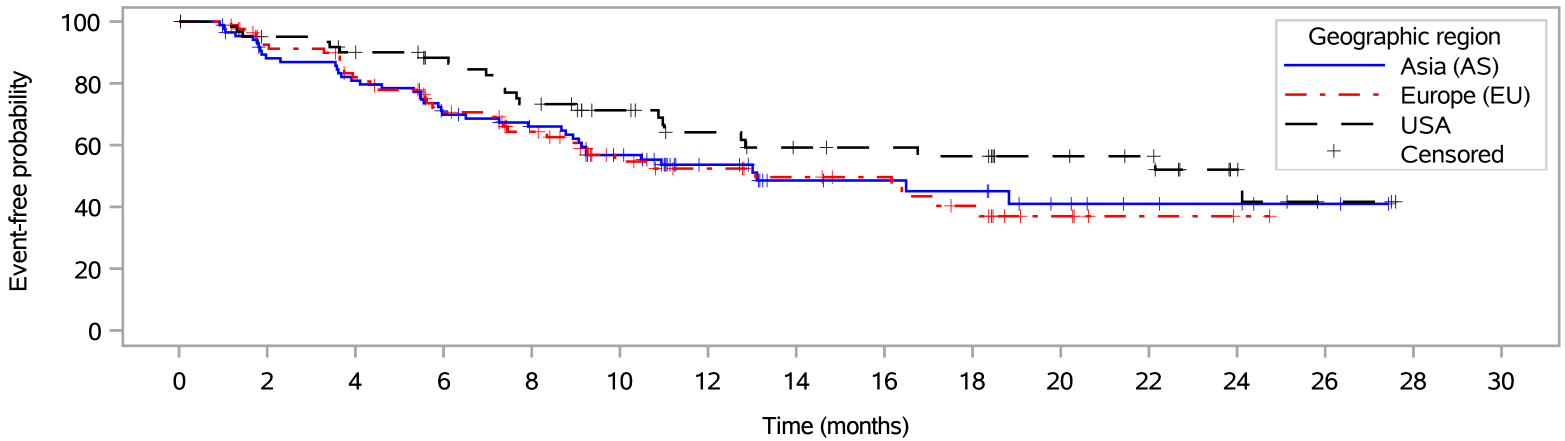


Patients at risk																
0	78	70	65	54	48	37	34	30	29	24	17	12	8	3	NE	NE
1	149	125	111	95	77	58	36	25	22	21	12	9	3	1	NE	NE
2	6	6	5	2	2	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																
0	0	4	5	12	15	22	24	27	28	29	34	39	43	48	NE	NE
1	0	9	11	16	22	33	51	58	61	61	70	73	78	79	NE	NE
2	0	0	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_PFSEMAR_SGECOG.pdf
23MAR2021 8:39

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

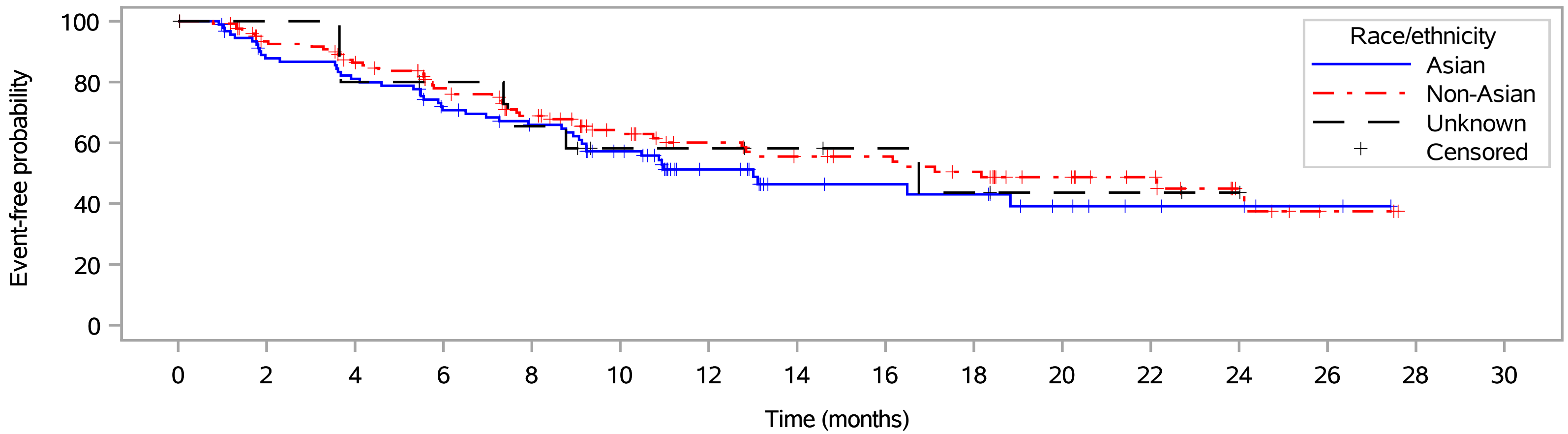


Patients at risk																
Asia (AS)	86	73	67	56	50	39	23	15	14	13	8	5	4	2	NE	NE
Europe (EU)	85	71	61	48	38	25	21	18	16	12	5	2	1	NE	NE	NE
USA	62	57	53	47	39	32	26	22	21	20	16	14	6	2	NE	NE
Patients censored																
Asia (AS)	0	3	3	5	8	12	26	32	33	33	37	40	41	43	NE	NE
Europe (EU)	0	8	10	15	21	29	32	34	36	37	43	46	47	NE	NE	NE
USA	0	2	3	8	8	14	17	19	20	20	24	26	33	36	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_PFSEMAR_SGGEO.pdf
23MAR2021 8:40

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)

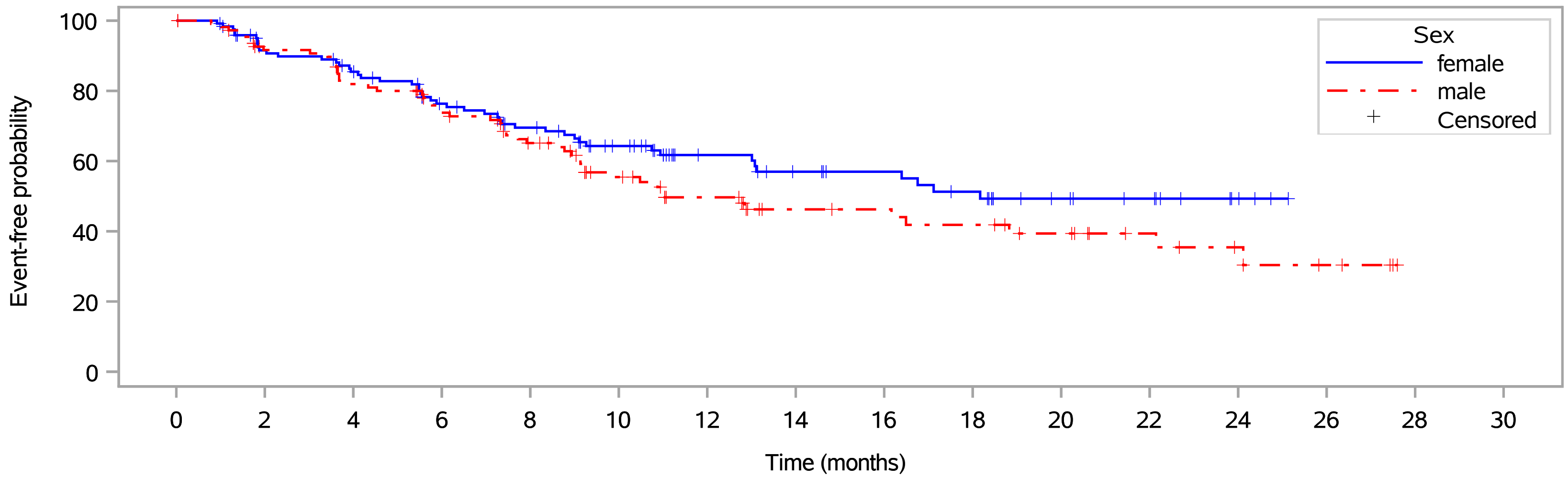


	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Patients at risk																
Asian	92	78	72	60	53	42	24	15	14	13	8	5	4	2	NE	NE
Non-Asian	125	108	97	80	65	48	40	35	33	29	19	14	6	2	NE	NE
Unknown	16	15	12	11	9	6	6	5	4	3	2	2	1	NE	NE	NE
Patients censored																
Asian	0	3	3	6	9	13	27	34	35	35	39	42	43	45	NE	NE
Non-Asian	0	9	12	20	26	38	44	46	48	49	58	63	70	73	NE	NE
Unknown	0	1	1	2	2	4	4	5	6	6	7	7	8	NE	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_PFSEMAR_SGRE.pdf
23MAR2021 8:40

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Kaplan-Meier plot of time to first event (months)



Patients at risk																
female	122	106	97	80	69	55	39	33	30	26	14	11	4	NE	NE	NE
male	111	95	84	71	58	41	31	22	21	19	15	10	7	4	NE	NE
Patients censored																
female	0	6	8	15	19	28	42	45	48	49	60	63	70	NE	NE	NE
male	0	7	8	13	18	27	33	40	41	41	44	49	51	53	NE	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_g_tte_km.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_g_tte_km_B63_06NOV2020_EF_TO_PFSEMAR_SGSEX.pdf
23MAR2021 8:38

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
STUDY: BO42863
Time to Event Landmark Analysis

	400 mg QD (N=281)
Patients with Event, n(%)	
n (Total Patients)	106 (37.7%)
Progressive Disease (PD)	77 (27.4%)
Death without PD before the 1st Scheduled Assessment	11 (3.9%)
Death without PD before the 2nd Scheduled Assessment	15 (5.3%)
Death without PD after 2nd and between Scheduled Assessments	14 (5.0%)
Patients Censored, n (%)	
n (Total Patients)	175 (62.3%)
No Baseline Assessment	8 (2.8%)
No Documented PD	167 (59.4%)
Duration of PFS Follow-up Kaplan-Meier Estimates (Months) [2]	
Median	11
95% CI for Median	(10.1, 12.8)
Min - Max	0.0 - 27.6
Progression Free Survival Kaplan-Meier Estimates (Months) [3]	
Median	16.4
95% CI	(11.0, 24.1)
25% and 75%-ile	6.0 - NE
Events	98
Censored	133
Patients remaining at risk	50
Progression Free Survival Rate	
3-months	
Events	25
Censored	48
Patients remaining at risk	208
Event free proportion (%)	90.11
95% CI	(86.43, 93.80)
6-months	
Events	58
Censored	72
Patients remaining at risk	151
Event free proportion (%)	74.88

95% CI	(69.22, 80.53)
9-months	
Events	78
Censored	86
Patients remaining at risk	117
Event free proportion (%)	64.49
95% CI	(58.03, 70.94)
12-months	
Events	92
Censored	119
Patients remaining at risk	70
Event free proportion (%)	55.85
95% CI	(48.83, 62.87)
18-months	
Events	102
Censored	134
Patients remaining at risk	45
Event free proportion (%)	46.56
95% CI	(38.67, 54.46)
24-months	
Events	105
Censored	165
Patients remaining at risk	11
Event free proportion (%)	41.94
95% CI	(33.10, 50.78)
30-months	
Events	NE
Censored	NE
Patients remaining at risk	NE
Event free proportion (%)	NE
95% CI	NE

[1] At least 2 consecutively scheduled disease assessment is defined as at least 128 days before end of treatment (EOT) visit or 197 days if the death of progression is after EOT.
[2] Duration of response follow-up is based on reverse Kaplan-Meier method, with censoring at the event date.
[3] The 95% CI is based on Greenwood formula.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_lma.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_lma_BO42863_SAF_NSCLCO_PFSEMAR.xls
12MAR2021 12:16

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Efficacy Population
ENDPOINT: Subgroup analysis, Progression-Free Survival per EMA Censoring Rule, Central Radiology Assessment per RECIST v1.1
MODEL: Unstratified analysis
STUDY: BO42863
Time to event analysis

		(N=233)								
		Patients		Patients with Event		Censored		Time To Event		
Name	Level	n	%	n	%	n	%	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	233	100,0	102	43,8	131	56,2	16,4	11,0	24,1
Sex	Female	122	52,4	48	39,3	74	60,7	18,2	13,1	NE
	Male	111	47,6	54	48,6	57	51,4	11,0	9,1	22,1
Age	< 65	145	62,2	60	41,4	85	58,6	18,2	13,0	NE
	>= 65	88	37,8	42	47,7	46	52,3	10,5	8,3	18,8
ECOG performance status	0	78	33,5	27	34,6	51	65,4	NE	16,8	NE
	1	149	63,9	69	46,3	80	53,7	12,8	9,1	24,1
	2	6	2,6	6	100,0	0	0,0	-	-	-
Geographic region	USA	62	26,6	24	38,7	38	61,3	24,1	12,7	NE
	Europe (EU)	85	36,5	37	43,5	48	56,5	13,1	8,8	NE
	Asia (AS)	86	36,9	41	47,7	45	52,3	13,1	9,1	NE
Race/ethnicity	Asian	92	39,5	45	48,9	47	51,1	13,0	9,1	NE
	Non-Asian	125	53,6	50	40,0	75	60,0	18,2	12,7	NE
	Unknown	16	6,9	7	43,8	9	56,3	16,8	7,4	NE

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/eff_tte2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/eff_tte2_B63_06NOV2020_EF_TO_PFSEMAR_SG.xls
25FEB2021 20:54

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Appetite Loss
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=108)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	108	100.0	104	96.3	19.55	28.86	13.94	25.16
Week 4 (Day 29)	n/a	108	100.0	96	88.9	11.11	19.74	7.11	15.11
Week 8 (Day 57)	n/a	92	85.2	79	85.9	13.92	25.93	8.12	19.73
Week 12 (Day 85)	n/a	79	73.1	71	89.9	9.39	19.67	4.73	14.04
Week 16 (Day 113)	n/a	69	63.9	58	84.1	7.47	15.35	3.44	11.51
Week 20 (Day 141)	n/a	59	54.6	55	93.2	12.12	24.31	5.55	18.69
Week 24 (Day 169)	n/a	56	51.9	49	87.5	9.52	20.41	3.66	15.39
Week 28 (Day 197)	n/a	55	50.9	51	92.7	9.15	23.17	2.63	15.67
Week 32 (Day 225)	n/a	48	44.4	41	85.4	8.13	20.79	1.57	14.69
Week 36 (Day 253)	n/a	41	38.0	30	73.2	7.78	18.94	0.70	14.85
Week 40 (Day 281)	n/a	37	34.3	32	86.5	6.25	15.70	0.59	11.91
Week 44 (Day 309)	n/a	31	28.7	26	83.9	12.82	23.24	3.43	22.21
Week 48 (Day 337)	n/a	23	21.3	12	52.2	5.56	19.25	-6.67	17.78
Week 52 (Day 365)	n/a	19	17.6	4	21.1	8.33	16.67	-18.19	34.85
Week 56 (Day 393)	n/a	17	15.7	6	35.3	5.56	13.61	-8.73	19.84
Week 60 (Day 421)	n/a	11	10.2	1	9.1	0.00	NE	NE	NE
Week 64 (Day 449)	n/a	10	9.3	3	30.0	0.00	0.00	NE	NE
Week 68 (Day 477)	n/a	6	5.6	1	16.7	0.00	NE	NE	NE
Week 72 (Day 505)	n/a	6	5.6	1	16.7	0.00	NE	NE	NE
Week 76 (Day 533)	n/a	6	5.6	1	16.7	0.00	NE	NE	NE
Week 80 (Day 561)	n/a	5	4.6	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	n/a	1	0.9	0	0.0	NE	NE	NE	NE

Cycle 12 (LOCF)	n/a	108	100.0	108	100.0	13.27	24.52	8.60	17.95
End of Study (LOCF)	n/a	108	100.0	108	100.0	12.65	23.99	8.08	17.23
Sex									
Baseline	Female	59	100.0	56	94.9	23.21	30.43	15.06	31.36
Week 4 (Day 29)	Female	59	100.0	51	86.4	13.07	17.74	8.08	18.06
Week 8 (Day 57)	Female	49	83.1	44	89.8	18.18	29.16	9.32	27.05
Week 12 (Day 85)	Female	44	74.6	39	88.6	12.82	23.71	5.13	20.51
Week 16 (Day 113)	Female	38	64.4	31	81.6	9.68	17.62	3.21	16.14
Week 20 (Day 141)	Female	33	55.9	32	97.0	16.67	25.40	7.51	25.82
Week 24 (Day 169)	Female	31	52.5	27	87.1	11.11	18.49	3.80	18.43
Week 28 (Day 197)	Female	30	50.8	27	90.0	13.58	24.91	3.73	23.43
Week 32 (Day 225)	Female	27	45.8	23	85.2	7.25	17.28	-0.23	14.72
Week 36 (Day 253)	Female	22	37.3	15	68.2	6.67	18.69	-3.68	17.02
Week 40 (Day 281)	Female	18	30.5	16	88.9	6.25	13.44	-0.91	13.41
Week 44 (Day 309)	Female	15	25.4	12	80.0	19.44	26.43	2.65	36.24
Week 48 (Day 337)	Female	11	18.6	4	36.4	16.67	33.33	-36.37	69.71
Week 52 (Day 365)	Female	9	15.3	1	11.1	33.33	NE	NE	NE
Week 56 (Day 393)	Female	7	11.9	1	14.3	33.33	NE	NE	NE
Week 60 (Day 421)	Female	5	8.5	1	20.0	0.00	NE	NE	NE
Week 64 (Day 449)	Female	4	6.8	2	50.0	0.00	0.00	NE	NE
Week 68 (Day 477)	Female	3	5.1	1	33.3	0.00	NE	NE	NE
Week 72 (Day 505)	Female	3	5.1	1	33.3	0.00	NE	NE	NE
Week 76 (Day 533)	Female	3	5.1	1	33.3	0.00	NE	NE	NE
Week 80 (Day 561)	Female	2	3.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	59	100.0	59	100.0	16.38	27.24	9.28	23.48
End of Study (LOCF)	Female	59	100.0	59	100.0	15.25	26.50	8.35	22.16
Baseline	Male	49	100.0	48	98.0	15.28	26.59	7.56	23.00
Week 4 (Day 29)	Male	49	100.0	45	91.8	8.89	21.79	2.34	15.43
Week 8 (Day 57)	Male	43	87.8	35	81.4	8.57	20.36	1.58	15.57
Week 12 (Day 85)	Male	35	71.4	32	91.4	5.21	12.30	0.77	9.64
Week 16 (Day 113)	Male	31	63.3	27	87.1	4.94	12.07	0.16	9.71
Week 20 (Day 141)	Male	26	53.1	23	88.5	5.80	21.68	-3.58	15.17
Week 24 (Day 169)	Male	25	51.0	22	88.0	7.58	22.84	-2.55	17.70
Week 28 (Day 197)	Male	25	51.0	24	96.0	4.17	20.41	-4.45	12.79

Week 32 (Day 225)	Male	21	42.9	18	85.7	9.26	25.06	-3.20	21.72
Week 36 (Day 253)	Male	19	38.8	15	78.9	8.89	19.79	-2.07	19.85
Week 40 (Day 281)	Male	19	38.8	16	84.2	6.25	18.13	-3.41	15.91
Week 44 (Day 309)	Male	16	32.7	14	87.5	7.14	19.30	-4.00	18.29
Week 48 (Day 337)	Male	12	24.5	8	66.7	0.00	0.00	NE	NE
Week 52 (Day 365)	Male	10	20.4	3	30.0	0.00	0.00	NE	NE
Week 56 (Day 393)	Male	10	20.4	5	50.0	0.00	0.00	NE	NE
Week 60 (Day 421)	Male	6	12.2	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Male	6	12.2	1	16.7	0.00	NE	NE	NE
Week 68 (Day 477)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	49	100.0	49	100.0	9.52	20.41	3.66	15.39
End of Study (LOCF)	Male	49	100.0	49	100.0	9.52	20.41	3.66	15.39
Age									
Baseline	< 65	63	100.0	60	95.2	20.00	28.26	12.70	27.30
Week 4 (Day 29)	< 65	63	100.0	55	87.3	7.88	14.29	4.02	11.74
Week 8 (Day 57)	< 65	54	85.7	47	87.0	8.51	18.99	2.93	14.09
Week 12 (Day 85)	< 65	47	74.6	42	89.4	7.94	20.57	1.53	14.35
Week 16 (Day 113)	< 65	39	61.9	34	87.2	6.86	15.95	1.30	12.43
Week 20 (Day 141)	< 65	35	55.6	35	100.0	14.29	24.64	5.82	22.75
Week 24 (Day 169)	< 65	34	54.0	31	91.2	8.60	14.83	3.16	14.04
Week 28 (Day 197)	< 65	33	52.4	32	97.0	6.25	15.70	0.59	11.91
Week 32 (Day 225)	< 65	30	47.6	25	83.3	5.33	12.47	0.19	10.48
Week 36 (Day 253)	< 65	25	39.7	20	80.0	3.33	10.26	-1.47	8.14
Week 40 (Day 281)	< 65	23	36.5	21	91.3	4.76	11.95	-0.68	10.20
Week 44 (Day 309)	< 65	19	30.2	17	89.5	13.73	23.74	1.52	25.93
Week 48 (Day 337)	< 65	14	22.2	7	50.0	9.52	25.20	-13.78	32.83

Week 52 (Day 365)	< 65	12	19.0	2	16.7	16.67	23.57	-195.10	228.44
Week 56 (Day 393)	< 65	11	17.5	2	18.2	16.67	23.57	-195.10	228.44
Week 60 (Day 421)	< 65	8	12.7	1	12.5	0.00	NE	NE	NE
Week 64 (Day 449)	< 65	7	11.1	3	42.9	0.00	0.00	NE	NE
Week 68 (Day 477)	< 65	4	6.3	1	25.0	0.00	NE	NE	NE
Week 72 (Day 505)	< 65	4	6.3	1	25.0	0.00	NE	NE	NE
Week 76 (Day 533)	< 65	4	6.3	1	25.0	0.00	NE	NE	NE
Week 80 (Day 561)	< 65	3	4.8	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	63	100.0	63	100.0	10.58	21.44	5.18	15.98
End of Study (LOCF)	< 65	63	100.0	63	100.0	9.52	20.24	4.43	14.62
Baseline	>= 65	45	100.0	44	97.8	18.94	29.99	9.82	28.06
Week 4 (Day 29)	>= 65	45	100.0	41	91.1	15.45	24.83	7.61	23.28
Week 8 (Day 57)	>= 65	38	84.4	32	84.2	21.87	32.36	10.21	33.54
Week 12 (Day 85)	>= 65	32	71.1	29	90.6	11.49	18.42	4.49	18.50
Week 16 (Day 113)	>= 65	30	66.7	24	80.0	8.33	14.74	2.11	14.56
Week 20 (Day 141)	>= 65	24	53.3	20	83.3	8.33	23.88	-2.84	19.51
Week 24 (Day 169)	>= 65	22	48.9	18	81.8	11.11	28.01	-2.82	25.04
Week 28 (Day 197)	>= 65	22	48.9	19	86.4	14.04	32.04	-1.41	29.48
Week 32 (Day 225)	>= 65	18	40.0	16	88.9	12.50	29.50	-3.22	28.22
Week 36 (Day 253)	>= 65	16	35.6	10	62.5	16.67	28.33	-3.60	36.93
Week 40 (Day 281)	>= 65	14	31.1	11	78.6	9.09	21.56	-5.39	23.57
Week 44 (Day 309)	>= 65	12	26.7	9	75.0	11.11	23.57	-7.01	29.23
Week 48 (Day 337)	>= 65	9	20.0	5	55.6	0.00	0.00	NE	NE
Week 52 (Day 365)	>= 65	7	15.6	2	28.6	0.00	0.00	NE	NE
Week 56 (Day 393)	>= 65	6	13.3	4	66.7	0.00	0.00	NE	NE
Week 60 (Day 421)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE

Week 76 (Day 533)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	45	100.0	45	100.0	17.04	28.09	8.60	25.48
End of Study (LOCF)	>= 65	45	100.0	45	100.0	17.04	28.09	8.60	25.48
ECOG performance status									
Baseline	0	30	100.0	29	96.7	14.94	27.58	4.45	25.43
Week 4 (Day 29)	0	30	100.0	29	96.7	9.20	17.59	2.51	15.88
Week 8 (Day 57)	0	28	93.3	25	89.3	17.33	30.61	4.70	29.97
Week 12 (Day 85)	0	26	86.7	24	92.3	11.11	23.40	1.23	20.99
Week 16 (Day 113)	0	26	86.7	21	80.8	3.17	10.03	-1.39	7.74
Week 20 (Day 141)	0	26	86.7	24	92.3	6.94	16.97	-0.22	14.11
Week 24 (Day 169)	0	25	83.3	23	92.0	2.90	9.60	-1.25	7.05
Week 28 (Day 197)	0	25	83.3	23	92.0	7.25	22.38	-2.43	16.92
Week 32 (Day 225)	0	20	66.7	16	80.0	2.08	8.33	-2.36	6.52
Week 36 (Day 253)	0	18	60.0	11	61.1	0.00	0.00	NE	NE
Week 40 (Day 281)	0	16	53.3	11	68.8	0.00	0.00	NE	NE
Week 44 (Day 309)	0	15	50.0	12	80.0	8.33	20.72	-4.83	21.50
Week 48 (Day 337)	0	9	30.0	6	66.7	11.11	27.22	-17.45	39.67
Week 52 (Day 365)	0	9	30.0	3	33.3	11.11	19.25	-36.70	58.92
Week 56 (Day 393)	0	8	26.7	3	37.5	0.00	0.00	NE	NE
Week 60 (Day 421)	0	5	16.7	1	20.0	0.00	NE	NE	NE
Week 64 (Day 449)	0	5	16.7	2	40.0	0.00	0.00	NE	NE
Week 68 (Day 477)	0	3	10.0	1	33.3	0.00	NE	NE	NE
Week 72 (Day 505)	0	3	10.0	1	33.3	0.00	NE	NE	NE
Week 76 (Day 533)	0	3	10.0	1	33.3	0.00	NE	NE	NE
Week 80 (Day 561)	0	2	6.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	0	1	3.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	30	100.0	30	100.0	15.56	32.44	3.44	27.67
End of Study (LOCF)	0	30	100.0	30	100.0	13.33	31.07	1.73	24.94
Baseline	1	78	100.0	75	96.2	21.33	29.33	14.59	28.08
Week 4 (Day 29)	1	78	100.0	67	85.9	11.94	20.68	6.90	16.98

Week 8 (Day 57)	1	64	82.1	54	84.4	12.35	23.61	5.90	18.79
Week 12 (Day 85)	1	53	67.9	47	88.7	8.51	17.68	3.32	13.70
Week 16 (Day 113)	1	43	55.1	37	86.0	9.91	17.33	4.13	15.69
Week 20 (Day 141)	1	33	42.3	31	93.9	16.13	28.38	5.72	26.54
Week 24 (Day 169)	1	31	39.7	26	83.9	15.38	25.35	5.14	25.62
Week 28 (Day 197)	1	30	38.5	28	93.3	10.71	24.09	1.37	20.06
Week 32 (Day 225)	1	28	35.9	25	89.3	12.00	25.24	1.58	22.42
Week 36 (Day 253)	1	23	29.5	19	82.6	12.28	22.80	1.29	23.27
Week 40 (Day 281)	1	21	26.9	21	100.0	9.52	18.69	1.02	18.03
Week 44 (Day 309)	1	16	20.5	14	87.5	16.67	25.32	2.05	31.29
Week 48 (Day 337)	1	14	17.9	6	42.9	0.00	0.00	NE	NE
Week 52 (Day 365)	1	10	12.8	1	10.0	0.00	NE	NE	NE
Week 56 (Day 393)	1	9	11.5	3	33.3	11.11	19.25	-36.70	58.92
Week 60 (Day 421)	1	6	7.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	5	6.4	1	20.0	0.00	NE	NE	NE
Week 68 (Day 477)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	3	3.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	78	100.0	78	100.0	12.39	20.88	7.69	17.10
End of Study (LOCF)	1	78	100.0	78	100.0	12.39	20.88	7.69	17.10
Geographic region									
Baseline	USA	21	100.0	19	90.5	15.79	30.16	1.25	30.33
Week 4 (Day 29)	USA	21	100.0	20	95.2	8.33	14.81	1.40	15.26
Week 8 (Day 57)	USA	21	100.0	19	90.5	12.28	16.52	4.32	20.24
Week 12 (Day 85)	USA	21	100.0	19	90.5	12.28	19.91	2.68	21.88
Week 16 (Day 113)	USA	21	100.0	16	76.2	6.25	13.44	-0.91	13.41
Week 20 (Day 141)	USA	20	95.2	18	90.0	14.81	32.78	-1.49	31.12
Week 24 (Day 169)	USA	20	95.2	19	95.0	7.02	23.78	-4.44	18.48
Week 28 (Day 197)	USA	20	95.2	19	95.0	5.26	22.94	-5.79	16.32
Week 32 (Day 225)	USA	17	81.0	15	88.2	8.89	26.63	-5.86	23.63
Week 36 (Day 253)	USA	17	81.0	11	64.7	6.06	20.10	-7.44	19.56
Week 40 (Day 281)	USA	15	71.4	12	80.0	8.33	20.72	-4.83	21.50

Week 44 (Day 309)	USA	13	61.9	10	76.9	13.33	23.31	-3.34	30.01
Week 48 (Day 337)	USA	8	38.1	5	62.5	0.00	0.00	NE	NE
Week 52 (Day 365)	USA	6	28.6	1	16.7	0.00	NE	NE	NE
Week 56 (Day 393)	USA	6	28.6	3	50.0	11.11	19.25	-36.70	58.92
Week 60 (Day 421)	USA	5	23.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	4	19.0	1	25.0	0.00	NE	NE	NE
Week 68 (Day 477)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	21	100.0	21	100.0	7.94	17.97	-0.24	16.11
End of Study (LOCF)	USA	21	100.0	21	100.0	7.94	17.97	-0.24	16.11
Baseline	Europe (EU)	42	100.0	40	95.2	19.17	26.03	10.84	27.49
Week 4 (Day 29)	Europe (EU)	42	100.0	39	92.9	11.97	20.92	5.18	18.75
Week 8 (Day 57)	Europe (EU)	36	85.7	30	83.3	15.56	29.99	4.36	26.75
Week 12 (Day 85)	Europe (EU)	31	73.8	25	80.6	12.00	25.24	1.58	22.42
Week 16 (Day 113)	Europe (EU)	30	71.4	24	80.0	9.72	18.33	1.98	17.46
Week 20 (Day 141)	Europe (EU)	26	61.9	24	92.3	9.72	18.33	1.98	17.46
Week 24 (Day 169)	Europe (EU)	26	61.9	22	84.6	10.61	18.93	2.21	19.00
Week 28 (Day 197)	Europe (EU)	25	59.5	23	92.0	11.59	23.80	1.30	21.89
Week 32 (Day 225)	Europe (EU)	21	50.0	19	90.5	5.26	12.49	-0.76	11.28
Week 36 (Day 253)	Europe (EU)	16	38.1	13	81.3	5.13	18.49	-6.05	16.30
Week 40 (Day 281)	Europe (EU)	14	33.3	14	100.0	2.38	8.91	-2.76	7.52
Week 44 (Day 309)	Europe (EU)	11	26.2	10	90.9	10.00	22.50	-6.09	26.09
Week 48 (Day 337)	Europe (EU)	8	19.0	6	75.0	11.11	27.22	-17.45	39.67
Week 52 (Day 365)	Europe (EU)	6	14.3	3	50.0	11.11	19.25	-36.70	58.92
Week 56 (Day 393)	Europe (EU)	6	14.3	2	33.3	0.00	0.00	NE	NE

Week 60 (Day 421)	Europe (EU)	4	9.5	1	25.0	0.00	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	4	9.5	2	50.0	0.00	0.00	NE	NE
Week 68 (Day 477)	Europe (EU)	3	7.1	1	33.3	0.00	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	3	7.1	1	33.3	0.00	NE	NE	NE
Week 76 (Day 533)	Europe (EU)	3	7.1	1	33.3	0.00	NE	NE	NE
Week 80 (Day 561)	Europe (EU)	2	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Europe (EU)	42	100.0	42	100.0	19.05	27.69	10.42	27.68
End of Study (LOCF)	Europe (EU)	42	100.0	42	100.0	17.46	26.79	9.11	25.81
Baseline	Asia (AS)	45	100.0	45	100.0	21.48	31.10	12.14	30.83
Week 4 (Day 29)	Asia (AS)	45	100.0	37	82.2	11.71	21.11	4.67	18.75
Week 8 (Day 57)	Asia (AS)	35	77.8	30	85.7	13.33	27.12	3.21	23.46
Week 12 (Day 85)	Asia (AS)	27	60.0	27	100.0	4.94	12.07	0.16	9.71
Week 16 (Day 113)	Asia (AS)	18	40.0	18	100.0	5.56	12.78	-0.80	11.91
Week 20 (Day 141)	Asia (AS)	13	28.9	13	100.0	12.82	21.68	-0.28	25.92
Week 24 (Day 169)	Asia (AS)	10	22.2	8	80.0	12.50	17.25	-1.92	26.92
Week 28 (Day 197)	Asia (AS)	10	22.2	9	90.0	11.11	23.57	-7.01	29.23
Week 32 (Day 225)	Asia (AS)	10	22.2	7	70.0	14.29	26.23	-9.97	38.54
Week 36 (Day 253)	Asia (AS)	8	17.8	6	75.0	16.67	18.26	-2.49	35.83
Week 40 (Day 281)	Asia (AS)	8	17.8	6	75.0	11.11	17.21	-6.95	29.18
Week 44 (Day 309)	Asia (AS)	7	15.6	6	85.7	16.67	27.89	-12.60	45.93
Week 48 (Day 337)	Asia (AS)	7	15.6	1	14.3	0.00	NE	NE	NE
Week 52 (Day 365)	Asia (AS)	7	15.6	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Asia (AS)	5	11.1	1	20.0	0.00	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	45	100.0	45	100.0	10.37	23.38	3.35	17.39
End of Study (LOCF)	Asia (AS)	45	100.0	45	100.0	10.37	23.38	3.35	17.39

Race/ethnicity									
Baseline	Asian	48	100.0	48	100.0	22.22	32.50	12.79	31.66
Week 4 (Day 29)	Asian	48	100.0	40	83.3	11.67	20.74	5.03	18.30
Week 8 (Day 57)	Asian	38	79.2	31	81.6	13.98	26.91	4.11	23.85
Week 12 (Day 85)	Asian	30	62.5	30	100.0	6.67	13.56	1.60	11.73
Week 16 (Day 113)	Asian	21	43.8	21	100.0	6.35	13.41	0.24	12.45
Week 20 (Day 141)	Asian	16	33.3	15	93.8	17.78	30.52	0.88	34.68
Week 24 (Day 169)	Asian	13	27.1	11	84.6	18.18	31.14	-2.74	39.10
Week 28 (Day 197)	Asian	13	27.1	12	92.3	16.67	33.33	-4.51	37.85
Week 32 (Day 225)	Asian	12	25.0	9	75.0	22.22	37.27	-6.42	50.87
Week 36 (Day 253)	Asian	10	20.8	8	80.0	20.83	24.80	0.10	41.57
Week 40 (Day 281)	Asian	10	20.8	8	80.0	16.67	25.20	-4.40	37.73
Week 44 (Day 309)	Asian	9	18.8	8	88.9	20.83	30.54	-4.70	46.36
Week 48 (Day 337)	Asian	9	18.8	2	22.2	0.00	0.00	NE	NE
Week 52 (Day 365)	Asian	9	18.8	1	11.1	0.00	NE	NE	NE
Week 56 (Day 393)	Asian	7	14.6	2	28.6	0.00	0.00	NE	NE
Week 60 (Day 421)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	48	100.0	48	100.0	11.11	24.15	4.10	18.12
End of Study (LOCF)	Asian	48	100.0	48	100.0	11.11	24.15	4.10	18.12
Baseline	Non-Asian	54	100.0	52	96.3	17.31	25.98	10.07	24.54
Week 4 (Day 29)	Non-Asian	54	100.0	50	92.6	12.00	19.93	6.34	17.66
Week 8 (Day 57)	Non-Asian	49	90.7	44	89.8	15.15	26.37	7.13	23.17
Week 12 (Day 85)	Non-Asian	44	81.5	37	84.1	10.81	22.30	3.38	18.25
Week 16 (Day 113)	Non-Asian	43	79.6	34	79.1	8.82	17.03	2.88	14.77
Week 20 (Day 141)	Non-Asian	38	70.4	35	92.1	11.43	22.78	3.60	19.26
Week 24 (Day 169)	Non-Asian	38	70.4	34	89.5	7.84	16.53	2.07	13.61
Week 28 (Day 197)	Non-Asian	37	68.5	35	94.6	7.62	19.94	0.77	14.47
Week 32 (Day 225)	Non-Asian	32	59.3	28	87.5	4.76	11.88	0.16	9.37
Week 36 (Day 253)	Non-Asian	27	50.0	20	74.1	0.00	0.00	NE	NE

Week 40 (Day 281)	Non-Asian	23	42.6	21	91.3	1.59	7.27	-1.72	4.90
Week 44 (Day 309)	Non-Asian	18	33.3	14	77.8	9.52	20.37	-2.24	21.29
Week 48 (Day 337)	Non-Asian	12	22.2	9	75.0	7.41	22.22	-9.67	24.49
Week 52 (Day 365)	Non-Asian	8	14.8	3	37.5	11.11	19.25	-36.70	58.92
Week 56 (Day 393)	Non-Asian	8	14.8	4	50.0	8.33	16.67	-18.19	34.85
Week 60 (Day 421)	Non-Asian	7	13.0	1	14.3	0.00	NE	NE	NE
Week 64 (Day 449)	Non-Asian	6	11.1	2	33.3	0.00	0.00	NE	NE
Week 68 (Day 477)	Non-Asian	3	5.6	1	33.3	0.00	NE	NE	NE
Week 72 (Day 505)	Non-Asian	3	5.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Non-Asian	3	5.6	1	33.3	0.00	NE	NE	NE
Week 80 (Day 561)	Non-Asian	2	3.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	54	100.0	54	100.0	16.05	25.69	9.04	23.06
End of Study (LOCF)	Non-Asian	54	100.0	54	100.0	14.81	24.80	8.05	21.58
Baseline	Unknown	6	100.0	4	66.7	16.67	19.25	-13.96	47.29
Week 4 (Day 29)	Unknown	6	100.0	6	100.0	0.00	0.00	NE	NE
Week 8 (Day 57)	Unknown	5	83.3	4	80.0	0.00	0.00	NE	NE
Week 12 (Day 85)	Unknown	5	83.3	4	80.0	16.67	33.33	-36.37	69.71
Week 16 (Day 113)	Unknown	5	83.3	3	60.0	0.00	0.00	NE	NE
Week 20 (Day 141)	Unknown	5	83.3	5	100.0	0.00	0.00	NE	NE
Week 24 (Day 169)	Unknown	5	83.3	4	80.0	0.00	0.00	NE	NE
Week 28 (Day 197)	Unknown	5	83.3	4	80.0	0.00	0.00	NE	NE
Week 32 (Day 225)	Unknown	4	66.7	4	100.0	0.00	0.00	NE	NE
Week 36 (Day 253)	Unknown	4	66.7	2	50.0	33.33	47.14	-390.21	456.87
Week 40 (Day 281)	Unknown	4	66.7	3	75.0	11.11	19.25	-36.70	58.92
Week 44 (Day 309)	Unknown	4	66.7	4	100.0	8.33	16.67	-18.19	34.85
Week 48 (Day 337)	Unknown	2	33.3	1	50.0	0.00	NE	NE	NE
Week 52 (Day 365)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 60 (Day 421)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE

Week 64 (Day 449)	Unknown	1	16.7	1	100.0	0.00	NE	NE	NE
Week 68 (Day 477)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	1	16.7	1	100.0	0.00	NE	NE	NE
Week 76 (Day 533)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	6	100.0	6	100.0	5.56	13.61	-8.73	19.84
End of Study (LOCF)	Unknown	6	100.0	6	100.0	5.56	13.61	-8.73	19.84

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TN_QSC30AP_SG.xls
27OCT2021 7:33

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Appetite Loss
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	26	25.0	17.7	34.1
	Cycle 12 (LOCF)	n/a	104	96.3	12	11.5	6.7	19.1
	End of Study (LOCF)	n/a	104	96.3	11	10.6	6.0	18.0
Sex	All visits	Female	56	51.9	18	32.1	21.4	45.2
		Male	48	44.4	8	16.7	8.7	29.6
	Cycle 12 (LOCF)	Female	56	51.9	8	14.3	7.4	25.7
		Male	48	44.4	4	8.3	3.3	19.6
	End of Study (LOCF)	Female	56	51.9	7	12.5	6.2	23.6
		Male	48	44.4	4	8.3	3.3	19.6
Age	All visits	< 65	60	55.6	13	21.7	13.1	33.6
		>= 65	44	40.7	13	29.5	18.2	44.2
	Cycle 12 (LOCF)	< 65	60	55.6	5	8.3	3.6	18.1
		>= 65	44	40.7	7	15.9	7.9	29.4
	End of Study (LOCF)	< 65	60	55.6	4	6.7	2.6	15.9
		>= 65	44	40.7	7	15.9	7.9	29.4
ECOG performance status	All visits	0	29	26.9	10	34.5	19.9	52.7
		1	75	69.4	16	21.3	13.6	31.9
	Cycle 12 (LOCF)	0	29	26.9	5	17.2	7.6	34.5
		1	75	69.4	7	9.3	4.6	18.0
	End of Study (LOCF)	0	29	26.9	4	13.8	5.5	30.6
		1	75	69.4	7	9.3	4.6	18.0
Geographic region	All visits	USA	19	17.6	4	21.1	8.5	43.3
		Europe (EU)	40	37.0	15	37.5	24.2	53.0
		Asia (AS)	45	41.7	7	15.6	7.7	28.8
	Cycle 12 (LOCF)	USA	19	17.6	1	5.3	0.9	24.6
		Europe (EU)	40	37.0	9	22.5	12.3	37.5
		Asia (AS)	45	41.7	2	4.4	1.2	14.8
	End of Study (LOCF)	USA	19	17.6	1	5.3	0.9	24.6
		Europe (EU)	40	37.0	8	20.0	10.5	34.8
		Asia (AS)	45	41.7	2	4.4	1.2	14.8
Race/ethnicity	All visits	Asian	48	44.4	8	16.7	8.7	29.6
		Non-Asian	52	48.1	17	32.7	21.5	46.2
		Unknown	4	3.7	1	25.0	4.6	69.9
	Cycle 12 (LOCF)	Asian	48	44.4	2	4.2	1.2	14.0
		Non-Asian	52	48.1	9	17.3	9.4	29.7
		Unknown	4	3.7	1	25.0	4.6	69.9
	End of Study (LOCF)	Asian	48	44.4	2	4.2	1.2	14.0

		Non-Asian	52	48.1	8	15.4	8.0	27.5
		Unknown	4	3.7	1	25.0	4.6	69.9

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30AP_W10_SG.xls
15OCT2021 13:09

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Appetite Loss
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

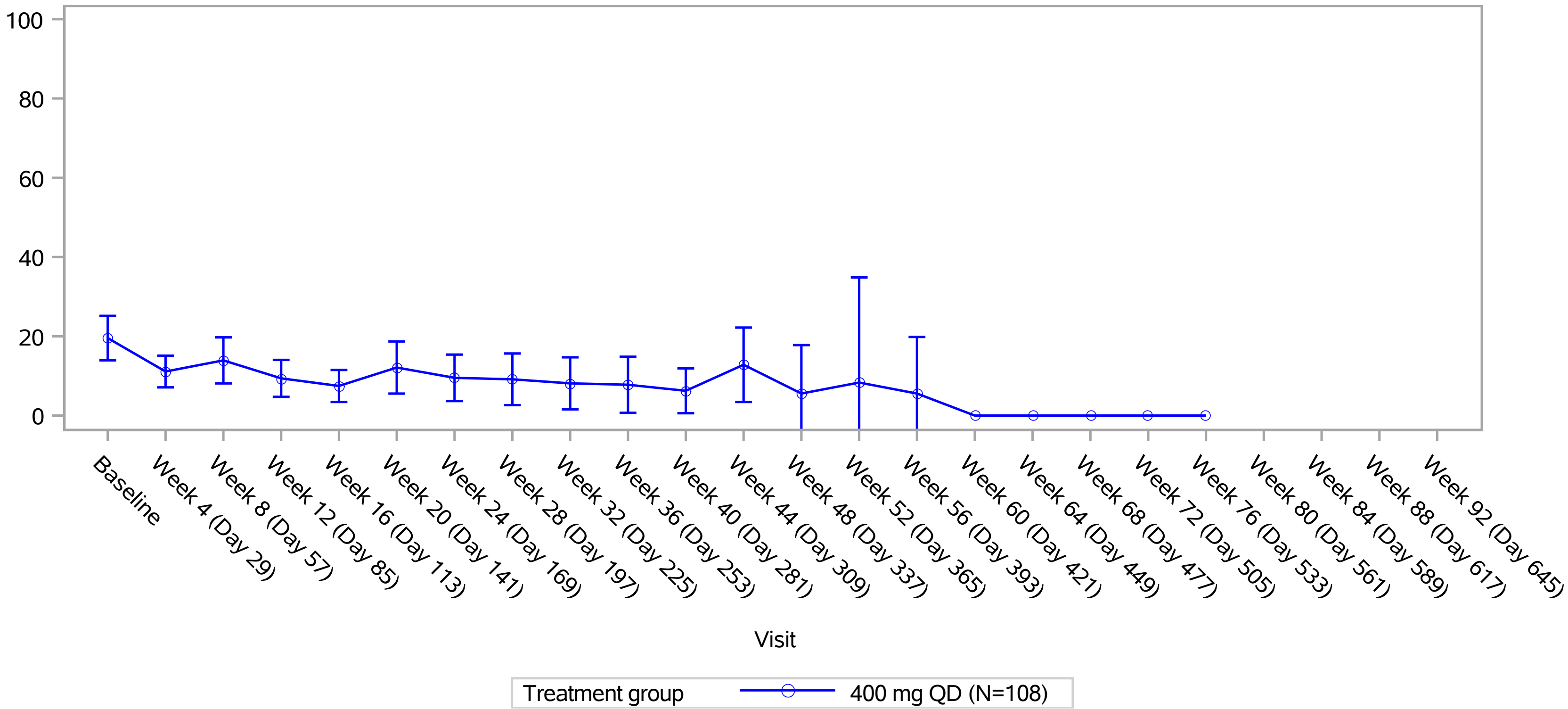
			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	26	25.0	17.7	34.1
	Cycle 12 (LOCF)	n/a	104	96.3	12	11.5	6.7	19.1
	End of Study (LOCF)	n/a	104	96.3	11	10.6	6.0	18.0
Sex	All visits	Female	56	51.9	18	32.1	21.4	45.2
		Male	48	44.4	8	16.7	8.7	29.6
	Cycle 12 (LOCF)	Female	56	51.9	8	14.3	7.4	25.7
		Male	48	44.4	4	8.3	3.3	19.6
	End of Study (LOCF)	Female	56	51.9	7	12.5	6.2	23.6
		Male	48	44.4	4	8.3	3.3	19.6
Age	All visits	< 65	60	55.6	13	21.7	13.1	33.6
		>= 65	44	40.7	13	29.5	18.2	44.2
	Cycle 12 (LOCF)	< 65	60	55.6	5	8.3	3.6	18.1
		>= 65	44	40.7	7	15.9	7.9	29.4
	End of Study (LOCF)	< 65	60	55.6	4	6.7	2.6	15.9
		>= 65	44	40.7	7	15.9	7.9	29.4
ECOG performance status	All visits	0	29	26.9	10	34.5	19.9	52.7
		1	75	69.4	16	21.3	13.6	31.9
	Cycle 12 (LOCF)	0	29	26.9	5	17.2	7.6	34.5
		1	75	69.4	7	9.3	4.6	18.0
	End of Study (LOCF)	0	29	26.9	4	13.8	5.5	30.6
		1	75	69.4	7	9.3	4.6	18.0
Geographic region	All visits	USA	19	17.6	4	21.1	8.5	43.3
		Europe (EU)	40	37.0	15	37.5	24.2	53.0
		Asia (AS)	45	41.7	7	15.6	7.7	28.8
	Cycle 12 (LOCF)	USA	19	17.6	1	5.3	0.9	24.6
		Europe (EU)	40	37.0	9	22.5	12.3	37.5
		Asia (AS)	45	41.7	2	4.4	1.2	14.8
	End of Study (LOCF)	USA	19	17.6	1	5.3	0.9	24.6
		Europe (EU)	40	37.0	8	20.0	10.5	34.8
		Asia (AS)	45	41.7	2	4.4	1.2	14.8
Race/ethnicity	All visits	Asian	48	44.4	8	16.7	8.7	29.6
		Non-Asian	52	48.1	17	32.7	21.5	46.2
		Unknown	4	3.7	1	25.0	4.6	69.9
	Cycle 12 (LOCF)	Asian	48	44.4	2	4.2	1.2	14.0
		Non-Asian	52	48.1	9	17.3	9.4	29.7
		Unknown	4	3.7	1	25.0	4.6	69.9
	End of Study (LOCF)	Asian	48	44.4	2	4.2	1.2	14.0

		Non-Asian	52	48.1	8	15.4	8.0	27.5
		Unknown	4	3.7	1	25.0	4.6	69.9

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30AP_W15_SG.xls
15OCT2021 12:59

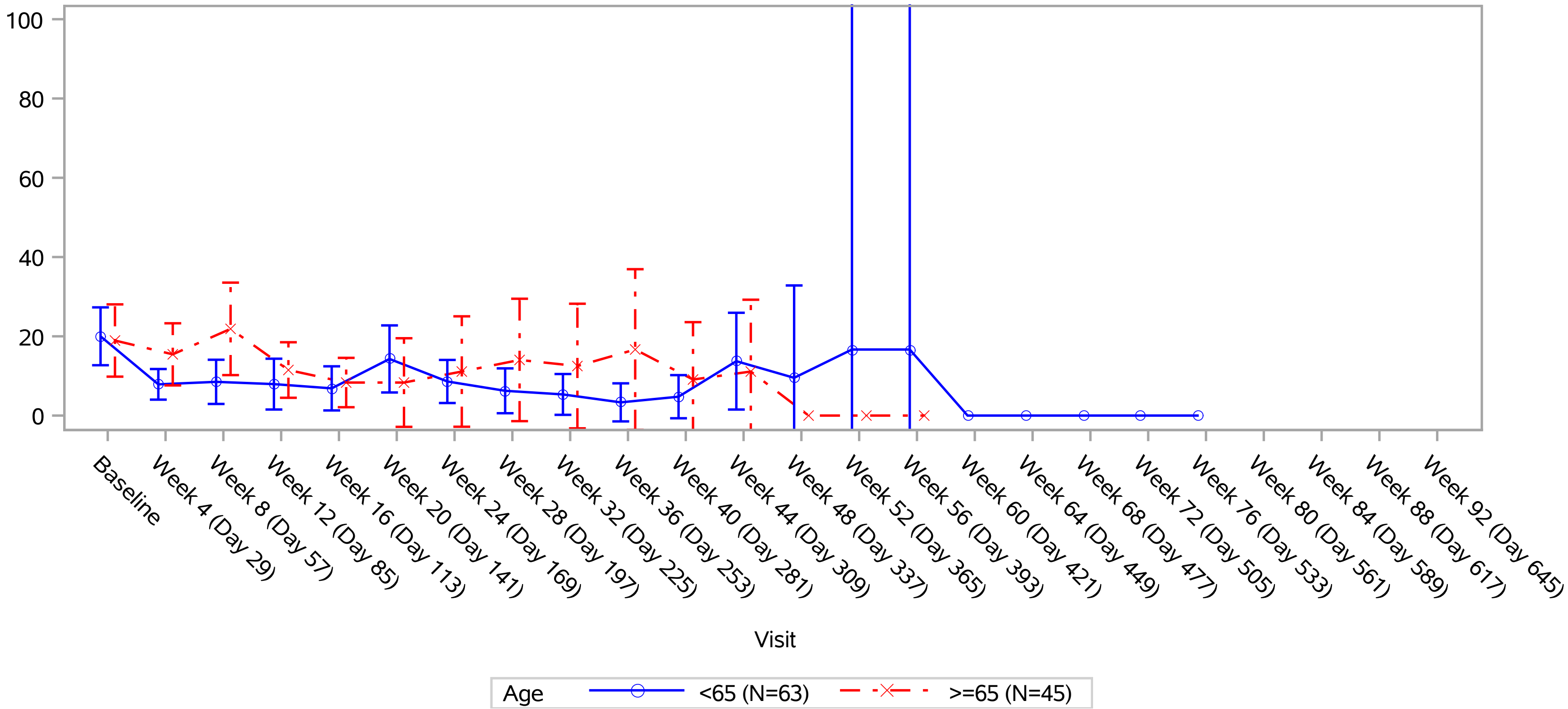
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Appetite Loss
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30AP.pdf
15OCT2021 17:22

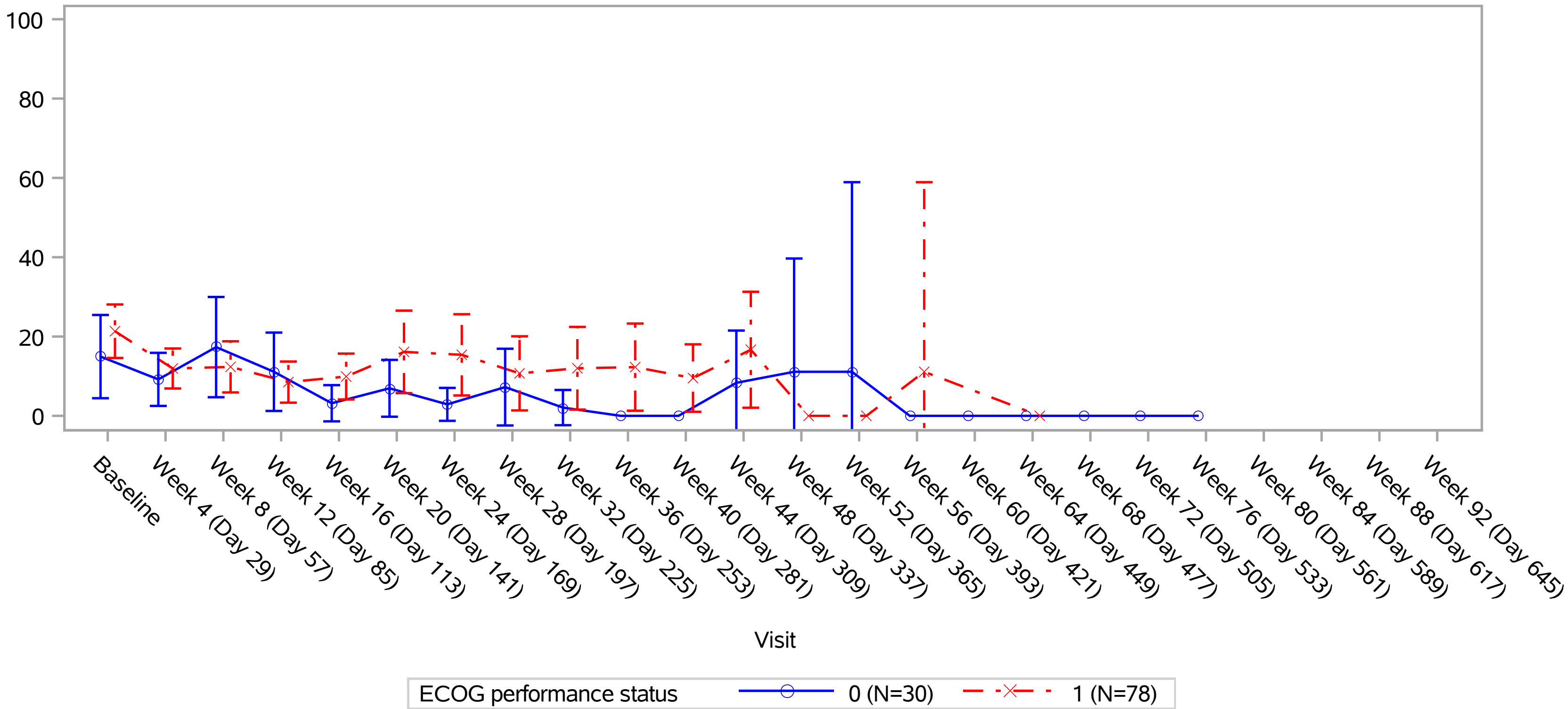
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Appetite Loss
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30AP_SGAGE65.pdf
15OCT2021 17:51

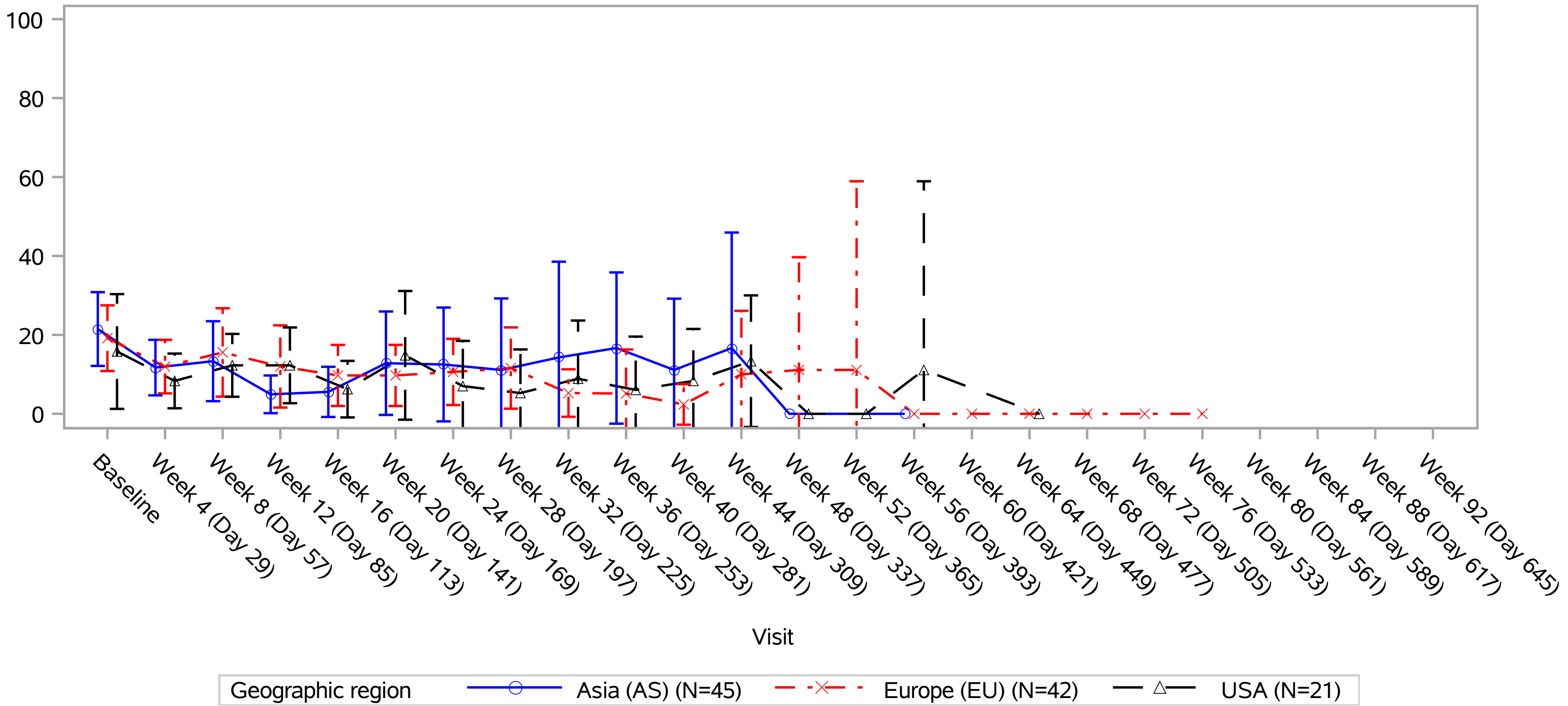
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Appetite Loss
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30AP_SGECOG.pdf
15OCT2021 18:22

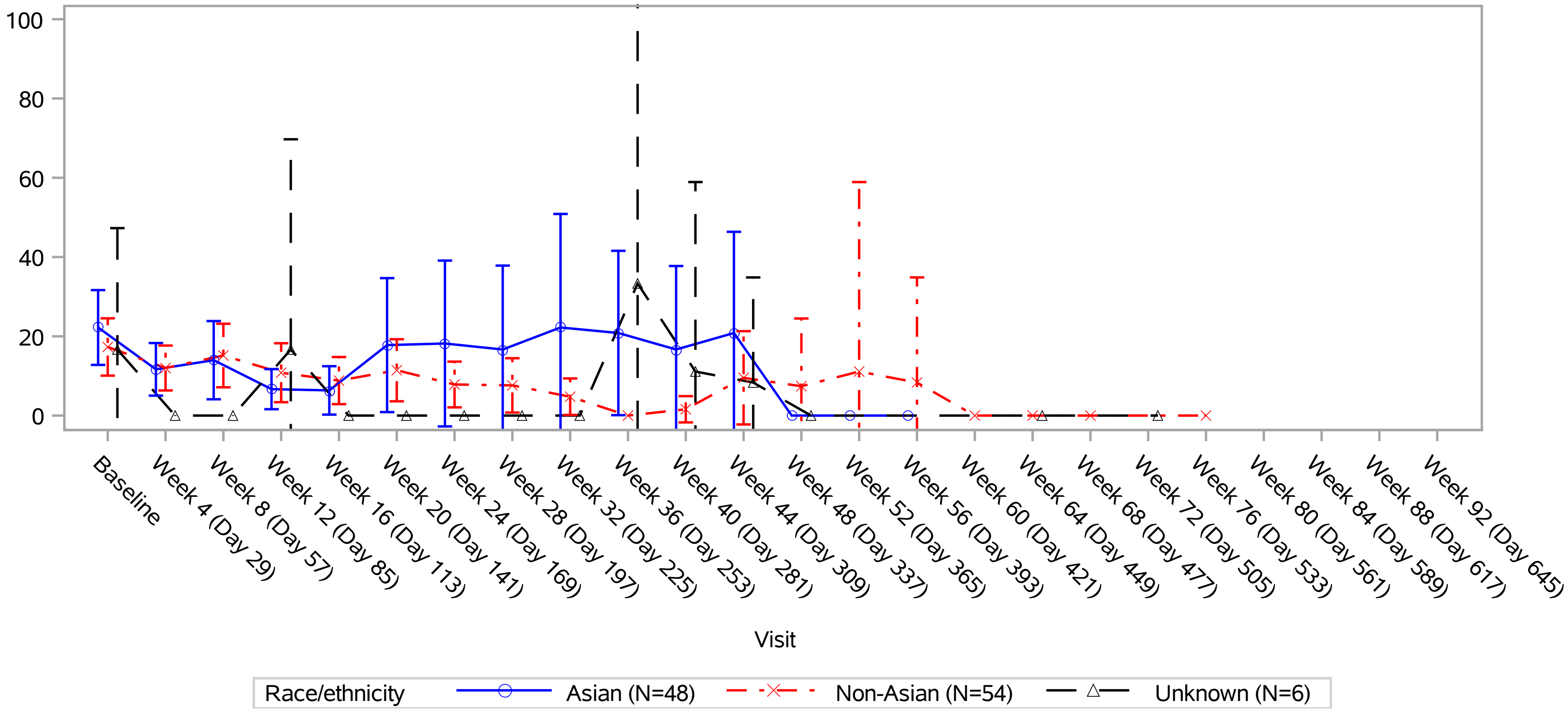
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Appetite Loss
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30AP_SGGEO.pdf
15OCT2021 18:52

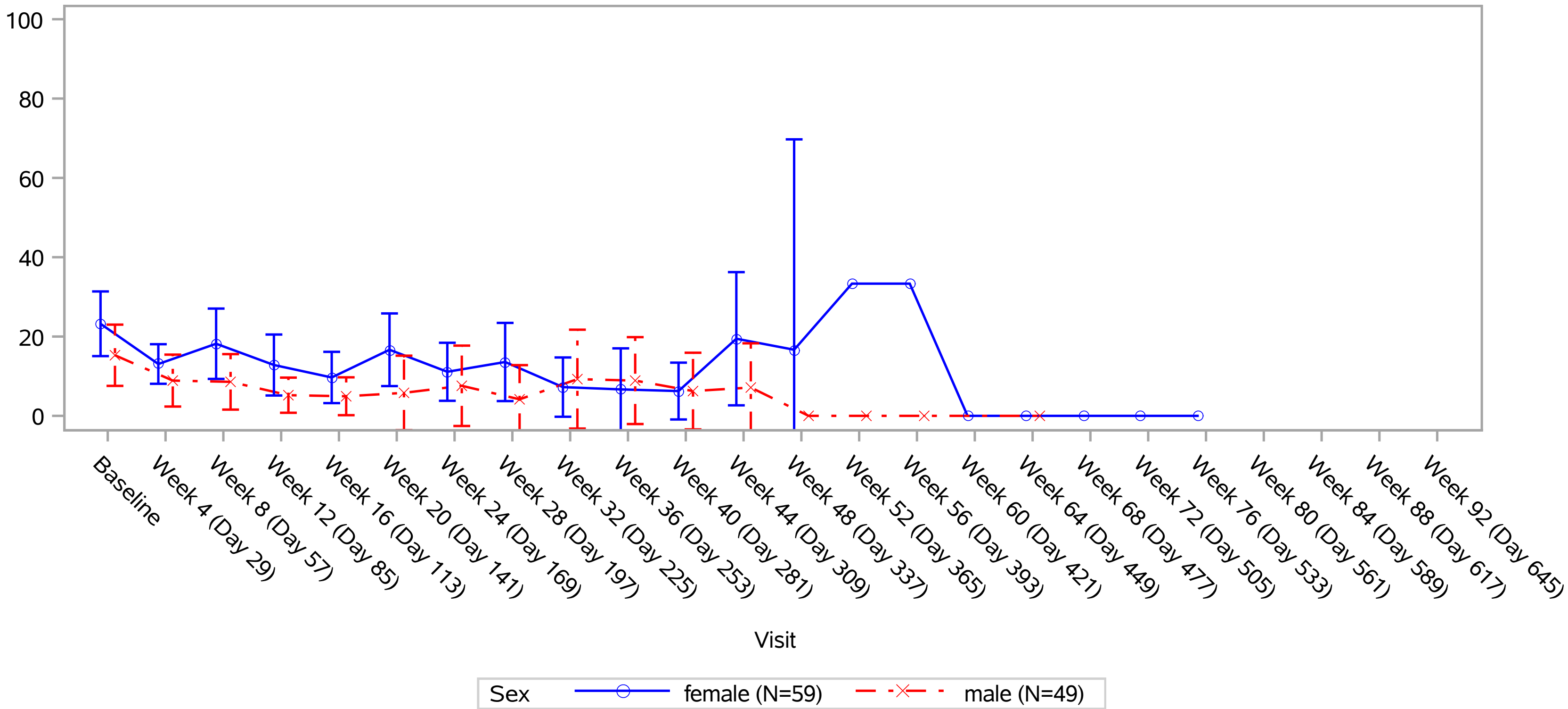
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Appetite Loss
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30AP_SGRE.pdf
15OCT2021 19:23

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Appetite Loss
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30AP_SGSEX.pdf
15OCT2021 19:53

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Cognitive functioning
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=108)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	108	100.0	104	96.3	88.62	19.61	84.81	92.43
Week 4 (Day 29)	n/a	108	100.0	96	88.9	91.49	16.22	88.21	94.78
Week 8 (Day 57)	n/a	92	85.2	79	85.9	91.35	15.53	87.87	94.83
Week 12 (Day 85)	n/a	79	73.1	70	88.6	90.95	13.51	87.73	94.17
Week 16 (Day 113)	n/a	69	63.9	58	84.1	89.66	14.59	85.82	93.49
Week 20 (Day 141)	n/a	59	54.6	55	93.2	92.73	12.32	89.40	96.06
Week 24 (Day 169)	n/a	56	51.9	49	87.5	92.86	11.79	89.47	96.24
Week 28 (Day 197)	n/a	55	50.9	51	92.7	89.54	15.26	85.25	93.83
Week 32 (Day 225)	n/a	48	44.4	41	85.4	91.87	13.50	87.61	96.13
Week 36 (Day 253)	n/a	41	38.0	30	73.2	90.00	15.54	84.20	95.80
Week 40 (Day 281)	n/a	37	34.3	32	86.5	88.54	20.05	81.31	95.77
Week 44 (Day 309)	n/a	31	28.7	26	83.9	85.26	19.62	77.33	93.18
Week 48 (Day 337)	n/a	23	21.3	12	52.2	86.11	18.58	74.31	97.91
Week 52 (Day 365)	n/a	19	17.6	4	21.1	95.83	8.33	82.57	109.09
Week 56 (Day 393)	n/a	17	15.7	6	35.3	86.11	12.55	72.94	99.28
Week 60 (Day 421)	n/a	11	10.2	1	9.1	100.00	NE	NE	NE
Week 64 (Day 449)	n/a	10	9.3	3	30.0	83.33	16.67	41.93	124.74
Week 68 (Day 477)	n/a	6	5.6	1	16.7	100.00	NE	NE	NE
Week 72 (Day 505)	n/a	6	5.6	1	16.7	100.00	NE	NE	NE
Week 76 (Day 533)	n/a	6	5.6	1	16.7	100.00	NE	NE	NE
Week 80 (Day 561)	n/a	5	4.6	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	n/a	1	0.9	0	0.0	NE	NE	NE	NE

Cycle 12 (LOCF)	n/a	108	100.0	108	100.0	89.04	16.92	85.81	92.27
End of Study (LOCF)	n/a	108	100.0	108	100.0	89.81	14.91	86.97	92.66
Sex									
Baseline	Female	59	100.0	56	94.9	84.52	24.38	77.99	91.05
Week 4 (Day 29)	Female	59	100.0	51	86.4	91.18	17.75	86.18	96.17
Week 8 (Day 57)	Female	49	83.1	44	89.8	89.77	17.32	84.51	95.04
Week 12 (Day 85)	Female	44	74.6	38	86.4	89.91	13.72	85.40	94.42
Week 16 (Day 113)	Female	38	64.4	31	81.6	88.17	15.03	82.66	93.68
Week 20 (Day 141)	Female	33	55.9	32	97.0	93.23	12.60	88.69	97.77
Week 24 (Day 169)	Female	31	52.5	27	87.1	93.83	11.46	89.29	98.36
Week 28 (Day 197)	Female	30	50.8	27	90.0	87.65	16.40	81.17	94.14
Week 32 (Day 225)	Female	27	45.8	23	85.2	89.86	15.68	83.07	96.64
Week 36 (Day 253)	Female	22	37.3	15	68.2	85.56	17.67	75.77	95.34
Week 40 (Day 281)	Female	18	30.5	16	88.9	86.46	22.13	74.67	98.25
Week 44 (Day 309)	Female	15	25.4	12	80.0	83.33	22.47	69.05	97.61
Week 48 (Day 337)	Female	11	18.6	4	36.4	83.33	19.25	52.71	113.96
Week 52 (Day 365)	Female	9	15.3	1	11.1	100.00	NE	NE	NE
Week 56 (Day 393)	Female	7	11.9	1	14.3	83.33	NE	NE	NE
Week 60 (Day 421)	Female	5	8.5	1	20.0	100.00	NE	NE	NE
Week 64 (Day 449)	Female	4	6.8	2	50.0	91.67	11.79	-14.22	197.55
Week 68 (Day 477)	Female	3	5.1	1	33.3	100.00	NE	NE	NE
Week 72 (Day 505)	Female	3	5.1	1	33.3	100.00	NE	NE	NE
Week 76 (Day 533)	Female	3	5.1	1	33.3	100.00	NE	NE	NE
Week 80 (Day 561)	Female	2	3.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	59	100.0	59	100.0	87.29	18.40	82.49	92.08
End of Study (LOCF)	Female	59	100.0	59	100.0	88.98	15.66	84.90	93.06
Baseline	Male	49	100.0	48	98.0	93.40	10.16	90.45	96.35
Week 4 (Day 29)	Male	49	100.0	45	91.8	91.85	14.49	87.50	96.20
Week 8 (Day 57)	Male	43	87.8	35	81.4	93.33	12.91	88.90	97.77
Week 12 (Day 85)	Male	35	71.4	32	91.4	92.19	13.38	87.36	97.01
Week 16 (Day 113)	Male	31	63.3	27	87.1	91.36	14.15	85.76	96.96
Week 20 (Day 141)	Male	26	53.1	23	88.5	92.03	12.17	86.76	97.29
Week 24 (Day 169)	Male	25	51.0	22	88.0	91.67	12.33	86.20	97.14
Week 28 (Day 197)	Male	25	51.0	24	96.0	91.67	13.90	85.80	97.54

Week 32 (Day 225)	Male	21	42.9	18	85.7	94.44	9.90	89.52	99.37
Week 36 (Day 253)	Male	19	38.8	15	78.9	94.44	12.06	87.76	101.12
Week 40 (Day 281)	Male	19	38.8	16	84.2	90.63	18.23	80.91	100.34
Week 44 (Day 309)	Male	16	32.7	14	87.5	86.90	17.52	76.79	97.02
Week 48 (Day 337)	Male	12	24.5	8	66.7	87.50	19.42	71.27	103.73
Week 52 (Day 365)	Male	10	20.4	3	30.0	94.44	9.62	70.54	118.35
Week 56 (Day 393)	Male	10	20.4	5	50.0	86.67	13.94	69.35	103.98
Week 60 (Day 421)	Male	6	12.2	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Male	6	12.2	1	16.7	66.67	NE	NE	NE
Week 68 (Day 477)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	49	100.0	49	100.0	91.16	14.87	86.89	95.43
End of Study (LOCF)	Male	49	100.0	49	100.0	90.82	14.05	86.78	94.85
Age									
Baseline	< 65	63	100.0	60	95.2	88.33	17.97	83.69	92.98
Week 4 (Day 29)	< 65	63	100.0	55	87.3	92.73	16.59	88.24	97.21
Week 8 (Day 57)	< 65	54	85.7	47	87.0	91.13	15.09	86.70	95.56
Week 12 (Day 85)	< 65	47	74.6	41	87.2	91.87	13.50	87.61	96.13
Week 16 (Day 113)	< 65	39	61.9	34	87.2	89.71	16.42	83.98	95.44
Week 20 (Day 141)	< 65	35	55.6	35	100.0	92.86	12.96	88.40	97.31
Week 24 (Day 169)	< 65	34	54.0	31	91.2	94.09	11.01	90.05	98.13
Week 28 (Day 197)	< 65	33	52.4	32	97.0	89.58	15.12	84.13	95.03
Week 32 (Day 225)	< 65	30	47.6	25	83.3	94.00	11.67	89.18	98.82
Week 36 (Day 253)	< 65	25	39.7	20	80.0	91.67	11.47	86.30	97.04
Week 40 (Day 281)	< 65	23	36.5	21	91.3	88.89	21.94	78.90	98.88
Week 44 (Day 309)	< 65	19	30.2	17	89.5	87.25	20.01	76.97	97.54
Week 48 (Day 337)	< 65	14	22.2	7	50.0	83.33	21.52	63.43	103.23

Week 52 (Day 365)	< 65	12	19.0	2	16.7	91.67	11.79	-14.22	197.55
Week 56 (Day 393)	< 65	11	17.5	2	18.2	75.00	11.79	-30.89	180.89
Week 60 (Day 421)	< 65	8	12.7	1	12.5	100.00	NE	NE	NE
Week 64 (Day 449)	< 65	7	11.1	3	42.9	83.33	16.67	41.93	124.74
Week 68 (Day 477)	< 65	4	6.3	1	25.0	100.00	NE	NE	NE
Week 72 (Day 505)	< 65	4	6.3	1	25.0	100.00	NE	NE	NE
Week 76 (Day 533)	< 65	4	6.3	1	25.0	100.00	NE	NE	NE
Week 80 (Day 561)	< 65	3	4.8	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	63	100.0	63	100.0	89.15	17.75	84.68	93.62
End of Study (LOCF)	< 65	63	100.0	63	100.0	91.01	14.30	87.40	94.61
Baseline	>= 65	45	100.0	44	97.8	89.02	21.85	82.37	95.66
Week 4 (Day 29)	>= 65	45	100.0	41	91.1	89.84	15.76	84.86	94.81
Week 8 (Day 57)	>= 65	38	84.4	32	84.2	91.67	16.40	85.76	97.58
Week 12 (Day 85)	>= 65	32	71.1	29	90.6	89.66	13.67	84.46	94.85
Week 16 (Day 113)	>= 65	30	66.7	24	80.0	89.58	11.85	84.58	94.59
Week 20 (Day 141)	>= 65	24	53.3	20	83.3	92.50	11.44	87.15	97.85
Week 24 (Day 169)	>= 65	22	48.9	18	81.8	90.74	13.06	84.24	97.24
Week 28 (Day 197)	>= 65	22	48.9	19	86.4	89.47	15.92	81.80	97.15
Week 32 (Day 225)	>= 65	18	40.0	16	88.9	88.54	15.77	80.14	96.95
Week 36 (Day 253)	>= 65	16	35.6	10	62.5	86.67	21.94	70.97	102.36
Week 40 (Day 281)	>= 65	14	31.1	11	78.6	87.88	16.82	76.58	99.18
Week 44 (Day 309)	>= 65	12	26.7	9	75.0	81.48	19.44	66.54	96.43
Week 48 (Day 337)	>= 65	9	20.0	5	55.6	90.00	14.91	71.49	108.51
Week 52 (Day 365)	>= 65	7	15.6	2	28.6	100.00	0.00	NE	NE
Week 56 (Day 393)	>= 65	6	13.3	4	66.7	91.67	9.62	76.36	106.98
Week 60 (Day 421)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE

Week 76 (Day 533)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	45	100.0	45	100.0	88.89	15.89	84.11	93.66
End of Study (LOCF)	>= 65	45	100.0	45	100.0	88.15	15.74	83.42	92.88
ECOG performance status									
Baseline	0	30	100.0	29	96.7	87.93	23.10	79.14	96.72
Week 4 (Day 29)	0	30	100.0	29	96.7	95.40	9.86	91.65	99.15
Week 8 (Day 57)	0	28	93.3	25	89.3	93.33	12.73	88.08	98.59
Week 12 (Day 85)	0	26	86.7	23	88.5	92.75	13.13	87.08	98.43
Week 16 (Day 113)	0	26	86.7	21	80.8	96.83	8.53	92.94	100.71
Week 20 (Day 141)	0	26	86.7	24	92.3	93.06	13.83	87.22	98.89
Week 24 (Day 169)	0	25	83.3	23	92.0	94.20	10.79	89.54	98.87
Week 28 (Day 197)	0	25	83.3	23	92.0	93.48	12.04	88.27	98.68
Week 32 (Day 225)	0	20	66.7	16	80.0	96.88	9.07	92.04	101.71
Week 36 (Day 253)	0	18	60.0	11	61.1	96.97	10.05	90.22	103.72
Week 40 (Day 281)	0	16	53.3	11	68.8	93.94	20.10	80.44	107.44
Week 44 (Day 309)	0	15	50.0	12	80.0	83.33	23.57	68.36	98.31
Week 48 (Day 337)	0	9	30.0	6	66.7	91.67	20.41	70.25	113.09
Week 52 (Day 365)	0	9	30.0	3	33.3	94.44	9.62	70.54	118.35
Week 56 (Day 393)	0	8	26.7	3	37.5	83.33	16.67	41.93	124.74
Week 60 (Day 421)	0	5	16.7	1	20.0	100.00	NE	NE	NE
Week 64 (Day 449)	0	5	16.7	2	40.0	83.33	23.57	-128.44	295.10
Week 68 (Day 477)	0	3	10.0	1	33.3	100.00	NE	NE	NE
Week 72 (Day 505)	0	3	10.0	1	33.3	100.00	NE	NE	NE
Week 76 (Day 533)	0	3	10.0	1	33.3	100.00	NE	NE	NE
Week 80 (Day 561)	0	2	6.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	0	1	3.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	30	100.0	30	100.0	90.00	18.36	83.14	96.86
End of Study (LOCF)	0	30	100.0	30	100.0	92.22	13.66	87.12	97.32
Baseline	1	78	100.0	75	96.2	88.89	18.24	84.69	93.09
Week 4 (Day 29)	1	78	100.0	67	85.9	89.80	18.11	85.38	94.22

Week 8 (Day 57)	1	64	82.1	54	84.4	90.43	16.70	85.87	94.99
Week 12 (Day 85)	1	53	67.9	47	88.7	90.07	13.75	86.03	94.11
Week 16 (Day 113)	1	43	55.1	37	86.0	85.59	15.79	80.32	90.85
Week 20 (Day 141)	1	33	42.3	31	93.9	92.47	11.25	88.35	96.60
Week 24 (Day 169)	1	31	39.7	26	83.9	91.67	12.69	86.54	96.79
Week 28 (Day 197)	1	30	38.5	28	93.3	86.31	17.00	79.72	92.90
Week 32 (Day 225)	1	28	35.9	25	89.3	88.67	15.00	82.47	94.86
Week 36 (Day 253)	1	23	29.5	19	82.6	85.96	16.91	77.82	94.11
Week 40 (Day 281)	1	21	26.9	21	100.0	85.71	19.92	76.65	94.78
Week 44 (Day 309)	1	16	20.5	14	87.5	86.90	16.25	77.52	96.29
Week 48 (Day 337)	1	14	17.9	6	42.9	80.56	16.39	63.36	97.75
Week 52 (Day 365)	1	10	12.8	1	10.0	100.00	NE	NE	NE
Week 56 (Day 393)	1	9	11.5	3	33.3	88.89	9.62	64.99	112.79
Week 60 (Day 421)	1	6	7.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	5	6.4	1	20.0	83.33	NE	NE	NE
Week 68 (Day 477)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	3	3.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	78	100.0	78	100.0	88.68	16.45	84.97	92.38
End of Study (LOCF)	1	78	100.0	78	100.0	88.89	15.35	85.43	92.35
Geographic region									
Baseline	USA	21	100.0	19	90.5	92.98	10.12	88.11	97.86
Week 4 (Day 29)	USA	21	100.0	20	95.2	92.50	12.65	86.58	98.42
Week 8 (Day 57)	USA	21	100.0	19	90.5	90.35	12.81	84.18	96.52
Week 12 (Day 85)	USA	21	100.0	18	85.7	87.96	12.53	81.73	94.19
Week 16 (Day 113)	USA	21	100.0	16	76.2	86.46	15.18	78.37	94.55
Week 20 (Day 141)	USA	20	95.2	18	90.0	92.59	11.75	86.75	98.43
Week 24 (Day 169)	USA	20	95.2	19	95.0	92.98	12.81	86.81	99.16
Week 28 (Day 197)	USA	20	95.2	19	95.0	91.23	16.07	83.48	98.97
Week 32 (Day 225)	USA	17	81.0	15	88.2	90.00	13.80	82.36	97.64
Week 36 (Day 253)	USA	17	81.0	11	64.7	87.88	13.10	79.08	96.68
Week 40 (Day 281)	USA	15	71.4	12	80.0	93.06	13.22	84.66	101.45

Week 44 (Day 309)	USA	13	61.9	10	76.9	88.33	13.72	78.52	98.15
Week 48 (Day 337)	USA	8	38.1	5	62.5	93.33	14.91	74.82	111.84
Week 52 (Day 365)	USA	6	28.6	1	16.7	100.00	NE	NE	NE
Week 56 (Day 393)	USA	6	28.6	3	50.0	88.89	9.62	64.99	112.79
Week 60 (Day 421)	USA	5	23.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	4	19.0	1	25.0	83.33	NE	NE	NE
Week 68 (Day 477)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	21	100.0	21	100.0	90.48	13.51	84.33	96.63
End of Study (LOCF)	USA	21	100.0	21	100.0	89.68	13.41	83.58	95.79
Baseline	Europe (EU)	42	100.0	40	95.2	83.75	22.80	76.46	91.04
Week 4 (Day 29)	Europe (EU)	42	100.0	39	92.9	90.60	18.65	84.55	96.64
Week 8 (Day 57)	Europe (EU)	36	85.7	30	83.3	91.11	15.62	85.28	96.94
Week 12 (Day 85)	Europe (EU)	31	73.8	25	80.6	90.00	17.35	82.84	97.16
Week 16 (Day 113)	Europe (EU)	30	71.4	24	80.0	88.19	16.65	81.16	95.23
Week 20 (Day 141)	Europe (EU)	26	61.9	24	92.3	90.28	14.68	84.08	96.47
Week 24 (Day 169)	Europe (EU)	26	61.9	22	84.6	92.42	12.31	86.97	97.88
Week 28 (Day 197)	Europe (EU)	25	59.5	23	92.0	86.96	15.86	80.10	93.81
Week 32 (Day 225)	Europe (EU)	21	50.0	19	90.5	93.86	11.40	88.37	99.35
Week 36 (Day 253)	Europe (EU)	16	38.1	13	81.3	91.03	19.97	78.96	103.09
Week 40 (Day 281)	Europe (EU)	14	33.3	14	100.0	83.33	26.15	68.24	98.43
Week 44 (Day 309)	Europe (EU)	11	26.2	10	90.9	80.00	26.99	60.69	99.31
Week 48 (Day 337)	Europe (EU)	8	19.0	6	75.0	80.56	22.15	57.31	103.80
Week 52 (Day 365)	Europe (EU)	6	14.3	3	50.0	94.44	9.62	70.54	118.35
Week 56 (Day 393)	Europe (EU)	6	14.3	2	33.3	83.33	23.57	-128.44	295.10

Week 60 (Day 421)	Europe (EU)	4	9.5	1	25.0	100.00	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	4	9.5	2	50.0	83.33	23.57	-128.44	295.10
Week 68 (Day 477)	Europe (EU)	3	7.1	1	33.3	100.00	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	3	7.1	1	33.3	100.00	NE	NE	NE
Week 76 (Day 533)	Europe (EU)	3	7.1	1	33.3	100.00	NE	NE	NE
Week 80 (Day 561)	Europe (EU)	2	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Europe (EU)	42	100.0	42	100.0	86.90	20.34	80.57	93.24
End of Study (LOCF)	Europe (EU)	42	100.0	42	100.0	88.89	16.32	83.80	93.98
Baseline	Asia (AS)	45	100.0	45	100.0	91.11	19.00	85.40	96.82
Week 4 (Day 29)	Asia (AS)	45	100.0	37	82.2	91.89	15.53	86.72	97.07
Week 8 (Day 57)	Asia (AS)	35	77.8	30	85.7	92.22	17.36	85.74	98.70
Week 12 (Day 85)	Asia (AS)	27	60.0	27	100.0	93.83	9.41	90.10	97.55
Week 16 (Day 113)	Asia (AS)	18	40.0	18	100.0	94.44	9.90	89.52	99.37
Week 20 (Day 141)	Asia (AS)	13	28.9	13	100.0	97.44	6.26	93.65	101.22
Week 24 (Day 169)	Asia (AS)	10	22.2	8	80.0	93.75	8.63	86.54	100.96
Week 28 (Day 197)	Asia (AS)	10	22.2	9	90.0	92.59	12.11	83.29	101.90
Week 32 (Day 225)	Asia (AS)	10	22.2	7	70.0	90.48	18.90	73.00	107.95
Week 36 (Day 253)	Asia (AS)	8	17.8	6	75.0	91.67	9.13	82.09	101.25
Week 40 (Day 281)	Asia (AS)	8	17.8	6	75.0	91.67	13.94	77.03	106.30
Week 44 (Day 309)	Asia (AS)	7	15.6	6	85.7	88.89	13.61	74.61	103.17
Week 48 (Day 337)	Asia (AS)	7	15.6	1	14.3	83.33	NE	NE	NE
Week 52 (Day 365)	Asia (AS)	7	15.6	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Asia (AS)	5	11.1	1	20.0	83.33	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	45	100.0	45	100.0	90.37	14.86	85.91	94.83
End of Study (LOCF)	Asia (AS)	45	100.0	45	100.0	90.74	14.46	86.40	95.08

Race/ethnicity									
Baseline	Asian	48	100.0	48	100.0	91.32	18.51	85.94	96.69
Week 4 (Day 29)	Asian	48	100.0	40	83.3	92.08	15.09	87.26	96.91
Week 8 (Day 57)	Asian	38	79.2	31	81.6	91.40	17.68	84.91	97.88
Week 12 (Day 85)	Asian	30	62.5	30	100.0	92.78	10.43	88.88	96.67
Week 16 (Day 113)	Asian	21	43.8	21	100.0	93.65	11.15	88.58	98.73
Week 20 (Day 141)	Asian	16	33.3	15	93.8	95.56	9.89	90.08	101.03
Week 24 (Day 169)	Asian	13	27.1	11	84.6	92.42	11.46	84.73	100.12
Week 28 (Day 197)	Asian	13	27.1	12	92.3	90.28	16.60	79.73	100.83
Week 32 (Day 225)	Asian	12	25.0	9	75.0	90.74	16.90	77.75	103.73
Week 36 (Day 253)	Asian	10	20.8	8	80.0	89.58	12.40	79.22	99.95
Week 40 (Day 281)	Asian	10	20.8	8	80.0	89.58	15.27	76.82	102.35
Week 44 (Day 309)	Asian	9	18.8	8	88.9	87.50	14.77	75.15	99.85
Week 48 (Day 337)	Asian	9	18.8	2	22.2	91.67	11.79	-14.22	197.55
Week 52 (Day 365)	Asian	9	18.8	1	11.1	100.00	NE	NE	NE
Week 56 (Day 393)	Asian	7	14.6	2	28.6	91.67	11.79	-14.22	197.55
Week 60 (Day 421)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	48	100.0	48	100.0	90.28	14.92	85.95	94.61
End of Study (LOCF)	Asian	48	100.0	48	100.0	90.63	14.55	86.40	94.85
Baseline	Non-Asian	54	100.0	52	96.3	86.86	20.70	81.10	92.62
Week 4 (Day 29)	Non-Asian	54	100.0	50	92.6	92.00	17.25	87.10	96.90
Week 8 (Day 57)	Non-Asian	49	90.7	44	89.8	92.05	14.15	87.74	96.35
Week 12 (Day 85)	Non-Asian	44	81.5	36	81.8	91.67	14.09	86.90	96.43
Week 16 (Day 113)	Non-Asian	43	79.6	34	79.1	87.75	16.05	82.14	93.35
Week 20 (Day 141)	Non-Asian	38	70.4	35	92.1	92.86	12.96	88.40	97.31
Week 24 (Day 169)	Non-Asian	38	70.4	34	89.5	94.61	11.40	90.63	98.59
Week 28 (Day 197)	Non-Asian	37	68.5	35	94.6	90.48	14.73	85.41	95.54
Week 32 (Day 225)	Non-Asian	32	59.3	28	87.5	94.05	11.31	89.66	98.43
Week 36 (Day 253)	Non-Asian	27	50.0	20	74.1	92.50	11.44	87.15	97.85

Week 40 (Day 281)	Non-Asian	23	42.6	21	91.3	89.68	21.39	79.94	99.42
Week 44 (Day 309)	Non-Asian	18	33.3	14	77.8	90.48	15.63	81.45	99.50
Week 48 (Day 337)	Non-Asian	12	22.2	9	75.0	87.04	20.03	71.64	102.43
Week 52 (Day 365)	Non-Asian	8	14.8	3	37.5	94.44	9.62	70.54	118.35
Week 56 (Day 393)	Non-Asian	8	14.8	4	50.0	83.33	13.61	61.68	104.99
Week 60 (Day 421)	Non-Asian	7	13.0	1	14.3	100.00	NE	NE	NE
Week 64 (Day 449)	Non-Asian	6	11.1	2	33.3	75.00	11.79	-30.89	180.89
Week 68 (Day 477)	Non-Asian	3	5.6	1	33.3	100.00	NE	NE	NE
Week 72 (Day 505)	Non-Asian	3	5.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Non-Asian	3	5.6	1	33.3	100.00	NE	NE	NE
Week 80 (Day 561)	Non-Asian	2	3.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	54	100.0	54	100.0	89.81	16.64	85.27	94.36
End of Study (LOCF)	Non-Asian	54	100.0	54	100.0	90.43	14.33	86.52	94.34
Baseline	Unknown	6	100.0	4	66.7	79.17	15.96	53.78	104.56
Week 4 (Day 29)	Unknown	6	100.0	6	100.0	83.33	14.91	67.69	98.98
Week 8 (Day 57)	Unknown	5	83.3	4	80.0	83.33	13.61	61.68	104.99
Week 12 (Day 85)	Unknown	5	83.3	4	80.0	70.83	15.96	45.44	96.22
Week 16 (Day 113)	Unknown	5	83.3	3	60.0	83.33	16.67	41.93	124.74
Week 20 (Day 141)	Unknown	5	83.3	5	100.0	83.33	11.79	68.70	97.97
Week 24 (Day 169)	Unknown	5	83.3	4	80.0	79.17	8.33	65.91	92.43
Week 28 (Day 197)	Unknown	5	83.3	4	80.0	79.17	15.96	53.78	104.56
Week 32 (Day 225)	Unknown	4	66.7	4	100.0	79.17	15.96	53.78	104.56
Week 36 (Day 253)	Unknown	4	66.7	2	50.0	66.67	47.14	-356.87	490.21
Week 40 (Day 281)	Unknown	4	66.7	3	75.0	77.78	25.46	14.53	141.02
Week 44 (Day 309)	Unknown	4	66.7	4	100.0	62.50	28.46	17.21	107.79
Week 48 (Day 337)	Unknown	2	33.3	1	50.0	66.67	NE	NE	NE
Week 52 (Day 365)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 60 (Day 421)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE

Week 64 (Day 449)	Unknown	1	16.7	1	100.0	100.00	NE	NE	NE
Week 68 (Day 477)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	1	16.7	1	100.0	100.00	NE	NE	NE
Week 76 (Day 533)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	6	100.0	6	100.0	72.22	27.22	43.66	100.78
End of Study (LOCF)	Unknown	6	100.0	6	100.0	77.78	20.18	56.60	98.96

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TN_QSC30CF_SG.xls
27OCT2021 7:34

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Cognitive functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	41	39.4	30.6	49.0
	Cycle 12 (LOCF)	n/a	104	96.3	19	18.3	12.0	26.8
	End of Study (LOCF)	n/a	104	96.3	19	18.3	12.0	26.8
Sex	All visits	Female	56	51.9	21	37.5	26.0	50.6
		Male	48	44.4	20	41.7	28.8	55.7
	Cycle 12 (LOCF)	Female	56	51.9	8	14.3	7.4	25.7
		Male	48	44.4	11	22.9	13.3	36.5
	End of Study (LOCF)	Female	56	51.9	8	14.3	7.4	25.7
		Male	48	44.4	11	22.9	13.3	36.5
Age	All visits	< 65	60	55.6	21	35.0	24.2	47.6
		>= 65	44	40.7	20	45.5	31.7	59.9
	Cycle 12 (LOCF)	< 65	60	55.6	8	13.3	6.9	24.2
		>= 65	44	40.7	11	25.0	14.6	39.4
	End of Study (LOCF)	< 65	60	55.6	8	13.3	6.9	24.2
		>= 65	44	40.7	11	25.0	14.6	39.4
ECOG performance status	All visits	0	29	26.9	12	41.4	25.5	59.3
		1	75	69.4	29	38.7	28.5	50.0
	Cycle 12 (LOCF)	0	29	26.9	4	13.8	5.5	30.6
		1	75	69.4	15	20.0	12.5	30.4
	End of Study (LOCF)	0	29	26.9	5	17.2	7.6	34.5
		1	75	69.4	14	18.7	11.5	28.9
Geographic region	All visits	USA	19	17.6	12	63.2	41.0	80.9
		Europe (EU)	40	37.0	17	42.5	28.5	57.8
		Asia (AS)	45	41.7	12	26.7	16.0	41.0
	Cycle 12 (LOCF)	USA	19	17.6	5	26.3	11.8	48.8
		Europe (EU)	40	37.0	7	17.5	8.7	31.9
		Asia (AS)	45	41.7	7	15.6	7.7	28.8
	End of Study (LOCF)	USA	19	17.6	6	31.6	15.4	54.0
		Europe (EU)	40	37.0	7	17.5	8.7	31.9
		Asia (AS)	45	41.7	6	13.3	6.3	26.2
Race/ethnicity	All visits	Asian	48	44.4	14	29.2	18.2	43.2
		Non-Asian	52	48.1	25	48.1	35.1	61.3
		Unknown	4	3.7	2	50.0	15.0	85.0
	Cycle 12 (LOCF)	Asian	48	44.4	8	16.7	8.7	29.6
		Non-Asian	52	48.1	9	17.3	9.4	29.7
		Unknown	4	3.7	2	50.0	15.0	85.0
	End of Study (LOCF)	Asian	48	44.4	7	14.6	7.2	27.2

		Non-Asian	52	48.1	10	19.2	10.8	31.9
		Unknown	4	3.7	2	50.0	15.0	85.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30CF_W10_SG.xls
15OCT2021 13:10

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Cognitive functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

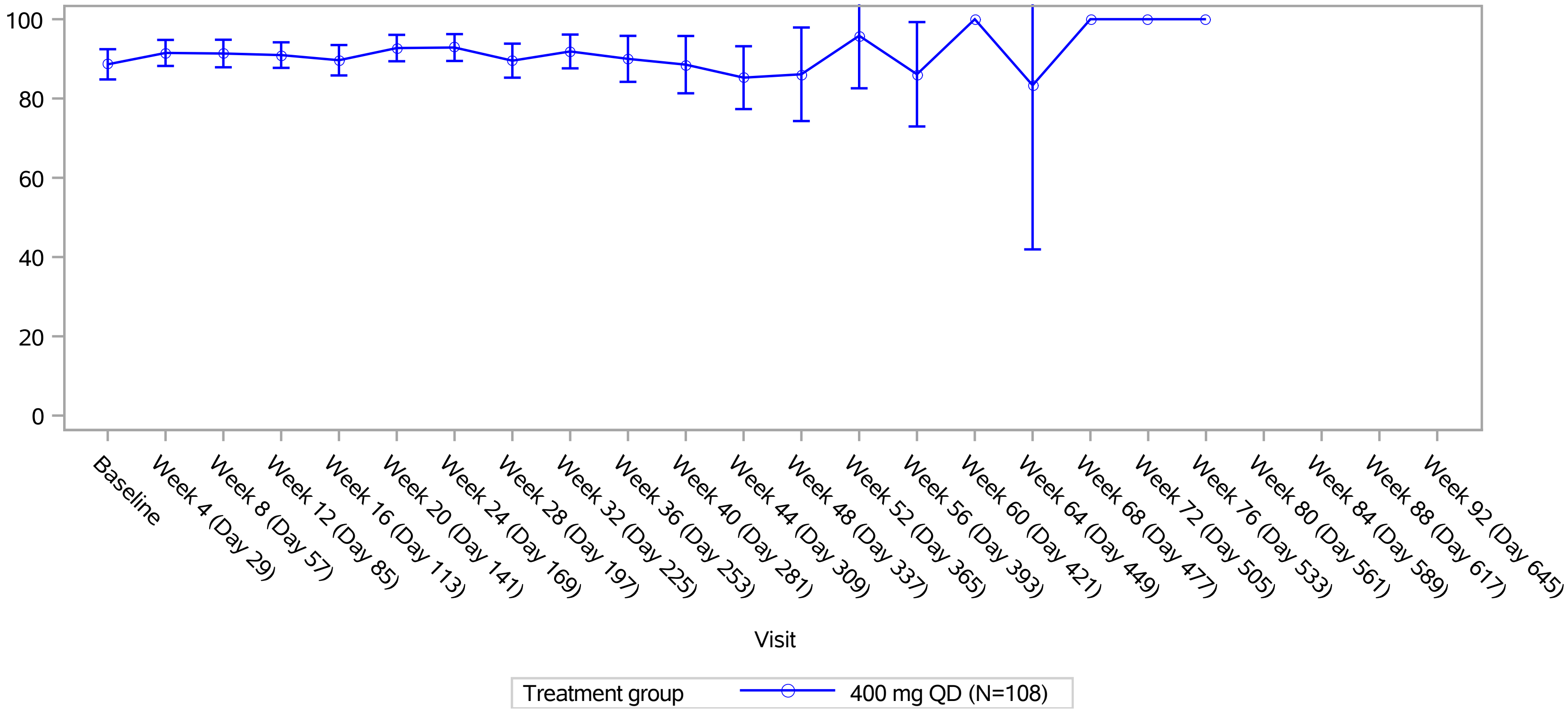
			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	41	39.4	30.6	49.0
	Cycle 12 (LOCF)	n/a	104	96.3	19	18.3	12.0	26.8
	End of Study (LOCF)	n/a	104	96.3	19	18.3	12.0	26.8
Sex	All visits	Female	56	51.9	21	37.5	26.0	50.6
		Male	48	44.4	20	41.7	28.8	55.7
	Cycle 12 (LOCF)	Female	56	51.9	8	14.3	7.4	25.7
		Male	48	44.4	11	22.9	13.3	36.5
	End of Study (LOCF)	Female	56	51.9	8	14.3	7.4	25.7
		Male	48	44.4	11	22.9	13.3	36.5
Age	All visits	< 65	60	55.6	21	35.0	24.2	47.6
		>= 65	44	40.7	20	45.5	31.7	59.9
	Cycle 12 (LOCF)	< 65	60	55.6	8	13.3	6.9	24.2
		>= 65	44	40.7	11	25.0	14.6	39.4
	End of Study (LOCF)	< 65	60	55.6	8	13.3	6.9	24.2
		>= 65	44	40.7	11	25.0	14.6	39.4
ECOG performance status	All visits	0	29	26.9	12	41.4	25.5	59.3
		1	75	69.4	29	38.7	28.5	50.0
	Cycle 12 (LOCF)	0	29	26.9	4	13.8	5.5	30.6
		1	75	69.4	15	20.0	12.5	30.4
	End of Study (LOCF)	0	29	26.9	5	17.2	7.6	34.5
		1	75	69.4	14	18.7	11.5	28.9
Geographic region	All visits	USA	19	17.6	12	63.2	41.0	80.9
		Europe (EU)	40	37.0	17	42.5	28.5	57.8
		Asia (AS)	45	41.7	12	26.7	16.0	41.0
	Cycle 12 (LOCF)	USA	19	17.6	5	26.3	11.8	48.8
		Europe (EU)	40	37.0	7	17.5	8.7	31.9
		Asia (AS)	45	41.7	7	15.6	7.7	28.8
	End of Study (LOCF)	USA	19	17.6	6	31.6	15.4	54.0
		Europe (EU)	40	37.0	7	17.5	8.7	31.9
		Asia (AS)	45	41.7	6	13.3	6.3	26.2
Race/ethnicity	All visits	Asian	48	44.4	14	29.2	18.2	43.2
		Non-Asian	52	48.1	25	48.1	35.1	61.3
		Unknown	4	3.7	2	50.0	15.0	85.0
	Cycle 12 (LOCF)	Asian	48	44.4	8	16.7	8.7	29.6
		Non-Asian	52	48.1	9	17.3	9.4	29.7
		Unknown	4	3.7	2	50.0	15.0	85.0
	End of Study (LOCF)	Asian	48	44.4	7	14.6	7.2	27.2

		Non-Asian	52	48.1	10	19.2	10.8	31.9
		Unknown	4	3.7	2	50.0	15.0	85.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30CF_W15_SG.xls
15OCT2021 13:00

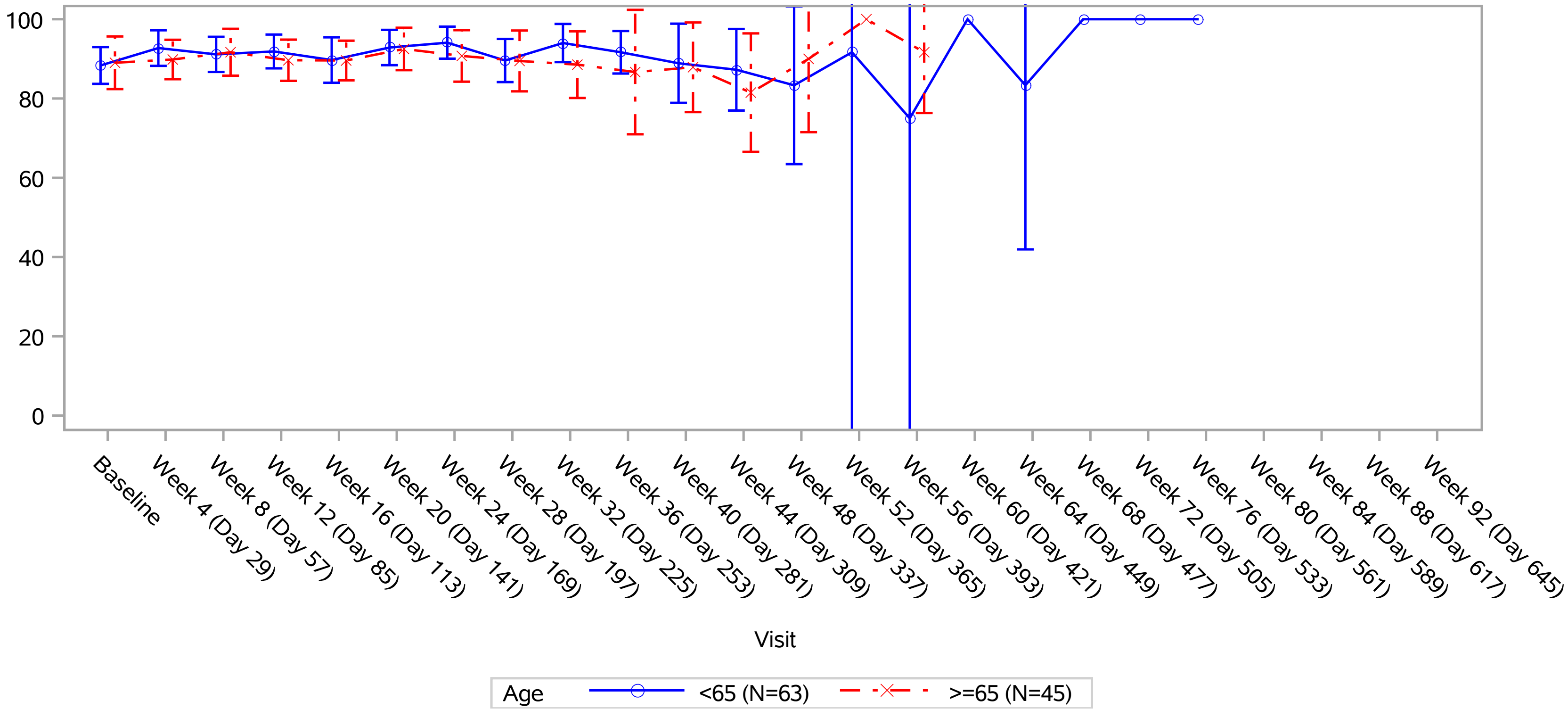
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Cognitive functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30CF.pdf
15OCT2021 17:22

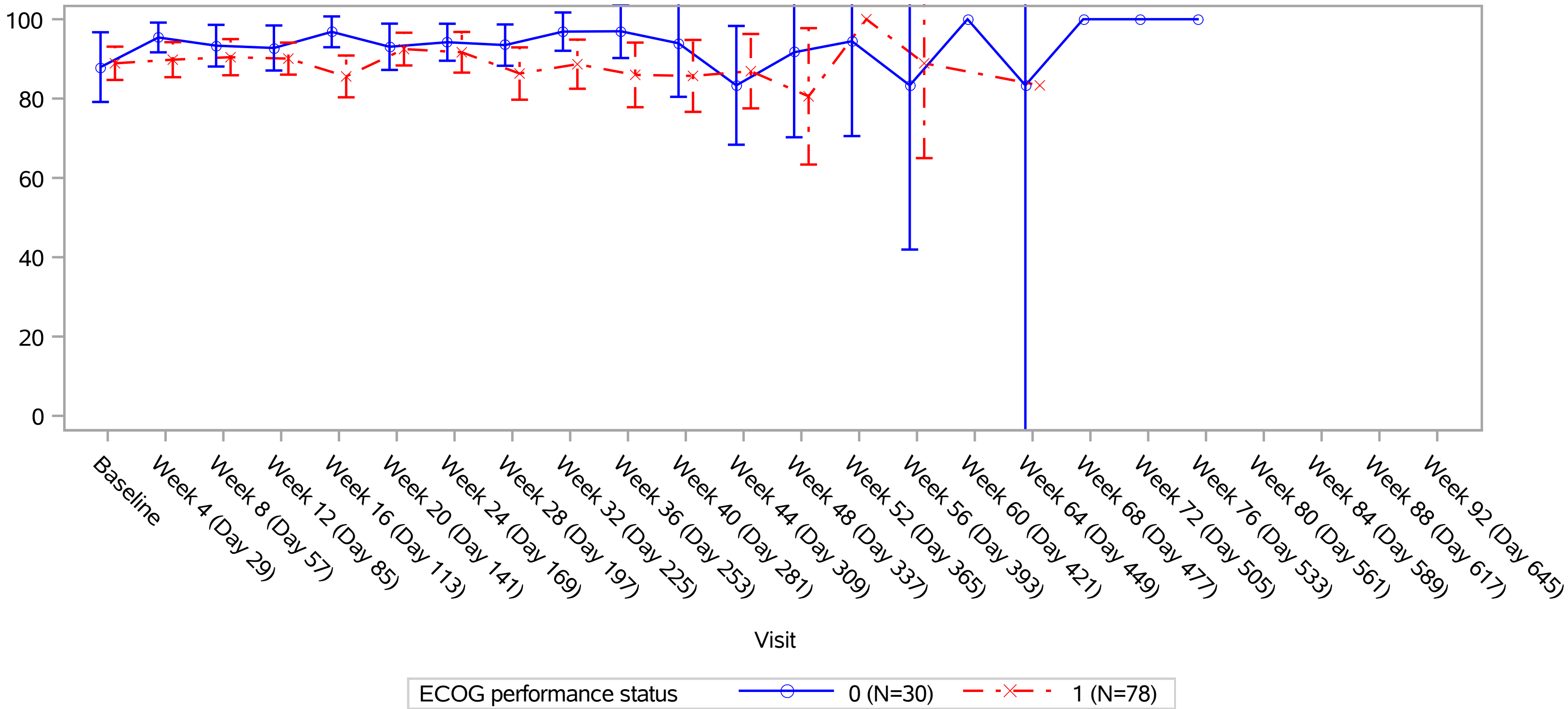
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Cognitive functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30CF_SGAGE65.pdf
15OCT2021 17:51

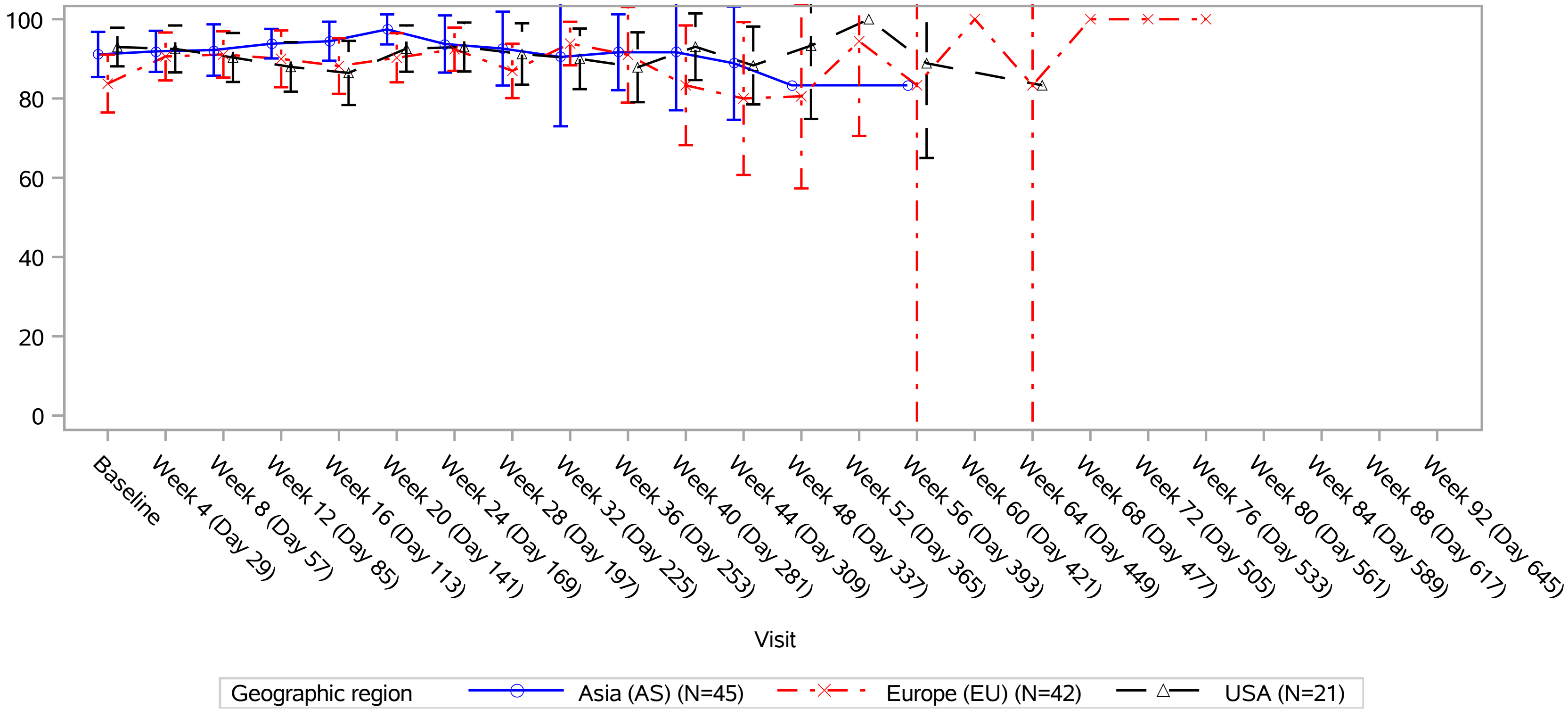
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Cognitive functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30CF_SGECOG.pdf
15OCT2021 18:22

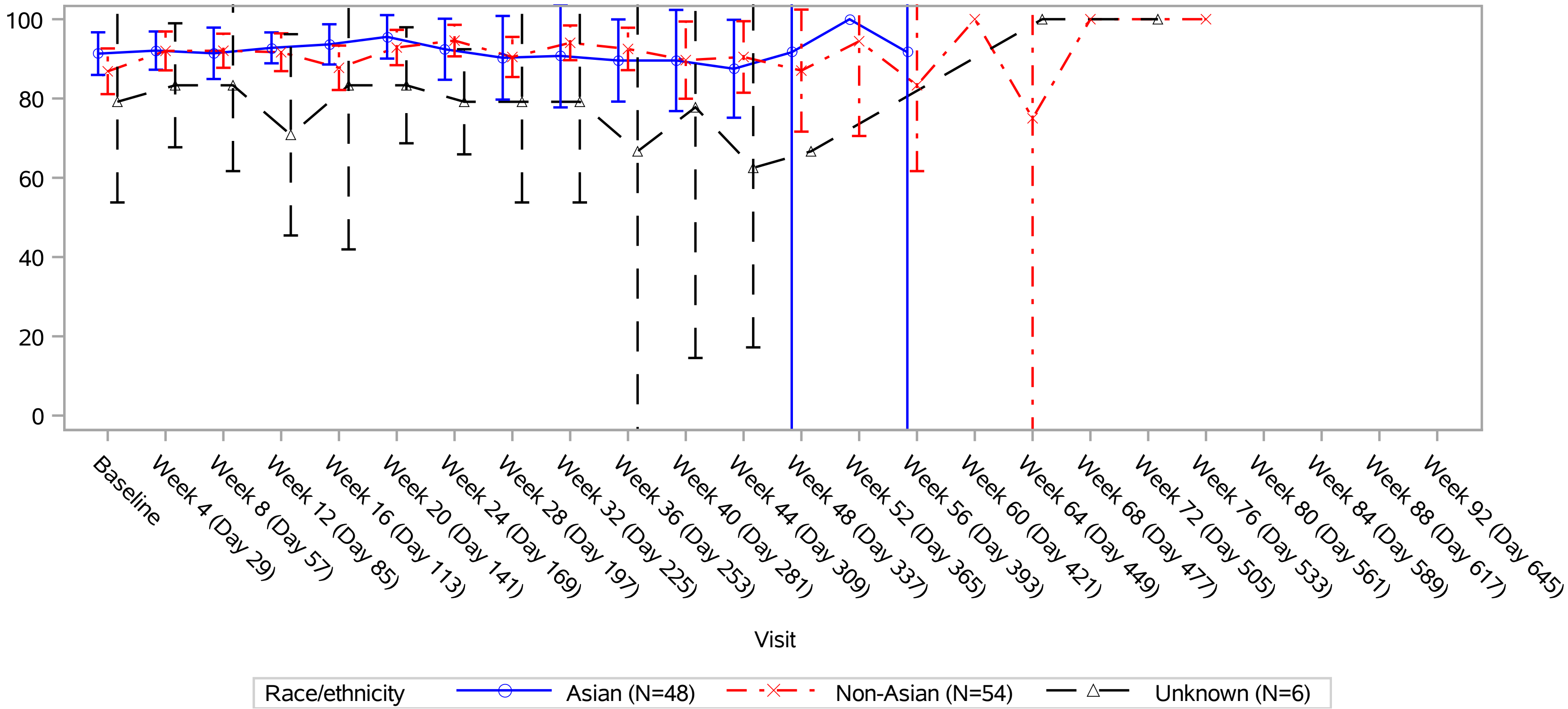
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Cognitive functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30CF_SGGEO.pdf
15OCT2021 18:53

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Cognitive functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
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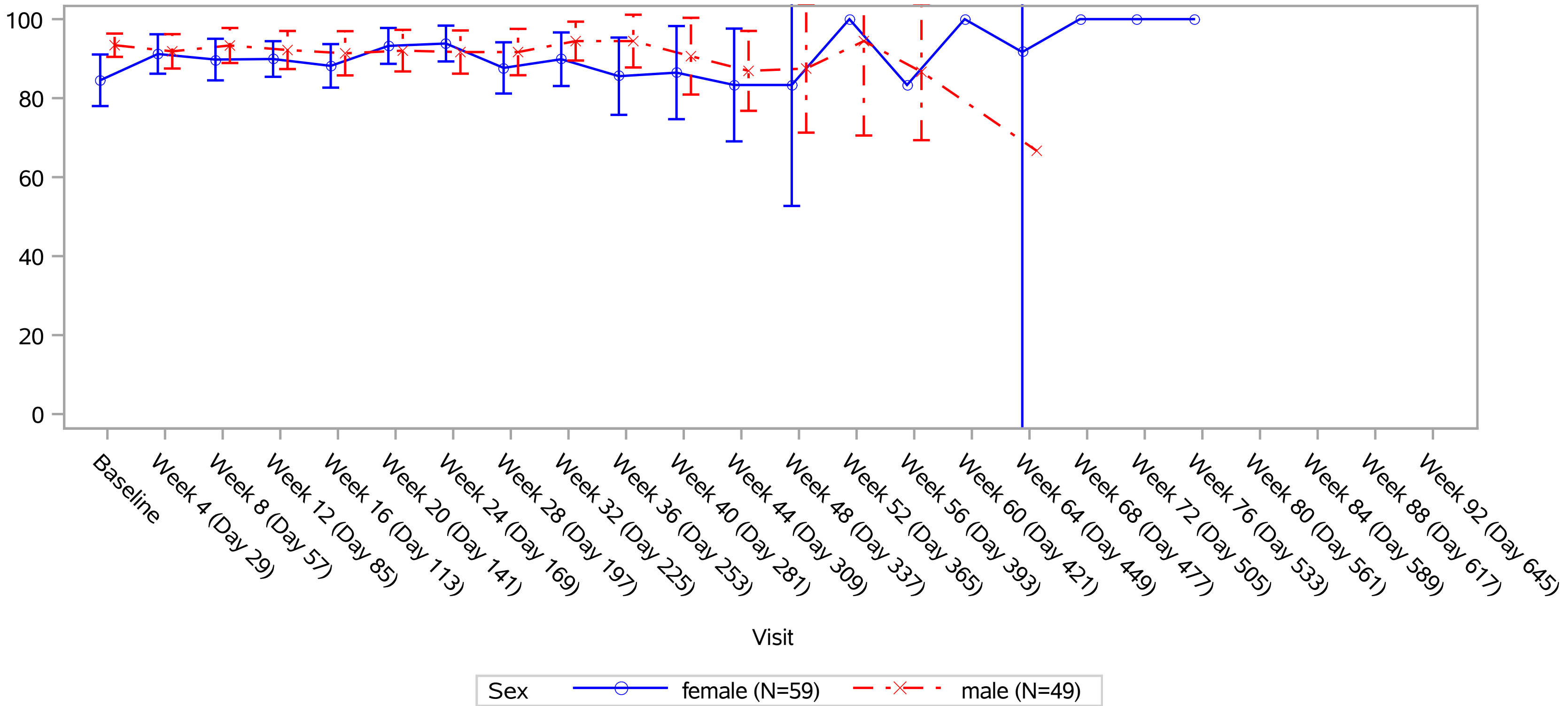
15OCT2021 19:23

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Cognitive functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30CF_SGSEX.pdf
15OCT2021 19:54

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Constipation
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=108)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	108	100.0	104	96.3	9.62	21.12	5.51	13.72
Week 4 (Day 29)	n/a	108	100.0	96	88.9	22.92	28.33	17.18	28.66
Week 8 (Day 57)	n/a	92	85.2	79	85.9	18.14	24.34	12.69	23.60
Week 12 (Day 85)	n/a	79	73.1	71	89.9	20.19	28.44	13.46	26.92
Week 16 (Day 113)	n/a	69	63.9	58	84.1	24.71	28.31	17.27	32.16
Week 20 (Day 141)	n/a	59	54.6	55	93.2	21.21	25.14	14.41	28.01
Week 24 (Day 169)	n/a	56	51.9	49	87.5	19.05	26.35	11.48	26.62
Week 28 (Day 197)	n/a	55	50.9	51	92.7	15.69	24.36	8.83	22.54
Week 32 (Day 225)	n/a	48	44.4	41	85.4	17.89	26.97	9.37	26.40
Week 36 (Day 253)	n/a	41	38.0	30	73.2	20.00	27.12	9.87	30.13
Week 40 (Day 281)	n/a	37	34.3	32	86.5	21.87	28.85	11.47	32.28
Week 44 (Day 309)	n/a	31	28.7	26	83.9	25.64	33.08	12.28	39.00
Week 48 (Day 337)	n/a	23	21.3	12	52.2	25.00	32.18	4.56	45.44
Week 52 (Day 365)	n/a	19	17.6	4	21.1	16.67	19.25	-13.96	47.29
Week 56 (Day 393)	n/a	17	15.7	6	35.3	38.89	38.97	-2.01	79.78
Week 60 (Day 421)	n/a	11	10.2	1	9.1	33.33	NE	NE	NE
Week 64 (Day 449)	n/a	10	9.3	3	30.0	55.56	38.49	-40.06	151.17
Week 68 (Day 477)	n/a	6	5.6	1	16.7	33.33	NE	NE	NE
Week 72 (Day 505)	n/a	6	5.6	1	16.7	33.33	NE	NE	NE
Week 76 (Day 533)	n/a	6	5.6	1	16.7	0.00	NE	NE	NE
Week 80 (Day 561)	n/a	5	4.6	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	n/a	1	0.9	0	0.0	NE	NE	NE	NE

Cycle 12 (LOCF)	n/a	108	100.0	108	100.0	19.14	27.04	13.98	24.29
End of Study (LOCF)	n/a	108	100.0	108	100.0	18.83	26.29	13.81	23.84
Sex									
Baseline	Female	59	100.0	56	94.9	13.10	25.96	6.14	20.05
Week 4 (Day 29)	Female	59	100.0	51	86.4	26.80	29.07	18.62	34.97
Week 8 (Day 57)	Female	49	83.1	44	89.8	22.73	27.63	14.33	31.13
Week 12 (Day 85)	Female	44	74.6	39	88.6	23.93	33.29	13.14	34.72
Week 16 (Day 113)	Female	38	64.4	31	81.6	27.96	33.44	15.69	40.22
Week 20 (Day 141)	Female	33	55.9	32	97.0	25.00	29.33	14.43	35.57
Week 24 (Day 169)	Female	31	52.5	27	87.1	22.22	30.66	10.09	34.35
Week 28 (Day 197)	Female	30	50.8	27	90.0	18.52	29.72	6.76	30.27
Week 32 (Day 225)	Female	27	45.8	23	85.2	21.74	32.74	7.58	35.89
Week 36 (Day 253)	Female	22	37.3	15	68.2	22.22	32.53	4.21	40.24
Week 40 (Day 281)	Female	18	30.5	16	88.9	29.17	36.26	9.84	48.49
Week 44 (Day 309)	Female	15	25.4	12	80.0	36.11	43.71	8.34	63.88
Week 48 (Day 337)	Female	11	18.6	4	36.4	33.33	47.14	-41.68	108.34
Week 52 (Day 365)	Female	9	15.3	1	11.1	0.00	NE	NE	NE
Week 56 (Day 393)	Female	7	11.9	1	14.3	100.00	NE	NE	NE
Week 60 (Day 421)	Female	5	8.5	1	20.0	33.33	NE	NE	NE
Week 64 (Day 449)	Female	4	6.8	2	50.0	66.67	47.14	-356.87	490.21
Week 68 (Day 477)	Female	3	5.1	1	33.3	33.33	NE	NE	NE
Week 72 (Day 505)	Female	3	5.1	1	33.3	33.33	NE	NE	NE
Week 76 (Day 533)	Female	3	5.1	1	33.3	0.00	NE	NE	NE
Week 80 (Day 561)	Female	2	3.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	59	100.0	59	100.0	20.90	31.50	12.69	29.11
End of Study (LOCF)	Female	59	100.0	59	100.0	19.77	29.76	12.02	27.53
Baseline	Male	49	100.0	48	98.0	5.56	12.55	1.91	9.20
Week 4 (Day 29)	Male	49	100.0	45	91.8	18.52	27.11	10.37	26.66
Week 8 (Day 57)	Male	43	87.8	35	81.4	12.38	18.23	6.12	18.64
Week 12 (Day 85)	Male	35	71.4	32	91.4	15.62	20.71	8.16	23.09
Week 16 (Day 113)	Male	31	63.3	27	87.1	20.99	20.98	12.69	29.29
Week 20 (Day 141)	Male	26	53.1	23	88.5	15.94	17.03	8.58	23.30
Week 24 (Day 169)	Male	25	51.0	22	88.0	15.15	19.86	6.35	23.96
Week 28 (Day 197)	Male	25	51.0	24	96.0	12.50	16.48	5.54	19.46

Week 32 (Day 225)	Male	21	42.9	18	85.7	12.96	16.72	4.65	21.28
Week 36 (Day 253)	Male	19	38.8	15	78.9	17.78	21.33	5.96	29.59
Week 40 (Day 281)	Male	19	38.8	16	84.2	14.58	17.08	5.48	23.68
Week 44 (Day 309)	Male	16	32.7	14	87.5	16.67	17.30	6.68	26.65
Week 48 (Day 337)	Male	12	24.5	8	66.7	20.83	24.80	0.10	41.57
Week 52 (Day 365)	Male	10	20.4	3	30.0	22.22	19.25	-25.59	70.03
Week 56 (Day 393)	Male	10	20.4	5	50.0	26.67	27.89	-7.96	61.30
Week 60 (Day 421)	Male	6	12.2	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Male	6	12.2	1	16.7	33.33	NE	NE	NE
Week 68 (Day 477)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	49	100.0	49	100.0	17.01	20.55	11.10	22.91
End of Study (LOCF)	Male	49	100.0	49	100.0	17.69	21.63	11.48	23.90
Age									
Baseline	< 65	63	100.0	60	95.2	11.11	23.50	5.04	17.18
Week 4 (Day 29)	< 65	63	100.0	55	87.3	24.24	28.29	16.59	31.89
Week 8 (Day 57)	< 65	54	85.7	47	87.0	23.40	26.84	15.52	31.29
Week 12 (Day 85)	< 65	47	74.6	42	89.4	19.84	29.50	10.65	29.04
Week 16 (Day 113)	< 65	39	61.9	34	87.2	22.55	29.27	12.34	32.76
Week 20 (Day 141)	< 65	35	55.6	35	100.0	20.00	28.24	10.30	29.70
Week 24 (Day 169)	< 65	34	54.0	31	91.2	21.51	29.25	10.78	32.23
Week 28 (Day 197)	< 65	33	52.4	32	97.0	18.75	26.69	9.13	28.37
Week 32 (Day 225)	< 65	30	47.6	25	83.3	18.67	30.55	6.06	31.28
Week 36 (Day 253)	< 65	25	39.7	20	80.0	16.67	27.57	3.76	29.57
Week 40 (Day 281)	< 65	23	36.5	21	91.3	20.63	32.45	5.86	35.41
Week 44 (Day 309)	< 65	19	30.2	17	89.5	25.49	38.24	5.83	45.15
Week 48 (Day 337)	< 65	14	22.2	7	50.0	23.81	37.09	-10.49	58.11

Week 52 (Day 365)	< 65	12	19.0	2	16.7	16.67	23.57	-195.10	228.44
Week 56 (Day 393)	< 65	11	17.5	2	18.2	50.00	70.71	-585.31	685.31
Week 60 (Day 421)	< 65	8	12.7	1	12.5	33.33	NE	NE	NE
Week 64 (Day 449)	< 65	7	11.1	3	42.9	55.56	38.49	-40.06	151.17
Week 68 (Day 477)	< 65	4	6.3	1	25.0	33.33	NE	NE	NE
Week 72 (Day 505)	< 65	4	6.3	1	25.0	33.33	NE	NE	NE
Week 76 (Day 533)	< 65	4	6.3	1	25.0	0.00	NE	NE	NE
Week 80 (Day 561)	< 65	3	4.8	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	63	100.0	63	100.0	19.05	28.53	11.86	26.23
End of Study (LOCF)	< 65	63	100.0	63	100.0	17.99	26.66	11.28	24.70
Baseline	>= 65	45	100.0	44	97.8	7.58	17.41	2.28	12.87
Week 4 (Day 29)	>= 65	45	100.0	41	91.1	21.14	28.63	12.10	30.18
Week 8 (Day 57)	>= 65	38	84.4	32	84.2	10.42	17.84	3.99	16.85
Week 12 (Day 85)	>= 65	32	71.1	29	90.6	20.69	27.33	10.29	31.09
Week 16 (Day 113)	>= 65	30	66.7	24	80.0	27.78	27.22	16.29	39.27
Week 20 (Day 141)	>= 65	24	53.3	20	83.3	23.33	19.04	14.42	32.24
Week 24 (Day 169)	>= 65	22	48.9	18	81.8	14.81	20.52	4.61	25.02
Week 28 (Day 197)	>= 65	22	48.9	19	86.4	10.53	19.41	1.17	19.88
Week 32 (Day 225)	>= 65	18	40.0	16	88.9	16.67	21.08	5.43	27.90
Week 36 (Day 253)	>= 65	16	35.6	10	62.5	26.67	26.29	7.86	45.48
Week 40 (Day 281)	>= 65	14	31.1	11	78.6	24.24	21.56	9.76	38.72
Week 44 (Day 309)	>= 65	12	26.7	9	75.0	25.93	22.22	8.84	43.01
Week 48 (Day 337)	>= 65	9	20.0	5	55.6	26.67	27.89	-7.96	61.30
Week 52 (Day 365)	>= 65	7	15.6	2	28.6	16.67	23.57	-195.10	228.44
Week 56 (Day 393)	>= 65	6	13.3	4	66.7	33.33	27.22	-9.97	76.64
Week 60 (Day 421)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE

Week 76 (Day 533)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	45	100.0	45	100.0	19.26	25.11	11.71	26.80
End of Study (LOCF)	>= 65	45	100.0	45	100.0	20.00	26.01	12.18	27.82
ECOG performance status									
Baseline	0	30	100.0	29	96.7	5.75	15.61	-0.19	11.68
Week 4 (Day 29)	0	30	100.0	29	96.7	28.74	27.78	18.17	39.30
Week 8 (Day 57)	0	28	93.3	25	89.3	21.33	28.67	9.50	33.17
Week 12 (Day 85)	0	26	86.7	24	92.3	13.89	21.80	4.69	23.09
Week 16 (Day 113)	0	26	86.7	21	80.8	19.05	24.88	7.72	30.37
Week 20 (Day 141)	0	26	86.7	24	92.3	11.11	16.05	4.33	17.89
Week 24 (Day 169)	0	25	83.3	23	92.0	13.04	21.88	3.58	22.50
Week 28 (Day 197)	0	25	83.3	23	92.0	7.25	14.06	1.17	13.33
Week 32 (Day 225)	0	20	66.7	16	80.0	8.33	19.25	-1.92	18.59
Week 36 (Day 253)	0	18	60.0	11	61.1	9.09	15.57	-1.37	19.55
Week 40 (Day 281)	0	16	53.3	11	68.8	6.06	20.10	-7.44	19.56
Week 44 (Day 309)	0	15	50.0	12	80.0	11.11	29.59	-7.69	29.91
Week 48 (Day 337)	0	9	30.0	6	66.7	11.11	17.21	-6.95	29.18
Week 52 (Day 365)	0	9	30.0	3	33.3	11.11	19.25	-36.70	58.92
Week 56 (Day 393)	0	8	26.7	3	37.5	11.11	19.25	-36.70	58.92
Week 60 (Day 421)	0	5	16.7	1	20.0	33.33	NE	NE	NE
Week 64 (Day 449)	0	5	16.7	2	40.0	33.33	0.00	NE	NE
Week 68 (Day 477)	0	3	10.0	1	33.3	33.33	NE	NE	NE
Week 72 (Day 505)	0	3	10.0	1	33.3	33.33	NE	NE	NE
Week 76 (Day 533)	0	3	10.0	1	33.3	0.00	NE	NE	NE
Week 80 (Day 561)	0	2	6.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	0	1	3.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	30	100.0	30	100.0	17.78	29.99	6.58	28.97
End of Study (LOCF)	0	30	100.0	30	100.0	15.56	25.87	5.90	25.22
Baseline	1	78	100.0	75	96.2	11.11	22.81	5.86	16.36
Week 4 (Day 29)	1	78	100.0	67	85.9	20.40	28.40	13.47	27.33

Week 8 (Day 57)	1	64	82.1	54	84.4	16.67	22.20	10.61	22.73
Week 12 (Day 85)	1	53	67.9	47	88.7	23.40	31.02	14.30	32.51
Week 16 (Day 113)	1	43	55.1	37	86.0	27.93	29.93	17.95	37.91
Week 20 (Day 141)	1	33	42.3	31	93.9	29.03	28.21	18.69	39.38
Week 24 (Day 169)	1	31	39.7	26	83.9	24.36	29.15	12.59	36.13
Week 28 (Day 197)	1	30	38.5	28	93.3	22.62	28.77	11.46	33.77
Week 32 (Day 225)	1	28	35.9	25	89.3	24.00	29.69	11.74	36.26
Week 36 (Day 253)	1	23	29.5	19	82.6	26.32	30.59	11.57	41.06
Week 40 (Day 281)	1	21	26.9	21	100.0	30.16	29.64	16.67	43.65
Week 44 (Day 309)	1	16	20.5	14	87.5	38.10	31.64	19.83	56.36
Week 48 (Day 337)	1	14	17.9	6	42.9	38.89	38.97	-2.01	79.78
Week 52 (Day 365)	1	10	12.8	1	10.0	33.33	NE	NE	NE
Week 56 (Day 393)	1	9	11.5	3	33.3	66.67	33.33	-16.14	149.47
Week 60 (Day 421)	1	6	7.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	5	6.4	1	20.0	100.00	NE	NE	NE
Week 68 (Day 477)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	3	3.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	78	100.0	78	100.0	19.66	26.01	13.79	25.52
End of Study (LOCF)	1	78	100.0	78	100.0	20.09	26.50	14.11	26.06
Geographic region									
Baseline	USA	21	100.0	19	90.5	8.77	15.08	1.50	16.04
Week 4 (Day 29)	USA	21	100.0	20	95.2	21.67	29.17	8.01	35.32
Week 8 (Day 57)	USA	21	100.0	19	90.5	14.04	16.91	5.89	22.18
Week 12 (Day 85)	USA	21	100.0	19	90.5	19.30	27.92	5.84	32.76
Week 16 (Day 113)	USA	21	100.0	16	76.2	18.75	29.74	2.90	34.60
Week 20 (Day 141)	USA	20	95.2	18	90.0	12.96	25.92	0.07	25.85
Week 24 (Day 169)	USA	20	95.2	19	95.0	15.79	28.04	2.27	29.30
Week 28 (Day 197)	USA	20	95.2	19	95.0	14.04	25.62	1.69	26.38
Week 32 (Day 225)	USA	17	81.0	15	88.2	13.33	27.60	-1.95	28.62
Week 36 (Day 253)	USA	17	81.0	11	64.7	24.24	33.63	1.65	46.84
Week 40 (Day 281)	USA	15	71.4	12	80.0	13.89	30.01	-5.18	32.96

Week 44 (Day 309)	USA	13	61.9	10	76.9	16.67	32.39	-6.51	39.84
Week 48 (Day 337)	USA	8	38.1	5	62.5	26.67	43.46	-27.30	80.63
Week 52 (Day 365)	USA	6	28.6	1	16.7	0.00	NE	NE	NE
Week 56 (Day 393)	USA	6	28.6	3	50.0	44.44	50.92	-82.04	170.93
Week 60 (Day 421)	USA	5	23.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	4	19.0	1	25.0	100.00	NE	NE	NE
Week 68 (Day 477)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	21	100.0	21	100.0	12.70	24.67	1.47	23.93
End of Study (LOCF)	USA	21	100.0	21	100.0	12.70	24.67	1.47	23.93
Baseline	Europe (EU)	42	100.0	40	95.2	10.83	23.13	3.44	18.23
Week 4 (Day 29)	Europe (EU)	42	100.0	39	92.9	29.91	31.34	19.76	40.07
Week 8 (Day 57)	Europe (EU)	36	85.7	30	83.3	21.11	23.95	12.17	30.05
Week 12 (Day 85)	Europe (EU)	31	73.8	25	80.6	29.33	30.91	16.57	42.09
Week 16 (Day 113)	Europe (EU)	30	71.4	24	80.0	31.94	26.88	20.59	43.30
Week 20 (Day 141)	Europe (EU)	26	61.9	24	92.3	25.00	20.26	16.44	33.56
Week 24 (Day 169)	Europe (EU)	26	61.9	22	84.6	16.67	19.92	7.83	25.50
Week 28 (Day 197)	Europe (EU)	25	59.5	23	92.0	14.49	19.66	5.99	22.99
Week 32 (Day 225)	Europe (EU)	21	50.0	19	90.5	17.54	23.22	6.35	28.74
Week 36 (Day 253)	Europe (EU)	16	38.1	13	81.3	23.08	25.04	7.95	38.21
Week 40 (Day 281)	Europe (EU)	14	33.3	14	100.0	23.81	24.21	9.83	37.79
Week 44 (Day 309)	Europe (EU)	11	26.2	10	90.9	30.00	33.15	6.29	53.71
Week 48 (Day 337)	Europe (EU)	8	19.0	6	75.0	27.78	25.09	1.44	54.11
Week 52 (Day 365)	Europe (EU)	6	14.3	3	50.0	22.22	19.25	-25.59	70.03
Week 56 (Day 393)	Europe (EU)	6	14.3	2	33.3	33.33	47.14	-390.21	456.87

Week 60 (Day 421)	Europe (EU)	4	9.5	1	25.0	33.33	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	4	9.5	2	50.0	33.33	0.00	NE	NE
Week 68 (Day 477)	Europe (EU)	3	7.1	1	33.3	33.33	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	3	7.1	1	33.3	33.33	NE	NE	NE
Week 76 (Day 533)	Europe (EU)	3	7.1	1	33.3	0.00	NE	NE	NE
Week 80 (Day 561)	Europe (EU)	2	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Europe (EU)	42	100.0	42	100.0	23.81	27.83	15.14	32.48
End of Study (LOCF)	Europe (EU)	42	100.0	42	100.0	23.02	26.02	14.91	31.12
Baseline	Asia (AS)	45	100.0	45	100.0	8.89	21.79	2.34	15.43
Week 4 (Day 29)	Asia (AS)	45	100.0	37	82.2	16.22	23.07	8.52	23.91
Week 8 (Day 57)	Asia (AS)	35	77.8	30	85.7	17.78	28.68	7.07	28.49
Week 12 (Day 85)	Asia (AS)	27	60.0	27	100.0	12.35	24.72	2.57	22.12
Week 16 (Day 113)	Asia (AS)	18	40.0	18	100.0	20.37	28.33	6.28	34.46
Week 20 (Day 141)	Asia (AS)	13	28.9	13	100.0	25.64	30.89	6.97	44.31
Week 24 (Day 169)	Asia (AS)	10	22.2	8	80.0	33.33	35.63	3.54	63.12
Week 28 (Day 197)	Asia (AS)	10	22.2	9	90.0	22.22	33.33	-3.40	47.84
Week 32 (Day 225)	Asia (AS)	10	22.2	7	70.0	28.57	35.63	-4.39	61.53
Week 36 (Day 253)	Asia (AS)	8	17.8	6	75.0	5.56	13.61	-8.73	19.84
Week 40 (Day 281)	Asia (AS)	8	17.8	6	75.0	33.33	36.51	-4.99	71.65
Week 44 (Day 309)	Asia (AS)	7	15.6	6	85.7	33.33	36.51	-4.99	71.65
Week 48 (Day 337)	Asia (AS)	7	15.6	1	14.3	0.00	NE	NE	NE
Week 52 (Day 365)	Asia (AS)	7	15.6	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Asia (AS)	5	11.1	1	20.0	33.33	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	45	100.0	45	100.0	17.78	27.15	9.62	25.94
End of Study (LOCF)	Asia (AS)	45	100.0	45	100.0	17.78	27.15	9.62	25.94

Race/ethnicity									
Baseline	Asian	48	100.0	48	100.0	9.03	21.46	2.80	15.26
Week 4 (Day 29)	Asian	48	100.0	40	83.3	15.00	22.58	7.78	22.22
Week 8 (Day 57)	Asian	38	79.2	31	81.6	17.20	28.38	6.80	27.61
Week 12 (Day 85)	Asian	30	62.5	30	100.0	11.11	23.71	2.26	19.96
Week 16 (Day 113)	Asian	21	43.8	21	100.0	19.05	27.02	6.75	31.35
Week 20 (Day 141)	Asian	16	33.3	15	93.8	24.44	29.46	8.13	40.76
Week 24 (Day 169)	Asian	13	27.1	11	84.6	27.27	32.72	5.29	49.26
Week 28 (Day 197)	Asian	13	27.1	12	92.3	19.44	30.01	0.38	38.51
Week 32 (Day 225)	Asian	12	25.0	9	75.0	22.22	33.33	-3.40	47.84
Week 36 (Day 253)	Asian	10	20.8	8	80.0	4.17	11.79	-5.69	14.02
Week 40 (Day 281)	Asian	10	20.8	8	80.0	25.00	34.50	-3.85	53.85
Week 44 (Day 309)	Asian	9	18.8	8	88.9	25.00	34.50	-3.85	53.85
Week 48 (Day 337)	Asian	9	18.8	2	22.2	0.00	0.00	NE	NE
Week 52 (Day 365)	Asian	9	18.8	1	11.1	0.00	NE	NE	NE
Week 56 (Day 393)	Asian	7	14.6	2	28.6	16.67	23.57	-195.10	228.44
Week 60 (Day 421)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	48	100.0	48	100.0	17.36	26.62	9.63	25.09
End of Study (LOCF)	Asian	48	100.0	48	100.0	17.36	26.62	9.63	25.09
Baseline	Non-Asian	54	100.0	52	96.3	10.90	21.61	4.88	16.91
Week 4 (Day 29)	Non-Asian	54	100.0	50	92.6	26.67	30.12	18.11	35.23
Week 8 (Day 57)	Non-Asian	49	90.7	44	89.8	17.42	19.67	11.44	23.41
Week 12 (Day 85)	Non-Asian	44	81.5	37	84.1	25.23	28.77	15.63	34.82
Week 16 (Day 113)	Non-Asian	43	79.6	34	79.1	26.47	29.34	16.23	36.71
Week 20 (Day 141)	Non-Asian	38	70.4	35	92.1	19.05	23.27	11.05	27.04
Week 24 (Day 169)	Non-Asian	38	70.4	34	89.5	16.67	24.96	7.96	25.37
Week 28 (Day 197)	Non-Asian	37	68.5	35	94.6	13.33	23.15	5.38	21.29
Week 32 (Day 225)	Non-Asian	32	59.3	28	87.5	14.29	24.73	4.70	23.87
Week 36 (Day 253)	Non-Asian	27	50.0	20	74.1	23.33	28.82	9.85	36.82

Week 40 (Day 281)	Non-Asian	23	42.6	21	91.3	15.87	24.99	4.50	27.25
Week 44 (Day 309)	Non-Asian	18	33.3	14	77.8	19.05	28.39	2.66	35.44
Week 48 (Day 337)	Non-Asian	12	22.2	9	75.0	29.63	35.14	2.62	56.64
Week 52 (Day 365)	Non-Asian	8	14.8	3	37.5	22.22	19.25	-25.59	70.03
Week 56 (Day 393)	Non-Asian	8	14.8	4	50.0	50.00	43.03	-18.48	118.48
Week 60 (Day 421)	Non-Asian	7	13.0	1	14.3	33.33	NE	NE	NE
Week 64 (Day 449)	Non-Asian	6	11.1	2	33.3	66.67	47.14	-356.87	490.21
Week 68 (Day 477)	Non-Asian	3	5.6	1	33.3	33.33	NE	NE	NE
Week 72 (Day 505)	Non-Asian	3	5.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Non-Asian	3	5.6	1	33.3	0.00	NE	NE	NE
Week 80 (Day 561)	Non-Asian	2	3.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	54	100.0	54	100.0	17.90	25.67	10.90	24.91
End of Study (LOCF)	Non-Asian	54	100.0	54	100.0	18.52	26.44	11.30	25.73
Baseline	Unknown	6	100.0	4	66.7	0.00	0.00	NE	NE
Week 4 (Day 29)	Unknown	6	100.0	6	100.0	44.44	34.43	8.32	80.57
Week 8 (Day 57)	Unknown	5	83.3	4	80.0	33.33	38.49	-27.91	94.58
Week 12 (Day 85)	Unknown	5	83.3	4	80.0	41.67	41.94	-25.07	108.41
Week 16 (Day 113)	Unknown	5	83.3	3	60.0	44.44	19.25	-3.36	92.25
Week 20 (Day 141)	Unknown	5	83.3	5	100.0	26.67	27.89	-7.96	61.30
Week 24 (Day 169)	Unknown	5	83.3	4	80.0	16.67	19.25	-13.96	47.29
Week 28 (Day 197)	Unknown	5	83.3	4	80.0	25.00	16.67	-1.52	51.52
Week 32 (Day 225)	Unknown	4	66.7	4	100.0	33.33	27.22	-9.97	76.64
Week 36 (Day 253)	Unknown	4	66.7	2	50.0	50.00	23.57	-161.77	261.77
Week 40 (Day 281)	Unknown	4	66.7	3	75.0	55.56	19.25	7.75	103.36
Week 44 (Day 309)	Unknown	4	66.7	4	100.0	50.00	43.03	-18.48	118.48
Week 48 (Day 337)	Unknown	2	33.3	1	50.0	33.33	NE	NE	NE
Week 52 (Day 365)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 60 (Day 421)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE

Week 64 (Day 449)	Unknown	1	16.7	1	100.0	33.33	NE	NE	NE
Week 68 (Day 477)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	1	16.7	1	100.0	33.33	NE	NE	NE
Week 76 (Day 533)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	6	100.0	6	100.0	44.44	34.43	8.32	80.57
End of Study (LOCF)	Unknown	6	100.0	6	100.0	33.33	21.08	11.21	55.46

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TN_QSC30CO_SG.xls
27OCT2021 7:34

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Constipation
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	56	53.8	44.3	63.1
	Cycle 12 (LOCF)	n/a	104	96.3	30	28.8	21.0	38.2
	End of Study (LOCF)	n/a	104	96.3	30	28.8	21.0	38.2
Sex	All visits	Female	56	51.9	29	51.8	39.0	64.3
		Male	48	44.4	27	56.3	42.3	69.3
	Cycle 12 (LOCF)	Female	56	51.9	13	23.2	14.1	35.8
		Male	48	44.4	17	35.4	23.4	49.6
	End of Study (LOCF)	Female	56	51.9	13	23.2	14.1	35.8
		Male	48	44.4	17	35.4	23.4	49.6
Age	All visits	< 65	60	55.6	31	51.7	39.3	63.8
		>= 65	44	40.7	25	56.8	42.2	70.3
	Cycle 12 (LOCF)	< 65	60	55.6	15	25.0	15.8	37.2
		>= 65	44	40.7	15	34.1	21.9	48.9
	End of Study (LOCF)	< 65	60	55.6	15	25.0	15.8	37.2
		>= 65	44	40.7	15	34.1	21.9	48.9
ECOG performance status	All visits	0	29	26.9	23	79.3	61.6	90.2
		1	75	69.4	33	44.0	33.3	55.3
	Cycle 12 (LOCF)	0	29	26.9	7	24.1	12.2	42.1
		1	75	69.4	23	30.7	21.4	41.8
	End of Study (LOCF)	0	29	26.9	7	24.1	12.2	42.1
		1	75	69.4	23	30.7	21.4	41.8
Geographic region	All visits	USA	19	17.6	14	73.7	51.2	88.2
		Europe (EU)	40	37.0	25	62.5	47.0	75.8
		Asia (AS)	45	41.7	17	37.8	25.1	52.4
	Cycle 12 (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	15	37.5	24.2	53.0
		Asia (AS)	45	41.7	12	26.7	16.0	41.0
	End of Study (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	15	37.5	24.2	53.0
		Asia (AS)	45	41.7	12	26.7	16.0	41.0
Race/ethnicity	All visits	Asian	48	44.4	17	35.4	23.4	49.6
		Non-Asian	52	48.1	35	67.3	53.8	78.5
		Unknown	4	3.7	4	100.0	51.0	100.0
	Cycle 12 (LOCF)	Asian	48	44.4	12	25.0	14.9	38.8
		Non-Asian	52	48.1	15	28.8	18.3	42.3
		Unknown	4	3.7	3	75.0	30.1	95.4
	End of Study (LOCF)	Asian	48	44.4	12	25.0	14.9	38.8

		Non-Asian	52	48.1	15	28.8	18.3	42.3
		Unknown	4	3.7	3	75.0	30.1	95.4

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30CO_W10_SG.xls
15OCT2021 13:11

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Constipation
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

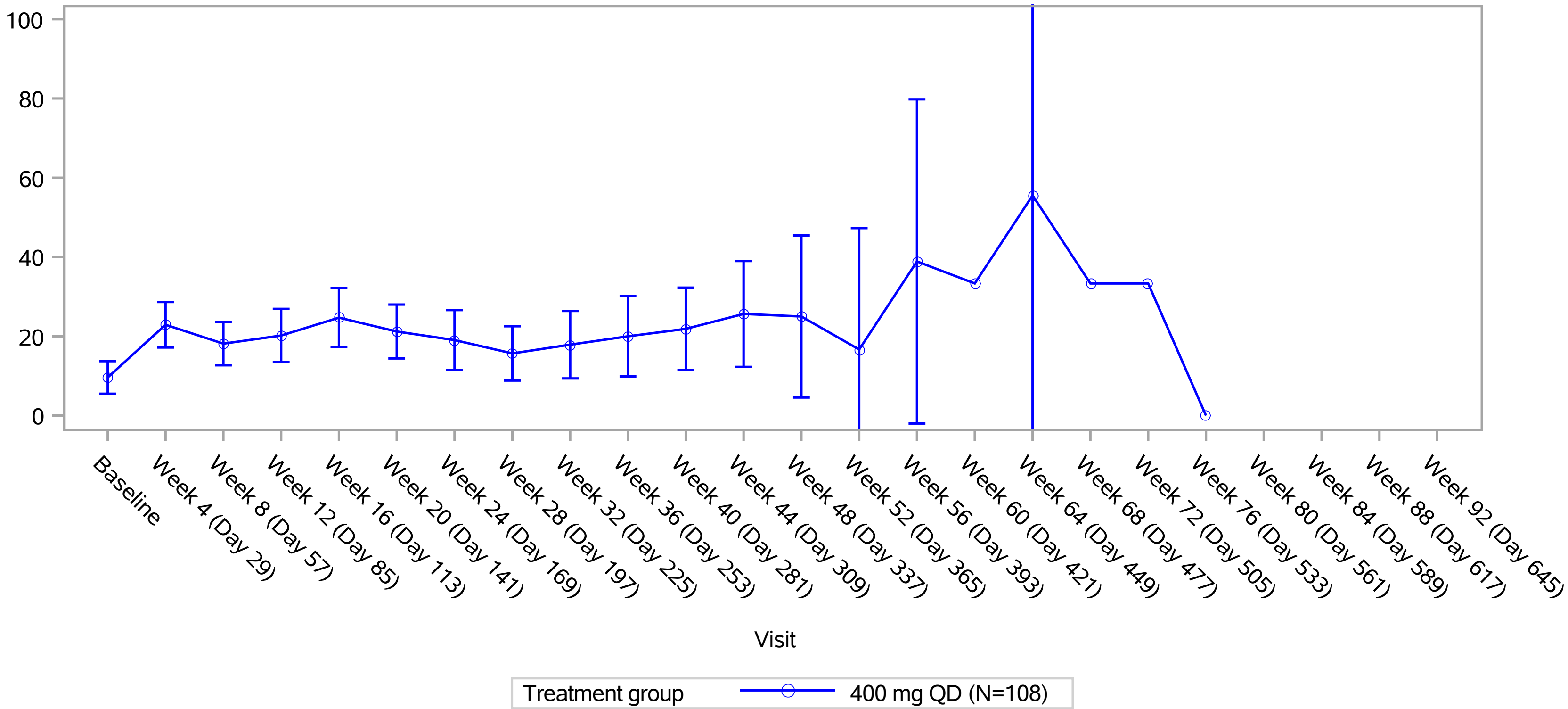
			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	56	53.8	44.3	63.1
	Cycle 12 (LOCF)	n/a	104	96.3	30	28.8	21.0	38.2
	End of Study (LOCF)	n/a	104	96.3	30	28.8	21.0	38.2
Sex	All visits	Female	56	51.9	29	51.8	39.0	64.3
		Male	48	44.4	27	56.3	42.3	69.3
	Cycle 12 (LOCF)	Female	56	51.9	13	23.2	14.1	35.8
		Male	48	44.4	17	35.4	23.4	49.6
	End of Study (LOCF)	Female	56	51.9	13	23.2	14.1	35.8
		Male	48	44.4	17	35.4	23.4	49.6
Age	All visits	< 65	60	55.6	31	51.7	39.3	63.8
		>= 65	44	40.7	25	56.8	42.2	70.3
	Cycle 12 (LOCF)	< 65	60	55.6	15	25.0	15.8	37.2
		>= 65	44	40.7	15	34.1	21.9	48.9
	End of Study (LOCF)	< 65	60	55.6	15	25.0	15.8	37.2
		>= 65	44	40.7	15	34.1	21.9	48.9
ECOG performance status	All visits	0	29	26.9	23	79.3	61.6	90.2
		1	75	69.4	33	44.0	33.3	55.3
	Cycle 12 (LOCF)	0	29	26.9	7	24.1	12.2	42.1
		1	75	69.4	23	30.7	21.4	41.8
	End of Study (LOCF)	0	29	26.9	7	24.1	12.2	42.1
		1	75	69.4	23	30.7	21.4	41.8
Geographic region	All visits	USA	19	17.6	14	73.7	51.2	88.2
		Europe (EU)	40	37.0	25	62.5	47.0	75.8
		Asia (AS)	45	41.7	17	37.8	25.1	52.4
	Cycle 12 (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	15	37.5	24.2	53.0
		Asia (AS)	45	41.7	12	26.7	16.0	41.0
	End of Study (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	15	37.5	24.2	53.0
		Asia (AS)	45	41.7	12	26.7	16.0	41.0
Race/ethnicity	All visits	Asian	48	44.4	17	35.4	23.4	49.6
		Non-Asian	52	48.1	35	67.3	53.8	78.5
		Unknown	4	3.7	4	100.0	51.0	100.0
	Cycle 12 (LOCF)	Asian	48	44.4	12	25.0	14.9	38.8
		Non-Asian	52	48.1	15	28.8	18.3	42.3
		Unknown	4	3.7	3	75.0	30.1	95.4
	End of Study (LOCF)	Asian	48	44.4	12	25.0	14.9	38.8

		Non-Asian	52	48.1	15	28.8	18.3	42.3
		Unknown	4	3.7	3	75.0	30.1	95.4

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30CO_W15_SG.xls
15OCT2021 13:00

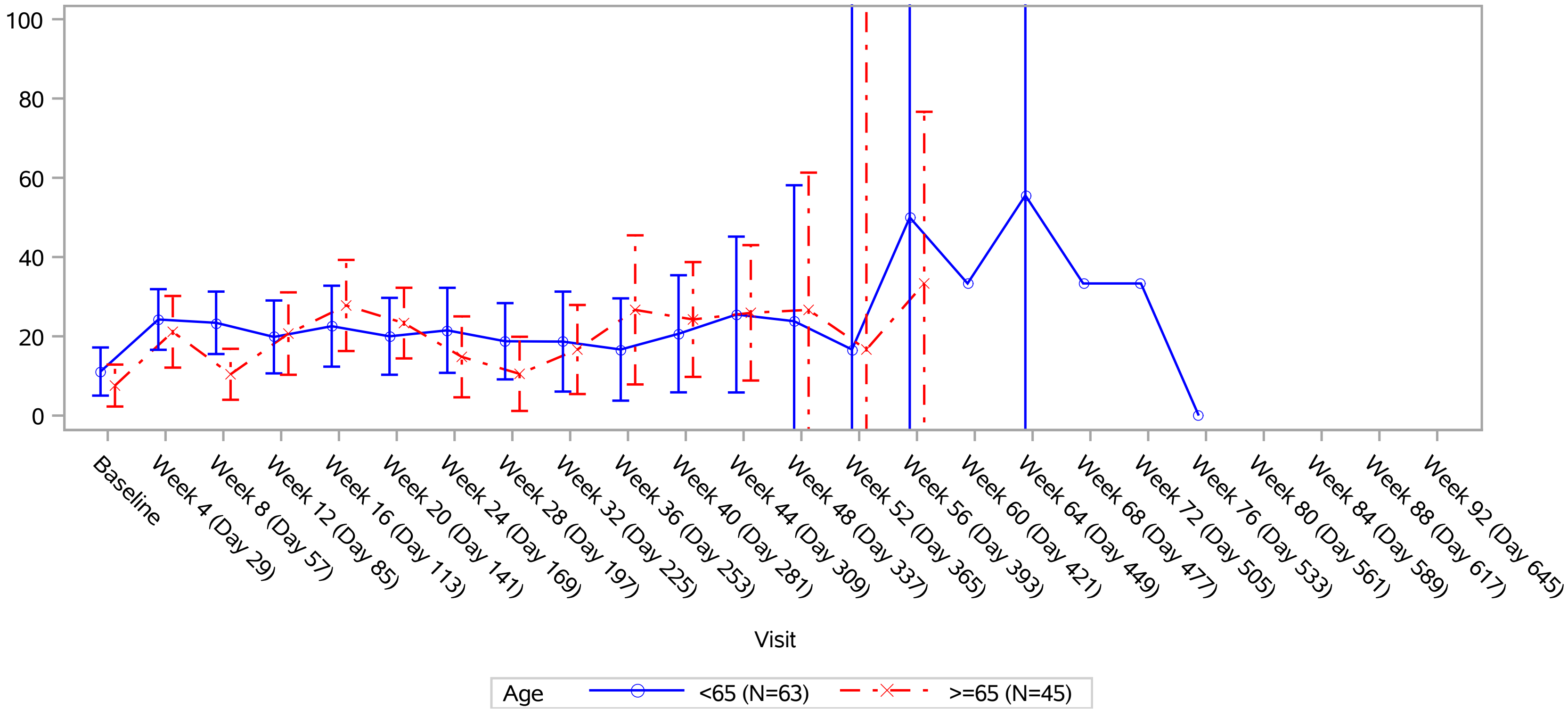
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Constipation
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30CO.pdf
15OCT2021 17:23

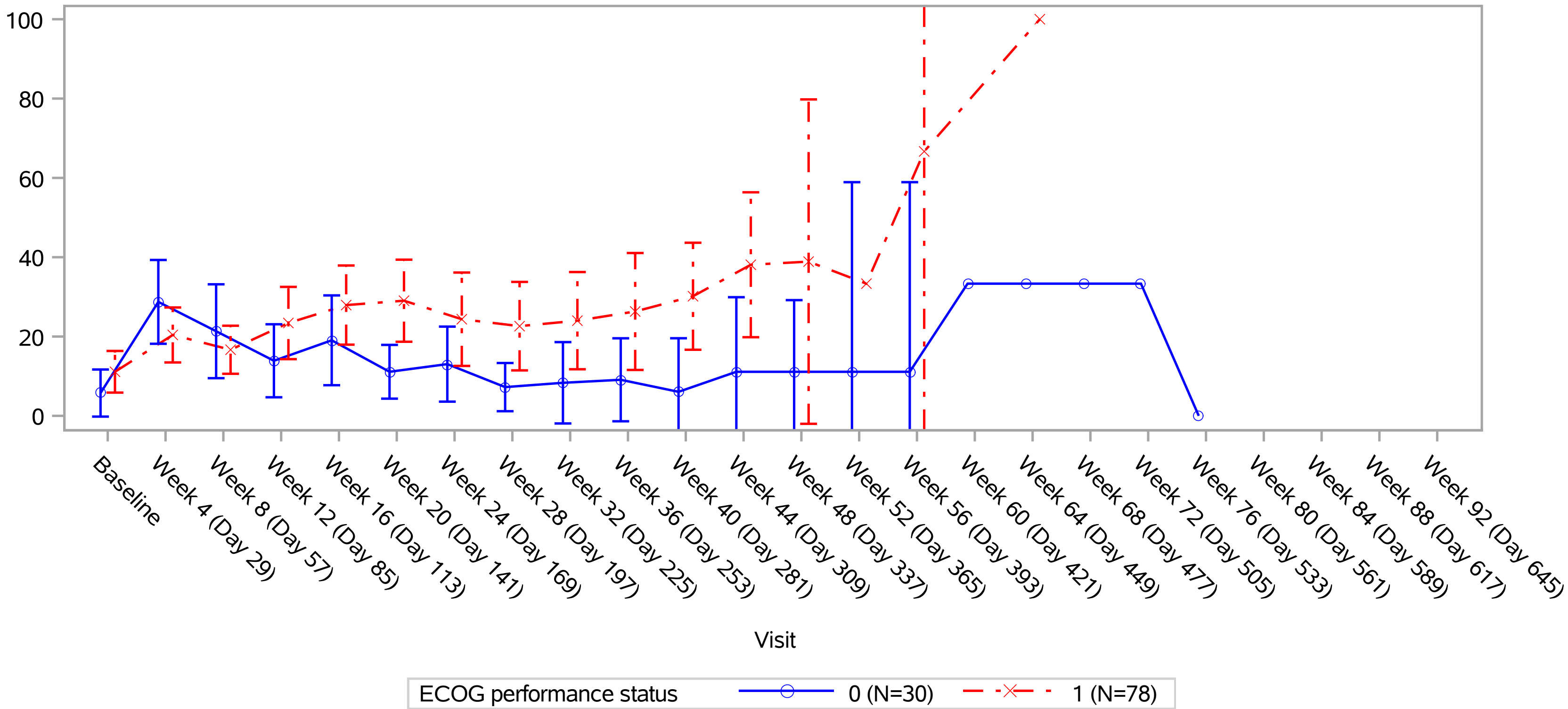
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Constipation
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30CO_SGAGE65.pdf
15OCT2021 17:52

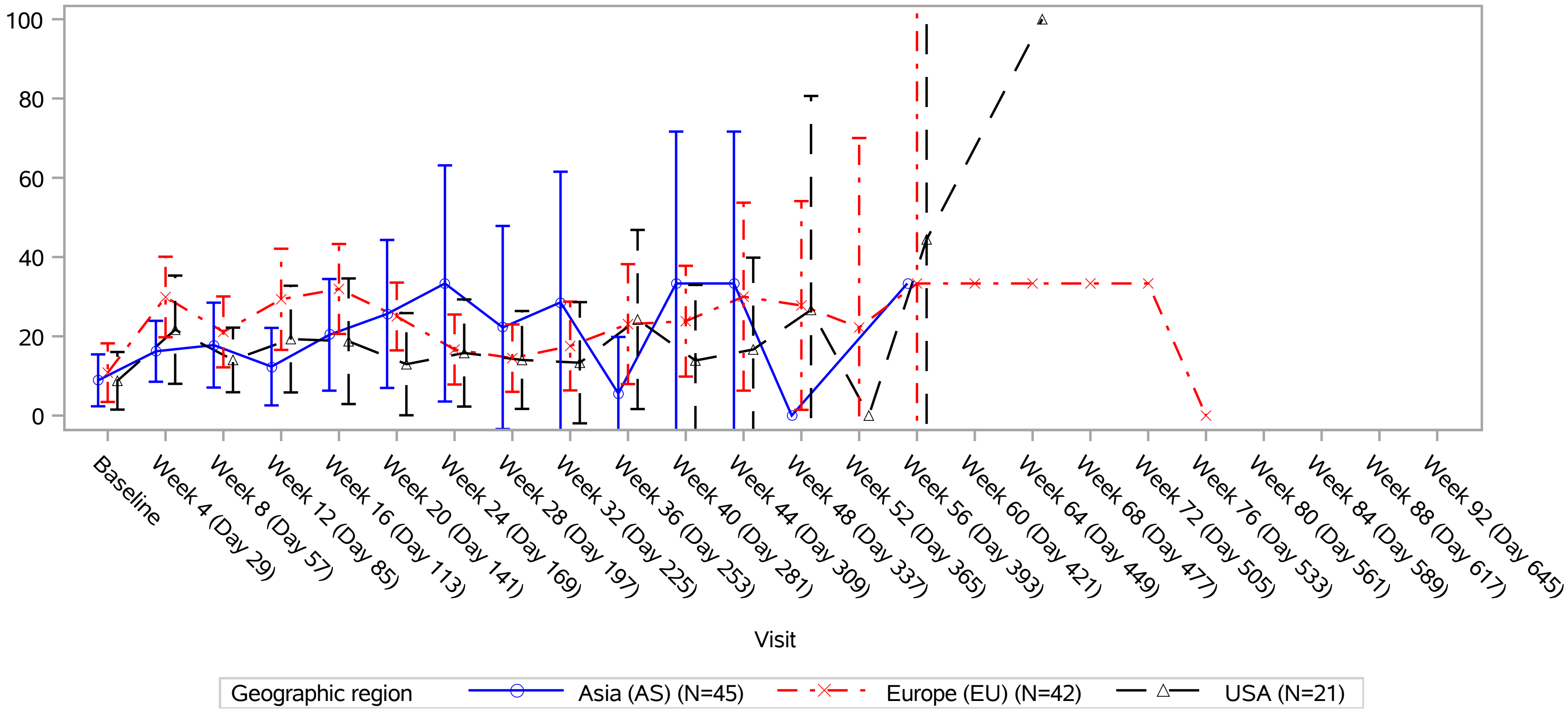
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Constipation
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30CO_SGECOG.pdf
15OCT2021 18:23

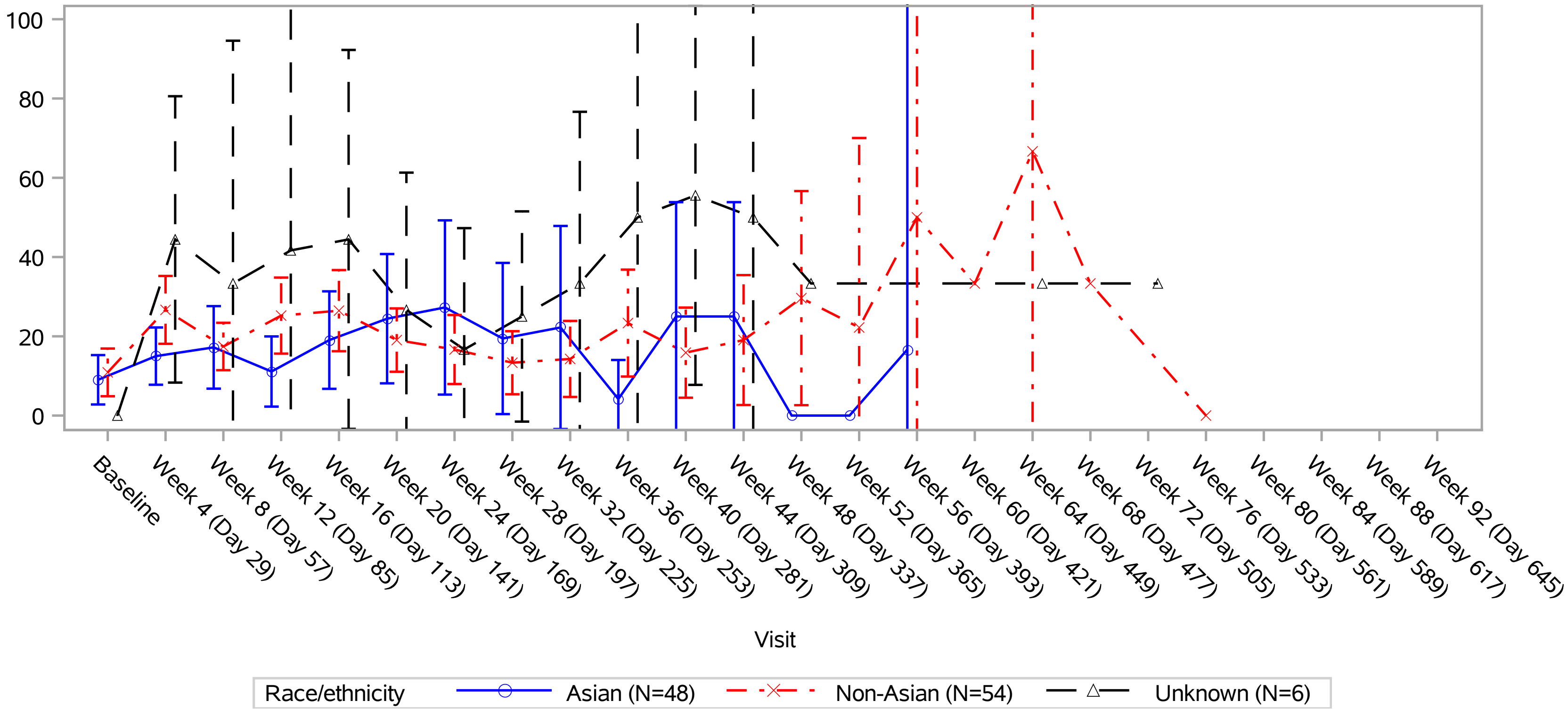
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Constipation
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30CO_SGGEO.pdf
15OCT2021 18:54

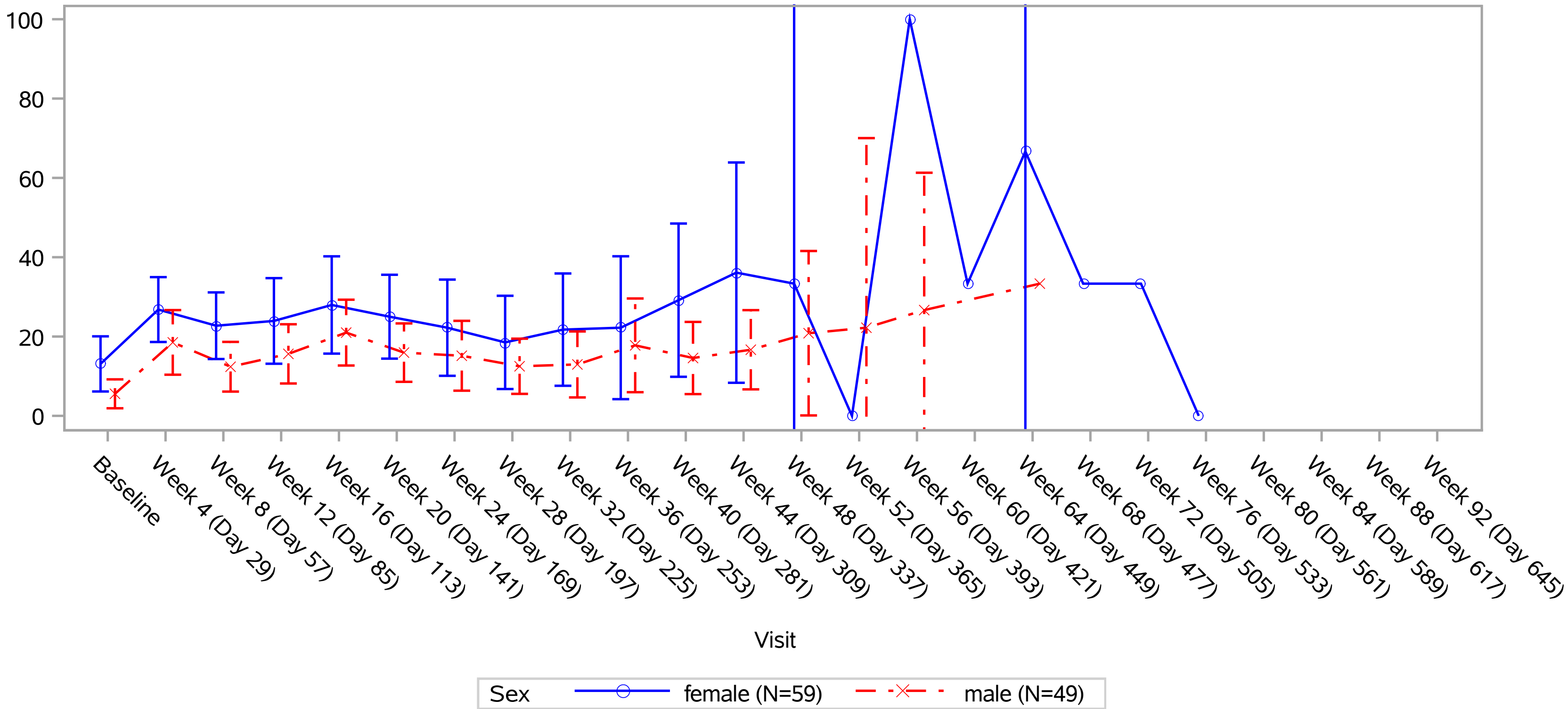
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Constipation
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30CO_SGRE.pdf
15OCT2021 19:24

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Constipation
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30CO_SGSEX.pdf
15OCT2021 19:55

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Diarrhoea
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=108)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	108	100.0	104	96.3	4.17	11.08	2.01	6.32
Week 4 (Day 29)	n/a	108	100.0	96	88.9	6.25	13.94	3.42	9.08
Week 8 (Day 57)	n/a	92	85.2	79	85.9	6.75	16.35	3.09	10.41
Week 12 (Day 85)	n/a	79	73.1	70	88.6	8.10	21.56	2.95	13.24
Week 16 (Day 113)	n/a	69	63.9	58	84.1	8.05	18.00	3.31	12.78
Week 20 (Day 141)	n/a	59	54.6	55	93.2	3.03	11.61	-0.11	6.17
Week 24 (Day 169)	n/a	56	51.9	49	87.5	6.80	19.22	1.28	12.32
Week 28 (Day 197)	n/a	55	50.9	51	92.7	6.54	17.66	1.57	11.50
Week 32 (Day 225)	n/a	48	44.4	41	85.4	7.32	19.02	1.31	13.32
Week 36 (Day 253)	n/a	41	38.0	30	73.2	5.56	15.37	-0.18	11.30
Week 40 (Day 281)	n/a	37	34.3	32	86.5	6.25	13.22	1.48	11.02
Week 44 (Day 309)	n/a	31	28.7	26	83.9	5.13	15.47	-1.12	11.38
Week 48 (Day 337)	n/a	23	21.3	12	52.2	2.78	9.62	-3.34	8.89
Week 52 (Day 365)	n/a	19	17.6	4	21.1	0.00	0.00	NE	NE
Week 56 (Day 393)	n/a	17	15.7	6	35.3	0.00	0.00	NE	NE
Week 60 (Day 421)	n/a	11	10.2	1	9.1	0.00	NE	NE	NE
Week 64 (Day 449)	n/a	10	9.3	3	30.0	11.11	19.25	-36.70	58.92
Week 68 (Day 477)	n/a	6	5.6	1	16.7	0.00	NE	NE	NE
Week 72 (Day 505)	n/a	6	5.6	1	16.7	0.00	NE	NE	NE
Week 76 (Day 533)	n/a	6	5.6	1	16.7	0.00	NE	NE	NE
Week 80 (Day 561)	n/a	5	4.6	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	n/a	1	0.9	0	0.0	NE	NE	NE	NE

Cycle 12 (LOCF)	n/a	108	100.0	108	100.0	7.10	18.26	3.62	10.58
End of Study (LOCF)	n/a	108	100.0	108	100.0	7.41	18.42	3.89	10.92
Sex									
Baseline	Female	59	100.0	56	94.9	7.14	13.80	3.45	10.84
Week 4 (Day 29)	Female	59	100.0	51	86.4	7.84	14.28	3.83	11.86
Week 8 (Day 57)	Female	49	83.1	44	89.8	9.09	18.13	3.58	14.60
Week 12 (Day 85)	Female	44	74.6	38	86.4	6.14	15.22	1.14	11.14
Week 16 (Day 113)	Female	38	64.4	31	81.6	9.68	21.42	1.82	17.53
Week 20 (Day 141)	Female	33	55.9	32	97.0	3.13	13.01	-1.56	7.81
Week 24 (Day 169)	Female	31	52.5	27	87.1	8.64	23.74	-0.75	18.03
Week 28 (Day 197)	Female	30	50.8	27	90.0	7.41	21.35	-1.04	15.85
Week 32 (Day 225)	Female	27	45.8	23	85.2	10.14	23.43	0.01	20.28
Week 36 (Day 253)	Female	22	37.3	15	68.2	8.89	19.79	-2.07	19.85
Week 40 (Day 281)	Female	18	30.5	16	88.9	8.33	14.91	0.39	16.28
Week 44 (Day 309)	Female	15	25.4	12	80.0	8.33	20.72	-4.83	21.50
Week 48 (Day 337)	Female	11	18.6	4	36.4	8.33	16.67	-18.19	34.85
Week 52 (Day 365)	Female	9	15.3	1	11.1	0.00	NE	NE	NE
Week 56 (Day 393)	Female	7	11.9	1	14.3	0.00	NE	NE	NE
Week 60 (Day 421)	Female	5	8.5	1	20.0	0.00	NE	NE	NE
Week 64 (Day 449)	Female	4	6.8	2	50.0	16.67	23.57	-195.10	228.44
Week 68 (Day 477)	Female	3	5.1	1	33.3	0.00	NE	NE	NE
Week 72 (Day 505)	Female	3	5.1	1	33.3	0.00	NE	NE	NE
Week 76 (Day 533)	Female	3	5.1	1	33.3	0.00	NE	NE	NE
Week 80 (Day 561)	Female	2	3.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	59	100.0	59	100.0	8.47	21.08	2.98	13.97
End of Study (LOCF)	Female	59	100.0	59	100.0	9.04	21.29	3.49	14.59
Baseline	Male	49	100.0	48	98.0	0.69	4.81	-0.70	2.09
Week 4 (Day 29)	Male	49	100.0	45	91.8	4.44	13.48	0.39	8.50
Week 8 (Day 57)	Male	43	87.8	35	81.4	3.81	13.46	-0.81	8.43
Week 12 (Day 85)	Male	35	71.4	32	91.4	10.42	27.35	0.55	20.28
Week 16 (Day 113)	Male	31	63.3	27	87.1	6.17	13.19	0.95	11.39
Week 20 (Day 141)	Male	26	53.1	23	88.5	2.90	9.60	-1.25	7.05
Week 24 (Day 169)	Male	25	51.0	22	88.0	4.55	11.71	-0.65	9.74
Week 28 (Day 197)	Male	25	51.0	24	96.0	5.56	12.69	0.20	10.91

Week 32 (Day 225)	Male	21	42.9	18	85.7	3.70	10.78	-1.66	9.06
Week 36 (Day 253)	Male	19	38.8	15	78.9	2.22	8.61	-2.54	6.99
Week 40 (Day 281)	Male	19	38.8	16	84.2	4.17	11.39	-1.90	10.23
Week 44 (Day 309)	Male	16	32.7	14	87.5	2.38	8.91	-2.76	7.52
Week 48 (Day 337)	Male	12	24.5	8	66.7	0.00	0.00	NE	NE
Week 52 (Day 365)	Male	10	20.4	3	30.0	0.00	0.00	NE	NE
Week 56 (Day 393)	Male	10	20.4	5	50.0	0.00	0.00	NE	NE
Week 60 (Day 421)	Male	6	12.2	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Male	6	12.2	1	16.7	0.00	NE	NE	NE
Week 68 (Day 477)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	49	100.0	49	100.0	5.44	14.19	1.37	9.52
End of Study (LOCF)	Male	49	100.0	49	100.0	5.44	14.19	1.37	9.52
Age									
Baseline	< 65	63	100.0	60	95.2	5.56	12.53	2.32	8.79
Week 4 (Day 29)	< 65	63	100.0	55	87.3	6.06	14.47	2.15	9.97
Week 8 (Day 57)	< 65	54	85.7	47	87.0	4.96	13.86	0.89	9.04
Week 12 (Day 85)	< 65	47	74.6	41	87.2	7.32	20.43	0.87	13.77
Week 16 (Day 113)	< 65	39	61.9	34	87.2	7.84	18.46	1.40	14.28
Week 20 (Day 141)	< 65	35	55.6	35	100.0	3.81	13.46	-0.81	8.43
Week 24 (Day 169)	< 65	34	54.0	31	91.2	4.30	14.25	-0.93	9.53
Week 28 (Day 197)	< 65	33	52.4	32	97.0	9.38	21.14	1.75	17.00
Week 32 (Day 225)	< 65	30	47.6	25	83.3	4.00	14.66	-2.05	10.05
Week 36 (Day 253)	< 65	25	39.7	20	80.0	3.33	10.26	-1.47	8.14
Week 40 (Day 281)	< 65	23	36.5	21	91.3	6.35	13.41	0.24	12.45
Week 44 (Day 309)	< 65	19	30.2	17	89.5	1.96	8.08	-2.20	6.12
Week 48 (Day 337)	< 65	14	22.2	7	50.0	4.76	12.60	-6.89	16.41

Week 52 (Day 365)	< 65	12	19.0	2	16.7	0.00	0.00	NE	NE
Week 56 (Day 393)	< 65	11	17.5	2	18.2	0.00	0.00	NE	NE
Week 60 (Day 421)	< 65	8	12.7	1	12.5	0.00	NE	NE	NE
Week 64 (Day 449)	< 65	7	11.1	3	42.9	11.11	19.25	-36.70	58.92
Week 68 (Day 477)	< 65	4	6.3	1	25.0	0.00	NE	NE	NE
Week 72 (Day 505)	< 65	4	6.3	1	25.0	0.00	NE	NE	NE
Week 76 (Day 533)	< 65	4	6.3	1	25.0	0.00	NE	NE	NE
Week 80 (Day 561)	< 65	3	4.8	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	63	100.0	63	100.0	7.41	19.35	2.53	12.28
End of Study (LOCF)	< 65	63	100.0	63	100.0	7.94	19.60	3.00	12.87
Baseline	>= 65	45	100.0	44	97.8	2.27	8.50	-0.31	4.86
Week 4 (Day 29)	>= 65	45	100.0	41	91.1	6.50	13.37	2.28	10.73
Week 8 (Day 57)	>= 65	38	84.4	32	84.2	9.37	19.37	2.39	16.36
Week 12 (Day 85)	>= 65	32	71.1	29	90.6	9.20	23.40	0.30	18.09
Week 16 (Day 113)	>= 65	30	66.7	24	80.0	8.33	17.72	0.85	15.82
Week 20 (Day 141)	>= 65	24	53.3	20	83.3	1.67	7.45	-1.82	5.16
Week 24 (Day 169)	>= 65	22	48.9	18	81.8	11.11	25.57	-1.60	23.82
Week 28 (Day 197)	>= 65	22	48.9	19	86.4	1.75	7.65	-1.93	5.44
Week 32 (Day 225)	>= 65	18	40.0	16	88.9	12.50	23.96	-0.27	25.27
Week 36 (Day 253)	>= 65	16	35.6	10	62.5	10.00	22.50	-6.09	26.09
Week 40 (Day 281)	>= 65	14	31.1	11	78.6	6.06	13.48	-3.00	15.12
Week 44 (Day 309)	>= 65	12	26.7	9	75.0	11.11	23.57	-7.01	29.23
Week 48 (Day 337)	>= 65	9	20.0	5	55.6	0.00	0.00	NE	NE
Week 52 (Day 365)	>= 65	7	15.6	2	28.6	0.00	0.00	NE	NE
Week 56 (Day 393)	>= 65	6	13.3	4	66.7	0.00	0.00	NE	NE
Week 60 (Day 421)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE

Week 76 (Day 533)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	45	100.0	45	100.0	6.67	16.82	1.61	11.72
End of Study (LOCF)	>= 65	45	100.0	45	100.0	6.67	16.82	1.61	11.72
ECOG performance status									
Baseline	0	30	100.0	29	96.7	3.45	10.33	-0.48	7.38
Week 4 (Day 29)	0	30	100.0	29	96.7	4.60	11.70	0.15	9.05
Week 8 (Day 57)	0	28	93.3	25	89.3	9.33	18.05	1.88	16.79
Week 12 (Day 85)	0	26	86.7	23	88.5	13.04	26.09	1.76	24.33
Week 16 (Day 113)	0	26	86.7	21	80.8	6.35	17.06	-1.42	14.11
Week 20 (Day 141)	0	26	86.7	24	92.3	2.78	9.41	-1.20	6.75
Week 24 (Day 169)	0	25	83.3	23	92.0	4.35	15.26	-2.25	10.95
Week 28 (Day 197)	0	25	83.3	23	92.0	10.14	23.43	0.01	20.28
Week 32 (Day 225)	0	20	66.7	16	80.0	4.17	16.67	-4.71	13.05
Week 36 (Day 253)	0	18	60.0	11	61.1	0.00	0.00	NE	NE
Week 40 (Day 281)	0	16	53.3	11	68.8	0.00	0.00	NE	NE
Week 44 (Day 309)	0	15	50.0	12	80.0	0.00	0.00	NE	NE
Week 48 (Day 337)	0	9	30.0	6	66.7	0.00	0.00	NE	NE
Week 52 (Day 365)	0	9	30.0	3	33.3	0.00	0.00	NE	NE
Week 56 (Day 393)	0	8	26.7	3	37.5	0.00	0.00	NE	NE
Week 60 (Day 421)	0	5	16.7	1	20.0	0.00	NE	NE	NE
Week 64 (Day 449)	0	5	16.7	2	40.0	0.00	0.00	NE	NE
Week 68 (Day 477)	0	3	10.0	1	33.3	0.00	NE	NE	NE
Week 72 (Day 505)	0	3	10.0	1	33.3	0.00	NE	NE	NE
Week 76 (Day 533)	0	3	10.0	1	33.3	0.00	NE	NE	NE
Week 80 (Day 561)	0	2	6.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	0	1	3.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	30	100.0	30	100.0	8.89	23.05	0.28	17.50
End of Study (LOCF)	0	30	100.0	30	100.0	8.89	23.05	0.28	17.50
Baseline	1	78	100.0	75	96.2	4.44	11.41	1.82	7.07
Week 4 (Day 29)	1	78	100.0	67	85.9	6.97	14.84	3.35	10.58

Week 8 (Day 57)	1	64	82.1	54	84.4	5.56	15.53	1.32	9.79
Week 12 (Day 85)	1	53	67.9	47	88.7	5.67	18.80	0.15	11.19
Week 16 (Day 113)	1	43	55.1	37	86.0	9.01	18.67	2.78	15.23
Week 20 (Day 141)	1	33	42.3	31	93.9	3.23	13.21	-1.62	8.07
Week 24 (Day 169)	1	31	39.7	26	83.9	8.97	22.23	0.00	17.95
Week 28 (Day 197)	1	30	38.5	28	93.3	3.57	10.50	-0.50	7.64
Week 32 (Day 225)	1	28	35.9	25	89.3	9.33	20.46	0.89	17.78
Week 36 (Day 253)	1	23	29.5	19	82.6	8.77	18.73	-0.26	17.80
Week 40 (Day 281)	1	21	26.9	21	100.0	9.52	15.43	2.50	16.55
Week 44 (Day 309)	1	16	20.5	14	87.5	9.52	20.37	-2.24	21.29
Week 48 (Day 337)	1	14	17.9	6	42.9	5.56	13.61	-8.73	19.84
Week 52 (Day 365)	1	10	12.8	1	10.0	0.00	NE	NE	NE
Week 56 (Day 393)	1	9	11.5	3	33.3	0.00	0.00	NE	NE
Week 60 (Day 421)	1	6	7.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	5	6.4	1	20.0	33.33	NE	NE	NE
Week 68 (Day 477)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	3	3.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	78	100.0	78	100.0	6.41	16.17	2.76	10.06
End of Study (LOCF)	1	78	100.0	78	100.0	6.84	16.43	3.13	10.54
Geographic region									
Baseline	USA	21	100.0	19	90.5	10.53	15.92	2.85	18.20
Week 4 (Day 29)	USA	21	100.0	20	95.2	6.67	13.68	0.26	13.07
Week 8 (Day 57)	USA	21	100.0	19	90.5	10.53	19.41	1.17	19.88
Week 12 (Day 85)	USA	21	100.0	18	85.7	12.96	28.33	-1.12	27.05
Week 16 (Day 113)	USA	21	100.0	16	76.2	14.58	24.25	1.66	27.50
Week 20 (Day 141)	USA	20	95.2	18	90.0	7.41	18.28	-1.68	16.50
Week 24 (Day 169)	USA	20	95.2	19	95.0	8.77	18.73	-0.26	17.80
Week 28 (Day 197)	USA	20	95.2	19	95.0	8.77	24.45	-3.01	20.56
Week 32 (Day 225)	USA	17	81.0	15	88.2	13.33	24.56	-0.27	26.93
Week 36 (Day 253)	USA	17	81.0	11	64.7	6.06	13.48	-3.00	15.12
Week 40 (Day 281)	USA	15	71.4	12	80.0	13.89	17.16	2.98	24.79

Week 44 (Day 309)	USA	13	61.9	10	76.9	6.67	14.05	-3.39	16.72
Week 48 (Day 337)	USA	8	38.1	5	62.5	6.67	14.91	-11.84	25.18
Week 52 (Day 365)	USA	6	28.6	1	16.7	0.00	NE	NE	NE
Week 56 (Day 393)	USA	6	28.6	3	50.0	0.00	0.00	NE	NE
Week 60 (Day 421)	USA	5	23.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	4	19.0	1	25.0	33.33	NE	NE	NE
Week 68 (Day 477)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	21	100.0	21	100.0	12.70	24.67	1.47	23.93
End of Study (LOCF)	USA	21	100.0	21	100.0	14.29	24.88	2.96	25.61
Baseline	Europe (EU)	42	100.0	40	95.2	4.17	11.16	0.60	7.74
Week 4 (Day 29)	Europe (EU)	42	100.0	39	92.9	4.27	11.29	0.61	7.93
Week 8 (Day 57)	Europe (EU)	36	85.7	30	83.3	4.44	14.47	-0.96	9.85
Week 12 (Day 85)	Europe (EU)	31	73.8	25	80.6	10.67	24.94	0.37	20.96
Week 16 (Day 113)	Europe (EU)	30	71.4	24	80.0	6.94	16.97	-0.22	14.11
Week 20 (Day 141)	Europe (EU)	26	61.9	24	92.3	0.00	0.00	NE	NE
Week 24 (Day 169)	Europe (EU)	26	61.9	22	84.6	7.58	22.84	-2.55	17.70
Week 28 (Day 197)	Europe (EU)	25	59.5	23	92.0	5.80	12.92	0.21	11.38
Week 32 (Day 225)	Europe (EU)	21	50.0	19	90.5	5.26	16.72	-2.79	13.32
Week 36 (Day 253)	Europe (EU)	16	38.1	13	81.3	7.69	19.97	-4.38	19.76
Week 40 (Day 281)	Europe (EU)	14	33.3	14	100.0	0.00	0.00	NE	NE
Week 44 (Day 309)	Europe (EU)	11	26.2	10	90.9	6.67	21.08	-8.41	21.75
Week 48 (Day 337)	Europe (EU)	8	19.0	6	75.0	0.00	0.00	NE	NE
Week 52 (Day 365)	Europe (EU)	6	14.3	3	50.0	0.00	0.00	NE	NE
Week 56 (Day 393)	Europe (EU)	6	14.3	2	33.3	0.00	0.00	NE	NE

Week 60 (Day 421)	Europe (EU)	4	9.5	1	25.0	0.00	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	4	9.5	2	50.0	0.00	0.00	NE	NE
Week 68 (Day 477)	Europe (EU)	3	7.1	1	33.3	0.00	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	3	7.1	1	33.3	0.00	NE	NE	NE
Week 76 (Day 533)	Europe (EU)	3	7.1	1	33.3	0.00	NE	NE	NE
Week 80 (Day 561)	Europe (EU)	2	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Europe (EU)	42	100.0	42	100.0	6.35	16.85	1.10	11.60
End of Study (LOCF)	Europe (EU)	42	100.0	42	100.0	6.35	16.85	1.10	11.60
Baseline	Asia (AS)	45	100.0	45	100.0	1.48	6.95	-0.61	3.57
Week 4 (Day 29)	Asia (AS)	45	100.0	37	82.2	8.11	16.49	2.61	13.61
Week 8 (Day 57)	Asia (AS)	35	77.8	30	85.7	6.67	16.14	0.64	12.69
Week 12 (Day 85)	Asia (AS)	27	60.0	27	100.0	2.47	8.90	-1.05	5.99
Week 16 (Day 113)	Asia (AS)	18	40.0	18	100.0	3.70	10.78	-1.66	9.06
Week 20 (Day 141)	Asia (AS)	13	28.9	13	100.0	2.56	9.25	-3.02	8.15
Week 24 (Day 169)	Asia (AS)	10	22.2	8	80.0	0.00	0.00	NE	NE
Week 28 (Day 197)	Asia (AS)	10	22.2	9	90.0	3.70	11.11	-4.84	12.24
Week 32 (Day 225)	Asia (AS)	10	22.2	7	70.0	0.00	0.00	NE	NE
Week 36 (Day 253)	Asia (AS)	8	17.8	6	75.0	0.00	0.00	NE	NE
Week 40 (Day 281)	Asia (AS)	8	17.8	6	75.0	5.56	13.61	-8.73	19.84
Week 44 (Day 309)	Asia (AS)	7	15.6	6	85.7	0.00	0.00	NE	NE
Week 48 (Day 337)	Asia (AS)	7	15.6	1	14.3	0.00	NE	NE	NE
Week 52 (Day 365)	Asia (AS)	7	15.6	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Asia (AS)	5	11.1	1	20.0	0.00	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	45	100.0	45	100.0	5.19	15.82	0.43	9.94
End of Study (LOCF)	Asia (AS)	45	100.0	45	100.0	5.19	15.82	0.43	9.94

Race/ethnicity									
Baseline	Asian	48	100.0	48	100.0	2.08	8.15	-0.28	4.45
Week 4 (Day 29)	Asian	48	100.0	40	83.3	7.50	15.99	2.39	12.61
Week 8 (Day 57)	Asian	38	79.2	31	81.6	6.45	15.91	0.61	12.29
Week 12 (Day 85)	Asian	30	62.5	30	100.0	2.22	8.46	-0.94	5.38
Week 16 (Day 113)	Asian	21	43.8	21	100.0	4.76	11.95	-0.68	10.20
Week 20 (Day 141)	Asian	16	33.3	15	93.8	4.44	11.73	-2.05	10.94
Week 24 (Day 169)	Asian	13	27.1	11	84.6	3.03	10.05	-3.72	9.78
Week 28 (Day 197)	Asian	13	27.1	12	92.3	5.56	12.97	-2.69	13.80
Week 32 (Day 225)	Asian	12	25.0	9	75.0	3.70	11.11	-4.84	12.24
Week 36 (Day 253)	Asian	10	20.8	8	80.0	4.17	11.79	-5.69	14.02
Week 40 (Day 281)	Asian	10	20.8	8	80.0	8.33	15.43	-4.57	21.23
Week 44 (Day 309)	Asian	9	18.8	8	88.9	0.00	0.00	NE	NE
Week 48 (Day 337)	Asian	9	18.8	2	22.2	0.00	0.00	NE	NE
Week 52 (Day 365)	Asian	9	18.8	1	11.1	0.00	NE	NE	NE
Week 56 (Day 393)	Asian	7	14.6	2	28.6	0.00	0.00	NE	NE
Week 60 (Day 421)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	48	100.0	48	100.0	4.86	15.36	0.40	9.32
End of Study (LOCF)	Asian	48	100.0	48	100.0	4.86	15.36	0.40	9.32
Baseline	Non-Asian	54	100.0	52	96.3	6.41	13.27	2.72	10.10
Week 4 (Day 29)	Non-Asian	54	100.0	50	92.6	5.33	12.34	1.83	8.84
Week 8 (Day 57)	Non-Asian	49	90.7	44	89.8	7.58	17.41	2.28	12.87
Week 12 (Day 85)	Non-Asian	44	81.5	36	81.8	13.89	28.03	4.40	23.37
Week 16 (Day 113)	Non-Asian	43	79.6	34	79.1	9.80	20.97	2.49	17.12
Week 20 (Day 141)	Non-Asian	38	70.4	35	92.1	2.86	12.45	-1.42	7.13
Week 24 (Day 169)	Non-Asian	38	70.4	34	89.5	7.84	21.80	0.24	15.45
Week 28 (Day 197)	Non-Asian	37	68.5	35	94.6	6.67	19.47	-0.02	13.35
Week 32 (Day 225)	Non-Asian	32	59.3	28	87.5	9.52	21.96	1.01	18.04
Week 36 (Day 253)	Non-Asian	27	50.0	20	74.1	3.33	10.26	-1.47	8.14

Week 40 (Day 281)	Non-Asian	23	42.6	21	91.3	6.35	13.41	0.24	12.45
Week 44 (Day 309)	Non-Asian	18	33.3	14	77.8	4.76	12.10	-2.23	11.75
Week 48 (Day 337)	Non-Asian	12	22.2	9	75.0	3.70	11.11	-4.84	12.24
Week 52 (Day 365)	Non-Asian	8	14.8	3	37.5	0.00	0.00	NE	NE
Week 56 (Day 393)	Non-Asian	8	14.8	4	50.0	0.00	0.00	NE	NE
Week 60 (Day 421)	Non-Asian	7	13.0	1	14.3	0.00	NE	NE	NE
Week 64 (Day 449)	Non-Asian	6	11.1	2	33.3	16.67	23.57	-195.10	228.44
Week 68 (Day 477)	Non-Asian	3	5.6	1	33.3	0.00	NE	NE	NE
Week 72 (Day 505)	Non-Asian	3	5.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Non-Asian	3	5.6	1	33.3	0.00	NE	NE	NE
Week 80 (Day 561)	Non-Asian	2	3.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	54	100.0	54	100.0	7.41	19.06	2.20	12.61
End of Study (LOCF)	Non-Asian	54	100.0	54	100.0	8.02	19.36	2.74	13.31
Baseline	Unknown	6	100.0	4	66.7	0.00	0.00	NE	NE
Week 4 (Day 29)	Unknown	6	100.0	6	100.0	5.56	13.61	-8.73	19.84
Week 8 (Day 57)	Unknown	5	83.3	4	80.0	0.00	0.00	NE	NE
Week 12 (Day 85)	Unknown	5	83.3	4	80.0	0.00	0.00	NE	NE
Week 16 (Day 113)	Unknown	5	83.3	3	60.0	11.11	19.25	-36.70	58.92
Week 20 (Day 141)	Unknown	5	83.3	5	100.0	0.00	0.00	NE	NE
Week 24 (Day 169)	Unknown	5	83.3	4	80.0	8.33	16.67	-18.19	34.85
Week 28 (Day 197)	Unknown	5	83.3	4	80.0	8.33	16.67	-18.19	34.85
Week 32 (Day 225)	Unknown	4	66.7	4	100.0	0.00	0.00	NE	NE
Week 36 (Day 253)	Unknown	4	66.7	2	50.0	33.33	47.14	-390.21	456.87
Week 40 (Day 281)	Unknown	4	66.7	3	75.0	0.00	0.00	NE	NE
Week 44 (Day 309)	Unknown	4	66.7	4	100.0	16.67	33.33	-36.37	69.71
Week 48 (Day 337)	Unknown	2	33.3	1	50.0	0.00	NE	NE	NE
Week 52 (Day 365)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 60 (Day 421)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE

Week 64 (Day 449)	Unknown	1	16.7	1	100.0	0.00	NE	NE	NE
Week 68 (Day 477)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	1	16.7	1	100.0	0.00	NE	NE	NE
Week 76 (Day 533)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	6	100.0	6	100.0	22.22	27.22	-6.34	50.78
End of Study (LOCF)	Unknown	6	100.0	6	100.0	22.22	27.22	-6.34	50.78

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TN_QSC30DI_SG.xls
27OCT2021 7:35

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Diarrhoea
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	33	31.7	23.6	41.2
	Cycle 12 (LOCF)	n/a	104	96.3	13	12.5	7.5	20.2
	End of Study (LOCF)	n/a	104	96.3	14	13.5	8.2	21.3
Sex	All visits	Female	56	51.9	19	33.9	22.9	47.0
		Male	48	44.4	14	29.2	18.2	43.2
	Cycle 12 (LOCF)	Female	56	51.9	6	10.7	5.0	21.5
		Male	48	44.4	7	14.6	7.2	27.2
	End of Study (LOCF)	Female	56	51.9	7	12.5	6.2	23.6
		Male	48	44.4	7	14.6	7.2	27.2
Age	All visits	< 65	60	55.6	18	30.0	19.9	42.5
		>= 65	44	40.7	15	34.1	21.9	48.9
	Cycle 12 (LOCF)	< 65	60	55.6	7	11.7	5.8	22.2
		>= 65	44	40.7	6	13.6	6.4	26.7
	End of Study (LOCF)	< 65	60	55.6	8	13.3	6.9	24.2
		>= 65	44	40.7	6	13.6	6.4	26.7
ECOG performance status	All visits	0	29	26.9	15	51.7	34.4	68.6
		1	75	69.4	18	24.0	15.8	34.8
	Cycle 12 (LOCF)	0	29	26.9	5	17.2	7.6	34.5
		1	75	69.4	8	10.7	5.5	19.7
	End of Study (LOCF)	0	29	26.9	5	17.2	7.6	34.5
		1	75	69.4	9	12.0	6.4	21.3
Geographic region	All visits	USA	19	17.6	7	36.8	19.1	59.0
		Europe (EU)	40	37.0	14	35.0	22.1	50.5
		Asia (AS)	45	41.7	12	26.7	16.0	41.0
	Cycle 12 (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	5	12.5	5.5	26.1
		Asia (AS)	45	41.7	5	11.1	4.8	23.5
	End of Study (LOCF)	USA	19	17.6	4	21.1	8.5	43.3
		Europe (EU)	40	37.0	5	12.5	5.5	26.1
		Asia (AS)	45	41.7	5	11.1	4.8	23.5
Race/ethnicity	All visits	Asian	48	44.4	12	25.0	14.9	38.8
		Non-Asian	52	48.1	18	34.6	23.2	48.2
		Unknown	4	3.7	3	75.0	30.1	95.4
	Cycle 12 (LOCF)	Asian	48	44.4	5	10.4	4.5	22.2
		Non-Asian	52	48.1	5	9.6	4.2	20.6
		Unknown	4	3.7	3	75.0	30.1	95.4
	End of Study (LOCF)	Asian	48	44.4	5	10.4	4.5	22.2

		Non-Asian	52	48.1	6	11.5	5.4	23.0
		Unknown	4	3.7	3	75.0	30.1	95.4

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30DI_W10_SG.xls
15OCT2021 13:11

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Diarrhoea
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

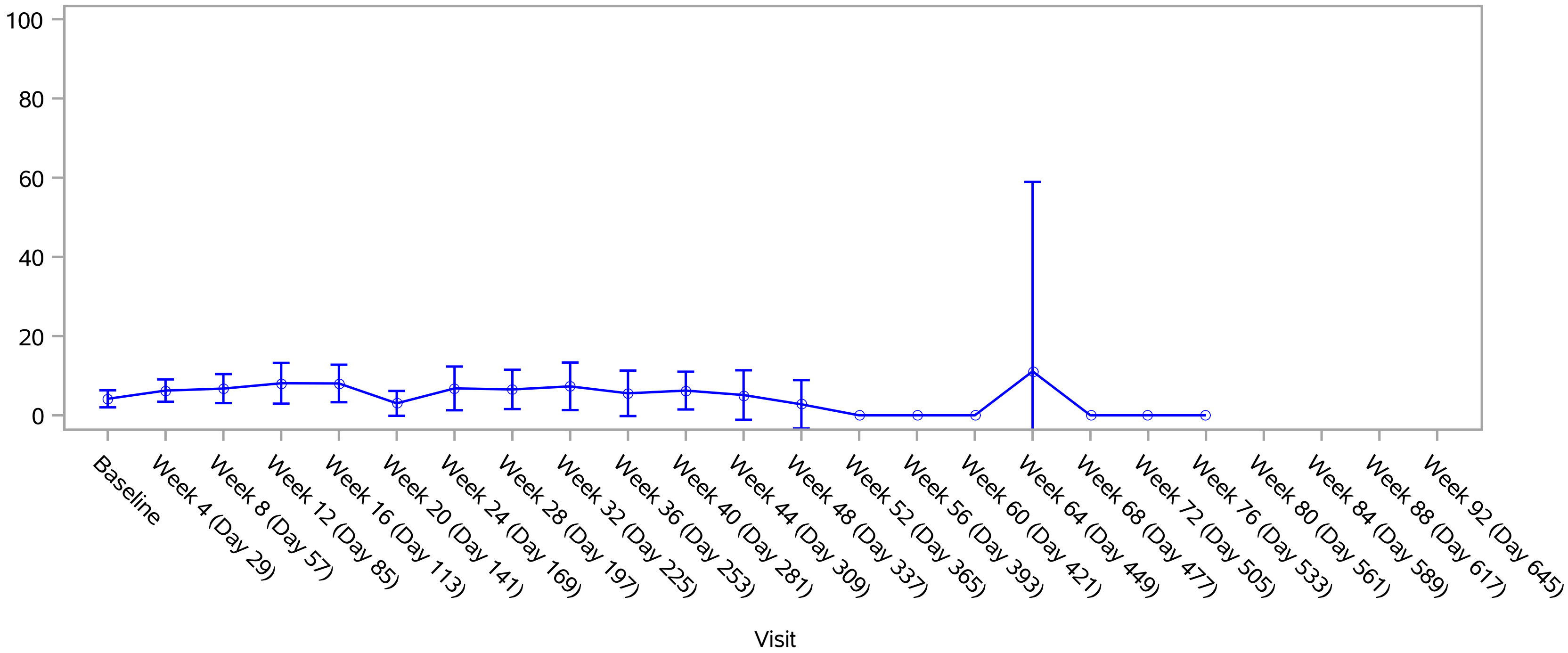
			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	33	31.7	23.6	41.2
	Cycle 12 (LOCF)	n/a	104	96.3	13	12.5	7.5	20.2
	End of Study (LOCF)	n/a	104	96.3	14	13.5	8.2	21.3
Sex	All visits	Female	56	51.9	19	33.9	22.9	47.0
		Male	48	44.4	14	29.2	18.2	43.2
	Cycle 12 (LOCF)	Female	56	51.9	6	10.7	5.0	21.5
		Male	48	44.4	7	14.6	7.2	27.2
	End of Study (LOCF)	Female	56	51.9	7	12.5	6.2	23.6
		Male	48	44.4	7	14.6	7.2	27.2
Age	All visits	< 65	60	55.6	18	30.0	19.9	42.5
		>= 65	44	40.7	15	34.1	21.9	48.9
	Cycle 12 (LOCF)	< 65	60	55.6	7	11.7	5.8	22.2
		>= 65	44	40.7	6	13.6	6.4	26.7
	End of Study (LOCF)	< 65	60	55.6	8	13.3	6.9	24.2
		>= 65	44	40.7	6	13.6	6.4	26.7
ECOG performance status	All visits	0	29	26.9	15	51.7	34.4	68.6
		1	75	69.4	18	24.0	15.8	34.8
	Cycle 12 (LOCF)	0	29	26.9	5	17.2	7.6	34.5
		1	75	69.4	8	10.7	5.5	19.7
	End of Study (LOCF)	0	29	26.9	5	17.2	7.6	34.5
		1	75	69.4	9	12.0	6.4	21.3
Geographic region	All visits	USA	19	17.6	7	36.8	19.1	59.0
		Europe (EU)	40	37.0	14	35.0	22.1	50.5
		Asia (AS)	45	41.7	12	26.7	16.0	41.0
	Cycle 12 (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	5	12.5	5.5	26.1
		Asia (AS)	45	41.7	5	11.1	4.8	23.5
	End of Study (LOCF)	USA	19	17.6	4	21.1	8.5	43.3
		Europe (EU)	40	37.0	5	12.5	5.5	26.1
		Asia (AS)	45	41.7	5	11.1	4.8	23.5
Race/ethnicity	All visits	Asian	48	44.4	12	25.0	14.9	38.8
		Non-Asian	52	48.1	18	34.6	23.2	48.2
		Unknown	4	3.7	3	75.0	30.1	95.4
	Cycle 12 (LOCF)	Asian	48	44.4	5	10.4	4.5	22.2
		Non-Asian	52	48.1	5	9.6	4.2	20.6
		Unknown	4	3.7	3	75.0	30.1	95.4
	End of Study (LOCF)	Asian	48	44.4	5	10.4	4.5	22.2

		Non-Asian	52	48.1	6	11.5	5.4	23.0
		Unknown	4	3.7	3	75.0	30.1	95.4

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30DI_W15_SG.xls
15OCT2021 13:01

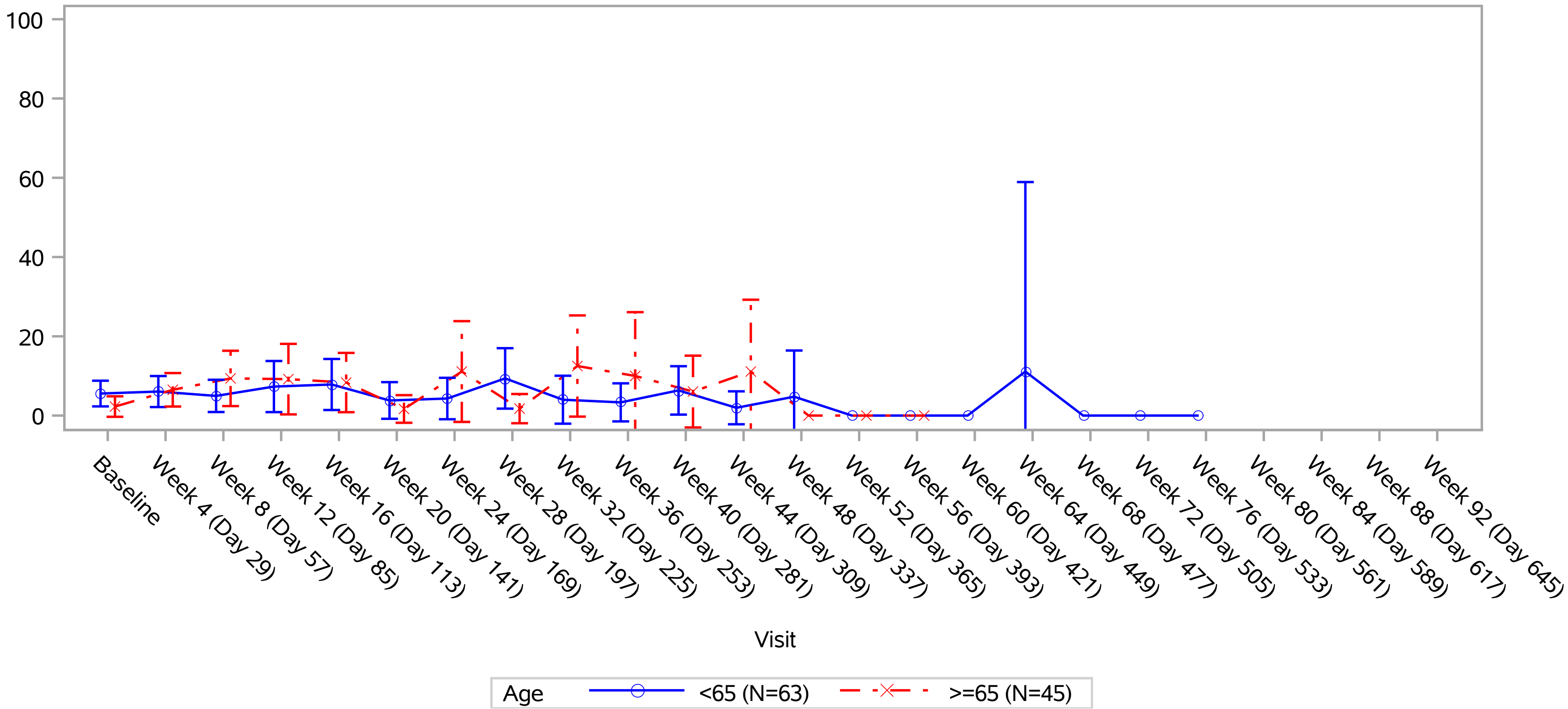
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Diarrhoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30DI.pdf
15OCT2021 17:24

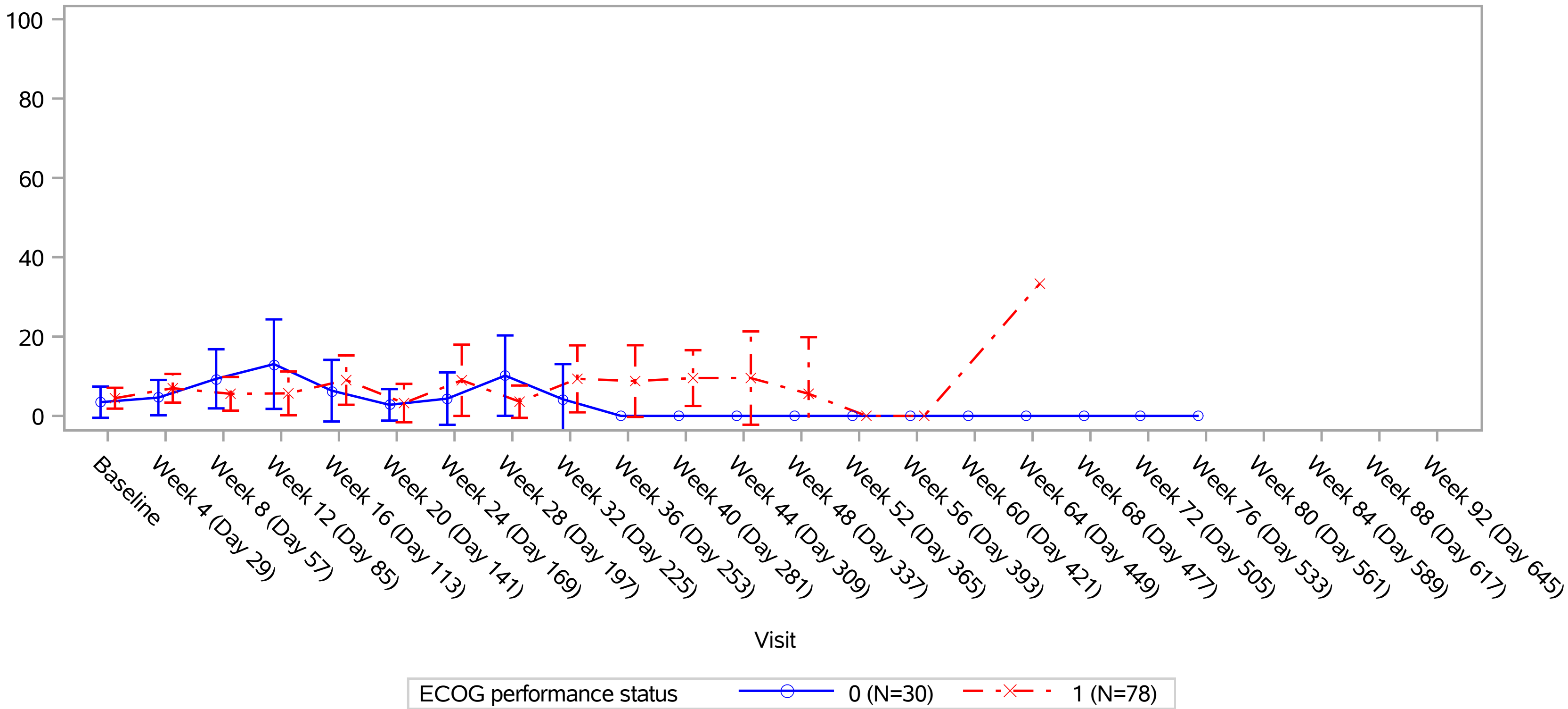
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Diarrhoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30DI_SGAGE65.pdf
15OCT2021 17:53

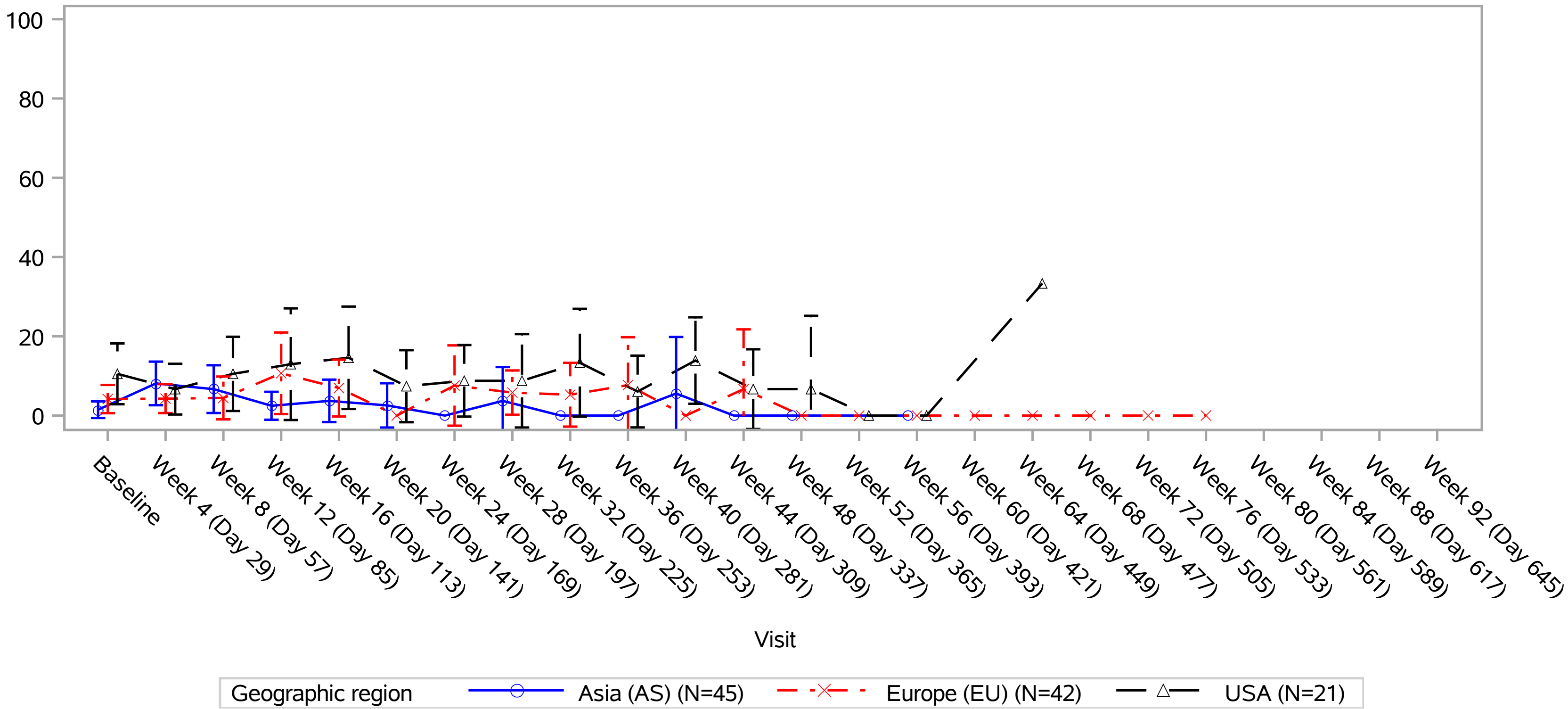
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Diarrhoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30DI_SGECOG.pdf
15OCT2021 18:24

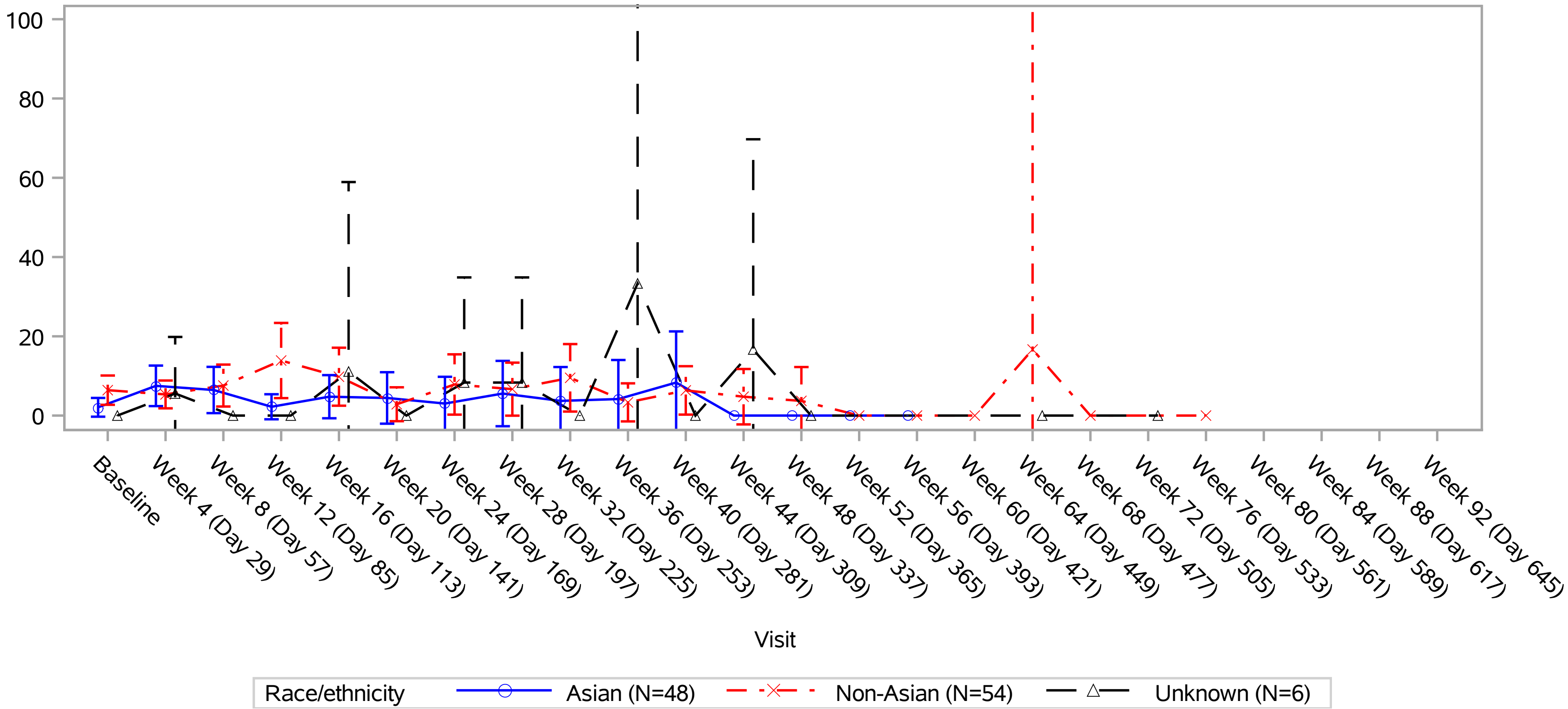
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Diarrhoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30DI_SGGEO.pdf
15OCT2021 18:54

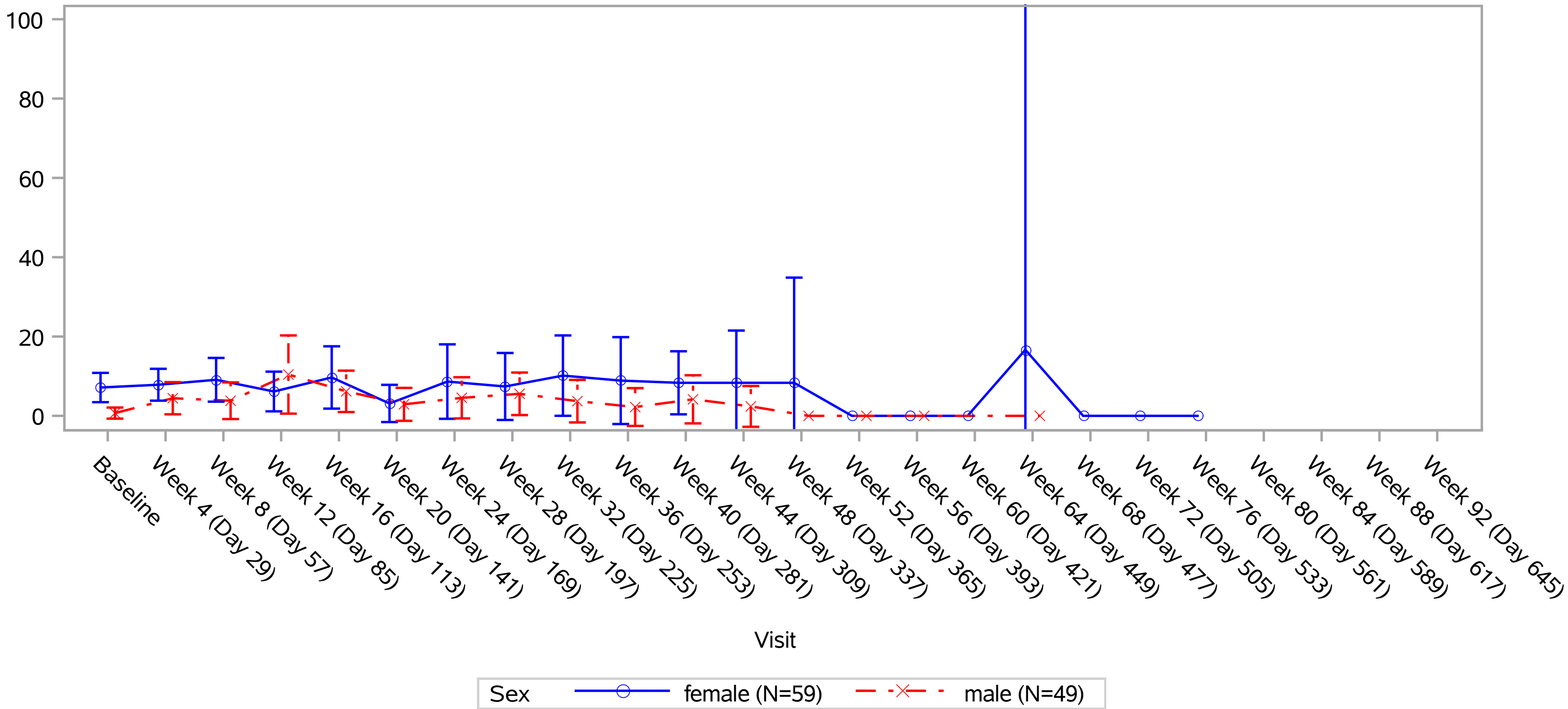
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Diarrhoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30DI_SGRE.pdf
15OCT2021 19:25

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Diarrhoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30DI_SGSEX.pdf
15OCT2021 19:55

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Dyspnoea
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=108)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	108	100.0	104	96.3	32.37	33.32	25.89	38.85
Week 4 (Day 29)	n/a	108	100.0	95	88.0	20.35	23.97	15.47	25.23
Week 8 (Day 57)	n/a	92	85.2	79	85.9	20.25	25.27	14.59	25.91
Week 12 (Day 85)	n/a	79	73.1	71	89.9	19.25	25.61	13.19	25.31
Week 16 (Day 113)	n/a	69	63.9	58	84.1	15.52	19.96	10.27	20.76
Week 20 (Day 141)	n/a	59	54.6	55	93.2	21.21	26.73	13.99	28.44
Week 24 (Day 169)	n/a	56	51.9	49	87.5	17.69	24.63	10.61	24.76
Week 28 (Day 197)	n/a	55	50.9	51	92.7	15.03	21.41	9.01	21.05
Week 32 (Day 225)	n/a	48	44.4	41	85.4	18.70	22.42	11.62	25.78
Week 36 (Day 253)	n/a	41	38.0	30	73.2	13.33	20.72	5.60	21.07
Week 40 (Day 281)	n/a	37	34.3	32	86.5	17.71	23.92	9.08	26.33
Week 44 (Day 309)	n/a	31	28.7	26	83.9	20.51	26.79	9.69	31.34
Week 48 (Day 337)	n/a	23	21.3	12	52.2	19.44	17.16	8.54	30.35
Week 52 (Day 365)	n/a	19	17.6	4	21.1	16.67	19.25	-13.96	47.29
Week 56 (Day 393)	n/a	17	15.7	6	35.3	22.22	17.21	4.16	40.29
Week 60 (Day 421)	n/a	11	10.2	1	9.1	33.33	NE	NE	NE
Week 64 (Day 449)	n/a	10	9.3	3	30.0	33.33	0.00	NE	NE
Week 68 (Day 477)	n/a	6	5.6	1	16.7	33.33	NE	NE	NE
Week 72 (Day 505)	n/a	6	5.6	1	16.7	66.67	NE	NE	NE
Week 76 (Day 533)	n/a	6	5.6	1	16.7	33.33	NE	NE	NE
Week 80 (Day 561)	n/a	5	4.6	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	n/a	1	0.9	0	0.0	NE	NE	NE	NE

Cycle 12 (LOCF)	n/a	108	100.0	108	100.0	23.46	29.27	17.87	29.04
End of Study (LOCF)	n/a	108	100.0	108	100.0	24.07	28.40	18.66	29.49
Sex									
Baseline	Female	59	100.0	56	94.9	36.31	31.96	27.75	44.87
Week 4 (Day 29)	Female	59	100.0	50	84.7	22.67	21.76	16.48	28.85
Week 8 (Day 57)	Female	49	83.1	44	89.8	23.48	26.49	15.43	31.54
Week 12 (Day 85)	Female	44	74.6	39	88.6	23.93	27.52	15.01	32.85
Week 16 (Day 113)	Female	38	64.4	31	81.6	15.05	20.80	7.43	22.68
Week 20 (Day 141)	Female	33	55.9	32	97.0	25.00	31.68	13.58	36.42
Week 24 (Day 169)	Female	31	52.5	27	87.1	23.46	27.45	12.60	34.31
Week 28 (Day 197)	Female	30	50.8	27	90.0	18.52	23.27	9.31	27.72
Week 32 (Day 225)	Female	27	45.8	23	85.2	21.74	23.80	11.45	32.03
Week 36 (Day 253)	Female	22	37.3	15	68.2	15.56	24.77	1.84	29.28
Week 40 (Day 281)	Female	18	30.5	16	88.9	22.92	29.11	7.41	38.43
Week 44 (Day 309)	Female	15	25.4	12	80.0	27.78	34.33	5.97	49.59
Week 48 (Day 337)	Female	11	18.6	4	36.4	33.33	0.00	NE	NE
Week 52 (Day 365)	Female	9	15.3	1	11.1	33.33	NE	NE	NE
Week 56 (Day 393)	Female	7	11.9	1	14.3	33.33	NE	NE	NE
Week 60 (Day 421)	Female	5	8.5	1	20.0	33.33	NE	NE	NE
Week 64 (Day 449)	Female	4	6.8	2	50.0	33.33	0.00	NE	NE
Week 68 (Day 477)	Female	3	5.1	1	33.3	33.33	NE	NE	NE
Week 72 (Day 505)	Female	3	5.1	1	33.3	66.67	NE	NE	NE
Week 76 (Day 533)	Female	3	5.1	1	33.3	33.33	NE	NE	NE
Week 80 (Day 561)	Female	2	3.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	59	100.0	59	100.0	24.29	29.58	16.59	32.00
End of Study (LOCF)	Female	59	100.0	59	100.0	24.86	28.09	17.54	32.18
Baseline	Male	49	100.0	48	98.0	27.78	34.61	17.73	37.83
Week 4 (Day 29)	Male	49	100.0	45	91.8	17.78	26.21	9.90	25.65
Week 8 (Day 57)	Male	43	87.8	35	81.4	16.19	23.39	8.16	24.23
Week 12 (Day 85)	Male	35	71.4	32	91.4	13.54	22.17	5.55	21.54
Week 16 (Day 113)	Male	31	63.3	27	87.1	16.05	19.33	8.40	23.69
Week 20 (Day 141)	Male	26	53.1	23	88.5	15.94	17.03	8.58	23.30
Week 24 (Day 169)	Male	25	51.0	22	88.0	10.61	18.93	2.21	19.00
Week 28 (Day 197)	Male	25	51.0	24	96.0	11.11	18.82	3.16	19.06

Week 32 (Day 225)	Male	21	42.9	18	85.7	14.81	20.52	4.61	25.02
Week 36 (Day 253)	Male	19	38.8	15	78.9	11.11	16.27	2.10	20.12
Week 40 (Day 281)	Male	19	38.8	16	84.2	12.50	16.67	3.62	21.38
Week 44 (Day 309)	Male	16	32.7	14	87.5	14.29	17.12	4.40	24.17
Week 48 (Day 337)	Male	12	24.5	8	66.7	12.50	17.25	-1.92	26.92
Week 52 (Day 365)	Male	10	20.4	3	30.0	11.11	19.25	-36.70	58.92
Week 56 (Day 393)	Male	10	20.4	5	50.0	20.00	18.26	-2.67	42.67
Week 60 (Day 421)	Male	6	12.2	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Male	6	12.2	1	16.7	33.33	NE	NE	NE
Week 68 (Day 477)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	49	100.0	49	100.0	22.45	29.18	14.07	30.83
End of Study (LOCF)	Male	49	100.0	49	100.0	23.13	29.03	14.79	31.47
Age									
Baseline	< 65	63	100.0	60	95.2	36.11	33.22	27.53	44.69
Week 4 (Day 29)	< 65	63	100.0	54	85.7	19.75	23.81	13.25	26.25
Week 8 (Day 57)	< 65	54	85.7	47	87.0	19.86	24.73	12.60	27.12
Week 12 (Day 85)	< 65	47	74.6	42	89.4	19.84	24.48	12.21	27.47
Week 16 (Day 113)	< 65	39	61.9	34	87.2	17.65	22.07	9.95	25.35
Week 20 (Day 141)	< 65	35	55.6	35	100.0	23.81	29.78	13.58	34.04
Week 24 (Day 169)	< 65	34	54.0	31	91.2	16.13	22.56	7.85	24.40
Week 28 (Day 197)	< 65	33	52.4	32	97.0	17.71	22.38	9.64	25.78
Week 32 (Day 225)	< 65	30	47.6	25	83.3	16.00	19.53	7.94	24.06
Week 36 (Day 253)	< 65	25	39.7	20	80.0	11.67	19.57	2.51	20.83
Week 40 (Day 281)	< 65	23	36.5	21	91.3	15.87	20.05	6.75	25.00
Week 44 (Day 309)	< 65	19	30.2	17	89.5	19.61	29.01	4.69	34.52
Week 48 (Day 337)	< 65	14	22.2	7	50.0	19.05	17.82	2.57	35.53

Week 52 (Day 365)	< 65	12	19.0	2	16.7	16.67	23.57	-195.10	228.44
Week 56 (Day 393)	< 65	11	17.5	2	18.2	33.33	0.00	NE	NE
Week 60 (Day 421)	< 65	8	12.7	1	12.5	33.33	NE	NE	NE
Week 64 (Day 449)	< 65	7	11.1	3	42.9	33.33	0.00	NE	NE
Week 68 (Day 477)	< 65	4	6.3	1	25.0	33.33	NE	NE	NE
Week 72 (Day 505)	< 65	4	6.3	1	25.0	66.67	NE	NE	NE
Week 76 (Day 533)	< 65	4	6.3	1	25.0	33.33	NE	NE	NE
Week 80 (Day 561)	< 65	3	4.8	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	63	100.0	63	100.0	22.75	29.83	15.24	30.26
End of Study (LOCF)	< 65	63	100.0	63	100.0	23.81	28.35	16.67	30.95
Baseline	>= 65	45	100.0	44	97.8	27.27	33.16	17.19	37.35
Week 4 (Day 29)	>= 65	45	100.0	41	91.1	21.14	24.45	13.42	28.85
Week 8 (Day 57)	>= 65	38	84.4	32	84.2	20.83	26.44	11.30	30.36
Week 12 (Day 85)	>= 65	32	71.1	29	90.6	18.39	27.58	7.90	28.88
Week 16 (Day 113)	>= 65	30	66.7	24	80.0	12.50	16.48	5.54	19.46
Week 20 (Day 141)	>= 65	24	53.3	20	83.3	16.67	20.23	7.20	26.14
Week 24 (Day 169)	>= 65	22	48.9	18	81.8	20.37	28.33	6.28	34.46
Week 28 (Day 197)	>= 65	22	48.9	19	86.4	10.53	19.41	1.17	19.88
Week 32 (Day 225)	>= 65	18	40.0	16	88.9	22.92	26.44	8.83	37.01
Week 36 (Day 253)	>= 65	16	35.6	10	62.5	16.67	23.57	-0.19	33.53
Week 40 (Day 281)	>= 65	14	31.1	11	78.6	21.21	30.81	0.51	41.91
Week 44 (Day 309)	>= 65	12	26.7	9	75.0	22.22	23.57	4.10	40.34
Week 48 (Day 337)	>= 65	9	20.0	5	55.6	20.00	18.26	-2.67	42.67
Week 52 (Day 365)	>= 65	7	15.6	2	28.6	16.67	23.57	-195.10	228.44
Week 56 (Day 393)	>= 65	6	13.3	4	66.7	16.67	19.25	-13.96	47.29
Week 60 (Day 421)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE

Week 76 (Day 533)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	45	100.0	45	100.0	24.44	28.78	15.80	33.09
End of Study (LOCF)	>= 65	45	100.0	45	100.0	24.44	28.78	15.80	33.09
ECOG performance status									
Baseline	0	30	100.0	29	96.7	32.18	33.90	19.29	45.08
Week 4 (Day 29)	0	30	100.0	28	93.3	21.43	22.62	12.66	30.20
Week 8 (Day 57)	0	28	93.3	25	89.3	22.67	31.51	9.66	35.67
Week 12 (Day 85)	0	26	86.7	24	92.3	16.67	21.98	7.39	25.95
Week 16 (Day 113)	0	26	86.7	21	80.8	14.29	19.92	5.22	23.35
Week 20 (Day 141)	0	26	86.7	24	92.3	20.83	25.66	10.00	31.67
Week 24 (Day 169)	0	25	83.3	23	92.0	10.14	18.63	2.09	18.20
Week 28 (Day 197)	0	25	83.3	23	92.0	14.49	22.08	4.95	24.04
Week 32 (Day 225)	0	20	66.7	16	80.0	14.58	17.08	5.48	23.68
Week 36 (Day 253)	0	18	60.0	11	61.1	12.12	22.47	-2.98	27.22
Week 40 (Day 281)	0	16	53.3	11	68.8	21.21	22.47	6.11	36.31
Week 44 (Day 309)	0	15	50.0	12	80.0	22.22	32.82	1.37	43.08
Week 48 (Day 337)	0	9	30.0	6	66.7	5.56	13.61	-8.73	19.84
Week 52 (Day 365)	0	9	30.0	3	33.3	11.11	19.25	-36.70	58.92
Week 56 (Day 393)	0	8	26.7	3	37.5	11.11	19.25	-36.70	58.92
Week 60 (Day 421)	0	5	16.7	1	20.0	33.33	NE	NE	NE
Week 64 (Day 449)	0	5	16.7	2	40.0	33.33	0.00	NE	NE
Week 68 (Day 477)	0	3	10.0	1	33.3	33.33	NE	NE	NE
Week 72 (Day 505)	0	3	10.0	1	33.3	66.67	NE	NE	NE
Week 76 (Day 533)	0	3	10.0	1	33.3	33.33	NE	NE	NE
Week 80 (Day 561)	0	2	6.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	0	1	3.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	30	100.0	30	100.0	24.44	33.83	11.81	37.08
End of Study (LOCF)	0	30	100.0	30	100.0	24.44	31.48	12.69	36.20
Baseline	1	78	100.0	75	96.2	32.44	33.32	24.78	40.11
Week 4 (Day 29)	1	78	100.0	67	85.9	19.90	24.66	13.89	25.92

Week 8 (Day 57)	1	64	82.1	54	84.4	19.14	22.06	13.12	25.16
Week 12 (Day 85)	1	53	67.9	47	88.7	20.57	27.41	12.52	28.62
Week 16 (Day 113)	1	43	55.1	37	86.0	16.22	20.22	9.48	22.96
Week 20 (Day 141)	1	33	42.3	31	93.9	21.51	27.95	11.25	31.76
Week 24 (Day 169)	1	31	39.7	26	83.9	24.36	27.58	13.22	35.50
Week 28 (Day 197)	1	30	38.5	28	93.3	15.48	21.24	7.24	23.71
Week 32 (Day 225)	1	28	35.9	25	89.3	21.33	25.24	10.91	31.75
Week 36 (Day 253)	1	23	29.5	19	82.6	14.04	20.23	4.28	23.79
Week 40 (Day 281)	1	21	26.9	21	100.0	15.87	24.99	4.50	27.25
Week 44 (Day 309)	1	16	20.5	14	87.5	19.05	21.54	6.61	31.48
Week 48 (Day 337)	1	14	17.9	6	42.9	33.33	0.00	NE	NE
Week 52 (Day 365)	1	10	12.8	1	10.0	33.33	NE	NE	NE
Week 56 (Day 393)	1	9	11.5	3	33.3	33.33	0.00	NE	NE
Week 60 (Day 421)	1	6	7.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	5	6.4	1	20.0	33.33	NE	NE	NE
Week 68 (Day 477)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	3	3.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	78	100.0	78	100.0	23.08	27.55	16.86	29.29
End of Study (LOCF)	1	78	100.0	78	100.0	23.93	27.34	17.77	30.10
Geographic region									
Baseline	USA	21	100.0	19	90.5	28.07	37.29	10.10	46.04
Week 4 (Day 29)	USA	21	100.0	20	95.2	20.00	19.94	10.67	29.33
Week 8 (Day 57)	USA	21	100.0	19	90.5	17.54	20.39	7.71	27.37
Week 12 (Day 85)	USA	21	100.0	19	90.5	17.54	20.39	7.71	27.37
Week 16 (Day 113)	USA	21	100.0	16	76.2	18.75	20.97	7.57	29.93
Week 20 (Day 141)	USA	20	95.2	18	90.0	22.22	25.57	9.51	34.94
Week 24 (Day 169)	USA	20	95.2	19	95.0	14.04	20.23	4.28	23.79
Week 28 (Day 197)	USA	20	95.2	19	95.0	14.04	20.23	4.28	23.79
Week 32 (Day 225)	USA	17	81.0	15	88.2	22.22	24.12	8.86	35.58
Week 36 (Day 253)	USA	17	81.0	11	64.7	6.06	13.48	-3.00	15.12
Week 40 (Day 281)	USA	15	71.4	12	80.0	16.67	17.41	5.61	27.73

Week 44 (Day 309)	USA	13	61.9	10	76.9	10.00	16.10	-1.52	21.52
Week 48 (Day 337)	USA	8	38.1	5	62.5	13.33	18.26	-9.34	36.00
Week 52 (Day 365)	USA	6	28.6	1	16.7	0.00	NE	NE	NE
Week 56 (Day 393)	USA	6	28.6	3	50.0	11.11	19.25	-36.70	58.92
Week 60 (Day 421)	USA	5	23.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	4	19.0	1	25.0	33.33	NE	NE	NE
Week 68 (Day 477)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	21	100.0	21	100.0	11.11	16.10	3.78	18.44
End of Study (LOCF)	USA	21	100.0	21	100.0	12.70	16.59	5.15	20.25
Baseline	Europe (EU)	42	100.0	40	95.2	38.33	35.04	27.13	49.54
Week 4 (Day 29)	Europe (EU)	42	100.0	38	90.5	21.05	23.79	13.23	28.87
Week 8 (Day 57)	Europe (EU)	36	85.7	30	83.3	26.67	29.56	15.63	37.70
Week 12 (Day 85)	Europe (EU)	31	73.8	25	80.6	24.00	35.38	9.40	38.60
Week 16 (Day 113)	Europe (EU)	30	71.4	24	80.0	18.06	21.93	8.79	27.32
Week 20 (Day 141)	Europe (EU)	26	61.9	24	92.3	25.00	31.47	11.71	38.29
Week 24 (Day 169)	Europe (EU)	26	61.9	22	84.6	22.73	29.79	9.52	35.94
Week 28 (Day 197)	Europe (EU)	25	59.5	23	92.0	17.39	24.35	6.86	27.92
Week 32 (Day 225)	Europe (EU)	21	50.0	19	90.5	15.79	20.39	5.96	25.62
Week 36 (Day 253)	Europe (EU)	16	38.1	13	81.3	20.51	25.60	5.04	35.98
Week 40 (Day 281)	Europe (EU)	14	33.3	14	100.0	21.43	30.96	3.55	39.30
Week 44 (Day 309)	Europe (EU)	11	26.2	10	90.9	36.67	33.15	12.95	60.38
Week 48 (Day 337)	Europe (EU)	8	19.0	6	75.0	22.22	17.21	4.16	40.29
Week 52 (Day 365)	Europe (EU)	6	14.3	3	50.0	22.22	19.25	-25.59	70.03
Week 56 (Day 393)	Europe (EU)	6	14.3	2	33.3	33.33	0.00	NE	NE

Week 60 (Day 421)	Europe (EU)	4	9.5	1	25.0	33.33	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	4	9.5	2	50.0	33.33	0.00	NE	NE
Week 68 (Day 477)	Europe (EU)	3	7.1	1	33.3	33.33	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	3	7.1	1	33.3	66.67	NE	NE	NE
Week 76 (Day 533)	Europe (EU)	3	7.1	1	33.3	33.33	NE	NE	NE
Week 80 (Day 561)	Europe (EU)	2	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Europe (EU)	42	100.0	42	100.0	33.33	32.92	23.07	43.59
End of Study (LOCF)	Europe (EU)	42	100.0	42	100.0	34.13	30.79	24.53	43.72
Baseline	Asia (AS)	45	100.0	45	100.0	28.89	29.81	19.93	37.85
Week 4 (Day 29)	Asia (AS)	45	100.0	37	82.2	19.82	26.60	10.95	28.69
Week 8 (Day 57)	Asia (AS)	35	77.8	30	85.7	15.56	22.71	7.07	24.04
Week 12 (Day 85)	Asia (AS)	27	60.0	27	100.0	16.05	16.97	9.34	22.76
Week 16 (Day 113)	Asia (AS)	18	40.0	18	100.0	9.26	15.36	1.62	16.90
Week 20 (Day 141)	Asia (AS)	13	28.9	13	100.0	12.82	16.88	2.62	23.02
Week 24 (Day 169)	Asia (AS)	10	22.2	8	80.0	12.50	17.25	-1.92	26.92
Week 28 (Day 197)	Asia (AS)	10	22.2	9	90.0	11.11	16.67	-1.70	23.92
Week 32 (Day 225)	Asia (AS)	10	22.2	7	70.0	19.05	26.23	-5.21	43.30
Week 36 (Day 253)	Asia (AS)	8	17.8	6	75.0	11.11	17.21	-6.95	29.18
Week 40 (Day 281)	Asia (AS)	8	17.8	6	75.0	11.11	17.21	-6.95	29.18
Week 44 (Day 309)	Asia (AS)	7	15.6	6	85.7	11.11	17.21	-6.95	29.18
Week 48 (Day 337)	Asia (AS)	7	15.6	1	14.3	33.33	NE	NE	NE
Week 52 (Day 365)	Asia (AS)	7	15.6	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Asia (AS)	5	11.1	1	20.0	33.33	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	45	100.0	45	100.0	20.00	27.89	11.62	28.38
End of Study (LOCF)	Asia (AS)	45	100.0	45	100.0	20.00	27.89	11.62	28.38

Race/ethnicity									
Baseline	Asian	48	100.0	48	100.0	29.17	31.23	20.10	38.23
Week 4 (Day 29)	Asian	48	100.0	40	83.3	20.00	27.01	11.36	28.64
Week 8 (Day 57)	Asian	38	79.2	31	81.6	16.13	22.56	7.85	24.40
Week 12 (Day 85)	Asian	30	62.5	30	100.0	15.56	16.91	9.24	21.87
Week 16 (Day 113)	Asian	21	43.8	21	100.0	7.94	14.55	1.31	14.56
Week 20 (Day 141)	Asian	16	33.3	15	93.8	15.56	17.21	6.02	25.09
Week 24 (Day 169)	Asian	13	27.1	11	84.6	12.12	16.82	0.82	23.42
Week 28 (Day 197)	Asian	13	27.1	12	92.3	13.89	17.16	2.98	24.79
Week 32 (Day 225)	Asian	12	25.0	9	75.0	22.22	28.87	0.03	44.41
Week 36 (Day 253)	Asian	10	20.8	8	80.0	12.50	17.25	-1.92	26.92
Week 40 (Day 281)	Asian	10	20.8	8	80.0	12.50	17.25	-1.92	26.92
Week 44 (Day 309)	Asian	9	18.8	8	88.9	8.33	15.43	-4.57	21.23
Week 48 (Day 337)	Asian	9	18.8	2	22.2	16.67	23.57	-195.10	228.44
Week 52 (Day 365)	Asian	9	18.8	1	11.1	0.00	NE	NE	NE
Week 56 (Day 393)	Asian	7	14.6	2	28.6	16.67	23.57	-195.10	228.44
Week 60 (Day 421)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	48	100.0	48	100.0	19.44	27.36	11.50	27.39
End of Study (LOCF)	Asian	48	100.0	48	100.0	19.44	27.36	11.50	27.39
Baseline	Non-Asian	54	100.0	52	96.3	35.26	35.19	25.46	45.05
Week 4 (Day 29)	Non-Asian	54	100.0	50	92.6	18.67	20.38	12.87	24.46
Week 8 (Day 57)	Non-Asian	49	90.7	44	89.8	22.73	26.68	14.62	30.84
Week 12 (Day 85)	Non-Asian	44	81.5	37	84.1	19.82	28.82	10.21	29.43
Week 16 (Day 113)	Non-Asian	43	79.6	34	79.1	18.63	22.01	10.95	26.31
Week 20 (Day 141)	Non-Asian	38	70.4	35	92.1	21.90	30.19	11.53	32.27
Week 24 (Day 169)	Non-Asian	38	70.4	34	89.5	18.63	27.45	9.05	28.21
Week 28 (Day 197)	Non-Asian	37	68.5	35	94.6	12.38	19.94	5.53	19.23
Week 32 (Day 225)	Non-Asian	32	59.3	28	87.5	15.48	19.21	8.03	22.92
Week 36 (Day 253)	Non-Asian	27	50.0	20	74.1	8.33	14.81	1.40	15.26

Week 40 (Day 281)	Non-Asian	23	42.6	21	91.3	14.29	16.90	6.59	21.98
Week 44 (Day 309)	Non-Asian	18	33.3	14	77.8	16.67	21.68	4.15	29.19
Week 48 (Day 337)	Non-Asian	12	22.2	9	75.0	18.52	17.57	5.01	32.02
Week 52 (Day 365)	Non-Asian	8	14.8	3	37.5	22.22	19.25	-25.59	70.03
Week 56 (Day 393)	Non-Asian	8	14.8	4	50.0	25.00	16.67	-1.52	51.52
Week 60 (Day 421)	Non-Asian	7	13.0	1	14.3	33.33	NE	NE	NE
Week 64 (Day 449)	Non-Asian	6	11.1	2	33.3	33.33	0.00	NE	NE
Week 68 (Day 477)	Non-Asian	3	5.6	1	33.3	33.33	NE	NE	NE
Week 72 (Day 505)	Non-Asian	3	5.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Non-Asian	3	5.6	1	33.3	33.33	NE	NE	NE
Week 80 (Day 561)	Non-Asian	2	3.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	54	100.0	54	100.0	23.46	29.41	15.43	31.48
End of Study (LOCF)	Non-Asian	54	100.0	54	100.0	25.31	28.91	17.42	33.20
Baseline	Unknown	6	100.0	4	66.7	33.33	38.49	-27.91	94.58
Week 4 (Day 29)	Unknown	6	100.0	5	83.3	40.00	27.89	5.37	74.63
Week 8 (Day 57)	Unknown	5	83.3	4	80.0	25.00	31.91	-25.78	75.78
Week 12 (Day 85)	Unknown	5	83.3	4	80.0	41.67	41.94	-25.07	108.41
Week 16 (Day 113)	Unknown	5	83.3	3	60.0	33.33	0.00	NE	NE
Week 20 (Day 141)	Unknown	5	83.3	5	100.0	33.33	23.57	4.07	62.60
Week 24 (Day 169)	Unknown	5	83.3	4	80.0	25.00	16.67	-1.52	51.52
Week 28 (Day 197)	Unknown	5	83.3	4	80.0	41.67	31.91	-9.12	92.45
Week 32 (Day 225)	Unknown	4	66.7	4	100.0	33.33	27.22	-9.97	76.64
Week 36 (Day 253)	Unknown	4	66.7	2	50.0	66.67	0.00	NE	NE
Week 40 (Day 281)	Unknown	4	66.7	3	75.0	55.56	50.92	-70.93	182.04
Week 44 (Day 309)	Unknown	4	66.7	4	100.0	58.33	31.91	7.55	109.12
Week 48 (Day 337)	Unknown	2	33.3	1	50.0	33.33	NE	NE	NE
Week 52 (Day 365)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 60 (Day 421)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE

Week 64 (Day 449)	Unknown	1	16.7	1	100.0	33.33	NE	NE	NE
Week 68 (Day 477)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	1	16.7	1	100.0	66.67	NE	NE	NE
Week 76 (Day 533)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	6	100.0	6	100.0	55.56	27.22	26.99	84.12
End of Study (LOCF)	Unknown	6	100.0	6	100.0	50.00	18.26	30.84	69.16

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TN_QSC30DY_SG.xls
27OCT2021 7:36

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Dyspnoea
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	29	27.9	20.2	37.2
	Cycle 12 (LOCF)	n/a	104	96.3	18	17.3	11.2	25.7
	End of Study (LOCF)	n/a	104	96.3	19	18.3	12.0	26.8
Sex	All visits	Female	56	51.9	13	23.2	14.1	35.8
		Male	48	44.4	16	33.3	21.7	47.5
	Cycle 12 (LOCF)	Female	56	51.9	6	10.7	5.0	21.5
		Male	48	44.4	12	25.0	14.9	38.8
	End of Study (LOCF)	Female	56	51.9	6	10.7	5.0	21.5
		Male	48	44.4	13	27.1	16.6	41.0
Age	All visits	< 65	60	55.6	12	20.0	11.8	31.8
		>= 65	44	40.7	17	38.6	25.7	53.4
	Cycle 12 (LOCF)	< 65	60	55.6	7	11.7	5.8	22.2
		>= 65	44	40.7	11	25.0	14.6	39.4
	End of Study (LOCF)	< 65	60	55.6	8	13.3	6.9	24.2
		>= 65	44	40.7	11	25.0	14.6	39.4
ECOG performance status	All visits	0	29	26.9	8	27.6	14.7	45.7
		1	75	69.4	21	28.0	19.1	39.0
	Cycle 12 (LOCF)	0	29	26.9	3	10.3	3.6	26.4
		1	75	69.4	15	20.0	12.5	30.4
	End of Study (LOCF)	0	29	26.9	4	13.8	5.5	30.6
		1	75	69.4	15	20.0	12.5	30.4
Geographic region	All visits	USA	19	17.6	7	36.8	19.1	59.0
		Europe (EU)	40	37.0	14	35.0	22.1	50.5
		Asia (AS)	45	41.7	8	17.8	9.3	31.3
	Cycle 12 (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	10	25.0	14.2	40.2
		Asia (AS)	45	41.7	5	11.1	4.8	23.5
	End of Study (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	11	27.5	16.1	42.8
		Asia (AS)	45	41.7	5	11.1	4.8	23.5
Race/ethnicity	All visits	Asian	48	44.4	9	18.8	10.2	31.9
		Non-Asian	52	48.1	17	32.7	21.5	46.2
		Unknown	4	3.7	3	75.0	30.1	95.4
	Cycle 12 (LOCF)	Asian	48	44.4	6	12.5	5.9	24.7
		Non-Asian	52	48.1	10	19.2	10.8	31.9
		Unknown	4	3.7	2	50.0	15.0	85.0
	End of Study (LOCF)	Asian	48	44.4	6	12.5	5.9	24.7

		Non-Asian	52	48.1	11	21.2	12.2	34.0
		Unknown	4	3.7	2	50.0	15.0	85.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30DY_W10_SG.xls
15OCT2021 13:12

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Dyspnoea
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

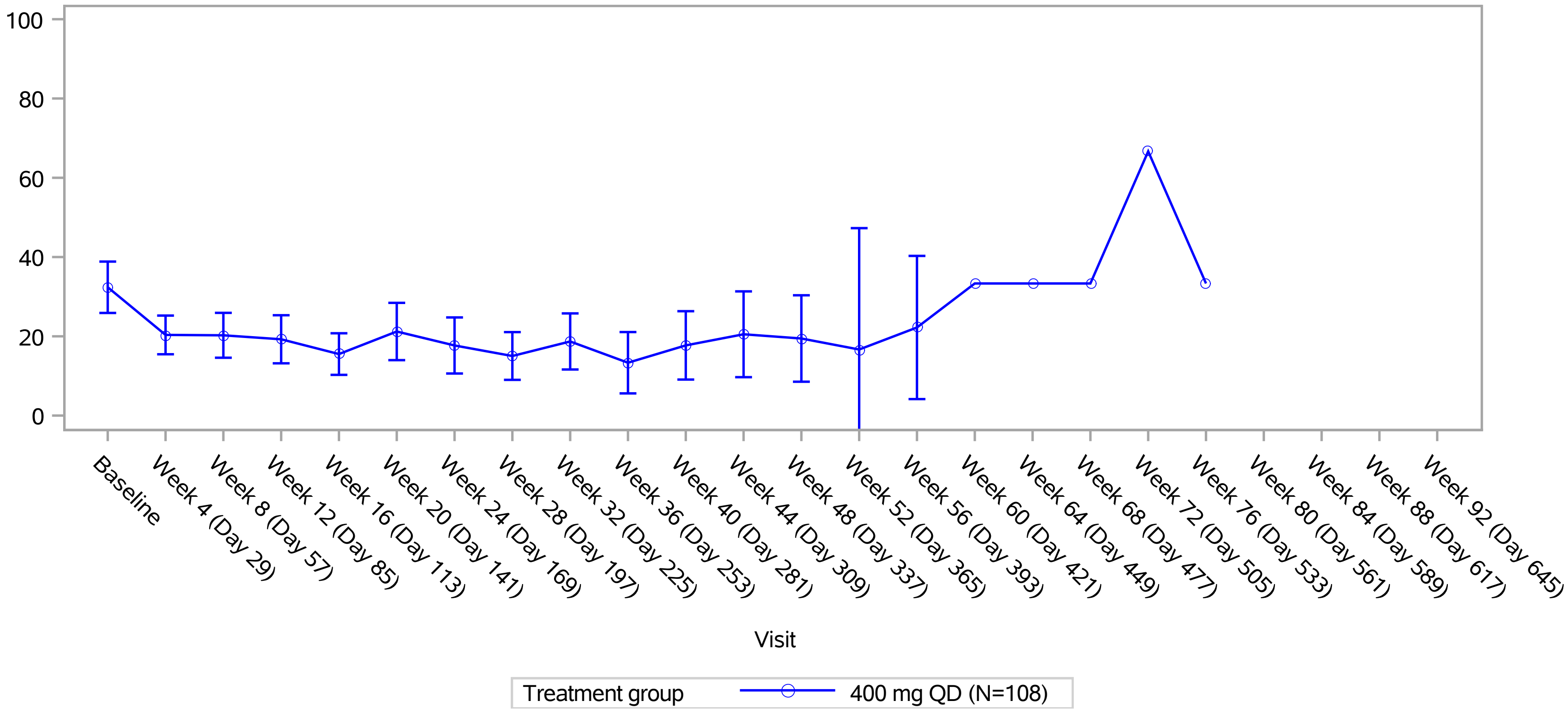
			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	29	27.9	20.2	37.2
	Cycle 12 (LOCF)	n/a	104	96.3	18	17.3	11.2	25.7
	End of Study (LOCF)	n/a	104	96.3	19	18.3	12.0	26.8
Sex	All visits	Female	56	51.9	13	23.2	14.1	35.8
		Male	48	44.4	16	33.3	21.7	47.5
	Cycle 12 (LOCF)	Female	56	51.9	6	10.7	5.0	21.5
		Male	48	44.4	12	25.0	14.9	38.8
	End of Study (LOCF)	Female	56	51.9	6	10.7	5.0	21.5
		Male	48	44.4	13	27.1	16.6	41.0
Age	All visits	< 65	60	55.6	12	20.0	11.8	31.8
		>= 65	44	40.7	17	38.6	25.7	53.4
	Cycle 12 (LOCF)	< 65	60	55.6	7	11.7	5.8	22.2
		>= 65	44	40.7	11	25.0	14.6	39.4
	End of Study (LOCF)	< 65	60	55.6	8	13.3	6.9	24.2
		>= 65	44	40.7	11	25.0	14.6	39.4
ECOG performance status	All visits	0	29	26.9	8	27.6	14.7	45.7
		1	75	69.4	21	28.0	19.1	39.0
	Cycle 12 (LOCF)	0	29	26.9	3	10.3	3.6	26.4
		1	75	69.4	15	20.0	12.5	30.4
	End of Study (LOCF)	0	29	26.9	4	13.8	5.5	30.6
		1	75	69.4	15	20.0	12.5	30.4
Geographic region	All visits	USA	19	17.6	7	36.8	19.1	59.0
		Europe (EU)	40	37.0	14	35.0	22.1	50.5
		Asia (AS)	45	41.7	8	17.8	9.3	31.3
	Cycle 12 (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	10	25.0	14.2	40.2
		Asia (AS)	45	41.7	5	11.1	4.8	23.5
	End of Study (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	11	27.5	16.1	42.8
		Asia (AS)	45	41.7	5	11.1	4.8	23.5
Race/ethnicity	All visits	Asian	48	44.4	9	18.8	10.2	31.9
		Non-Asian	52	48.1	17	32.7	21.5	46.2
		Unknown	4	3.7	3	75.0	30.1	95.4
	Cycle 12 (LOCF)	Asian	48	44.4	6	12.5	5.9	24.7
		Non-Asian	52	48.1	10	19.2	10.8	31.9
		Unknown	4	3.7	2	50.0	15.0	85.0
	End of Study (LOCF)	Asian	48	44.4	6	12.5	5.9	24.7

		Non-Asian	52	48.1	11	21.2	12.2	34.0
		Unknown	4	3.7	2	50.0	15.0	85.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30DY_W15_SG.xls
15OCT2021 13:02

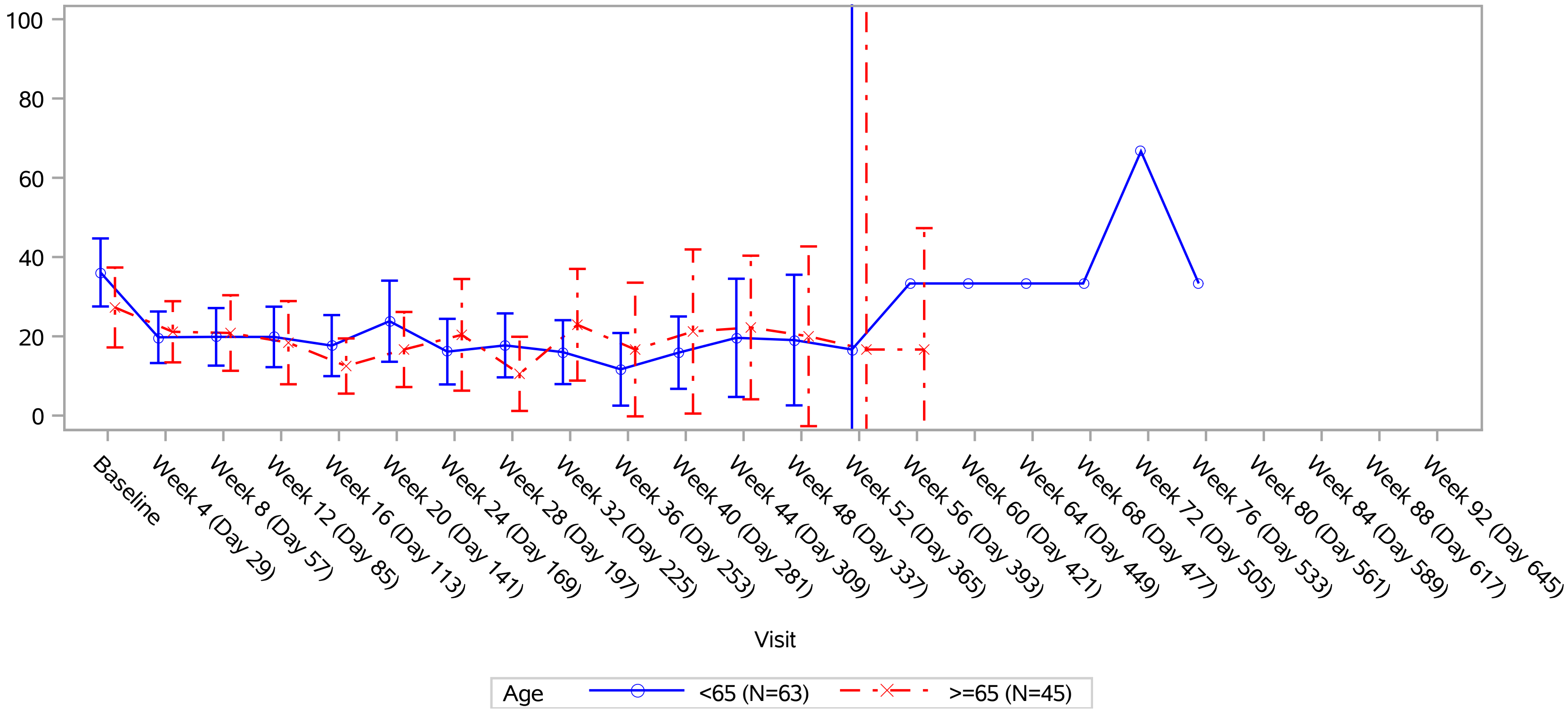
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Dyspnoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30DY.pdf
15OCT2021 17:24

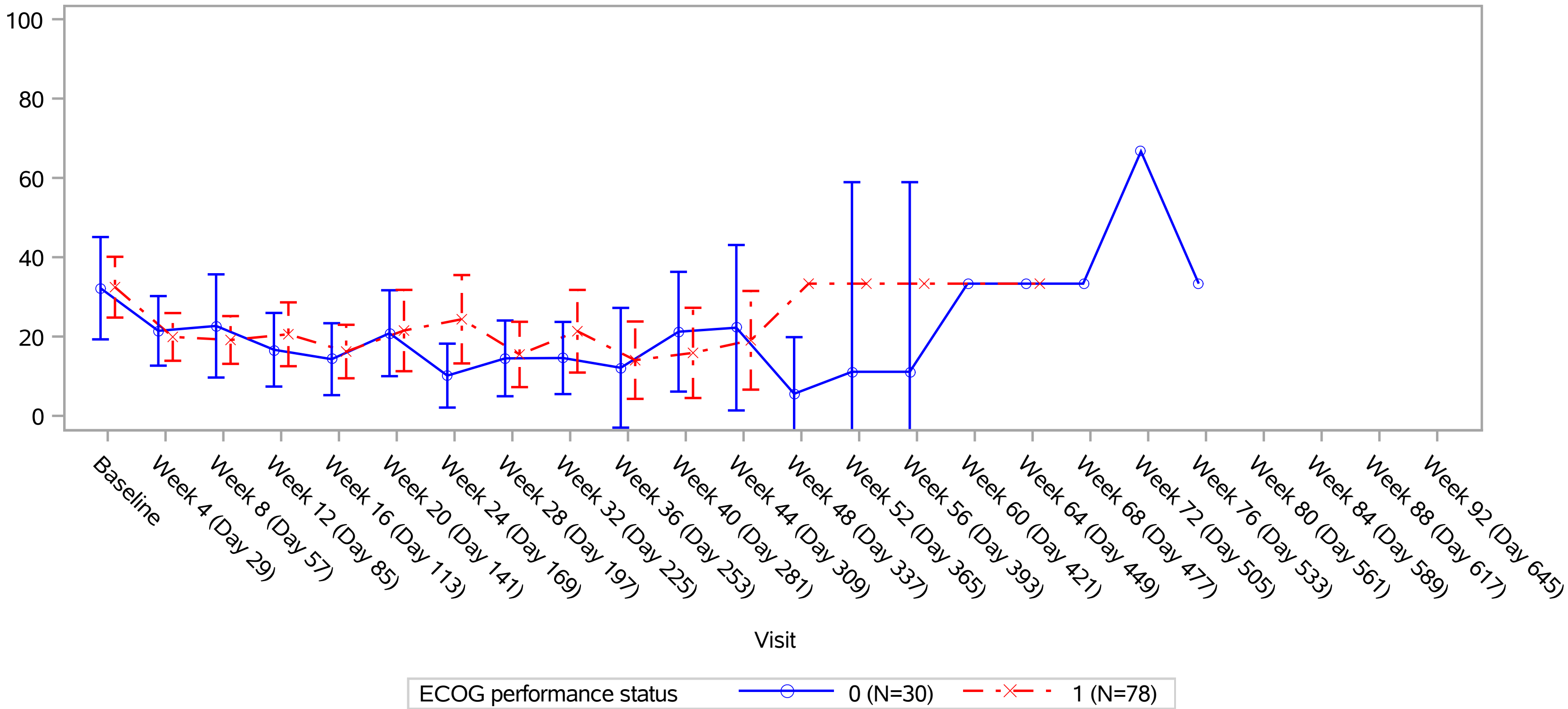
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Dyspnoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30DY_SGAGE65.pdf
15OCT2021 17:53

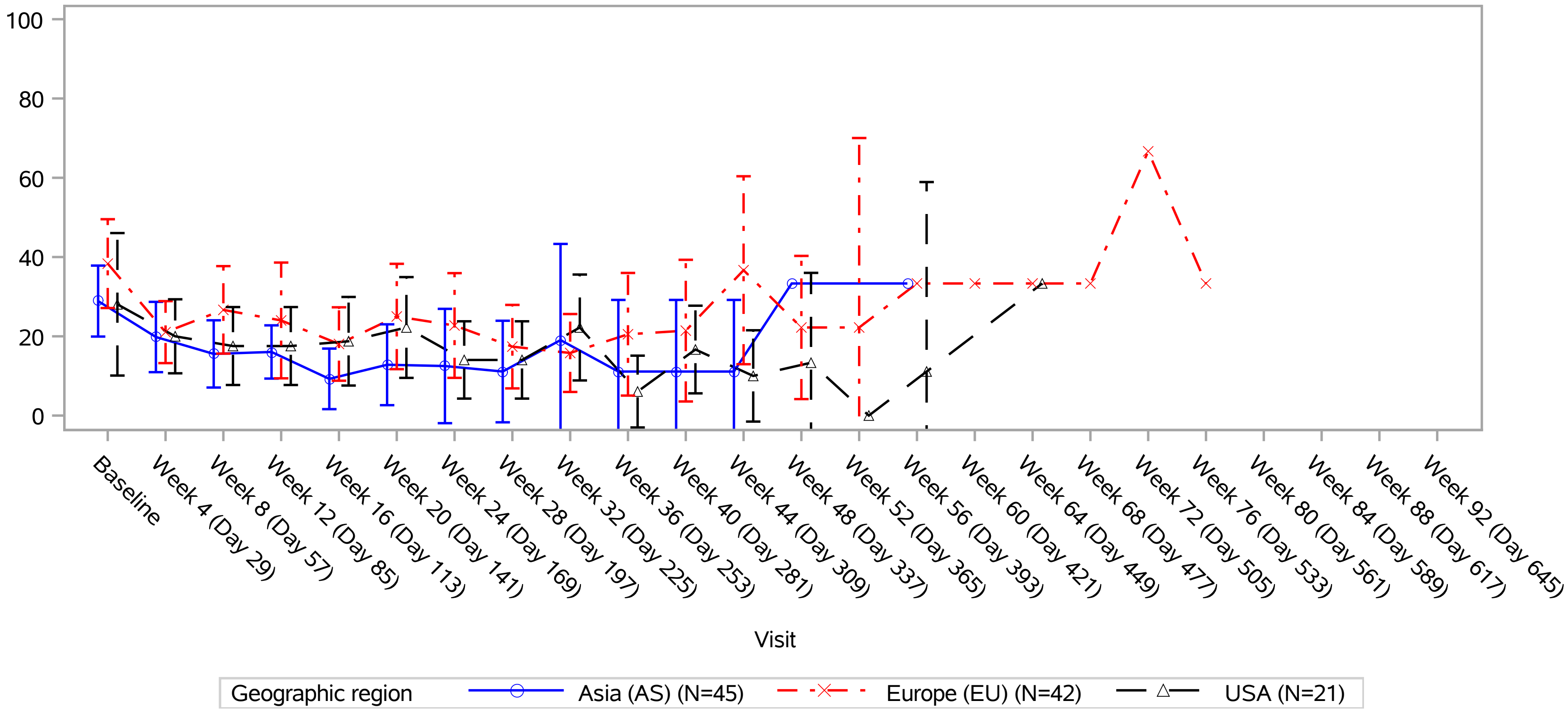
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Dyspnoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30DY_SGECOG.pdf
15OCT2021 18:24

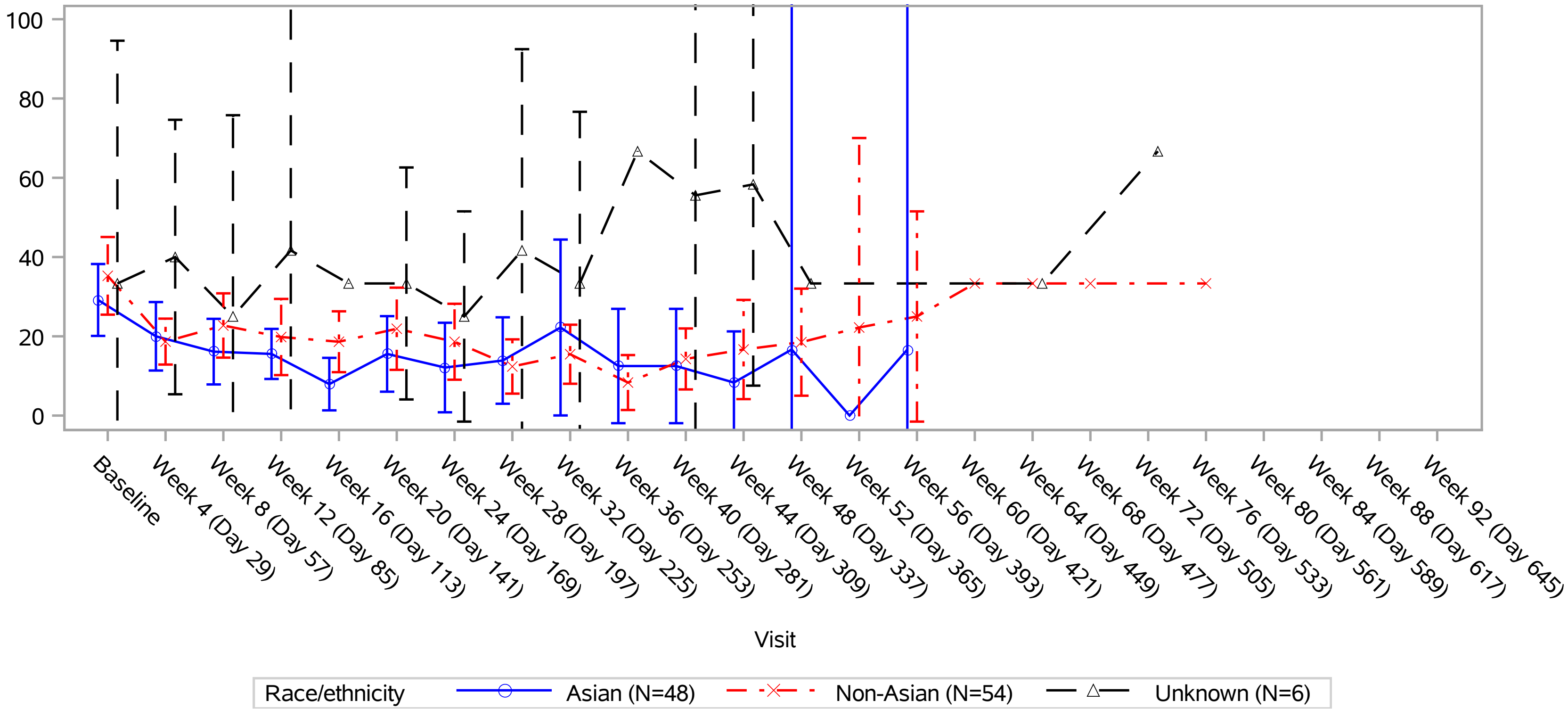
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Dyspnoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30DY_SGGEO.pdf
15OCT2021 18:55

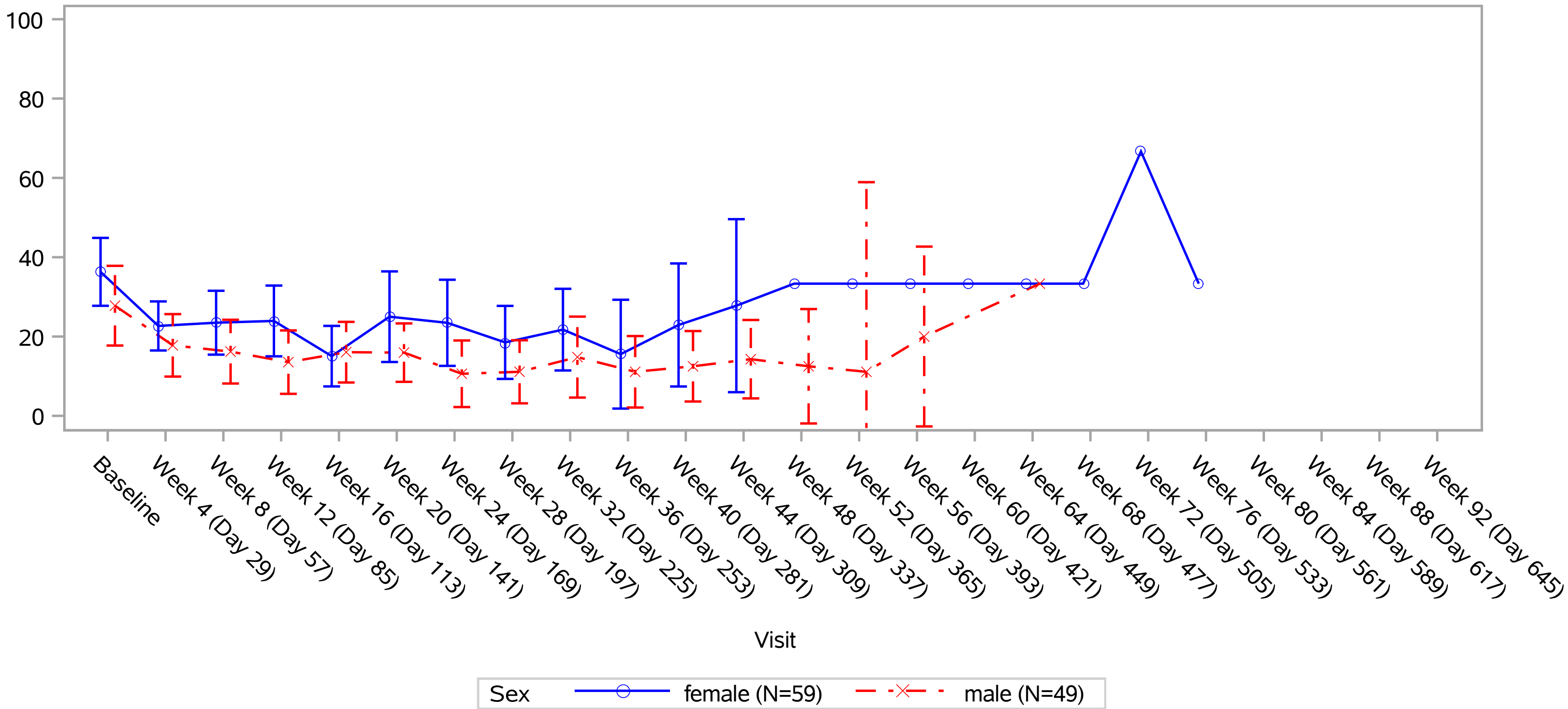
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Dyspnoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30DY_SGRE.pdf
15OCT2021 19:25

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Dyspnoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30DY_SGSEX.pdf
15OCT2021 19:56

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Emotional functioning
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=108)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	108	100.0	104	96.3	80.56	21.61	76.35	84.76
Week 4 (Day 29)	n/a	108	100.0	96	88.9	82.47	19.06	78.60	86.33
Week 8 (Day 57)	n/a	92	85.2	79	85.9	84.60	16.35	80.94	88.26
Week 12 (Day 85)	n/a	79	73.1	70	88.6	86.79	16.27	82.91	90.66
Week 16 (Day 113)	n/a	69	63.9	58	84.1	85.20	17.73	80.54	89.86
Week 20 (Day 141)	n/a	59	54.6	55	93.2	83.03	18.14	78.13	87.93
Week 24 (Day 169)	n/a	56	51.9	49	87.5	83.84	17.55	78.80	88.88
Week 28 (Day 197)	n/a	55	50.9	51	92.7	86.27	14.51	82.19	90.36
Week 32 (Day 225)	n/a	48	44.4	41	85.4	83.33	18.82	77.39	89.27
Week 36 (Day 253)	n/a	41	38.0	30	73.2	82.50	17.14	76.10	88.90
Week 40 (Day 281)	n/a	37	34.3	32	86.5	78.39	21.47	70.65	86.13
Week 44 (Day 309)	n/a	31	28.7	26	83.9	82.37	23.13	73.03	91.72
Week 48 (Day 337)	n/a	23	21.3	12	52.2	79.17	18.29	67.54	90.79
Week 52 (Day 365)	n/a	19	17.6	4	21.1	81.25	32.19	30.04	132.46
Week 56 (Day 393)	n/a	17	15.7	6	35.3	80.56	16.39	63.36	97.75
Week 60 (Day 421)	n/a	11	10.2	1	9.1	58.33	NE	NE	NE
Week 64 (Day 449)	n/a	10	9.3	3	30.0	66.67	14.43	30.81	102.52
Week 68 (Day 477)	n/a	6	5.6	1	16.7	58.33	NE	NE	NE
Week 72 (Day 505)	n/a	6	5.6	1	16.7	50.00	NE	NE	NE
Week 76 (Day 533)	n/a	6	5.6	1	16.7	83.33	NE	NE	NE
Week 80 (Day 561)	n/a	5	4.6	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	n/a	1	0.9	0	0.0	NE	NE	NE	NE

Cycle 12 (LOCF)	n/a	108	100.0	108	100.0	84.88	18.76	81.30	88.46
End of Study (LOCF)	n/a	108	100.0	108	100.0	84.72	17.85	81.32	88.13
Sex									
Baseline	Female	59	100.0	56	94.9	77.88	23.74	71.52	84.24
Week 4 (Day 29)	Female	59	100.0	51	86.4	82.03	19.18	76.63	87.42
Week 8 (Day 57)	Female	49	83.1	44	89.8	83.71	18.67	78.03	89.39
Week 12 (Day 85)	Female	44	74.6	38	86.4	85.31	17.16	79.67	90.95
Week 16 (Day 113)	Female	38	64.4	31	81.6	84.95	18.31	78.23	91.66
Week 20 (Day 141)	Female	33	55.9	32	97.0	82.29	19.49	75.27	89.32
Week 24 (Day 169)	Female	31	52.5	27	87.1	82.72	18.33	75.46	89.97
Week 28 (Day 197)	Female	30	50.8	27	90.0	84.26	16.72	77.65	90.87
Week 32 (Day 225)	Female	27	45.8	23	85.2	79.35	21.60	70.01	88.69
Week 36 (Day 253)	Female	22	37.3	15	68.2	81.11	15.58	72.48	89.74
Week 40 (Day 281)	Female	18	30.5	16	88.9	73.44	24.57	60.34	86.53
Week 44 (Day 309)	Female	15	25.4	12	80.0	78.47	28.53	60.35	96.60
Week 48 (Day 337)	Female	11	18.6	4	36.4	68.75	4.17	62.12	75.38
Week 52 (Day 365)	Female	9	15.3	1	11.1	91.67	NE	NE	NE
Week 56 (Day 393)	Female	7	11.9	1	14.3	66.67	NE	NE	NE
Week 60 (Day 421)	Female	5	8.5	1	20.0	58.33	NE	NE	NE
Week 64 (Day 449)	Female	4	6.8	2	50.0	75.00	0.00	NE	NE
Week 68 (Day 477)	Female	3	5.1	1	33.3	58.33	NE	NE	NE
Week 72 (Day 505)	Female	3	5.1	1	33.3	50.00	NE	NE	NE
Week 76 (Day 533)	Female	3	5.1	1	33.3	83.33	NE	NE	NE
Week 80 (Day 561)	Female	2	3.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	59	100.0	59	100.0	83.19	21.86	77.50	88.89
End of Study (LOCF)	Female	59	100.0	59	100.0	83.05	20.99	77.58	88.52
Baseline	Male	49	100.0	48	98.0	83.68	18.59	78.28	89.08
Week 4 (Day 29)	Male	49	100.0	45	91.8	82.96	19.13	77.22	88.71
Week 8 (Day 57)	Male	43	87.8	35	81.4	85.71	13.03	81.24	90.19
Week 12 (Day 85)	Male	35	71.4	32	91.4	88.54	15.23	83.05	94.03
Week 16 (Day 113)	Male	31	63.3	27	87.1	85.49	17.39	78.62	92.37
Week 20 (Day 141)	Male	26	53.1	23	88.5	84.06	16.46	76.94	91.18
Week 24 (Day 169)	Male	25	51.0	22	88.0	85.23	16.85	77.76	92.70
Week 28 (Day 197)	Male	25	51.0	24	96.0	88.54	11.48	83.70	93.39

Week 32 (Day 225)	Male	21	42.9	18	85.7	88.43	13.45	81.74	95.11
Week 36 (Day 253)	Male	19	38.8	15	78.9	83.89	19.02	73.36	94.42
Week 40 (Day 281)	Male	19	38.8	16	84.2	83.33	17.21	74.16	92.51
Week 44 (Day 309)	Male	16	32.7	14	87.5	85.71	17.73	75.48	95.95
Week 48 (Day 337)	Male	12	24.5	8	66.7	84.38	20.62	67.13	101.62
Week 52 (Day 365)	Male	10	20.4	3	30.0	77.78	38.49	-17.84	173.39
Week 56 (Day 393)	Male	10	20.4	5	50.0	83.33	16.67	62.64	104.03
Week 60 (Day 421)	Male	6	12.2	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Male	6	12.2	1	16.7	50.00	NE	NE	NE
Week 68 (Day 477)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	49	100.0	49	100.0	86.90	14.13	82.85	90.96
End of Study (LOCF)	Male	49	100.0	49	100.0	86.73	13.06	82.98	90.49
Age									
Baseline	< 65	63	100.0	60	95.2	79.03	21.51	73.47	84.58
Week 4 (Day 29)	< 65	63	100.0	55	87.3	81.67	19.60	76.37	86.97
Week 8 (Day 57)	< 65	54	85.7	47	87.0	83.87	18.75	78.36	89.37
Week 12 (Day 85)	< 65	47	74.6	41	87.2	85.57	19.10	79.54	91.60
Week 16 (Day 113)	< 65	39	61.9	34	87.2	82.35	19.87	75.42	89.28
Week 20 (Day 141)	< 65	35	55.6	35	100.0	79.52	20.14	72.60	86.44
Week 24 (Day 169)	< 65	34	54.0	31	91.2	82.80	19.48	75.65	89.94
Week 28 (Day 197)	< 65	33	52.4	32	97.0	83.85	14.96	78.46	89.25
Week 32 (Day 225)	< 65	30	47.6	25	83.3	81.67	19.84	73.48	89.86
Week 36 (Day 253)	< 65	25	39.7	20	80.0	79.58	18.82	70.77	88.39
Week 40 (Day 281)	< 65	23	36.5	21	91.3	74.60	24.36	63.51	85.69
Week 44 (Day 309)	< 65	19	30.2	17	89.5	79.90	27.65	65.69	94.12
Week 48 (Day 337)	< 65	14	22.2	7	50.0	72.62	19.07	54.98	90.26

Week 52 (Day 365)	< 65	12	19.0	2	16.7	62.50	41.25	-308.10	433.10
Week 56 (Day 393)	< 65	11	17.5	2	18.2	62.50	5.89	9.56	115.44
Week 60 (Day 421)	< 65	8	12.7	1	12.5	58.33	NE	NE	NE
Week 64 (Day 449)	< 65	7	11.1	3	42.9	66.67	14.43	30.81	102.52
Week 68 (Day 477)	< 65	4	6.3	1	25.0	58.33	NE	NE	NE
Week 72 (Day 505)	< 65	4	6.3	1	25.0	50.00	NE	NE	NE
Week 76 (Day 533)	< 65	4	6.3	1	25.0	83.33	NE	NE	NE
Week 80 (Day 561)	< 65	3	4.8	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	63	100.0	63	100.0	83.33	21.48	77.92	88.74
End of Study (LOCF)	< 65	63	100.0	63	100.0	83.60	20.13	78.53	88.67
Baseline	>= 65	45	100.0	44	97.8	82.64	21.83	76.00	89.28
Week 4 (Day 29)	>= 65	45	100.0	41	91.1	83.54	18.49	77.70	89.37
Week 8 (Day 57)	>= 65	38	84.4	32	84.2	85.68	12.20	81.28	90.08
Week 12 (Day 85)	>= 65	32	71.1	29	90.6	88.51	11.23	84.23	92.78
Week 16 (Day 113)	>= 65	30	66.7	24	80.0	89.24	13.57	83.51	94.96
Week 20 (Day 141)	>= 65	24	53.3	20	83.3	89.17	12.12	83.49	94.84
Week 24 (Day 169)	>= 65	22	48.9	18	81.8	85.65	13.95	78.71	92.58
Week 28 (Day 197)	>= 65	22	48.9	19	86.4	90.35	13.11	84.03	96.67
Week 32 (Day 225)	>= 65	18	40.0	16	88.9	85.94	17.41	76.66	95.21
Week 36 (Day 253)	>= 65	16	35.6	10	62.5	88.33	11.92	79.81	96.86
Week 40 (Day 281)	>= 65	14	31.1	11	78.6	85.61	12.41	77.27	93.94
Week 44 (Day 309)	>= 65	12	26.7	9	75.0	87.04	10.30	79.12	94.95
Week 48 (Day 337)	>= 65	9	20.0	5	55.6	88.33	13.94	71.02	105.65
Week 52 (Day 365)	>= 65	7	15.6	2	28.6	100.00	0.00	NE	NE
Week 56 (Day 393)	>= 65	6	13.3	4	66.7	89.58	10.49	72.90	106.27
Week 60 (Day 421)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE

Week 76 (Day 533)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	45	100.0	45	100.0	87.04	14.05	82.82	91.26
End of Study (LOCF)	>= 65	45	100.0	45	100.0	86.30	14.12	82.05	90.54
ECOG performance status									
Baseline	0	30	100.0	29	96.7	74.52	22.60	65.92	83.12
Week 4 (Day 29)	0	30	100.0	29	96.7	79.60	18.58	72.53	86.66
Week 8 (Day 57)	0	28	93.3	25	89.3	78.67	18.17	71.16	86.17
Week 12 (Day 85)	0	26	86.7	23	88.5	87.32	17.92	79.57	95.07
Week 16 (Day 113)	0	26	86.7	21	80.8	81.75	19.30	72.96	90.53
Week 20 (Day 141)	0	26	86.7	24	92.3	79.17	21.70	70.00	88.33
Week 24 (Day 169)	0	25	83.3	23	92.0	84.42	18.69	76.34	92.50
Week 28 (Day 197)	0	25	83.3	23	92.0	87.68	11.75	82.60	92.76
Week 32 (Day 225)	0	20	66.7	16	80.0	83.33	16.39	74.60	92.07
Week 36 (Day 253)	0	18	60.0	11	61.1	78.03	19.46	64.96	91.11
Week 40 (Day 281)	0	16	53.3	11	68.8	74.24	19.53	61.12	87.36
Week 44 (Day 309)	0	15	50.0	12	80.0	77.78	31.65	57.67	97.89
Week 48 (Day 337)	0	9	30.0	6	66.7	80.56	20.86	58.66	102.45
Week 52 (Day 365)	0	9	30.0	3	33.3	75.00	36.32	-15.23	165.23
Week 56 (Day 393)	0	8	26.7	3	37.5	77.78	20.97	25.68	129.87
Week 60 (Day 421)	0	5	16.7	1	20.0	58.33	NE	NE	NE
Week 64 (Day 449)	0	5	16.7	2	40.0	62.50	17.68	-96.33	221.33
Week 68 (Day 477)	0	3	10.0	1	33.3	58.33	NE	NE	NE
Week 72 (Day 505)	0	3	10.0	1	33.3	50.00	NE	NE	NE
Week 76 (Day 533)	0	3	10.0	1	33.3	83.33	NE	NE	NE
Week 80 (Day 561)	0	2	6.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	0	1	3.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	30	100.0	30	100.0	81.39	22.81	72.87	89.91
End of Study (LOCF)	0	30	100.0	30	100.0	81.39	21.07	73.52	89.26
Baseline	1	78	100.0	75	96.2	82.89	20.91	78.08	87.70
Week 4 (Day 29)	1	78	100.0	67	85.9	83.71	19.27	79.01	88.41

Week 8 (Day 57)	1	64	82.1	54	84.4	87.35	14.81	83.30	91.39
Week 12 (Day 85)	1	53	67.9	47	88.7	86.52	15.60	81.95	91.10
Week 16 (Day 113)	1	43	55.1	37	86.0	87.16	16.74	81.58	92.74
Week 20 (Day 141)	1	33	42.3	31	93.9	86.02	14.50	80.70	91.34
Week 24 (Day 169)	1	31	39.7	26	83.9	83.33	16.83	76.53	90.13
Week 28 (Day 197)	1	30	38.5	28	93.3	85.12	16.57	78.69	91.54
Week 32 (Day 225)	1	28	35.9	25	89.3	83.33	20.55	74.85	91.82
Week 36 (Day 253)	1	23	29.5	19	82.6	85.09	15.61	77.56	92.61
Week 40 (Day 281)	1	21	26.9	21	100.0	80.56	22.57	70.28	90.83
Week 44 (Day 309)	1	16	20.5	14	87.5	86.31	12.06	79.35	93.27
Week 48 (Day 337)	1	14	17.9	6	42.9	77.78	17.21	59.71	95.84
Week 52 (Day 365)	1	10	12.8	1	10.0	100.00	NE	NE	NE
Week 56 (Day 393)	1	9	11.5	3	33.3	83.33	14.43	47.48	119.19
Week 60 (Day 421)	1	6	7.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	5	6.4	1	20.0	75.00	NE	NE	NE
Week 68 (Day 477)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	3	3.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	78	100.0	78	100.0	86.22	16.93	82.40	90.03
End of Study (LOCF)	1	78	100.0	78	100.0	86.00	16.42	82.30	89.71
Geographic region									
Baseline	USA	21	100.0	19	90.5	83.33	15.21	76.00	90.67
Week 4 (Day 29)	USA	21	100.0	20	95.2	82.50	14.53	75.70	89.30
Week 8 (Day 57)	USA	21	100.0	19	90.5	82.89	15.08	75.63	90.16
Week 12 (Day 85)	USA	21	100.0	18	85.7	84.72	16.97	76.28	93.16
Week 16 (Day 113)	USA	21	100.0	16	76.2	81.25	17.35	72.01	90.49
Week 20 (Day 141)	USA	20	95.2	18	90.0	81.02	16.12	73.00	89.03
Week 24 (Day 169)	USA	20	95.2	19	95.0	83.33	16.43	75.41	91.25
Week 28 (Day 197)	USA	20	95.2	19	95.0	86.40	14.22	79.55	93.26
Week 32 (Day 225)	USA	17	81.0	15	88.2	82.78	17.10	73.31	92.25
Week 36 (Day 253)	USA	17	81.0	11	64.7	80.30	15.93	69.60	91.01
Week 40 (Day 281)	USA	15	71.4	12	80.0	75.00	24.36	59.52	90.48

Week 44 (Day 309)	USA	13	61.9	10	76.9	90.00	10.97	82.15	97.85
Week 48 (Day 337)	USA	8	38.1	5	62.5	80.00	12.64	64.31	95.69
Week 52 (Day 365)	USA	6	28.6	1	16.7	100.00	NE	NE	NE
Week 56 (Day 393)	USA	6	28.6	3	50.0	80.56	17.35	37.46	123.65
Week 60 (Day 421)	USA	5	23.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	4	19.0	1	25.0	75.00	NE	NE	NE
Week 68 (Day 477)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	21	100.0	21	100.0	88.10	18.37	79.74	96.46
End of Study (LOCF)	USA	21	100.0	21	100.0	85.71	18.66	77.22	94.21
Baseline	Europe (EU)	42	100.0	40	95.2	72.57	24.63	64.69	80.45
Week 4 (Day 29)	Europe (EU)	42	100.0	39	92.9	76.92	21.50	69.95	83.89
Week 8 (Day 57)	Europe (EU)	36	85.7	30	83.3	79.44	17.88	72.77	86.12
Week 12 (Day 85)	Europe (EU)	31	73.8	25	80.6	80.67	18.43	73.06	88.28
Week 16 (Day 113)	Europe (EU)	30	71.4	24	80.0	79.51	19.66	71.21	87.81
Week 20 (Day 141)	Europe (EU)	26	61.9	24	92.3	78.82	20.99	69.95	87.68
Week 24 (Day 169)	Europe (EU)	26	61.9	22	84.6	79.92	19.36	71.34	88.51
Week 28 (Day 197)	Europe (EU)	25	59.5	23	92.0	82.61	15.27	76.01	89.21
Week 32 (Day 225)	Europe (EU)	21	50.0	19	90.5	83.77	16.78	75.69	91.86
Week 36 (Day 253)	Europe (EU)	16	38.1	13	81.3	80.77	19.66	68.89	92.65
Week 40 (Day 281)	Europe (EU)	14	33.3	14	100.0	74.40	20.53	62.55	86.26
Week 44 (Day 309)	Europe (EU)	11	26.2	10	90.9	70.00	31.48	47.48	92.52
Week 48 (Day 337)	Europe (EU)	8	19.0	6	75.0	75.00	22.36	51.53	98.47
Week 52 (Day 365)	Europe (EU)	6	14.3	3	50.0	75.00	36.32	-15.23	165.23
Week 56 (Day 393)	Europe (EU)	6	14.3	2	33.3	75.00	23.57	-136.77	286.77

Week 60 (Day 421)	Europe (EU)	4	9.5	1	25.0	58.33	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	4	9.5	2	50.0	62.50	17.68	-96.33	221.33
Week 68 (Day 477)	Europe (EU)	3	7.1	1	33.3	58.33	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	3	7.1	1	33.3	50.00	NE	NE	NE
Week 76 (Day 533)	Europe (EU)	3	7.1	1	33.3	83.33	NE	NE	NE
Week 80 (Day 561)	Europe (EU)	2	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Europe (EU)	42	100.0	42	100.0	78.77	20.26	72.46	85.08
End of Study (LOCF)	Europe (EU)	42	100.0	42	100.0	79.37	18.15	73.71	85.02
Baseline	Asia (AS)	45	100.0	45	100.0	86.48	19.08	80.75	92.21
Week 4 (Day 29)	Asia (AS)	45	100.0	37	82.2	88.29	17.06	82.60	93.98
Week 8 (Day 57)	Asia (AS)	35	77.8	30	85.7	90.83	13.73	85.71	95.96
Week 12 (Day 85)	Asia (AS)	27	60.0	27	100.0	93.83	10.49	89.68	97.98
Week 16 (Day 113)	Asia (AS)	18	40.0	18	100.0	96.30	8.68	91.98	100.61
Week 20 (Day 141)	Asia (AS)	13	28.9	13	100.0	93.59	10.29	87.37	99.81
Week 24 (Day 169)	Asia (AS)	10	22.2	8	80.0	95.83	8.91	88.39	103.28
Week 28 (Day 197)	Asia (AS)	10	22.2	9	90.0	95.37	9.42	88.13	102.61
Week 32 (Day 225)	Asia (AS)	10	22.2	7	70.0	83.33	28.87	56.64	110.03
Week 36 (Day 253)	Asia (AS)	8	17.8	6	75.0	90.28	13.35	76.27	104.29
Week 40 (Day 281)	Asia (AS)	8	17.8	6	75.0	94.44	8.61	85.41	103.48
Week 44 (Day 309)	Asia (AS)	7	15.6	6	85.7	90.28	13.35	76.27	104.29
Week 48 (Day 337)	Asia (AS)	7	15.6	1	14.3	100.00	NE	NE	NE
Week 52 (Day 365)	Asia (AS)	7	15.6	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Asia (AS)	5	11.1	1	20.0	91.67	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	45	100.0	45	100.0	89.07	16.17	84.22	93.93
End of Study (LOCF)	Asia (AS)	45	100.0	45	100.0	89.26	16.15	84.41	94.11

Race/ethnicity									
Baseline	Asian	48	100.0	48	100.0	86.98	18.67	81.56	92.40
Week 4 (Day 29)	Asian	48	100.0	40	83.3	88.54	16.53	83.26	93.83
Week 8 (Day 57)	Asian	38	79.2	31	81.6	91.13	13.60	86.14	96.12
Week 12 (Day 85)	Asian	30	62.5	30	100.0	93.89	10.01	90.15	97.63
Week 16 (Day 113)	Asian	21	43.8	21	100.0	96.03	8.17	92.31	99.75
Week 20 (Day 141)	Asian	16	33.3	15	93.8	93.89	9.69	88.52	99.26
Week 24 (Day 169)	Asian	13	27.1	11	84.6	93.94	9.92	87.27	100.61
Week 28 (Day 197)	Asian	13	27.1	12	92.3	92.36	11.49	85.06	99.66
Week 32 (Day 225)	Asian	12	25.0	9	75.0	86.11	25.69	66.37	105.85
Week 36 (Day 253)	Asian	10	20.8	8	80.0	91.67	11.79	81.81	101.52
Week 40 (Day 281)	Asian	10	20.8	8	80.0	93.75	7.39	87.57	99.93
Week 44 (Day 309)	Asian	9	18.8	8	88.9	92.71	12.15	82.55	102.86
Week 48 (Day 337)	Asian	9	18.8	2	22.2	95.83	5.89	42.89	148.78
Week 52 (Day 365)	Asian	9	18.8	1	11.1	100.00	NE	NE	NE
Week 56 (Day 393)	Asian	7	14.6	2	28.6	95.83	5.89	42.89	148.78
Week 60 (Day 421)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	48	100.0	48	100.0	89.06	16.14	84.38	93.75
End of Study (LOCF)	Asian	48	100.0	48	100.0	89.24	16.12	84.55	93.92
Baseline	Non-Asian	54	100.0	52	96.3	75.21	23.02	68.81	81.62
Week 4 (Day 29)	Non-Asian	54	100.0	50	92.6	79.00	20.08	73.29	84.71
Week 8 (Day 57)	Non-Asian	49	90.7	44	89.8	81.25	17.16	76.03	86.47
Week 12 (Day 85)	Non-Asian	44	81.5	36	81.8	82.41	18.66	76.09	88.72
Week 16 (Day 113)	Non-Asian	43	79.6	34	79.1	79.17	19.60	72.33	86.00
Week 20 (Day 141)	Non-Asian	38	70.4	35	92.1	80.00	19.30	73.37	86.63
Week 24 (Day 169)	Non-Asian	38	70.4	34	89.5	81.86	18.97	75.25	88.48
Week 28 (Day 197)	Non-Asian	37	68.5	35	94.6	84.76	15.19	79.54	89.98
Week 32 (Day 225)	Non-Asian	32	59.3	28	87.5	83.63	17.05	77.02	90.24
Week 36 (Day 253)	Non-Asian	27	50.0	20	74.1	80.00	18.42	71.38	88.62

Week 40 (Day 281)	Non-Asian	23	42.6	21	91.3	73.41	23.81	62.58	84.25
Week 44 (Day 309)	Non-Asian	18	33.3	14	77.8	79.76	27.29	64.00	95.52
Week 48 (Day 337)	Non-Asian	12	22.2	9	75.0	76.85	18.99	62.25	91.45
Week 52 (Day 365)	Non-Asian	8	14.8	3	37.5	75.00	36.32	-15.23	165.23
Week 56 (Day 393)	Non-Asian	8	14.8	4	50.0	72.92	14.23	50.27	95.56
Week 60 (Day 421)	Non-Asian	7	13.0	1	14.3	58.33	NE	NE	NE
Week 64 (Day 449)	Non-Asian	6	11.1	2	33.3	62.50	17.68	-96.33	221.33
Week 68 (Day 477)	Non-Asian	3	5.6	1	33.3	58.33	NE	NE	NE
Week 72 (Day 505)	Non-Asian	3	5.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Non-Asian	3	5.6	1	33.3	83.33	NE	NE	NE
Week 80 (Day 561)	Non-Asian	2	3.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	54	100.0	54	100.0	82.41	20.33	76.86	87.96
End of Study (LOCF)	Non-Asian	54	100.0	54	100.0	81.94	18.72	76.83	87.05
Baseline	Unknown	6	100.0	4	66.7	72.92	18.48	43.51	102.32
Week 4 (Day 29)	Unknown	6	100.0	6	100.0	70.83	15.59	54.47	87.19
Week 8 (Day 57)	Unknown	5	83.3	4	80.0	70.83	4.81	63.18	78.49
Week 12 (Day 85)	Unknown	5	83.3	4	80.0	72.92	7.98	60.22	85.61
Week 16 (Day 113)	Unknown	5	83.3	3	60.0	77.78	4.81	65.83	89.73
Week 20 (Day 141)	Unknown	5	83.3	5	100.0	71.67	16.24	51.50	91.84
Week 24 (Day 169)	Unknown	5	83.3	4	80.0	72.92	7.98	60.22	85.61
Week 28 (Day 197)	Unknown	5	83.3	4	80.0	81.25	14.23	58.60	103.90
Week 32 (Day 225)	Unknown	4	66.7	4	100.0	75.00	15.21	50.79	99.21
Week 36 (Day 253)	Unknown	4	66.7	2	50.0	70.83	5.89	17.89	123.78
Week 40 (Day 281)	Unknown	4	66.7	3	75.0	72.22	4.81	60.27	84.17
Week 44 (Day 309)	Unknown	4	66.7	4	100.0	70.83	19.84	39.27	102.40
Week 48 (Day 337)	Unknown	2	33.3	1	50.0	66.67	NE	NE	NE
Week 52 (Day 365)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 60 (Day 421)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE

Week 64 (Day 449)	Unknown	1	16.7	1	100.0	75.00	NE	NE	NE
Week 68 (Day 477)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	1	16.7	1	100.0	50.00	NE	NE	NE
Week 76 (Day 533)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	6	100.0	6	100.0	73.61	17.81	54.92	92.30
End of Study (LOCF)	Unknown	6	100.0	6	100.0	73.61	15.29	57.56	89.66

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TN_QSC30EF_SG.xls
27OCT2021 7:36

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Emotional functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	31	29.8	21.9	39.2
	Cycle 12 (LOCF)	n/a	104	96.3	16	15.4	9.7	23.5
	End of Study (LOCF)	n/a	104	96.3	18	17.3	11.2	25.7
Sex	All visits	Female	56	51.9	15	26.8	17.0	39.6
		Male	48	44.4	16	33.3	21.7	47.5
	Cycle 12 (LOCF)	Female	56	51.9	9	16.1	8.7	27.8
		Male	48	44.4	7	14.6	7.2	27.2
	End of Study (LOCF)	Female	56	51.9	10	17.9	10.0	29.8
		Male	48	44.4	8	16.7	8.7	29.6
Age	All visits	< 65	60	55.6	16	26.7	17.1	39.0
		>= 65	44	40.7	15	34.1	21.9	48.9
	Cycle 12 (LOCF)	< 65	60	55.6	10	16.7	9.3	28.0
		>= 65	44	40.7	6	13.6	6.4	26.7
	End of Study (LOCF)	< 65	60	55.6	11	18.3	10.6	29.9
		>= 65	44	40.7	7	15.9	7.9	29.4
ECOG performance status	All visits	0	29	26.9	13	44.8	28.4	62.5
		1	75	69.4	18	24.0	15.8	34.8
	Cycle 12 (LOCF)	0	29	26.9	5	17.2	7.6	34.5
		1	75	69.4	11	14.7	8.4	24.4
	End of Study (LOCF)	0	29	26.9	7	24.1	12.2	42.1
		1	75	69.4	11	14.7	8.4	24.4
Geographic region	All visits	USA	19	17.6	9	47.4	27.3	68.3
		Europe (EU)	40	37.0	14	35.0	22.1	50.5
		Asia (AS)	45	41.7	8	17.8	9.3	31.3
	Cycle 12 (LOCF)	USA	19	17.6	2	10.5	2.9	31.4
		Europe (EU)	40	37.0	8	20.0	10.5	34.8
		Asia (AS)	45	41.7	6	13.3	6.3	26.2
	End of Study (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	9	22.5	12.3	37.5
		Asia (AS)	45	41.7	6	13.3	6.3	26.2
Race/ethnicity	All visits	Asian	48	44.4	9	18.8	10.2	31.9
		Non-Asian	52	48.1	22	42.3	29.9	55.8
		Unknown	4	3.7	0	0.0	0.0	49.0
	Cycle 12 (LOCF)	Asian	48	44.4	7	14.6	7.2	27.2
		Non-Asian	52	48.1	9	17.3	9.4	29.7
		Unknown	4	3.7	0	0.0	0.0	49.0
	End of Study (LOCF)	Asian	48	44.4	7	14.6	7.2	27.2

		Non-Asian	52	48.1	11	21.2	12.2	34.0
		Unknown	4	3.7	0	0.0	0.0	49.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30EF_W10_SG.xls
15OCT2021 13:13

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Emotional functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

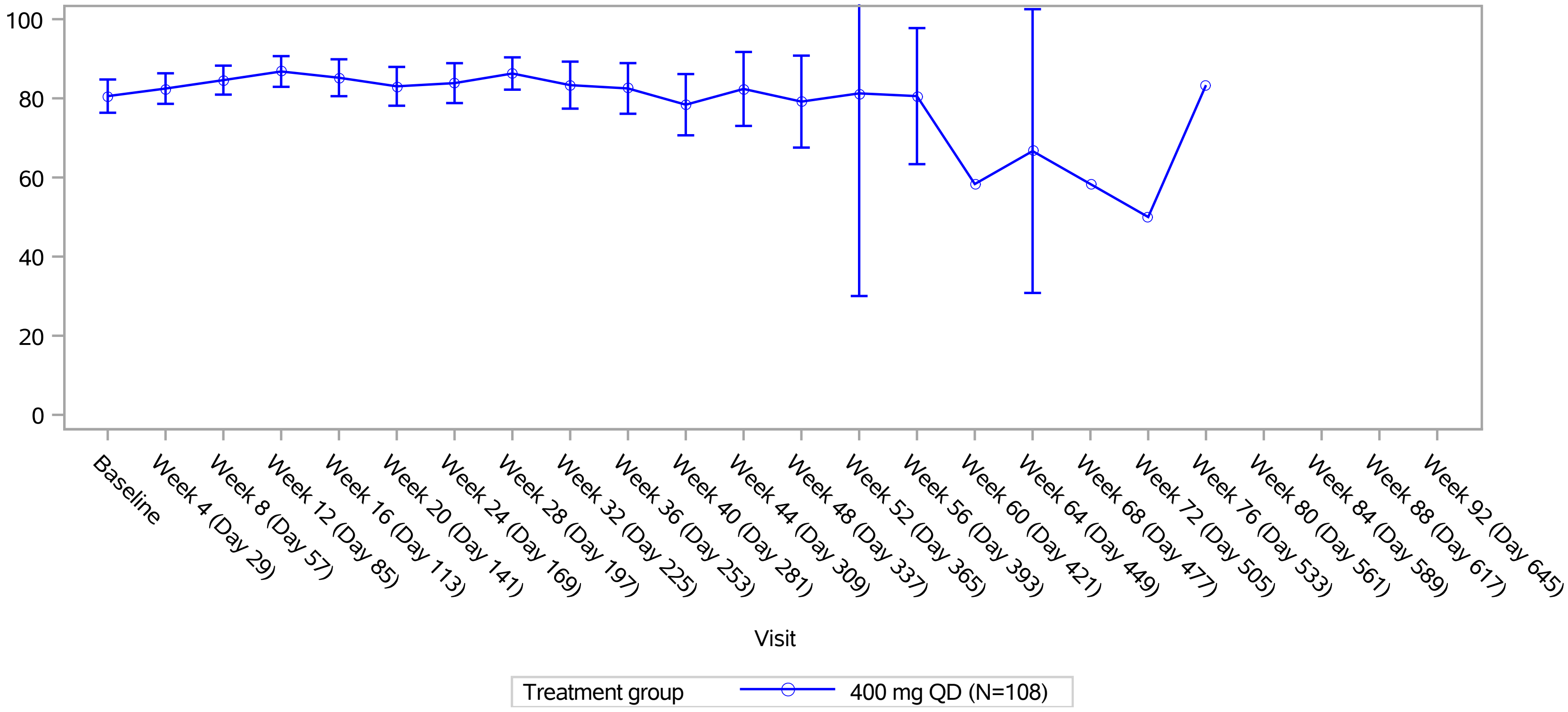
			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	31	29.8	21.9	39.2
	Cycle 12 (LOCF)	n/a	104	96.3	16	15.4	9.7	23.5
	End of Study (LOCF)	n/a	104	96.3	18	17.3	11.2	25.7
Sex	All visits	Female	56	51.9	15	26.8	17.0	39.6
		Male	48	44.4	16	33.3	21.7	47.5
	Cycle 12 (LOCF)	Female	56	51.9	9	16.1	8.7	27.8
		Male	48	44.4	7	14.6	7.2	27.2
	End of Study (LOCF)	Female	56	51.9	10	17.9	10.0	29.8
		Male	48	44.4	8	16.7	8.7	29.6
Age	All visits	< 65	60	55.6	16	26.7	17.1	39.0
		>= 65	44	40.7	15	34.1	21.9	48.9
	Cycle 12 (LOCF)	< 65	60	55.6	10	16.7	9.3	28.0
		>= 65	44	40.7	6	13.6	6.4	26.7
	End of Study (LOCF)	< 65	60	55.6	11	18.3	10.6	29.9
		>= 65	44	40.7	7	15.9	7.9	29.4
ECOG performance status	All visits	0	29	26.9	13	44.8	28.4	62.5
		1	75	69.4	18	24.0	15.8	34.8
	Cycle 12 (LOCF)	0	29	26.9	5	17.2	7.6	34.5
		1	75	69.4	11	14.7	8.4	24.4
	End of Study (LOCF)	0	29	26.9	7	24.1	12.2	42.1
		1	75	69.4	11	14.7	8.4	24.4
Geographic region	All visits	USA	19	17.6	9	47.4	27.3	68.3
		Europe (EU)	40	37.0	14	35.0	22.1	50.5
		Asia (AS)	45	41.7	8	17.8	9.3	31.3
	Cycle 12 (LOCF)	USA	19	17.6	2	10.5	2.9	31.4
		Europe (EU)	40	37.0	8	20.0	10.5	34.8
		Asia (AS)	45	41.7	6	13.3	6.3	26.2
	End of Study (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	9	22.5	12.3	37.5
		Asia (AS)	45	41.7	6	13.3	6.3	26.2
Race/ethnicity	All visits	Asian	48	44.4	9	18.8	10.2	31.9
		Non-Asian	52	48.1	22	42.3	29.9	55.8
		Unknown	4	3.7	0	0.0	0.0	49.0
	Cycle 12 (LOCF)	Asian	48	44.4	7	14.6	7.2	27.2
		Non-Asian	52	48.1	9	17.3	9.4	29.7
		Unknown	4	3.7	0	0.0	0.0	49.0
	End of Study (LOCF)	Asian	48	44.4	7	14.6	7.2	27.2

		Non-Asian	52	48.1	11	21.2	12.2	34.0
		Unknown	4	3.7	0	0.0	0.0	49.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30EF_W15_SG.xls
15OCT2021 13:03

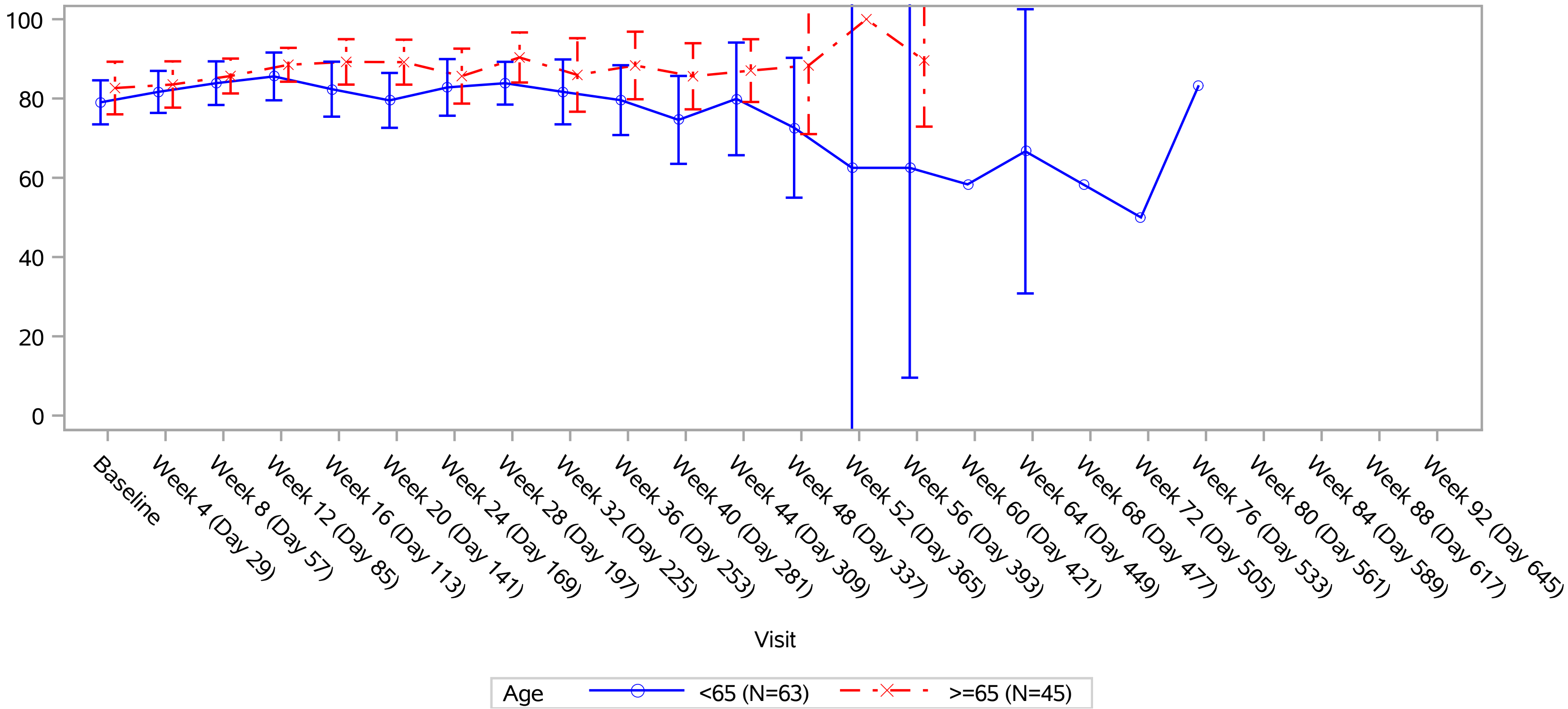
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Emotional functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30EF.pdf
15OCT2021 17:25

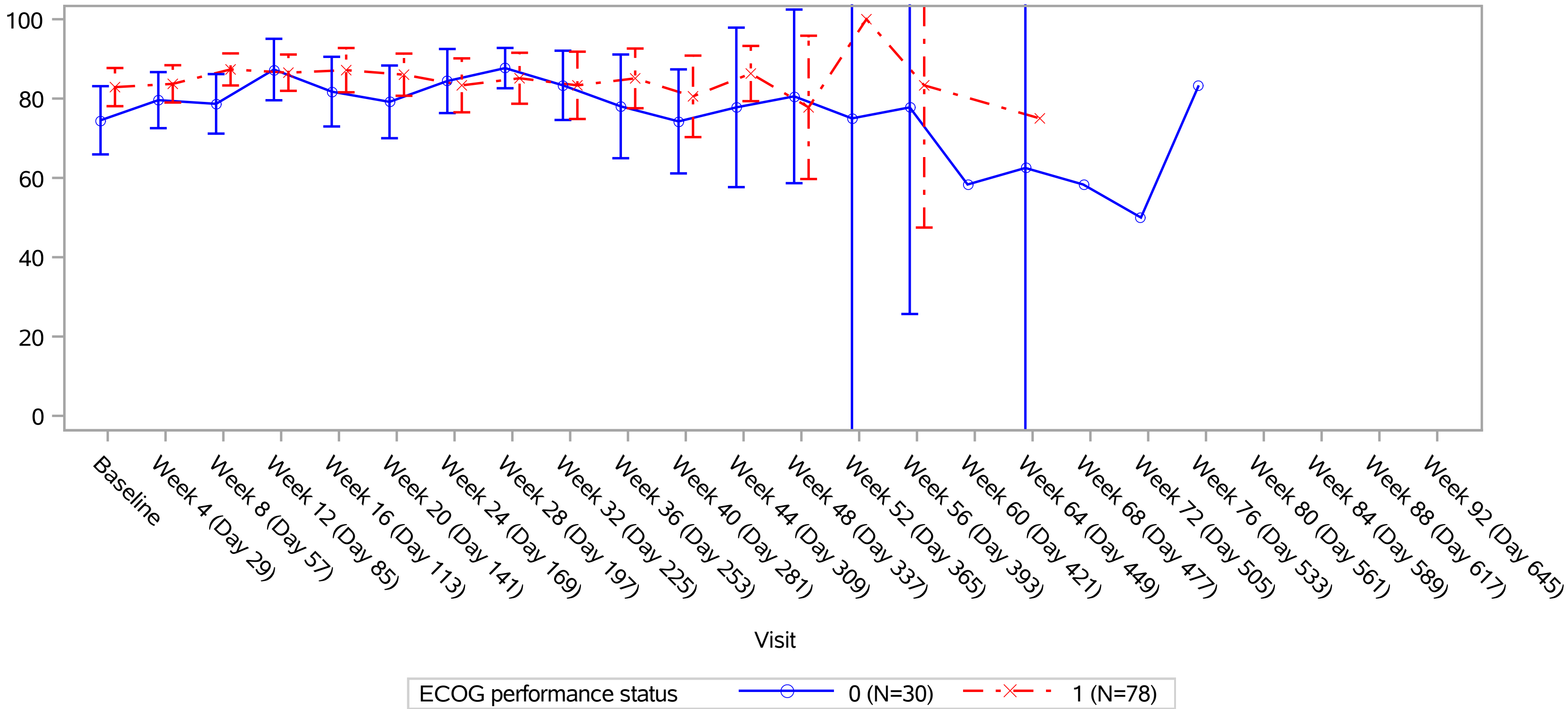
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Emotional functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30EF_SGAGE65.pdf
15OCT2021 17:54

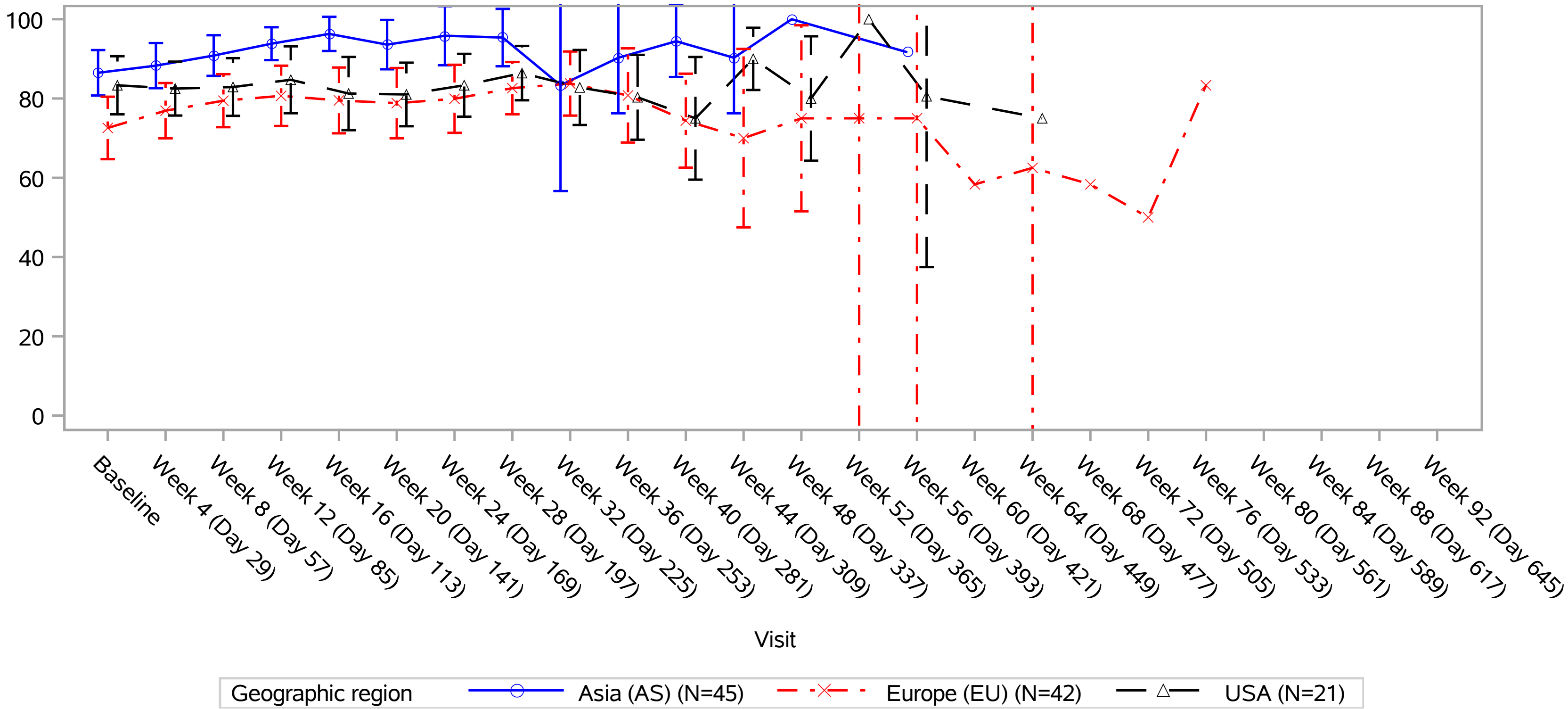
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Emotional functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30EF_SGECOG.pdf
15OCT2021 18:25

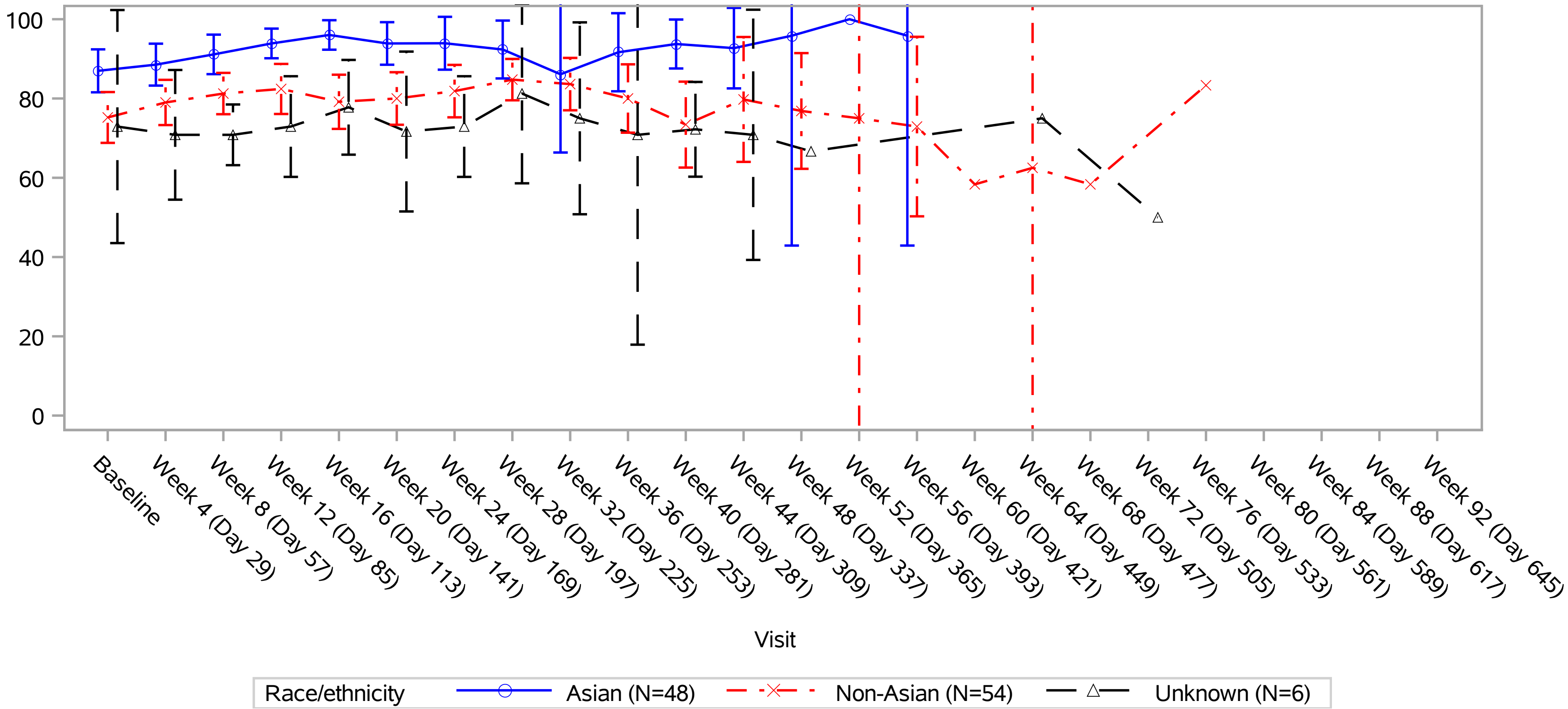
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Emotional functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30EF_SGGEO.pdf
15OCT2021 18:56

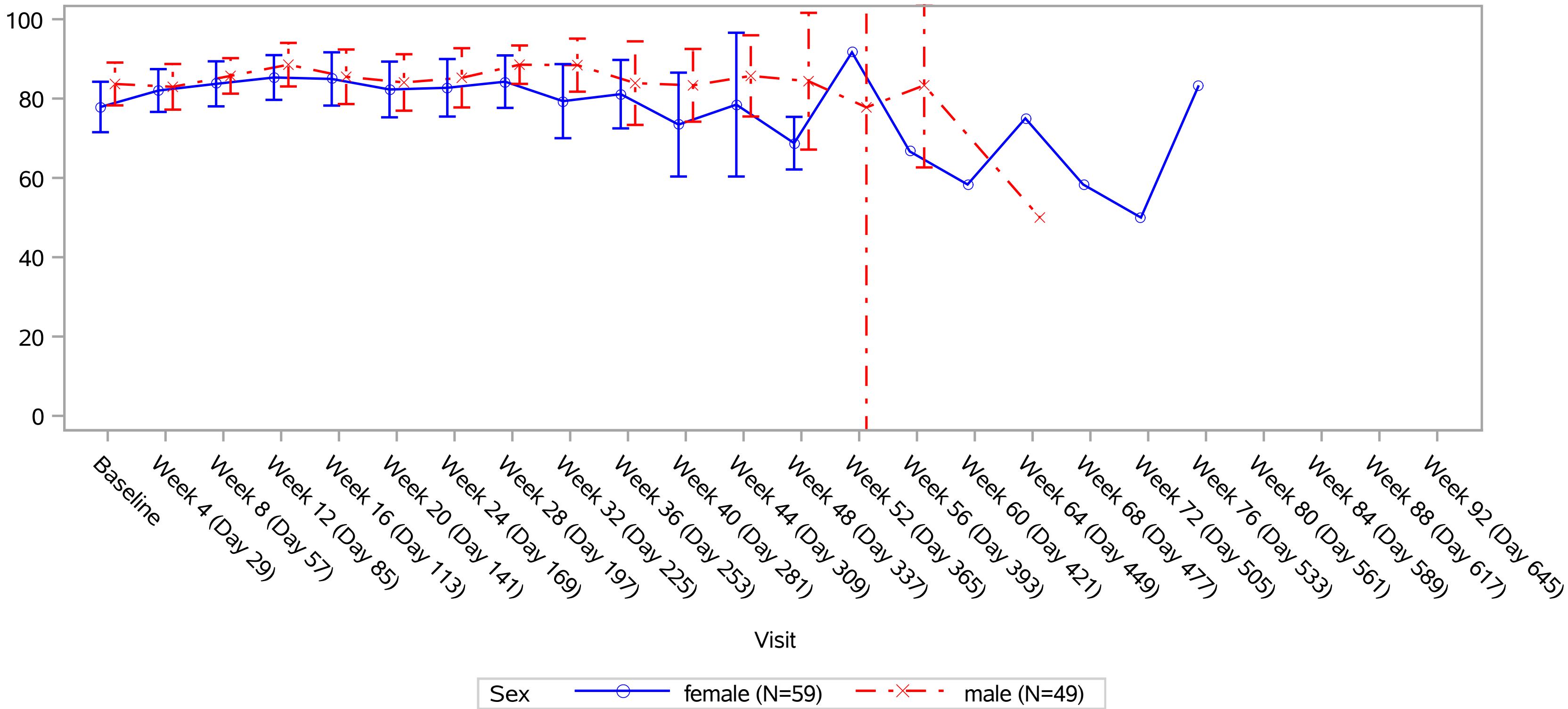
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Emotional functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30EF_SGRE.pdf
15OCT2021 19:26

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Emotional functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30EF_SGSEX.pdf
15OCT2021 19:57

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Fatigue
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=108)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	108	100.0	104	96.3	33.01	28.48	27.47	38.55
Week 4 (Day 29)	n/a	108	100.0	96	88.9	25.69	23.77	20.88	30.51
Week 8 (Day 57)	n/a	92	85.2	79	85.9	26.30	22.23	21.32	31.28
Week 12 (Day 85)	n/a	79	73.1	71	89.9	26.76	20.19	21.98	31.54
Week 16 (Day 113)	n/a	69	63.9	58	84.1	25.00	21.66	19.30	30.70
Week 20 (Day 141)	n/a	59	54.6	55	93.2	25.25	21.64	19.40	31.10
Week 24 (Day 169)	n/a	56	51.9	49	87.5	25.40	23.02	18.79	32.01
Week 28 (Day 197)	n/a	55	50.9	51	92.7	25.49	21.69	19.39	31.59
Week 32 (Day 225)	n/a	48	44.4	41	85.4	22.76	18.08	17.06	28.47
Week 36 (Day 253)	n/a	41	38.0	30	73.2	21.67	22.52	13.26	30.08
Week 40 (Day 281)	n/a	37	34.3	32	86.5	24.31	19.44	17.30	31.31
Week 44 (Day 309)	n/a	31	28.7	26	83.9	29.06	25.55	18.74	39.38
Week 48 (Day 337)	n/a	23	21.3	12	52.2	30.56	21.78	16.72	44.39
Week 52 (Day 365)	n/a	19	17.6	4	21.1	44.44	20.29	12.16	76.72
Week 56 (Day 393)	n/a	17	15.7	6	35.3	27.78	11.65	15.55	40.01
Week 60 (Day 421)	n/a	11	10.2	1	9.1	66.67	NE	NE	NE
Week 64 (Day 449)	n/a	10	9.3	3	30.0	37.04	16.97	-5.12	79.20
Week 68 (Day 477)	n/a	6	5.6	1	16.7	66.67	NE	NE	NE
Week 72 (Day 505)	n/a	6	5.6	1	16.7	66.67	NE	NE	NE
Week 76 (Day 533)	n/a	6	5.6	1	16.7	55.56	NE	NE	NE
Week 80 (Day 561)	n/a	5	4.6	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	n/a	1	0.9	0	0.0	NE	NE	NE	NE

Cycle 12 (LOCF)	n/a	108	100.0	108	100.0	26.85	23.44	22.38	31.32
End of Study (LOCF)	n/a	108	100.0	108	100.0	27.06	22.49	22.77	31.35
Sex									
Baseline	Female	59	100.0	56	94.9	39.09	30.34	30.96	47.21
Week 4 (Day 29)	Female	59	100.0	51	86.4	30.94	22.26	24.68	37.20
Week 8 (Day 57)	Female	49	83.1	44	89.8	31.31	23.63	24.13	38.50
Week 12 (Day 85)	Female	44	74.6	39	88.6	31.91	22.83	24.51	39.31
Week 16 (Day 113)	Female	38	64.4	31	81.6	27.78	23.44	19.18	36.38
Week 20 (Day 141)	Female	33	55.9	32	97.0	30.90	23.74	22.35	39.46
Week 24 (Day 169)	Female	31	52.5	27	87.1	29.22	24.87	19.38	39.06
Week 28 (Day 197)	Female	30	50.8	27	90.0	30.04	22.82	21.02	39.07
Week 32 (Day 225)	Female	27	45.8	23	85.2	28.50	18.60	20.46	36.55
Week 36 (Day 253)	Female	22	37.3	15	68.2	27.04	25.96	12.66	41.41
Week 40 (Day 281)	Female	18	30.5	16	88.9	29.17	21.03	17.96	40.37
Week 44 (Day 309)	Female	15	25.4	12	80.0	40.74	28.95	22.35	59.13
Week 48 (Day 337)	Female	11	18.6	4	36.4	50.00	21.28	16.14	83.86
Week 52 (Day 365)	Female	9	15.3	1	11.1	55.56	NE	NE	NE
Week 56 (Day 393)	Female	7	11.9	1	14.3	33.33	NE	NE	NE
Week 60 (Day 421)	Female	5	8.5	1	20.0	66.67	NE	NE	NE
Week 64 (Day 449)	Female	4	6.8	2	50.0	44.44	15.71	-96.74	185.62
Week 68 (Day 477)	Female	3	5.1	1	33.3	66.67	NE	NE	NE
Week 72 (Day 505)	Female	3	5.1	1	33.3	66.67	NE	NE	NE
Week 76 (Day 533)	Female	3	5.1	1	33.3	55.56	NE	NE	NE
Week 80 (Day 561)	Female	2	3.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	59	100.0	59	100.0	31.07	25.59	24.41	37.74
End of Study (LOCF)	Female	59	100.0	59	100.0	31.26	24.45	24.89	37.63
Baseline	Male	49	100.0	48	98.0	25.93	24.62	18.78	33.07
Week 4 (Day 29)	Male	49	100.0	45	91.8	19.75	24.26	12.46	27.04
Week 8 (Day 57)	Male	43	87.8	35	81.4	20.00	18.83	13.53	26.47
Week 12 (Day 85)	Male	35	71.4	32	91.4	20.49	14.42	15.29	25.69
Week 16 (Day 113)	Male	31	63.3	27	87.1	21.81	19.36	14.15	29.47
Week 20 (Day 141)	Male	26	53.1	23	88.5	17.39	15.65	10.62	24.16
Week 24 (Day 169)	Male	25	51.0	22	88.0	20.71	20.08	11.80	29.61
Week 28 (Day 197)	Male	25	51.0	24	96.0	20.37	19.57	12.11	28.63

Week 32 (Day 225)	Male	21	42.9	18	85.7	15.43	14.83	8.06	22.81
Week 36 (Day 253)	Male	19	38.8	15	78.9	16.30	17.75	6.47	26.13
Week 40 (Day 281)	Male	19	38.8	16	84.2	19.44	16.97	10.40	28.49
Week 44 (Day 309)	Male	16	32.7	14	87.5	19.05	17.66	8.85	29.25
Week 48 (Day 337)	Male	12	24.5	8	66.7	20.83	15.07	8.24	33.43
Week 52 (Day 365)	Male	10	20.4	3	30.0	40.74	23.13	-16.72	98.20
Week 56 (Day 393)	Male	10	20.4	5	50.0	26.67	12.67	10.94	42.40
Week 60 (Day 421)	Male	6	12.2	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Male	6	12.2	1	16.7	22.22	NE	NE	NE
Week 68 (Day 477)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	49	100.0	49	100.0	21.77	19.64	16.13	27.41
End of Study (LOCF)	Male	49	100.0	49	100.0	22.00	18.91	16.56	27.43
Age									
Baseline	< 65	63	100.0	60	95.2	35.19	27.69	28.03	42.34
Week 4 (Day 29)	< 65	63	100.0	55	87.3	23.64	24.29	17.07	30.20
Week 8 (Day 57)	< 65	54	85.7	47	87.0	23.64	21.56	17.31	29.97
Week 12 (Day 85)	< 65	47	74.6	42	89.4	26.46	21.39	19.79	33.12
Week 16 (Day 113)	< 65	39	61.9	34	87.2	25.00	24.01	16.62	33.38
Week 20 (Day 141)	< 65	35	55.6	35	100.0	27.62	22.77	19.80	35.44
Week 24 (Day 169)	< 65	34	54.0	31	91.2	26.52	23.25	18.00	35.05
Week 28 (Day 197)	< 65	33	52.4	32	97.0	26.04	17.98	19.56	32.53
Week 32 (Day 225)	< 65	30	47.6	25	83.3	22.67	18.00	15.24	30.10
Week 36 (Day 253)	< 65	25	39.7	20	80.0	22.22	21.02	12.38	32.06
Week 40 (Day 281)	< 65	23	36.5	21	91.3	24.87	20.16	15.69	34.04
Week 44 (Day 309)	< 65	19	30.2	17	89.5	30.07	28.54	15.39	44.74
Week 48 (Day 337)	< 65	14	22.2	7	50.0	34.92	26.00	10.87	58.97

Week 52 (Day 365)	< 65	12	19.0	2	16.7	61.11	7.86	-9.48	131.70
Week 56 (Day 393)	< 65	11	17.5	2	18.2	27.78	7.86	-42.81	98.37
Week 60 (Day 421)	< 65	8	12.7	1	12.5	66.67	NE	NE	NE
Week 64 (Day 449)	< 65	7	11.1	3	42.9	37.04	16.97	-5.12	79.20
Week 68 (Day 477)	< 65	4	6.3	1	25.0	66.67	NE	NE	NE
Week 72 (Day 505)	< 65	4	6.3	1	25.0	66.67	NE	NE	NE
Week 76 (Day 533)	< 65	4	6.3	1	25.0	55.56	NE	NE	NE
Week 80 (Day 561)	< 65	3	4.8	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	63	100.0	63	100.0	26.10	24.13	20.03	32.18
End of Study (LOCF)	< 65	63	100.0	63	100.0	25.93	22.58	20.24	31.61
Baseline	>= 65	45	100.0	44	97.8	30.05	29.60	21.05	39.05
Week 4 (Day 29)	>= 65	45	100.0	41	91.1	28.46	23.05	21.18	35.73
Week 8 (Day 57)	>= 65	38	84.4	32	84.2	30.21	22.97	21.93	38.49
Week 12 (Day 85)	>= 65	32	71.1	29	90.6	27.20	18.68	20.10	34.31
Week 16 (Day 113)	>= 65	30	66.7	24	80.0	25.00	18.32	17.27	32.73
Week 20 (Day 141)	>= 65	24	53.3	20	83.3	21.11	19.38	12.04	30.18
Week 24 (Day 169)	>= 65	22	48.9	18	81.8	23.46	23.15	11.95	34.97
Week 28 (Day 197)	>= 65	22	48.9	19	86.4	24.56	27.36	11.37	37.75
Week 32 (Day 225)	>= 65	18	40.0	16	88.9	22.92	18.80	12.90	32.93
Week 36 (Day 253)	>= 65	16	35.6	10	62.5	20.56	26.46	1.63	39.48
Week 40 (Day 281)	>= 65	14	31.1	11	78.6	23.23	18.89	10.54	35.92
Week 44 (Day 309)	>= 65	12	26.7	9	75.0	27.16	20.12	11.70	42.62
Week 48 (Day 337)	>= 65	9	20.0	5	55.6	24.44	14.49	6.46	42.43
Week 52 (Day 365)	>= 65	7	15.6	2	28.6	27.78	7.86	-42.81	98.37
Week 56 (Day 393)	>= 65	6	13.3	4	66.7	27.78	14.34	4.95	50.60
Week 60 (Day 421)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE

Week 76 (Day 533)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	45	100.0	45	100.0	27.90	22.67	21.09	34.71
End of Study (LOCF)	>= 65	45	100.0	45	100.0	28.64	22.53	21.87	35.41
ECOG performance status									
Baseline	0	30	100.0	29	96.7	29.50	30.47	17.91	41.09
Week 4 (Day 29)	0	30	100.0	29	96.7	23.75	19.86	16.20	31.31
Week 8 (Day 57)	0	28	93.3	25	89.3	32.00	29.28	19.91	44.09
Week 12 (Day 85)	0	26	86.7	24	92.3	26.85	19.91	18.45	35.26
Week 16 (Day 113)	0	26	86.7	21	80.8	25.40	20.83	15.92	34.88
Week 20 (Day 141)	0	26	86.7	24	92.3	27.78	20.72	19.03	36.53
Week 24 (Day 169)	0	25	83.3	23	92.0	28.02	25.49	17.00	39.04
Week 28 (Day 197)	0	25	83.3	23	92.0	24.64	18.34	16.71	32.57
Week 32 (Day 225)	0	20	66.7	16	80.0	20.83	20.24	10.05	31.62
Week 36 (Day 253)	0	18	60.0	11	61.1	22.22	26.29	4.56	39.89
Week 40 (Day 281)	0	16	53.3	11	68.8	28.28	24.02	12.15	44.42
Week 44 (Day 309)	0	15	50.0	12	80.0	29.63	33.95	8.06	51.20
Week 48 (Day 337)	0	9	30.0	6	66.7	24.07	29.33	-6.70	54.85
Week 52 (Day 365)	0	9	30.0	3	33.3	48.15	23.13	-9.31	105.61
Week 56 (Day 393)	0	8	26.7	3	37.5	18.52	6.42	2.58	34.45
Week 60 (Day 421)	0	5	16.7	1	20.0	66.67	NE	NE	NE
Week 64 (Day 449)	0	5	16.7	2	40.0	38.89	23.57	-172.88	250.66
Week 68 (Day 477)	0	3	10.0	1	33.3	66.67	NE	NE	NE
Week 72 (Day 505)	0	3	10.0	1	33.3	66.67	NE	NE	NE
Week 76 (Day 533)	0	3	10.0	1	33.3	55.56	NE	NE	NE
Week 80 (Day 561)	0	2	6.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	0	1	3.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	30	100.0	30	100.0	31.11	28.80	20.36	41.86
End of Study (LOCF)	0	30	100.0	30	100.0	29.63	25.49	20.11	39.15
Baseline	1	78	100.0	75	96.2	34.37	27.77	27.98	40.76
Week 4 (Day 29)	1	78	100.0	67	85.9	26.53	25.36	20.35	32.72

Week 8 (Day 57)	1	64	82.1	54	84.4	23.66	17.80	18.80	28.52
Week 12 (Day 85)	1	53	67.9	47	88.7	26.71	20.55	20.68	32.75
Week 16 (Day 113)	1	43	55.1	37	86.0	24.77	22.40	17.31	32.24
Week 20 (Day 141)	1	33	42.3	31	93.9	23.30	22.47	15.05	31.54
Week 24 (Day 169)	1	31	39.7	26	83.9	23.08	20.83	14.66	31.49
Week 28 (Day 197)	1	30	38.5	28	93.3	26.19	24.42	16.72	35.66
Week 32 (Day 225)	1	28	35.9	25	89.3	24.00	16.88	17.03	30.97
Week 36 (Day 253)	1	23	29.5	19	82.6	21.35	20.81	11.32	31.37
Week 40 (Day 281)	1	21	26.9	21	100.0	22.22	16.85	14.55	29.89
Week 44 (Day 309)	1	16	20.5	14	87.5	28.57	16.72	18.92	38.22
Week 48 (Day 337)	1	14	17.9	6	42.9	37.04	9.07	27.52	46.56
Week 52 (Day 365)	1	10	12.8	1	10.0	33.33	NE	NE	NE
Week 56 (Day 393)	1	9	11.5	3	33.3	37.04	6.42	21.10	52.97
Week 60 (Day 421)	1	6	7.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	5	6.4	1	20.0	33.33	NE	NE	NE
Week 68 (Day 477)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	3	3.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	78	100.0	78	100.0	25.21	21.01	20.48	29.95
End of Study (LOCF)	1	78	100.0	78	100.0	26.07	21.33	21.26	30.88
Geographic region									
Baseline	USA	21	100.0	19	90.5	25.73	26.20	13.10	38.36
Week 4 (Day 29)	USA	21	100.0	20	95.2	20.56	13.62	14.18	26.93
Week 8 (Day 57)	USA	21	100.0	19	90.5	25.73	17.78	17.16	34.30
Week 12 (Day 85)	USA	21	100.0	19	90.5	25.15	14.74	18.04	32.25
Week 16 (Day 113)	USA	21	100.0	16	76.2	22.57	12.90	15.69	29.45
Week 20 (Day 141)	USA	20	95.2	18	90.0	21.60	12.91	15.19	28.02
Week 24 (Day 169)	USA	20	95.2	19	95.0	18.71	13.38	12.26	25.16
Week 28 (Day 197)	USA	20	95.2	19	95.0	19.88	16.39	11.98	27.78
Week 32 (Day 225)	USA	17	81.0	15	88.2	22.96	15.97	14.12	31.81
Week 36 (Day 253)	USA	17	81.0	11	64.7	16.16	15.21	5.95	26.38
Week 40 (Day 281)	USA	15	71.4	12	80.0	19.44	15.80	9.40	29.48

Week 44 (Day 309)	USA	13	61.9	10	76.9	25.56	21.63	10.08	41.03
Week 48 (Day 337)	USA	8	38.1	5	62.5	20.00	14.49	2.01	37.99
Week 52 (Day 365)	USA	6	28.6	1	16.7	22.22	NE	NE	NE
Week 56 (Day 393)	USA	6	28.6	3	50.0	22.22	11.11	-5.38	49.82
Week 60 (Day 421)	USA	5	23.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	4	19.0	1	25.0	33.33	NE	NE	NE
Week 68 (Day 477)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	21	100.0	21	100.0	19.58	18.89	10.98	28.18
End of Study (LOCF)	USA	21	100.0	21	100.0	21.69	18.08	13.46	29.92
Baseline	Europe (EU)	42	100.0	40	95.2	40.00	30.17	30.35	49.65
Week 4 (Day 29)	Europe (EU)	42	100.0	39	92.9	28.49	25.34	20.28	36.70
Week 8 (Day 57)	Europe (EU)	36	85.7	30	83.3	31.48	23.90	22.56	40.41
Week 12 (Day 85)	Europe (EU)	31	73.8	25	80.6	32.89	25.56	22.34	43.44
Week 16 (Day 113)	Europe (EU)	30	71.4	24	80.0	33.80	27.31	22.26	45.33
Week 20 (Day 141)	Europe (EU)	26	61.9	24	92.3	32.41	27.40	20.84	43.98
Week 24 (Day 169)	Europe (EU)	26	61.9	22	84.6	35.35	28.82	22.58	48.13
Week 28 (Day 197)	Europe (EU)	25	59.5	23	92.0	34.30	24.60	23.66	44.94
Week 32 (Day 225)	Europe (EU)	21	50.0	19	90.5	23.98	18.62	15.00	32.95
Week 36 (Day 253)	Europe (EU)	16	38.1	13	81.3	31.20	28.47	13.99	48.40
Week 40 (Day 281)	Europe (EU)	14	33.3	14	100.0	32.54	21.99	19.84	45.24
Week 44 (Day 309)	Europe (EU)	11	26.2	10	90.9	38.89	31.97	16.02	61.76
Week 48 (Day 337)	Europe (EU)	8	19.0	6	75.0	38.89	26.06	11.54	66.23
Week 52 (Day 365)	Europe (EU)	6	14.3	3	50.0	51.85	16.97	9.69	94.01
Week 56 (Day 393)	Europe (EU)	6	14.3	2	33.3	27.78	7.86	-42.81	98.37

Week 60 (Day 421)	Europe (EU)	4	9.5	1	25.0	66.67	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	4	9.5	2	50.0	38.89	23.57	-172.88	250.66
Week 68 (Day 477)	Europe (EU)	3	7.1	1	33.3	66.67	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	3	7.1	1	33.3	66.67	NE	NE	NE
Week 76 (Day 533)	Europe (EU)	3	7.1	1	33.3	55.56	NE	NE	NE
Week 80 (Day 561)	Europe (EU)	2	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Europe (EU)	42	100.0	42	100.0	32.54	23.07	25.35	39.73
End of Study (LOCF)	Europe (EU)	42	100.0	42	100.0	31.75	21.19	25.14	38.35
Baseline	Asia (AS)	45	100.0	45	100.0	29.88	27.09	21.74	38.02
Week 4 (Day 29)	Asia (AS)	45	100.0	37	82.2	25.53	26.30	16.76	34.30
Week 8 (Day 57)	Asia (AS)	35	77.8	30	85.7	21.48	22.59	13.05	29.92
Week 12 (Day 85)	Asia (AS)	27	60.0	27	100.0	22.22	16.88	15.55	28.90
Week 16 (Day 113)	Asia (AS)	18	40.0	18	100.0	15.43	14.33	8.31	22.56
Week 20 (Day 141)	Asia (AS)	13	28.9	13	100.0	17.09	15.46	7.75	26.44
Week 24 (Day 169)	Asia (AS)	10	22.2	8	80.0	13.89	9.85	5.65	22.12
Week 28 (Day 197)	Asia (AS)	10	22.2	9	90.0	14.81	15.71	2.74	26.89
Week 32 (Day 225)	Asia (AS)	10	22.2	7	70.0	19.05	22.87	-2.11	40.20
Week 36 (Day 253)	Asia (AS)	8	17.8	6	75.0	11.11	9.94	0.68	21.54
Week 40 (Day 281)	Asia (AS)	8	17.8	6	75.0	14.81	13.46	0.69	28.94
Week 44 (Day 309)	Asia (AS)	7	15.6	6	85.7	18.52	15.18	2.59	34.45
Week 48 (Day 337)	Asia (AS)	7	15.6	1	14.3	33.33	NE	NE	NE
Week 52 (Day 365)	Asia (AS)	7	15.6	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Asia (AS)	5	11.1	1	20.0	44.44	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	45	100.0	45	100.0	24.94	24.86	17.47	32.41
End of Study (LOCF)	Asia (AS)	45	100.0	45	100.0	25.19	25.00	17.67	32.70

Race/ethnicity									
Baseline	Asian	48	100.0	48	100.0	30.32	27.48	22.34	38.30
Week 4 (Day 29)	Asian	48	100.0	40	83.3	24.72	25.60	16.54	32.91
Week 8 (Day 57)	Asian	38	79.2	31	81.6	22.22	22.59	13.94	30.51
Week 12 (Day 85)	Asian	30	62.5	30	100.0	22.96	17.49	16.43	29.49
Week 16 (Day 113)	Asian	21	43.8	21	100.0	16.40	15.16	9.50	23.30
Week 20 (Day 141)	Asian	16	33.3	15	93.8	17.78	15.02	9.46	26.10
Week 24 (Day 169)	Asian	13	27.1	11	84.6	16.16	12.54	7.74	24.58
Week 28 (Day 197)	Asian	13	27.1	12	92.3	18.52	19.15	6.35	30.68
Week 32 (Day 225)	Asian	12	25.0	9	75.0	18.52	21.52	1.98	35.06
Week 36 (Day 253)	Asian	10	20.8	8	80.0	12.50	12.51	2.04	22.96
Week 40 (Day 281)	Asian	10	20.8	8	80.0	15.28	14.47	3.18	27.38
Week 44 (Day 309)	Asian	9	18.8	8	88.9	18.06	15.64	4.98	31.13
Week 48 (Day 337)	Asian	9	18.8	2	22.2	16.67	23.57	-195.10	228.44
Week 52 (Day 365)	Asian	9	18.8	1	11.1	22.22	NE	NE	NE
Week 56 (Day 393)	Asian	7	14.6	2	28.6	27.78	23.57	-183.99	239.55
Week 60 (Day 421)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	48	100.0	48	100.0	24.77	24.39	17.69	31.85
End of Study (LOCF)	Asian	48	100.0	48	100.0	25.23	24.34	18.16	32.30
Baseline	Non-Asian	54	100.0	52	96.3	34.19	29.09	26.09	42.29
Week 4 (Day 29)	Non-Asian	54	100.0	50	92.6	24.00	22.15	17.71	30.29
Week 8 (Day 57)	Non-Asian	49	90.7	44	89.8	28.03	22.54	21.18	34.88
Week 12 (Day 85)	Non-Asian	44	81.5	37	84.1	28.23	21.85	20.94	35.51
Week 16 (Day 113)	Non-Asian	43	79.6	34	79.1	28.59	23.85	20.27	36.92
Week 20 (Day 141)	Non-Asian	38	70.4	35	92.1	26.67	23.83	18.48	34.85
Week 24 (Day 169)	Non-Asian	38	70.4	34	89.5	26.47	25.07	17.72	35.22
Week 28 (Day 197)	Non-Asian	37	68.5	35	94.6	25.71	22.35	18.04	33.39
Week 32 (Day 225)	Non-Asian	32	59.3	28	87.5	21.43	16.54	15.01	27.84
Week 36 (Day 253)	Non-Asian	27	50.0	20	74.1	20.56	20.48	10.97	30.14

Week 40 (Day 281)	Non-Asian	23	42.6	21	91.3	24.34	19.12	15.63	33.04
Week 44 (Day 309)	Non-Asian	18	33.3	14	77.8	28.57	23.35	15.09	42.06
Week 48 (Day 337)	Non-Asian	12	22.2	9	75.0	33.33	22.91	15.73	50.94
Week 52 (Day 365)	Non-Asian	8	14.8	3	37.5	51.85	16.97	9.69	94.01
Week 56 (Day 393)	Non-Asian	8	14.8	4	50.0	27.78	6.42	17.57	37.99
Week 60 (Day 421)	Non-Asian	7	13.0	1	14.3	66.67	NE	NE	NE
Week 64 (Day 449)	Non-Asian	6	11.1	2	33.3	27.78	7.86	-42.81	98.37
Week 68 (Day 477)	Non-Asian	3	5.6	1	33.3	66.67	NE	NE	NE
Week 72 (Day 505)	Non-Asian	3	5.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Non-Asian	3	5.6	1	33.3	55.56	NE	NE	NE
Week 80 (Day 561)	Non-Asian	2	3.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	54	100.0	54	100.0	26.13	20.72	20.48	31.79
End of Study (LOCF)	Non-Asian	54	100.0	54	100.0	26.54	20.41	20.97	32.11
Baseline	Unknown	6	100.0	4	66.7	50.00	33.33	-3.04	103.04
Week 4 (Day 29)	Unknown	6	100.0	6	100.0	46.30	16.36	29.13	63.46
Week 8 (Day 57)	Unknown	5	83.3	4	80.0	38.89	6.42	28.68	49.10
Week 12 (Day 85)	Unknown	5	83.3	4	80.0	41.67	18.98	11.47	71.86
Week 16 (Day 113)	Unknown	5	83.3	3	60.0	44.44	11.11	16.84	72.05
Week 20 (Day 141)	Unknown	5	83.3	5	100.0	37.78	16.85	16.85	58.70
Week 24 (Day 169)	Unknown	5	83.3	4	80.0	41.67	18.98	11.47	71.86
Week 28 (Day 197)	Unknown	5	83.3	4	80.0	44.44	12.83	24.03	64.86
Week 32 (Day 225)	Unknown	4	66.7	4	100.0	41.67	10.64	24.74	58.59
Week 36 (Day 253)	Unknown	4	66.7	2	50.0	69.44	19.64	-107.03	245.92
Week 40 (Day 281)	Unknown	4	66.7	3	75.0	48.15	16.97	5.99	90.31
Week 44 (Day 309)	Unknown	4	66.7	4	100.0	52.78	37.82	-7.40	112.95
Week 48 (Day 337)	Unknown	2	33.3	1	50.0	33.33	NE	NE	NE
Week 52 (Day 365)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 60 (Day 421)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE

Week 64 (Day 449)	Unknown	1	16.7	1	100.0	55.56	NE	NE	NE
Week 68 (Day 477)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	1	16.7	1	100.0	66.67	NE	NE	NE
Week 76 (Day 533)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	6	100.0	6	100.0	50.00	30.43	18.07	81.93
End of Study (LOCF)	Unknown	6	100.0	6	100.0	46.30	19.14	26.21	66.38

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TN_QSC30FA_SG.xls
27OCT2021 7:37

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Fatigue
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	44	42.3	33.3	51.9
	Cycle 12 (LOCF)	n/a	104	96.3	26	25.0	17.7	34.1
	End of Study (LOCF)	n/a	104	96.3	27	26.0	18.5	35.1
Sex	All visits	Female	56	51.9	23	41.1	29.2	54.1
		Male	48	44.4	21	43.8	30.7	57.7
	Cycle 12 (LOCF)	Female	56	51.9	12	21.4	12.7	33.8
		Male	48	44.4	14	29.2	18.2	43.2
	End of Study (LOCF)	Female	56	51.9	12	21.4	12.7	33.8
		Male	48	44.4	15	31.3	19.9	45.3
Age	All visits	< 65	60	55.6	20	33.3	22.7	45.9
		>= 65	44	40.7	24	54.5	40.1	68.3
	Cycle 12 (LOCF)	< 65	60	55.6	11	18.3	10.6	29.9
		>= 65	44	40.7	15	34.1	21.9	48.9
	End of Study (LOCF)	< 65	60	55.6	10	16.7	9.3	28.0
		>= 65	44	40.7	17	38.6	25.7	53.4
ECOG performance status	All visits	0	29	26.9	20	69.0	50.8	82.7
		1	75	69.4	24	32.0	22.5	43.2
	Cycle 12 (LOCF)	0	29	26.9	11	37.9	22.7	56.0
		1	75	69.4	15	20.0	12.5	30.4
	End of Study (LOCF)	0	29	26.9	11	37.9	22.7	56.0
		1	75	69.4	16	21.3	13.6	31.9
Geographic region	All visits	USA	19	17.6	13	68.4	46.0	84.6
		Europe (EU)	40	37.0	19	47.5	32.9	62.5
		Asia (AS)	45	41.7	12	26.7	16.0	41.0
	Cycle 12 (LOCF)	USA	19	17.6	6	31.6	15.4	54.0
		Europe (EU)	40	37.0	12	30.0	18.1	45.4
		Asia (AS)	45	41.7	8	17.8	9.3	31.3
	End of Study (LOCF)	USA	19	17.6	7	36.8	19.1	59.0
		Europe (EU)	40	37.0	11	27.5	16.1	42.8
		Asia (AS)	45	41.7	9	20.0	10.9	33.8
Race/ethnicity	All visits	Asian	48	44.4	13	27.1	16.6	41.0
		Non-Asian	52	48.1	28	53.8	40.5	66.7
		Unknown	4	3.7	3	75.0	30.1	95.4
	Cycle 12 (LOCF)	Asian	48	44.4	8	16.7	8.7	29.6
		Non-Asian	52	48.1	17	32.7	21.5	46.2
		Unknown	4	3.7	1	25.0	4.6	69.9
	End of Study (LOCF)	Asian	48	44.4	10	20.8	11.7	34.3

		Non-Asian	52	48.1	16	30.8	19.9	44.3
		Unknown	4	3.7	1	25.0	4.6	69.9

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30FA_W10_SG.xls
15OCT2021 13:13

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Fatigue
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

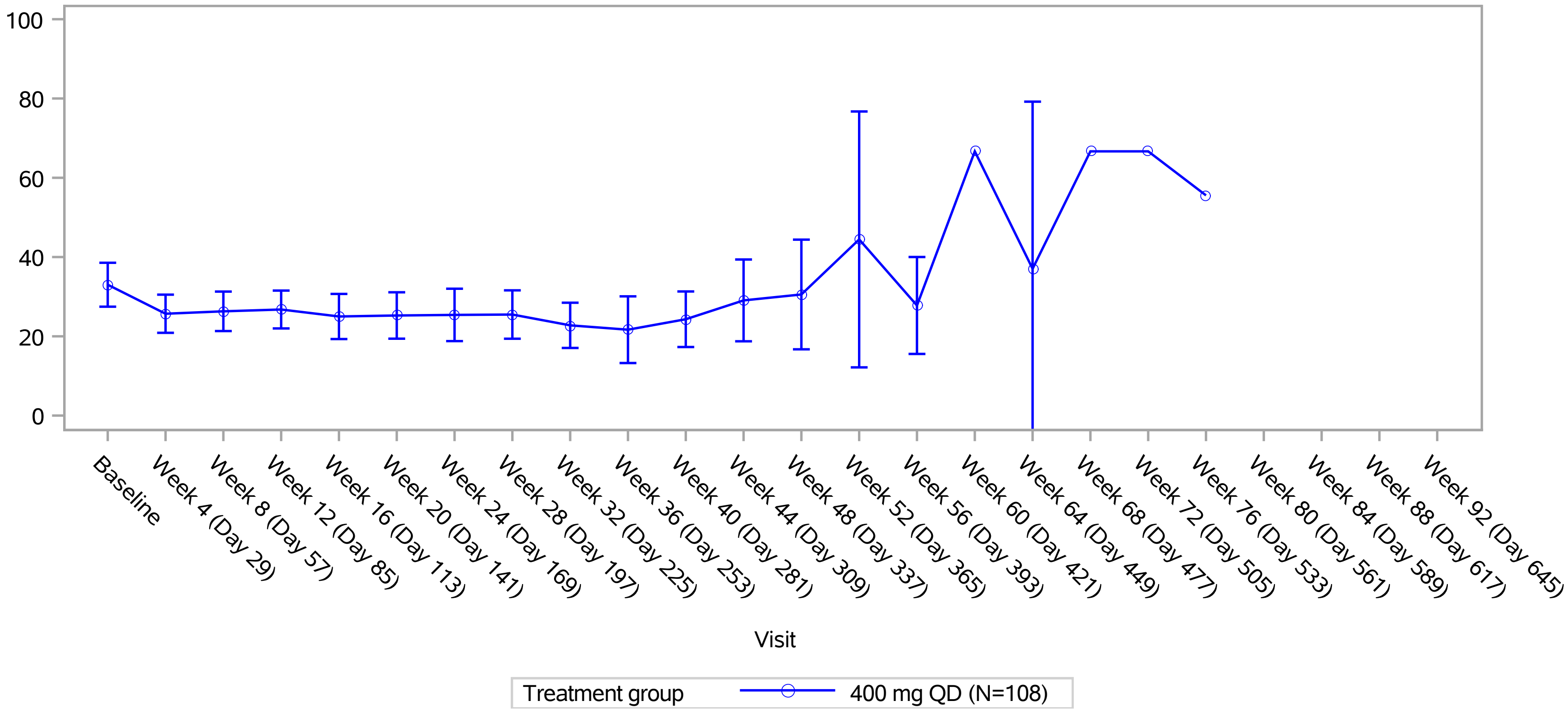
			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	30	28.8	21.0	38.2
	Cycle 12 (LOCF)	n/a	104	96.3	16	15.4	9.7	23.5
	End of Study (LOCF)	n/a	104	96.3	15	14.4	8.9	22.4
Sex	All visits	Female	56	51.9	17	30.4	19.9	43.3
		Male	48	44.4	13	27.1	16.6	41.0
	Cycle 12 (LOCF)	Female	56	51.9	8	14.3	7.4	25.7
		Male	48	44.4	8	16.7	8.7	29.6
	End of Study (LOCF)	Female	56	51.9	8	14.3	7.4	25.7
		Male	48	44.4	7	14.6	7.2	27.2
Age	All visits	< 65	60	55.6	13	21.7	13.1	33.6
		>= 65	44	40.7	17	38.6	25.7	53.4
	Cycle 12 (LOCF)	< 65	60	55.6	7	11.7	5.8	22.2
		>= 65	44	40.7	9	20.5	11.2	34.5
	End of Study (LOCF)	< 65	60	55.6	6	10.0	4.7	20.1
		>= 65	44	40.7	9	20.5	11.2	34.5
ECOG performance status	All visits	0	29	26.9	13	44.8	28.4	62.5
		1	75	69.4	17	22.7	14.7	33.3
	Cycle 12 (LOCF)	0	29	26.9	10	34.5	19.9	52.7
		1	75	69.4	6	8.0	3.7	16.4
	End of Study (LOCF)	0	29	26.9	9	31.0	17.3	49.2
		1	75	69.4	6	8.0	3.7	16.4
Geographic region	All visits	USA	19	17.6	8	42.1	23.1	63.7
		Europe (EU)	40	37.0	14	35.0	22.1	50.5
		Asia (AS)	45	41.7	8	17.8	9.3	31.3
	Cycle 12 (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	9	22.5	12.3	37.5
		Asia (AS)	45	41.7	4	8.9	3.5	20.7
	End of Study (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	8	20.0	10.5	34.8
		Asia (AS)	45	41.7	4	8.9	3.5	20.7
Race/ethnicity	All visits	Asian	48	44.4	9	18.8	10.2	31.9
		Non-Asian	52	48.1	20	38.5	26.5	52.0
		Unknown	4	3.7	1	25.0	4.6	69.9
	Cycle 12 (LOCF)	Asian	48	44.4	4	8.3	3.3	19.6
		Non-Asian	52	48.1	12	23.1	13.7	36.1
		Unknown	4	3.7	0	0.0	0.0	49.0
	End of Study (LOCF)	Asian	48	44.4	4	8.3	3.3	19.6

		Non-Asian	52	48.1	11	21.2	12.2	34.0
		Unknown	4	3.7	0	0.0	0.0	49.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30FA_W15_SG.xls
15OCT2021 13:03

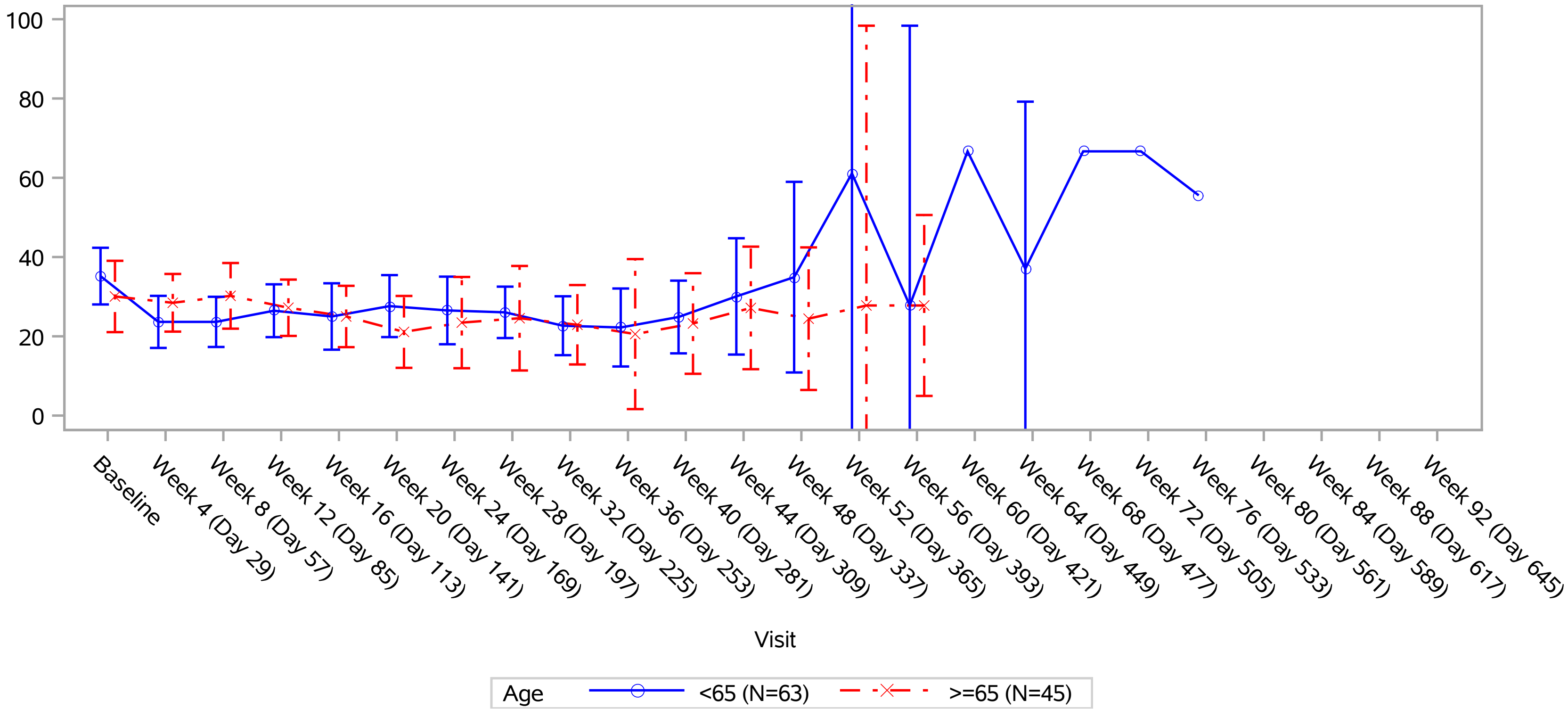
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Fatigue
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30FA.pdf
15OCT2021 17:26

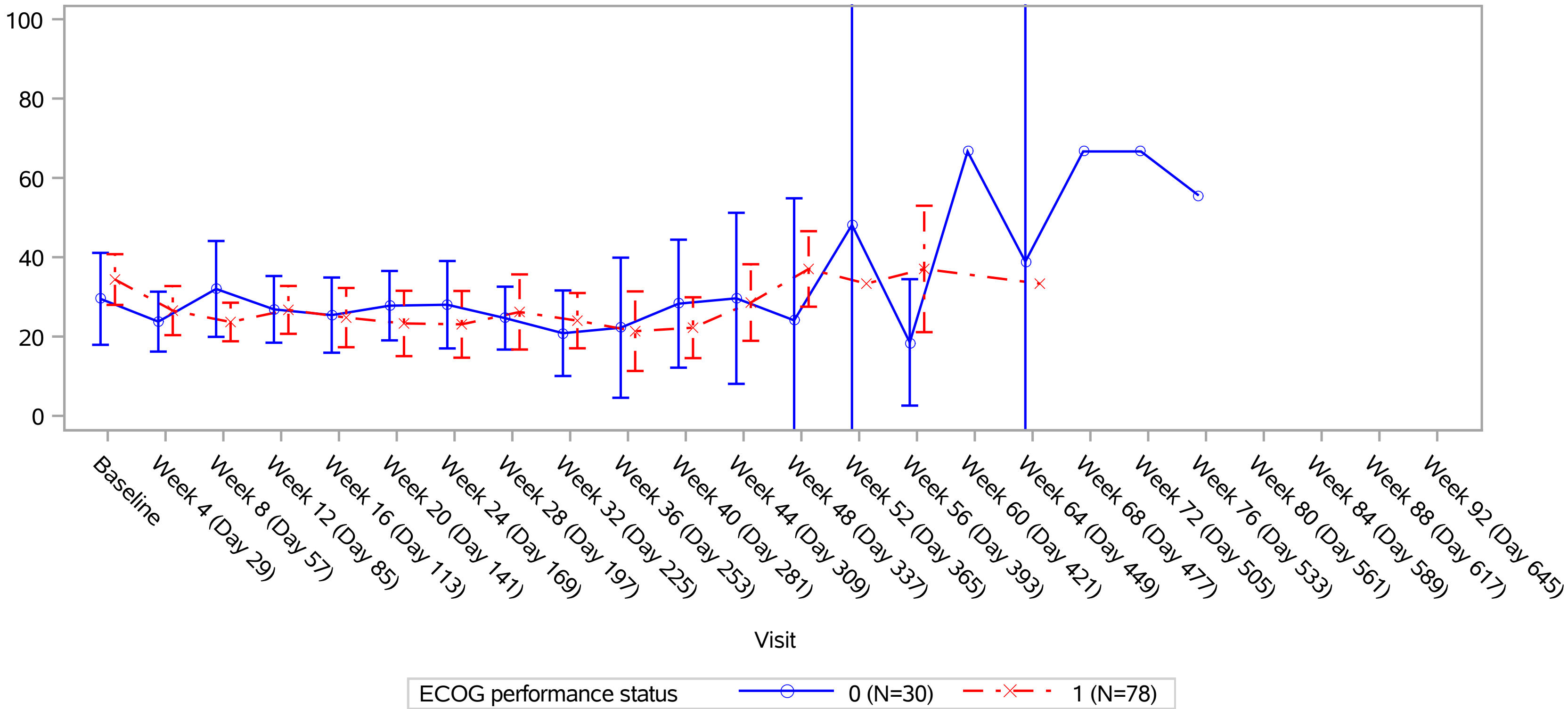
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Fatigue
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30FA_SGAGE65.pdf
15OCT2021 17:55

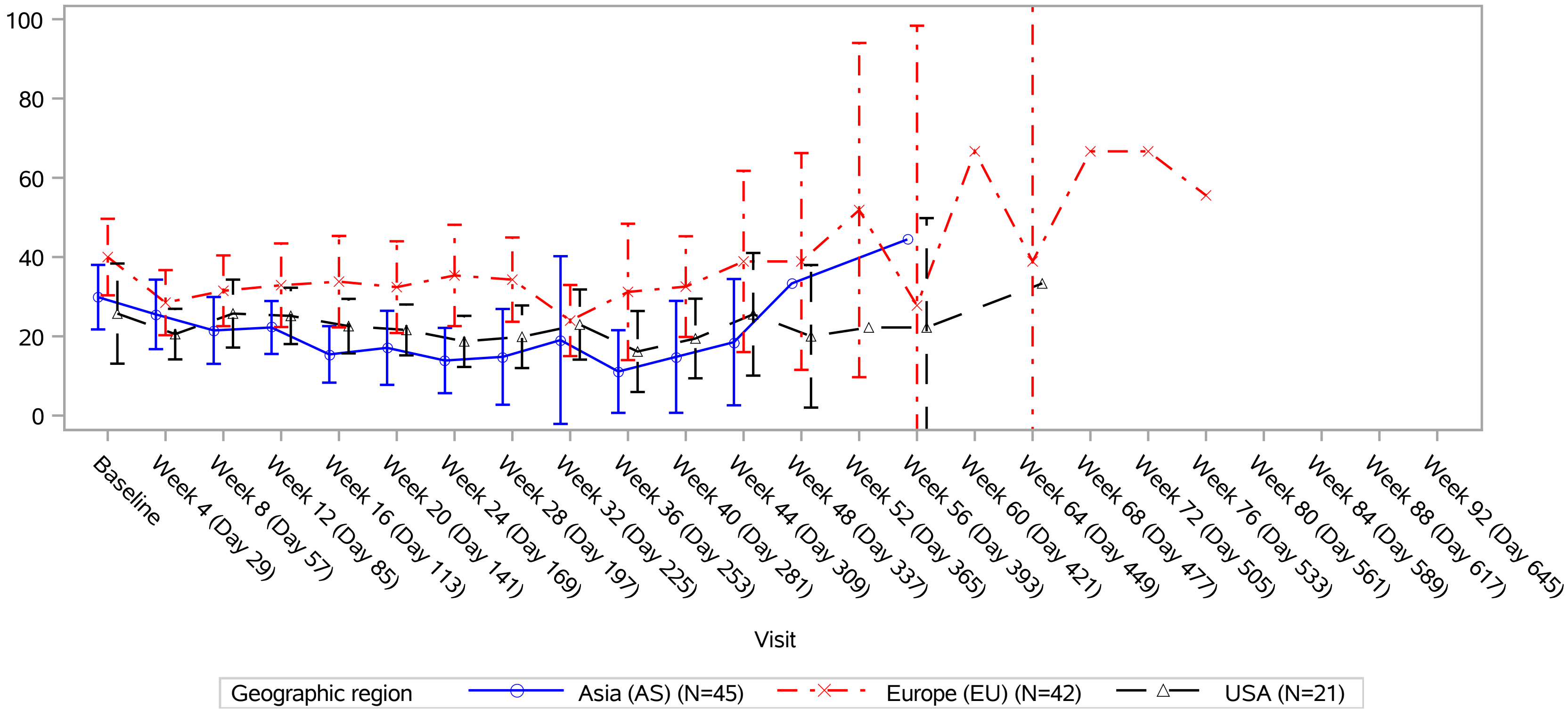
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Fatigue
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30FA_SGECOG.pdf
15OCT2021 18:26

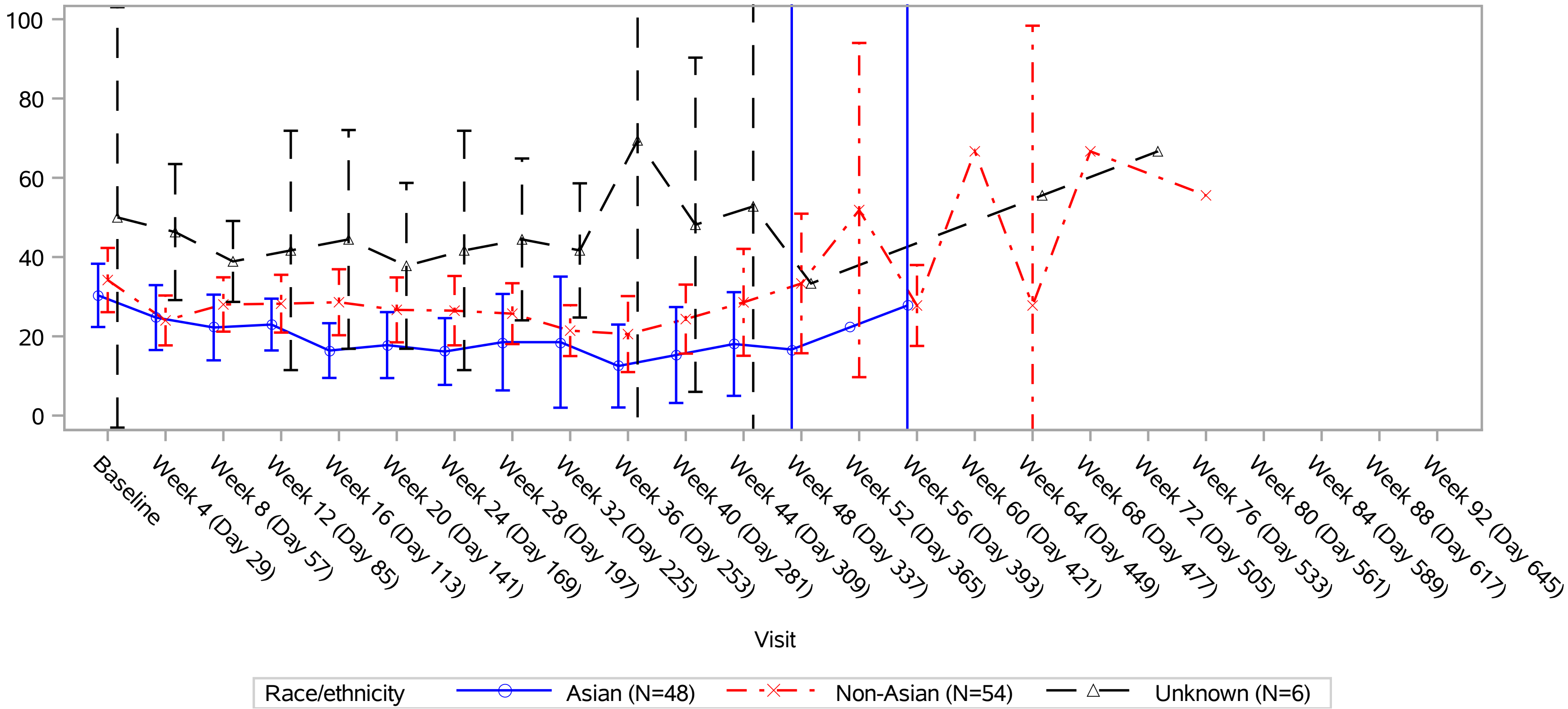
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Fatigue
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30FA_SGGEO.pdf
15OCT2021 18:56

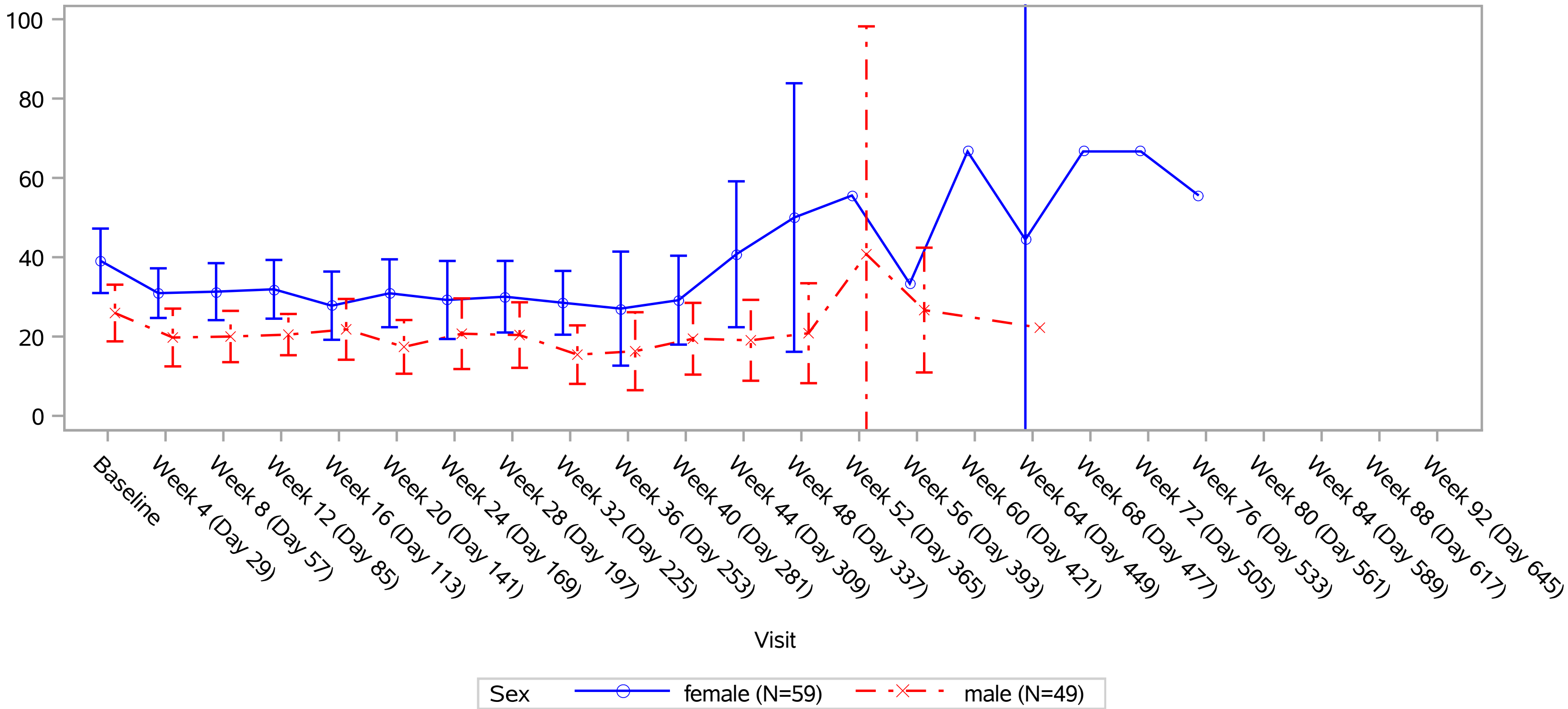
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Fatigue
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30FA_SGRE.pdf
15OCT2021 19:27

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Fatigue
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30FA_SGSEX.pdf
15OCT2021 19:57

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Nausea and vomiting
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=108)							
		Patients				Statistics			
Name Visit	Level	in study¹	%	with value¹	%	mean²	SD	CI LL	CI UL
All									
Baseline	n/a	108	100.0	104	96.3	8.97	18.71	5.34	12.61
Week 4 (Day 29)	n/a	108	100.0	96	88.9	2.08	6.51	0.76	3.40
Week 8 (Day 57)	n/a	92	85.2	79	85.9	3.16	7.10	1.57	4.75
Week 12 (Day 85)	n/a	79	73.1	71	89.9	2.82	8.90	0.71	4.92
Week 16 (Day 113)	n/a	69	63.9	58	84.1	2.59	9.26	0.15	5.02
Week 20 (Day 141)	n/a	59	54.6	55	93.2	3.03	7.92	0.89	5.17
Week 24 (Day 169)	n/a	56	51.9	49	87.5	2.38	6.80	0.43	4.34
Week 28 (Day 197)	n/a	55	50.9	51	92.7	3.59	11.21	0.44	6.75
Week 32 (Day 225)	n/a	48	44.4	41	85.4	5.28	13.66	0.97	9.60
Week 36 (Day 253)	n/a	41	38.0	30	73.2	1.67	5.09	-0.23	3.57
Week 40 (Day 281)	n/a	37	34.3	32	86.5	2.60	9.57	-0.85	6.05
Week 44 (Day 309)	n/a	31	28.7	26	83.9	4.49	12.96	-0.75	9.72
Week 48 (Day 337)	n/a	23	21.3	12	52.2	0.00	0.00	NE	NE
Week 52 (Day 365)	n/a	19	17.6	4	21.1	0.00	0.00	NE	NE
Week 56 (Day 393)	n/a	17	15.7	6	35.3	0.00	0.00	NE	NE
Week 60 (Day 421)	n/a	11	10.2	1	9.1	0.00	NE	NE	NE
Week 64 (Day 449)	n/a	10	9.3	3	30.0	0.00	0.00	NE	NE
Week 68 (Day 477)	n/a	6	5.6	1	16.7	0.00	NE	NE	NE
Week 72 (Day 505)	n/a	6	5.6	1	16.7	0.00	NE	NE	NE
Week 76 (Day 533)	n/a	6	5.6	1	16.7	0.00	NE	NE	NE
Week 80 (Day 561)	n/a	5	4.6	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	n/a	1	0.9	0	0.0	NE	NE	NE	NE

Cycle 12 (LOCF)	n/a	108	100.0	108	100.0	3.86	11.07	1.75	5.97
End of Study (LOCF)	n/a	108	100.0	108	100.0	3.55	10.70	1.51	5.59
Sex									
Baseline	Female	59	100.0	56	94.9	12.20	23.46	5.92	18.49
Week 4 (Day 29)	Female	59	100.0	51	86.4	2.94	7.96	0.70	5.18
Week 8 (Day 57)	Female	49	83.1	44	89.8	3.79	7.93	1.38	6.20
Week 12 (Day 85)	Female	44	74.6	39	88.6	3.85	10.44	0.46	7.23
Week 16 (Day 113)	Female	38	64.4	31	81.6	3.76	11.15	-0.33	7.85
Week 20 (Day 141)	Female	33	55.9	32	97.0	4.69	9.69	1.20	8.18
Week 24 (Day 169)	Female	31	52.5	27	87.1	4.32	8.76	0.86	7.79
Week 28 (Day 197)	Female	30	50.8	27	90.0	5.56	14.62	-0.23	11.34
Week 32 (Day 225)	Female	27	45.8	23	85.2	6.52	15.68	-0.26	13.30
Week 36 (Day 253)	Female	22	37.3	15	68.2	2.22	5.86	-1.03	5.47
Week 40 (Day 281)	Female	18	30.5	16	88.9	4.17	12.91	-2.71	11.05
Week 44 (Day 309)	Female	15	25.4	12	80.0	9.72	18.06	-1.75	21.20
Week 48 (Day 337)	Female	11	18.6	4	36.4	0.00	0.00	NE	NE
Week 52 (Day 365)	Female	9	15.3	1	11.1	0.00	NE	NE	NE
Week 56 (Day 393)	Female	7	11.9	1	14.3	0.00	NE	NE	NE
Week 60 (Day 421)	Female	5	8.5	1	20.0	0.00	NE	NE	NE
Week 64 (Day 449)	Female	4	6.8	2	50.0	0.00	0.00	NE	NE
Week 68 (Day 477)	Female	3	5.1	1	33.3	0.00	NE	NE	NE
Week 72 (Day 505)	Female	3	5.1	1	33.3	0.00	NE	NE	NE
Week 76 (Day 533)	Female	3	5.1	1	33.3	0.00	NE	NE	NE
Week 80 (Day 561)	Female	2	3.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	59	100.0	59	100.0	5.08	13.58	1.55	8.62
End of Study (LOCF)	Female	59	100.0	59	100.0	4.52	13.07	1.11	7.93
Baseline	Male	49	100.0	48	98.0	5.21	9.82	2.36	8.06
Week 4 (Day 29)	Male	49	100.0	45	91.8	1.11	4.20	-0.15	2.37
Week 8 (Day 57)	Male	43	87.8	35	81.4	2.38	5.92	0.35	4.41
Week 12 (Day 85)	Male	35	71.4	32	91.4	1.56	6.50	-0.78	3.91
Week 16 (Day 113)	Male	31	63.3	27	87.1	1.23	6.42	-1.30	3.77
Week 20 (Day 141)	Male	26	53.1	23	88.5	0.72	3.48	-0.78	2.23
Week 24 (Day 169)	Male	25	51.0	22	88.0	0.00	0.00	NE	NE
Week 28 (Day 197)	Male	25	51.0	24	96.0	1.39	4.71	-0.60	3.38

Week 32 (Day 225)	Male	21	42.9	18	85.7	3.70	10.78	-1.66	9.06
Week 36 (Day 253)	Male	19	38.8	15	78.9	1.11	4.30	-1.27	3.49
Week 40 (Day 281)	Male	19	38.8	16	84.2	1.04	4.17	-1.18	3.26
Week 44 (Day 309)	Male	16	32.7	14	87.5	0.00	0.00	NE	NE
Week 48 (Day 337)	Male	12	24.5	8	66.7	0.00	0.00	NE	NE
Week 52 (Day 365)	Male	10	20.4	3	30.0	0.00	0.00	NE	NE
Week 56 (Day 393)	Male	10	20.4	5	50.0	0.00	0.00	NE	NE
Week 60 (Day 421)	Male	6	12.2	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Male	6	12.2	1	16.7	0.00	NE	NE	NE
Week 68 (Day 477)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	49	100.0	49	100.0	2.38	6.80	0.43	4.34
End of Study (LOCF)	Male	49	100.0	49	100.0	2.38	6.80	0.43	4.34
Age									
Baseline	< 65	63	100.0	60	95.2	10.00	19.21	5.04	14.96
Week 4 (Day 29)	< 65	63	100.0	55	87.3	2.73	7.70	0.65	4.81
Week 8 (Day 57)	< 65	54	85.7	47	87.0	3.55	7.72	1.28	5.81
Week 12 (Day 85)	< 65	47	74.6	42	89.4	3.17	9.19	0.31	6.04
Week 16 (Day 113)	< 65	39	61.9	34	87.2	2.94	10.44	-0.70	6.58
Week 20 (Day 141)	< 65	35	55.6	35	100.0	3.81	9.12	0.68	6.94
Week 24 (Day 169)	< 65	34	54.0	31	91.2	2.69	7.57	-0.09	5.47
Week 28 (Day 197)	< 65	33	52.4	32	97.0	4.69	13.54	-0.20	9.57
Week 32 (Day 225)	< 65	30	47.6	25	83.3	4.67	10.23	0.44	8.89
Week 36 (Day 253)	< 65	25	39.7	20	80.0	1.67	5.13	-0.73	4.07
Week 40 (Day 281)	< 65	23	36.5	21	91.3	3.17	11.33	-1.98	8.33
Week 44 (Day 309)	< 65	19	30.2	17	89.5	6.86	15.66	-1.19	14.91
Week 48 (Day 337)	< 65	14	22.2	7	50.0	0.00	0.00	NE	NE

Week 52 (Day 365)	< 65	12	19.0	2	16.7	0.00	0.00	NE	NE
Week 56 (Day 393)	< 65	11	17.5	2	18.2	0.00	0.00	NE	NE
Week 60 (Day 421)	< 65	8	12.7	1	12.5	0.00	NE	NE	NE
Week 64 (Day 449)	< 65	7	11.1	3	42.9	0.00	0.00	NE	NE
Week 68 (Day 477)	< 65	4	6.3	1	25.0	0.00	NE	NE	NE
Week 72 (Day 505)	< 65	4	6.3	1	25.0	0.00	NE	NE	NE
Week 76 (Day 533)	< 65	4	6.3	1	25.0	0.00	NE	NE	NE
Week 80 (Day 561)	< 65	3	4.8	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	63	100.0	63	100.0	4.50	10.88	1.76	7.24
End of Study (LOCF)	< 65	63	100.0	63	100.0	3.97	10.25	1.39	6.55
Baseline	>= 65	45	100.0	44	97.8	7.58	18.13	2.06	13.09
Week 4 (Day 29)	>= 65	45	100.0	41	91.1	1.22	4.39	-0.17	2.61
Week 8 (Day 57)	>= 65	38	84.4	32	84.2	2.60	6.15	0.39	4.82
Week 12 (Day 85)	>= 65	32	71.1	29	90.6	2.30	8.60	-0.97	5.57
Week 16 (Day 113)	>= 65	30	66.7	24	80.0	2.08	7.47	-1.07	5.24
Week 20 (Day 141)	>= 65	24	53.3	20	83.3	1.67	5.13	-0.73	4.07
Week 24 (Day 169)	>= 65	22	48.9	18	81.8	1.85	5.39	-0.83	4.53
Week 28 (Day 197)	>= 65	22	48.9	19	86.4	1.75	5.26	-0.78	4.29
Week 32 (Day 225)	>= 65	18	40.0	16	88.9	6.25	18.13	-3.41	15.91
Week 36 (Day 253)	>= 65	16	35.6	10	62.5	1.67	5.27	-2.10	5.44
Week 40 (Day 281)	>= 65	14	31.1	11	78.6	1.52	5.03	-1.86	4.89
Week 44 (Day 309)	>= 65	12	26.7	9	75.0	0.00	0.00	NE	NE
Week 48 (Day 337)	>= 65	9	20.0	5	55.6	0.00	0.00	NE	NE
Week 52 (Day 365)	>= 65	7	15.6	2	28.6	0.00	0.00	NE	NE
Week 56 (Day 393)	>= 65	6	13.3	4	66.7	0.00	0.00	NE	NE
Week 60 (Day 421)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE

Week 76 (Day 533)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	45	100.0	45	100.0	2.96	11.40	-0.46	6.39
End of Study (LOCF)	>= 65	45	100.0	45	100.0	2.96	11.40	-0.46	6.39
ECOG performance status									
Baseline	0	30	100.0	29	96.7	7.47	16.42	1.23	13.72
Week 4 (Day 29)	0	30	100.0	29	96.7	2.87	7.80	-0.09	5.84
Week 8 (Day 57)	0	28	93.3	25	89.3	3.33	6.80	0.52	6.14
Week 12 (Day 85)	0	26	86.7	24	92.3	2.78	8.03	-0.61	6.17
Week 16 (Day 113)	0	26	86.7	21	80.8	1.59	5.01	-0.69	3.87
Week 20 (Day 141)	0	26	86.7	24	92.3	0.69	3.40	-0.74	2.13
Week 24 (Day 169)	0	25	83.3	23	92.0	0.72	3.48	-0.78	2.23
Week 28 (Day 197)	0	25	83.3	23	92.0	0.72	3.48	-0.78	2.23
Week 32 (Day 225)	0	20	66.7	16	80.0	3.13	9.07	-1.71	7.96
Week 36 (Day 253)	0	18	60.0	11	61.1	0.00	0.00	NE	NE
Week 40 (Day 281)	0	16	53.3	11	68.8	0.00	0.00	NE	NE
Week 44 (Day 309)	0	15	50.0	12	80.0	5.56	12.97	-2.69	13.80
Week 48 (Day 337)	0	9	30.0	6	66.7	0.00	0.00	NE	NE
Week 52 (Day 365)	0	9	30.0	3	33.3	0.00	0.00	NE	NE
Week 56 (Day 393)	0	8	26.7	3	37.5	0.00	0.00	NE	NE
Week 60 (Day 421)	0	5	16.7	1	20.0	0.00	NE	NE	NE
Week 64 (Day 449)	0	5	16.7	2	40.0	0.00	0.00	NE	NE
Week 68 (Day 477)	0	3	10.0	1	33.3	0.00	NE	NE	NE
Week 72 (Day 505)	0	3	10.0	1	33.3	0.00	NE	NE	NE
Week 76 (Day 533)	0	3	10.0	1	33.3	0.00	NE	NE	NE
Week 80 (Day 561)	0	2	6.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	0	1	3.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	30	100.0	30	100.0	3.89	10.43	-0.01	7.79
End of Study (LOCF)	0	30	100.0	30	100.0	2.78	8.84	-0.52	6.08
Baseline	1	78	100.0	75	96.2	9.56	19.60	5.05	14.07
Week 4 (Day 29)	1	78	100.0	67	85.9	1.74	5.90	0.30	3.18

Week 8 (Day 57)	1	64	82.1	54	84.4	3.09	7.29	1.10	5.08
Week 12 (Day 85)	1	53	67.9	47	88.7	2.84	9.40	0.08	5.60
Week 16 (Day 113)	1	43	55.1	37	86.0	3.15	11.00	-0.51	6.82
Week 20 (Day 141)	1	33	42.3	31	93.9	4.84	9.81	1.24	8.44
Week 24 (Day 169)	1	31	39.7	26	83.9	3.85	8.57	0.38	7.31
Week 28 (Day 197)	1	30	38.5	28	93.3	5.95	14.50	0.33	11.57
Week 32 (Day 225)	1	28	35.9	25	89.3	6.67	15.96	0.08	13.25
Week 36 (Day 253)	1	23	29.5	19	82.6	2.63	6.24	-0.38	5.64
Week 40 (Day 281)	1	21	26.9	21	100.0	3.97	11.67	-1.34	9.28
Week 44 (Day 309)	1	16	20.5	14	87.5	3.57	13.36	-4.14	11.29
Week 48 (Day 337)	1	14	17.9	6	42.9	0.00	0.00	NE	NE
Week 52 (Day 365)	1	10	12.8	1	10.0	0.00	NE	NE	NE
Week 56 (Day 393)	1	9	11.5	3	33.3	0.00	0.00	NE	NE
Week 60 (Day 421)	1	6	7.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	5	6.4	1	20.0	0.00	NE	NE	NE
Week 68 (Day 477)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	3	3.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	78	100.0	78	100.0	3.85	11.37	1.28	6.41
End of Study (LOCF)	1	78	100.0	78	100.0	3.85	11.37	1.28	6.41
Geographic region									
Baseline	USA	21	100.0	19	90.5	6.14	12.68	0.03	12.25
Week 4 (Day 29)	USA	21	100.0	20	95.2	1.67	5.13	-0.73	4.07
Week 8 (Day 57)	USA	21	100.0	19	90.5	6.14	9.95	1.34	10.94
Week 12 (Day 85)	USA	21	100.0	19	90.5	6.14	12.68	0.03	12.25
Week 16 (Day 113)	USA	21	100.0	16	76.2	6.25	14.75	-1.61	14.11
Week 20 (Day 141)	USA	20	95.2	18	90.0	4.63	9.58	-0.13	9.39
Week 24 (Day 169)	USA	20	95.2	19	95.0	1.75	5.26	-0.78	4.29
Week 28 (Day 197)	USA	20	95.2	19	95.0	1.75	5.26	-0.78	4.29
Week 32 (Day 225)	USA	17	81.0	15	88.2	5.56	10.29	-0.14	11.25
Week 36 (Day 253)	USA	17	81.0	11	64.7	4.55	7.78	-0.68	9.78
Week 40 (Day 281)	USA	15	71.4	12	80.0	2.78	6.49	-1.34	6.90

Week 44 (Day 309)	USA	13	61.9	10	76.9	3.33	10.54	-4.21	10.87
Week 48 (Day 337)	USA	8	38.1	5	62.5	0.00	0.00	NE	NE
Week 52 (Day 365)	USA	6	28.6	1	16.7	0.00	NE	NE	NE
Week 56 (Day 393)	USA	6	28.6	3	50.0	0.00	0.00	NE	NE
Week 60 (Day 421)	USA	5	23.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	4	19.0	1	25.0	0.00	NE	NE	NE
Week 68 (Day 477)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	21	100.0	21	100.0	1.59	7.27	-1.72	4.90
End of Study (LOCF)	USA	21	100.0	21	100.0	1.59	7.27	-1.72	4.90
Baseline	Europe (EU)	42	100.0	40	95.2	10.42	20.56	3.84	16.99
Week 4 (Day 29)	Europe (EU)	42	100.0	39	92.9	0.85	3.72	-0.35	2.06
Week 8 (Day 57)	Europe (EU)	36	85.7	30	83.3	0.56	3.04	-0.58	1.69
Week 12 (Day 85)	Europe (EU)	31	73.8	25	80.6	2.00	7.33	-1.02	5.02
Week 16 (Day 113)	Europe (EU)	30	71.4	24	80.0	2.08	7.47	-1.07	5.24
Week 20 (Day 141)	Europe (EU)	26	61.9	24	92.3	2.78	8.03	-0.61	6.17
Week 24 (Day 169)	Europe (EU)	26	61.9	22	84.6	2.27	5.85	-0.32	4.87
Week 28 (Day 197)	Europe (EU)	25	59.5	23	92.0	2.17	5.74	-0.31	4.66
Week 32 (Day 225)	Europe (EU)	21	50.0	19	90.5	1.75	7.65	-1.93	5.44
Week 36 (Day 253)	Europe (EU)	16	38.1	13	81.3	0.00	0.00	NE	NE
Week 40 (Day 281)	Europe (EU)	14	33.3	14	100.0	0.00	0.00	NE	NE
Week 44 (Day 309)	Europe (EU)	11	26.2	10	90.9	3.33	10.54	-4.21	10.87
Week 48 (Day 337)	Europe (EU)	8	19.0	6	75.0	0.00	0.00	NE	NE
Week 52 (Day 365)	Europe (EU)	6	14.3	3	50.0	0.00	0.00	NE	NE
Week 56 (Day 393)	Europe (EU)	6	14.3	2	33.3	0.00	0.00	NE	NE

Week 60 (Day 421)	Europe (EU)	4	9.5	1	25.0	0.00	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	4	9.5	2	50.0	0.00	0.00	NE	NE
Week 68 (Day 477)	Europe (EU)	3	7.1	1	33.3	0.00	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	3	7.1	1	33.3	0.00	NE	NE	NE
Week 76 (Day 533)	Europe (EU)	3	7.1	1	33.3	0.00	NE	NE	NE
Week 80 (Day 561)	Europe (EU)	2	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Europe (EU)	42	100.0	42	100.0	3.17	8.42	0.55	5.80
End of Study (LOCF)	Europe (EU)	42	100.0	42	100.0	2.38	6.96	0.21	4.55
Baseline	Asia (AS)	45	100.0	45	100.0	8.89	19.33	3.08	14.70
Week 4 (Day 29)	Asia (AS)	45	100.0	37	82.2	3.60	8.90	0.64	6.57
Week 8 (Day 57)	Asia (AS)	35	77.8	30	85.7	3.89	7.17	1.21	6.57
Week 12 (Day 85)	Asia (AS)	27	60.0	27	100.0	1.23	6.42	-1.30	3.77
Week 16 (Day 113)	Asia (AS)	18	40.0	18	100.0	0.00	0.00	NE	NE
Week 20 (Day 141)	Asia (AS)	13	28.9	13	100.0	1.28	4.62	-1.51	4.08
Week 24 (Day 169)	Asia (AS)	10	22.2	8	80.0	4.17	11.79	-5.69	14.02
Week 28 (Day 197)	Asia (AS)	10	22.2	9	90.0	11.11	23.57	-7.01	29.23
Week 32 (Day 225)	Asia (AS)	10	22.2	7	70.0	14.29	26.23	-9.97	38.54
Week 36 (Day 253)	Asia (AS)	8	17.8	6	75.0	0.00	0.00	NE	NE
Week 40 (Day 281)	Asia (AS)	8	17.8	6	75.0	8.33	20.41	-13.09	29.75
Week 44 (Day 309)	Asia (AS)	7	15.6	6	85.7	8.33	20.41	-13.09	29.75
Week 48 (Day 337)	Asia (AS)	7	15.6	1	14.3	0.00	NE	NE	NE
Week 52 (Day 365)	Asia (AS)	7	15.6	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Asia (AS)	5	11.1	1	20.0	0.00	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	45	100.0	45	100.0	5.56	14.21	1.29	9.83
End of Study (LOCF)	Asia (AS)	45	100.0	45	100.0	5.56	14.21	1.29	9.83

Race/ethnicity									
Baseline	Asian	48	100.0	48	100.0	8.33	18.83	2.87	13.80
Week 4 (Day 29)	Asian	48	100.0	40	83.3	3.33	8.61	0.58	6.09
Week 8 (Day 57)	Asian	38	79.2	31	81.6	4.30	7.41	1.58	7.02
Week 12 (Day 85)	Asian	30	62.5	30	100.0	2.22	8.46	-0.94	5.38
Week 16 (Day 113)	Asian	21	43.8	21	100.0	1.59	7.27	-1.72	4.90
Week 20 (Day 141)	Asian	16	33.3	15	93.8	2.22	5.86	-1.03	5.47
Week 24 (Day 169)	Asian	13	27.1	11	84.6	3.03	10.05	-3.72	9.78
Week 28 (Day 197)	Asian	13	27.1	12	92.3	8.33	20.72	-4.83	21.50
Week 32 (Day 225)	Asian	12	25.0	9	75.0	14.81	24.22	-3.80	33.43
Week 36 (Day 253)	Asian	10	20.8	8	80.0	2.08	5.89	-2.84	7.01
Week 40 (Day 281)	Asian	10	20.8	8	80.0	6.25	17.68	-8.53	21.03
Week 44 (Day 309)	Asian	9	18.8	8	88.9	6.25	17.68	-8.53	21.03
Week 48 (Day 337)	Asian	9	18.8	2	22.2	0.00	0.00	NE	NE
Week 52 (Day 365)	Asian	9	18.8	1	11.1	0.00	NE	NE	NE
Week 56 (Day 393)	Asian	7	14.6	2	28.6	0.00	0.00	NE	NE
Week 60 (Day 421)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	48	100.0	48	100.0	5.21	13.82	1.20	9.22
End of Study (LOCF)	Asian	48	100.0	48	100.0	5.21	13.82	1.20	9.22
Baseline	Non-Asian	54	100.0	52	96.3	8.97	18.51	3.82	14.13
Week 4 (Day 29)	Non-Asian	54	100.0	50	92.6	1.00	4.00	-0.14	2.14
Week 8 (Day 57)	Non-Asian	49	90.7	44	89.8	2.65	7.14	0.48	4.82
Week 12 (Day 85)	Non-Asian	44	81.5	37	84.1	3.60	9.73	0.36	6.85
Week 16 (Day 113)	Non-Asian	43	79.6	34	79.1	3.43	10.68	-0.30	7.16
Week 20 (Day 141)	Non-Asian	38	70.4	35	92.1	3.81	9.12	0.68	6.94
Week 24 (Day 169)	Non-Asian	38	70.4	34	89.5	2.45	5.99	0.36	4.54
Week 28 (Day 197)	Non-Asian	37	68.5	35	94.6	2.38	5.92	0.35	4.41
Week 32 (Day 225)	Non-Asian	32	59.3	28	87.5	2.98	7.93	-0.10	6.05
Week 36 (Day 253)	Non-Asian	27	50.0	20	74.1	1.67	5.13	-0.73	4.07

Week 40 (Day 281)	Non-Asian	23	42.6	21	91.3	1.59	5.01	-0.69	3.87
Week 44 (Day 309)	Non-Asian	18	33.3	14	77.8	2.38	8.91	-2.76	7.52
Week 48 (Day 337)	Non-Asian	12	22.2	9	75.0	0.00	0.00	NE	NE
Week 52 (Day 365)	Non-Asian	8	14.8	3	37.5	0.00	0.00	NE	NE
Week 56 (Day 393)	Non-Asian	8	14.8	4	50.0	0.00	0.00	NE	NE
Week 60 (Day 421)	Non-Asian	7	13.0	1	14.3	0.00	NE	NE	NE
Week 64 (Day 449)	Non-Asian	6	11.1	2	33.3	0.00	0.00	NE	NE
Week 68 (Day 477)	Non-Asian	3	5.6	1	33.3	0.00	NE	NE	NE
Week 72 (Day 505)	Non-Asian	3	5.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Non-Asian	3	5.6	1	33.3	0.00	NE	NE	NE
Week 80 (Day 561)	Non-Asian	2	3.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	54	100.0	54	100.0	2.16	7.27	0.18	4.15
End of Study (LOCF)	Non-Asian	54	100.0	54	100.0	2.16	7.27	0.18	4.15
Baseline	Unknown	6	100.0	4	66.7	16.67	23.57	-20.84	54.17
Week 4 (Day 29)	Unknown	6	100.0	6	100.0	2.78	6.80	-4.36	9.92
Week 8 (Day 57)	Unknown	5	83.3	4	80.0	0.00	0.00	NE	NE
Week 12 (Day 85)	Unknown	5	83.3	4	80.0	0.00	0.00	NE	NE
Week 16 (Day 113)	Unknown	5	83.3	3	60.0	0.00	0.00	NE	NE
Week 20 (Day 141)	Unknown	5	83.3	5	100.0	0.00	0.00	NE	NE
Week 24 (Day 169)	Unknown	5	83.3	4	80.0	0.00	0.00	NE	NE
Week 28 (Day 197)	Unknown	5	83.3	4	80.0	0.00	0.00	NE	NE
Week 32 (Day 225)	Unknown	4	66.7	4	100.0	0.00	0.00	NE	NE
Week 36 (Day 253)	Unknown	4	66.7	2	50.0	0.00	0.00	NE	NE
Week 40 (Day 281)	Unknown	4	66.7	3	75.0	0.00	0.00	NE	NE
Week 44 (Day 309)	Unknown	4	66.7	4	100.0	8.33	16.67	-18.19	34.85
Week 48 (Day 337)	Unknown	2	33.3	1	50.0	0.00	NE	NE	NE
Week 52 (Day 365)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 60 (Day 421)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE

Week 64 (Day 449)	Unknown	1	16.7	1	100.0	0.00	NE	NE	NE
Week 68 (Day 477)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	1	16.7	1	100.0	0.00	NE	NE	NE
Week 76 (Day 533)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	6	100.0	6	100.0	8.33	13.94	-6.30	22.97
End of Study (LOCF)	Unknown	6	100.0	6	100.0	2.78	6.80	-4.36	9.92

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TN_QSC30NV_SG.xls
27OCT2021 7:38

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Nausea and vomiting
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	17	16.3	10.5	24.6
	Cycle 12 (LOCF)	n/a	104	96.3	4	3.8	1.5	9.5
	End of Study (LOCF)	n/a	104	96.3	4	3.8	1.5	9.5
Sex	All visits	Female	56	51.9	12	21.4	12.7	33.8
		Male	48	44.4	5	10.4	4.5	22.2
	Cycle 12 (LOCF)	Female	56	51.9	3	5.4	1.8	14.6
		Male	48	44.4	1	2.1	0.4	10.9
	End of Study (LOCF)	Female	56	51.9	3	5.4	1.8	14.6
		Male	48	44.4	1	2.1	0.4	10.9
Age	All visits	< 65	60	55.6	9	15.0	8.1	26.1
		>= 65	44	40.7	8	18.2	9.5	32.0
	Cycle 12 (LOCF)	< 65	60	55.6	2	3.3	0.9	11.4
		>= 65	44	40.7	2	4.5	1.3	15.1
	End of Study (LOCF)	< 65	60	55.6	2	3.3	0.9	11.4
		>= 65	44	40.7	2	4.5	1.3	15.1
ECOG performance status	All visits	0	29	26.9	5	17.2	7.6	34.5
		1	75	69.4	12	16.0	9.4	25.9
	Cycle 12 (LOCF)	0	29	26.9	2	6.9	1.9	22.0
		1	75	69.4	2	2.7	0.7	9.2
	End of Study (LOCF)	0	29	26.9	2	6.9	1.9	22.0
		1	75	69.4	2	2.7	0.7	9.2
Geographic region	All visits	USA	19	17.6	4	21.1	8.5	43.3
		Europe (EU)	40	37.0	4	10.0	4.0	23.1
		Asia (AS)	45	41.7	9	20.0	10.9	33.8
	Cycle 12 (LOCF)	USA	19	17.6	0	0.0	0.0	16.8
		Europe (EU)	40	37.0	2	5.0	1.4	16.5
		Asia (AS)	45	41.7	2	4.4	1.2	14.8
	End of Study (LOCF)	USA	19	17.6	0	0.0	0.0	16.8
		Europe (EU)	40	37.0	2	5.0	1.4	16.5
		Asia (AS)	45	41.7	2	4.4	1.2	14.8
Race/ethnicity	All visits	Asian	48	44.4	10	20.8	11.7	34.3
		Non-Asian	52	48.1	7	13.5	6.7	25.3
		Unknown	4	3.7	0	0.0	0.0	49.0
	Cycle 12 (LOCF)	Asian	48	44.4	2	4.2	1.2	14.0
		Non-Asian	52	48.1	2	3.8	1.1	13.0
		Unknown	4	3.7	0	0.0	0.0	49.0
	End of Study (LOCF)	Asian	48	44.4	2	4.2	1.2	14.0

		Non-Asian	52	48.1	2	3.8	1.1	13.0
		Unknown	4	3.7	0	0.0	0.0	49.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30NV_W10_SG.xls
15OCT2021 13:15

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Nausea and vomiting
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

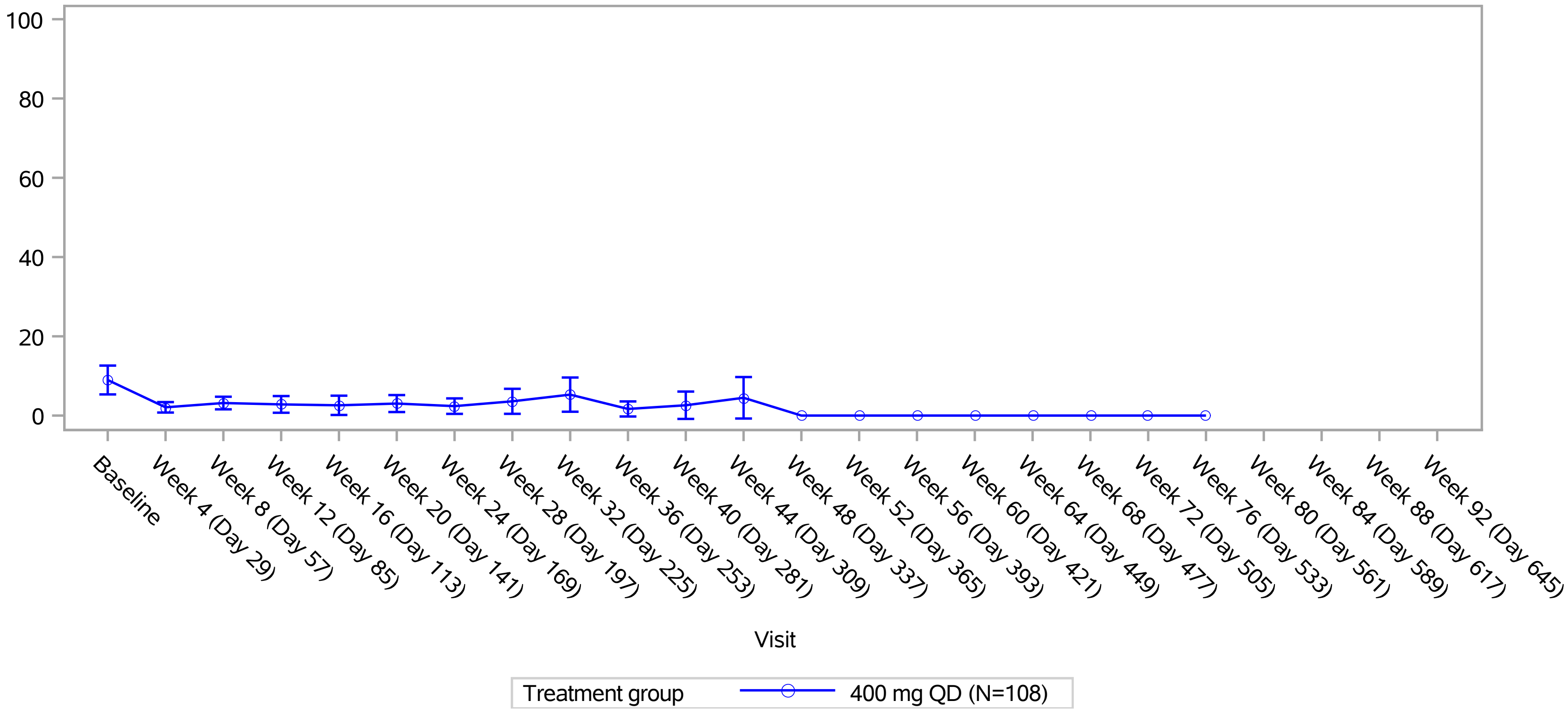
			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	17	16.3	10.5	24.6
	Cycle 12 (LOCF)	n/a	104	96.3	4	3.8	1.5	9.5
	End of Study (LOCF)	n/a	104	96.3	4	3.8	1.5	9.5
Sex	All visits	Female	56	51.9	12	21.4	12.7	33.8
		Male	48	44.4	5	10.4	4.5	22.2
	Cycle 12 (LOCF)	Female	56	51.9	3	5.4	1.8	14.6
		Male	48	44.4	1	2.1	0.4	10.9
	End of Study (LOCF)	Female	56	51.9	3	5.4	1.8	14.6
		Male	48	44.4	1	2.1	0.4	10.9
Age	All visits	< 65	60	55.6	9	15.0	8.1	26.1
		>= 65	44	40.7	8	18.2	9.5	32.0
	Cycle 12 (LOCF)	< 65	60	55.6	2	3.3	0.9	11.4
		>= 65	44	40.7	2	4.5	1.3	15.1
	End of Study (LOCF)	< 65	60	55.6	2	3.3	0.9	11.4
		>= 65	44	40.7	2	4.5	1.3	15.1
ECOG performance status	All visits	0	29	26.9	5	17.2	7.6	34.5
		1	75	69.4	12	16.0	9.4	25.9
	Cycle 12 (LOCF)	0	29	26.9	2	6.9	1.9	22.0
		1	75	69.4	2	2.7	0.7	9.2
	End of Study (LOCF)	0	29	26.9	2	6.9	1.9	22.0
		1	75	69.4	2	2.7	0.7	9.2
Geographic region	All visits	USA	19	17.6	4	21.1	8.5	43.3
		Europe (EU)	40	37.0	4	10.0	4.0	23.1
		Asia (AS)	45	41.7	9	20.0	10.9	33.8
	Cycle 12 (LOCF)	USA	19	17.6	0	0.0	0.0	16.8
		Europe (EU)	40	37.0	2	5.0	1.4	16.5
		Asia (AS)	45	41.7	2	4.4	1.2	14.8
	End of Study (LOCF)	USA	19	17.6	0	0.0	0.0	16.8
		Europe (EU)	40	37.0	2	5.0	1.4	16.5
		Asia (AS)	45	41.7	2	4.4	1.2	14.8
Race/ethnicity	All visits	Asian	48	44.4	10	20.8	11.7	34.3
		Non-Asian	52	48.1	7	13.5	6.7	25.3
		Unknown	4	3.7	0	0.0	0.0	49.0
	Cycle 12 (LOCF)	Asian	48	44.4	2	4.2	1.2	14.0
		Non-Asian	52	48.1	2	3.8	1.1	13.0
		Unknown	4	3.7	0	0.0	0.0	49.0
	End of Study (LOCF)	Asian	48	44.4	2	4.2	1.2	14.0

		Non-Asian	52	48.1	2	3.8	1.1	13.0
		Unknown	4	3.7	0	0.0	0.0	49.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30NV_W15_SG.xls
15OCT2021 13:05

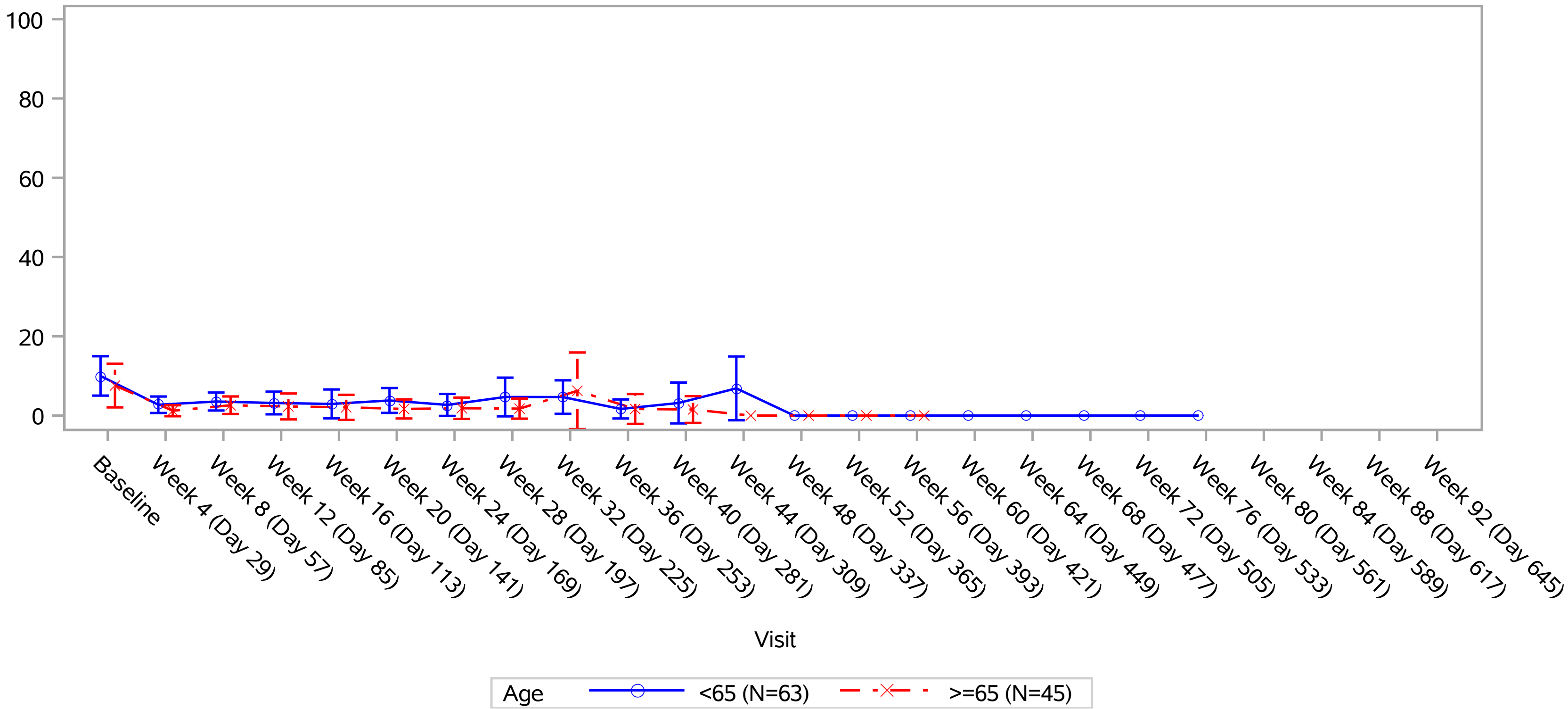
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Nausea and vomiting
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30NV.pdf
15OCT2021 17:27

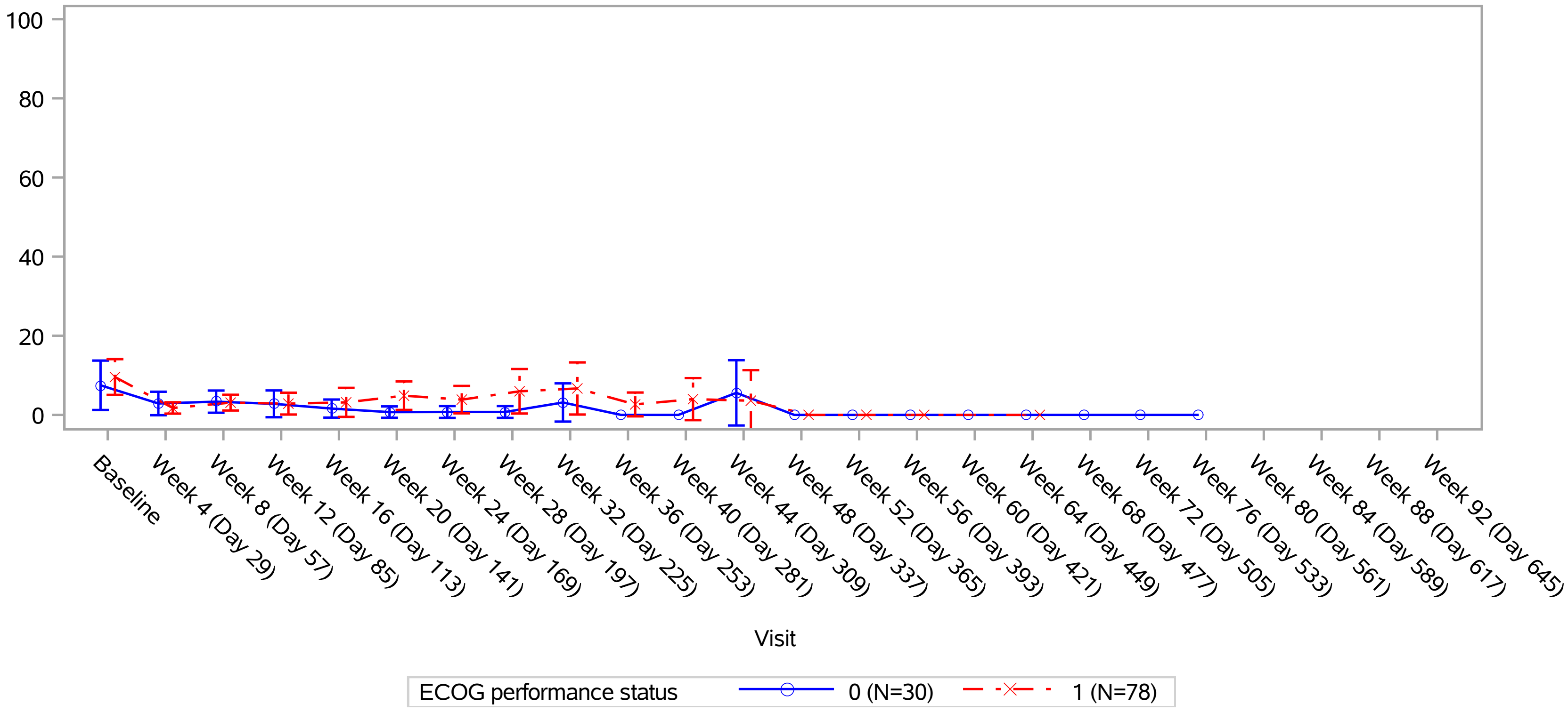
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Nausea and vomiting
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30NV_SGAGE65.pdf
15OCT2021 17:56

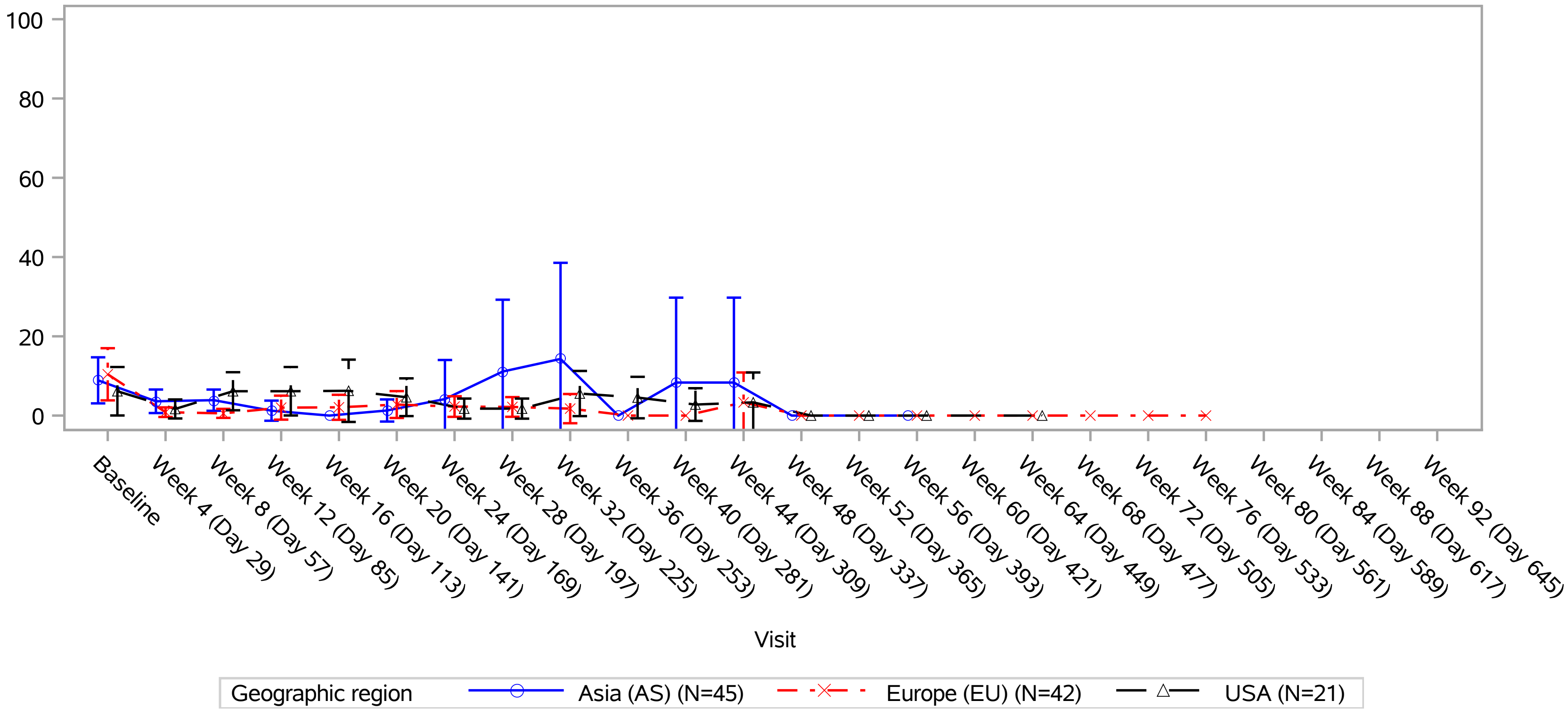
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Nausea and vomiting
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30NV_SGECOG.pdf
15OCT2021 18:27

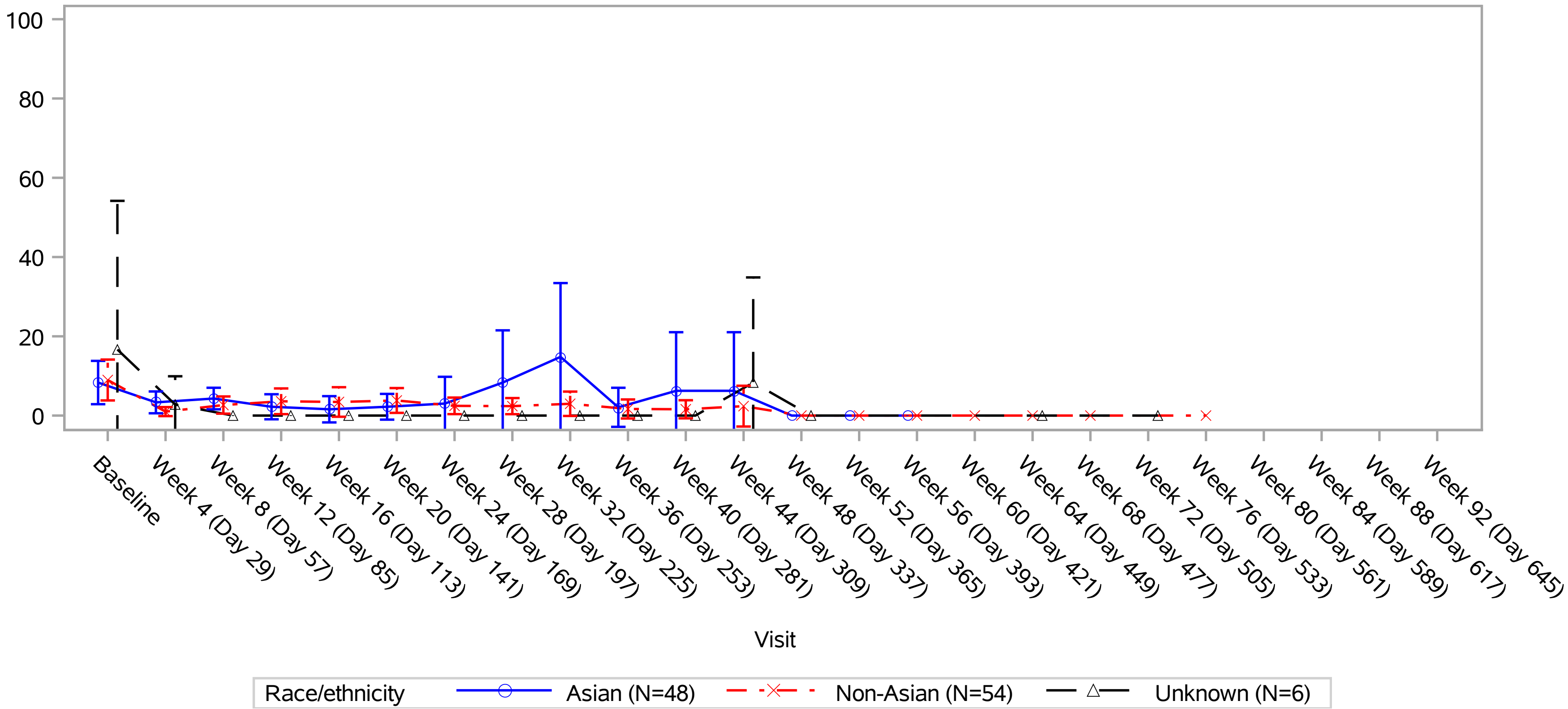
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Nausea and vomiting
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30NV_SGGEO.pdf
15OCT2021 18:58

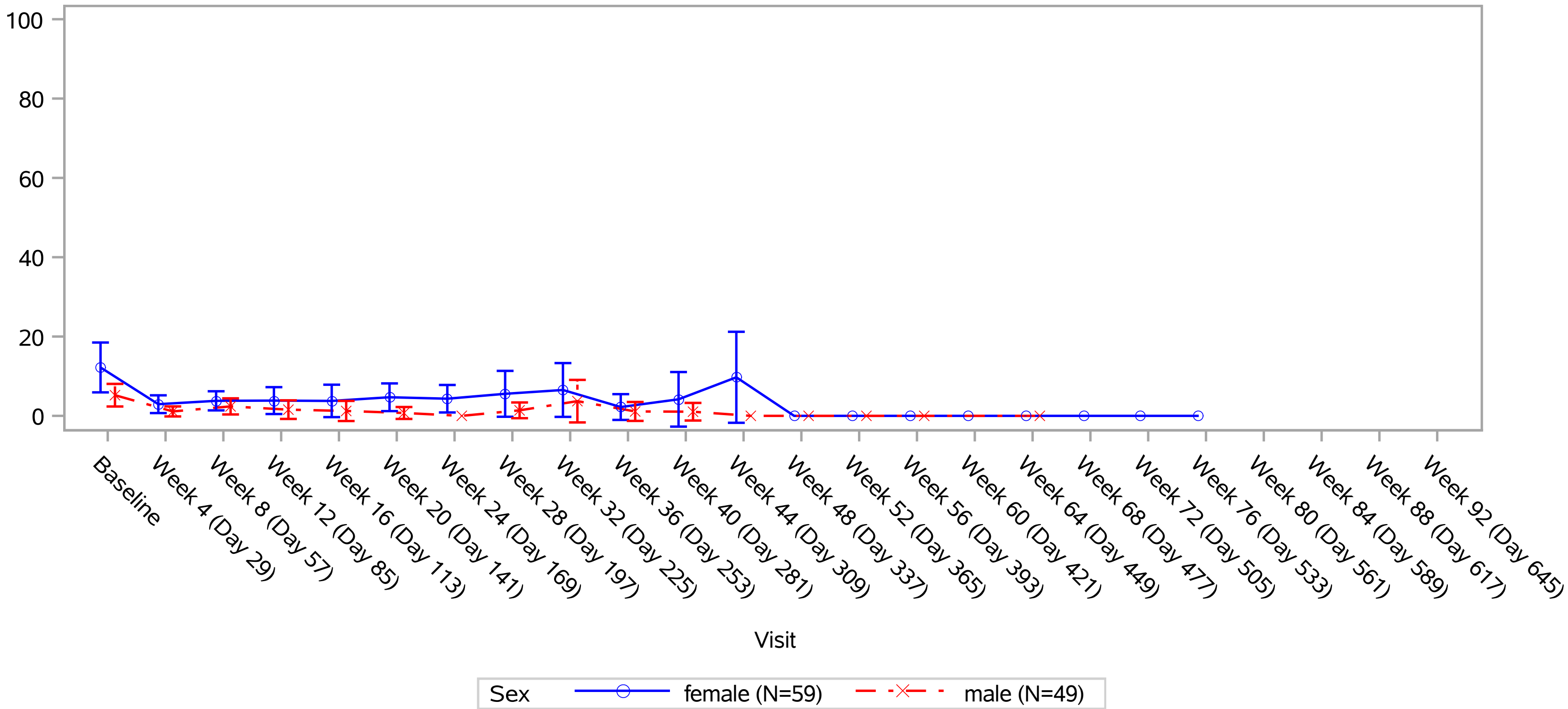
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Nausea and vomiting
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30NV_SGRE.pdf
15OCT2021 19:28

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Nausea and vomiting
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30NV_SGSEX.pdf
15OCT2021 19:59

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Pain
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=108)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	108	100.0	104	96.3	25.96	29.18	20.29	31.64
Week 4 (Day 29)	n/a	108	100.0	96	88.9	13.19	20.93	8.95	17.44
Week 8 (Day 57)	n/a	92	85.2	79	85.9	11.81	18.90	7.58	16.05
Week 12 (Day 85)	n/a	79	73.1	71	89.9	10.33	16.27	6.48	14.18
Week 16 (Day 113)	n/a	69	63.9	58	84.1	11.49	16.28	7.21	15.78
Week 20 (Day 141)	n/a	59	54.6	55	93.2	15.45	18.66	10.41	20.50
Week 24 (Day 169)	n/a	56	51.9	49	87.5	13.95	19.35	8.39	19.50
Week 28 (Day 197)	n/a	55	50.9	51	92.7	10.46	16.98	5.68	15.23
Week 32 (Day 225)	n/a	48	44.4	41	85.4	15.04	17.80	9.42	20.66
Week 36 (Day 253)	n/a	41	38.0	30	73.2	11.11	16.57	4.92	17.30
Week 40 (Day 281)	n/a	37	34.3	32	86.5	16.67	21.17	9.04	24.30
Week 44 (Day 309)	n/a	31	28.7	26	83.9	17.95	26.21	7.36	28.54
Week 48 (Day 337)	n/a	23	21.3	12	52.2	13.89	17.16	2.98	24.79
Week 52 (Day 365)	n/a	19	17.6	4	21.1	12.50	15.96	-12.89	37.89
Week 56 (Day 393)	n/a	17	15.7	6	35.3	11.11	13.61	-3.17	25.39
Week 60 (Day 421)	n/a	11	10.2	1	9.1	33.33	NE	NE	NE
Week 64 (Day 449)	n/a	10	9.3	3	30.0	11.11	19.25	-36.70	58.92
Week 68 (Day 477)	n/a	6	5.6	1	16.7	16.67	NE	NE	NE
Week 72 (Day 505)	n/a	6	5.6	1	16.7	33.33	NE	NE	NE
Week 76 (Day 533)	n/a	6	5.6	1	16.7	16.67	NE	NE	NE
Week 80 (Day 561)	n/a	5	4.6	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	n/a	1	0.9	0	0.0	NE	NE	NE	NE

Cycle 12 (LOCF)	n/a	108	100.0	108	100.0	14.20	21.35	10.12	18.27
End of Study (LOCF)	n/a	108	100.0	108	100.0	13.43	19.53	9.70	17.15
Sex									
Baseline	Female	59	100.0	56	94.9	31.85	31.67	23.36	40.33
Week 4 (Day 29)	Female	59	100.0	51	86.4	15.03	22.42	8.73	21.34
Week 8 (Day 57)	Female	49	83.1	44	89.8	14.02	22.43	7.20	20.83
Week 12 (Day 85)	Female	44	74.6	39	88.6	10.68	17.31	5.07	16.29
Week 16 (Day 113)	Female	38	64.4	31	81.6	11.29	16.32	5.30	17.28
Week 20 (Day 141)	Female	33	55.9	32	97.0	20.31	21.05	12.72	27.90
Week 24 (Day 169)	Female	31	52.5	27	87.1	16.67	20.15	8.70	24.64
Week 28 (Day 197)	Female	30	50.8	27	90.0	13.58	19.63	5.81	21.35
Week 32 (Day 225)	Female	27	45.8	23	85.2	17.39	19.12	9.12	25.66
Week 36 (Day 253)	Female	22	37.3	15	68.2	15.56	19.38	4.82	26.29
Week 40 (Day 281)	Female	18	30.5	16	88.9	21.87	26.33	7.84	35.91
Week 44 (Day 309)	Female	15	25.4	12	80.0	27.78	33.58	6.44	49.12
Week 48 (Day 337)	Female	11	18.6	4	36.4	20.83	20.97	-12.54	54.20
Week 52 (Day 365)	Female	9	15.3	1	11.1	33.33	NE	NE	NE
Week 56 (Day 393)	Female	7	11.9	1	14.3	16.67	NE	NE	NE
Week 60 (Day 421)	Female	5	8.5	1	20.0	33.33	NE	NE	NE
Week 64 (Day 449)	Female	4	6.8	2	50.0	16.67	23.57	-195.10	228.44
Week 68 (Day 477)	Female	3	5.1	1	33.3	16.67	NE	NE	NE
Week 72 (Day 505)	Female	3	5.1	1	33.3	33.33	NE	NE	NE
Week 76 (Day 533)	Female	3	5.1	1	33.3	16.67	NE	NE	NE
Week 80 (Day 561)	Female	2	3.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	59	100.0	59	100.0	18.36	25.84	11.63	25.09
End of Study (LOCF)	Female	59	100.0	59	100.0	17.51	23.25	11.46	23.57
Baseline	Male	49	100.0	48	98.0	19.10	24.55	11.97	26.23
Week 4 (Day 29)	Male	49	100.0	45	91.8	11.11	19.14	5.36	16.86
Week 8 (Day 57)	Male	43	87.8	35	81.4	9.05	13.00	4.58	13.51
Week 12 (Day 85)	Male	35	71.4	32	91.4	9.90	15.18	4.42	15.37
Week 16 (Day 113)	Male	31	63.3	27	87.1	11.73	16.55	5.18	18.27
Week 20 (Day 141)	Male	26	53.1	23	88.5	8.70	12.17	3.43	13.96
Week 24 (Day 169)	Male	25	51.0	22	88.0	10.61	18.22	2.53	18.68
Week 28 (Day 197)	Male	25	51.0	24	96.0	6.94	12.93	1.49	12.40

Week 32 (Day 225)	Male	21	42.9	18	85.7	12.04	15.97	4.09	19.98
Week 36 (Day 253)	Male	19	38.8	15	78.9	6.67	12.28	-0.13	13.47
Week 40 (Day 281)	Male	19	38.8	16	84.2	11.46	13.22	4.41	18.50
Week 44 (Day 309)	Male	16	32.7	14	87.5	9.52	14.19	1.33	17.72
Week 48 (Day 337)	Male	12	24.5	8	66.7	10.42	15.27	-2.35	23.18
Week 52 (Day 365)	Male	10	20.4	3	30.0	5.56	9.62	-18.35	29.46
Week 56 (Day 393)	Male	10	20.4	5	50.0	10.00	14.91	-8.51	28.51
Week 60 (Day 421)	Male	6	12.2	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Male	6	12.2	1	16.7	0.00	NE	NE	NE
Week 68 (Day 477)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	49	100.0	49	100.0	9.18	12.76	5.52	12.85
End of Study (LOCF)	Male	49	100.0	49	100.0	8.50	12.32	4.96	12.04
Age									
Baseline	< 65	63	100.0	60	95.2	31.94	28.67	24.54	39.35
Week 4 (Day 29)	< 65	63	100.0	55	87.3	12.12	18.27	7.18	17.06
Week 8 (Day 57)	< 65	54	85.7	47	87.0	12.06	15.03	7.64	16.47
Week 12 (Day 85)	< 65	47	74.6	42	89.4	11.11	16.73	5.90	16.33
Week 16 (Day 113)	< 65	39	61.9	34	87.2	11.27	15.20	5.97	16.58
Week 20 (Day 141)	< 65	35	55.6	35	100.0	14.29	17.69	8.21	20.36
Week 24 (Day 169)	< 65	34	54.0	31	91.2	13.98	19.77	6.73	21.23
Week 28 (Day 197)	< 65	33	52.4	32	97.0	9.90	18.38	3.27	16.52
Week 32 (Day 225)	< 65	30	47.6	25	83.3	13.33	15.96	6.75	19.92
Week 36 (Day 253)	< 65	25	39.7	20	80.0	11.67	18.02	3.24	20.10
Week 40 (Day 281)	< 65	23	36.5	21	91.3	17.46	24.42	6.34	28.58
Week 44 (Day 309)	< 65	19	30.2	17	89.5	20.59	30.35	4.98	36.19
Week 48 (Day 337)	< 65	14	22.2	7	50.0	16.67	19.25	-1.13	34.47

Week 52 (Day 365)	< 65	12	19.0	2	16.7	16.67	23.57	-195.10	228.44
Week 56 (Day 393)	< 65	11	17.5	2	18.2	25.00	11.79	-80.89	130.89
Week 60 (Day 421)	< 65	8	12.7	1	12.5	33.33	NE	NE	NE
Week 64 (Day 449)	< 65	7	11.1	3	42.9	11.11	19.25	-36.70	58.92
Week 68 (Day 477)	< 65	4	6.3	1	25.0	16.67	NE	NE	NE
Week 72 (Day 505)	< 65	4	6.3	1	25.0	33.33	NE	NE	NE
Week 76 (Day 533)	< 65	4	6.3	1	25.0	16.67	NE	NE	NE
Week 80 (Day 561)	< 65	3	4.8	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	63	100.0	63	100.0	14.29	21.14	8.96	19.61
End of Study (LOCF)	< 65	63	100.0	63	100.0	12.96	17.82	8.47	17.45
Baseline	>= 65	45	100.0	44	97.8	17.80	28.16	9.24	26.37
Week 4 (Day 29)	>= 65	45	100.0	41	91.1	14.63	24.21	6.99	22.28
Week 8 (Day 57)	>= 65	38	84.4	32	84.2	11.46	23.74	2.90	20.02
Week 12 (Day 85)	>= 65	32	71.1	29	90.6	9.20	15.80	3.18	15.21
Week 16 (Day 113)	>= 65	30	66.7	24	80.0	11.81	18.04	4.19	19.42
Week 20 (Day 141)	>= 65	24	53.3	20	83.3	17.50	20.57	7.87	27.13
Week 24 (Day 169)	>= 65	22	48.9	18	81.8	13.89	19.17	4.35	23.42
Week 28 (Day 197)	>= 65	22	48.9	19	86.4	11.40	14.75	4.29	18.51
Week 32 (Day 225)	>= 65	18	40.0	16	88.9	17.71	20.61	6.73	28.69
Week 36 (Day 253)	>= 65	16	35.6	10	62.5	10.00	14.05	-0.05	20.05
Week 40 (Day 281)	>= 65	14	31.1	11	78.6	15.15	13.85	5.84	24.46
Week 44 (Day 309)	>= 65	12	26.7	9	75.0	12.96	16.20	0.51	25.41
Week 48 (Day 337)	>= 65	9	20.0	5	55.6	10.00	14.91	-8.51	28.51
Week 52 (Day 365)	>= 65	7	15.6	2	28.6	8.33	11.79	-97.55	114.22
Week 56 (Day 393)	>= 65	6	13.3	4	66.7	4.17	8.33	-9.09	17.43
Week 60 (Day 421)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE

Week 76 (Day 533)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	45	100.0	45	100.0	14.07	21.89	7.50	20.65
End of Study (LOCF)	>= 65	45	100.0	45	100.0	14.07	21.89	7.50	20.65
ECOG performance status									
Baseline	0	30	100.0	29	96.7	26.44	32.28	14.16	38.72
Week 4 (Day 29)	0	30	100.0	29	96.7	13.79	23.60	4.82	22.77
Week 8 (Day 57)	0	28	93.3	25	89.3	13.33	19.84	5.14	21.52
Week 12 (Day 85)	0	26	86.7	24	92.3	9.03	12.98	3.55	14.51
Week 16 (Day 113)	0	26	86.7	21	80.8	11.11	16.10	3.78	18.44
Week 20 (Day 141)	0	26	86.7	24	92.3	10.42	15.40	3.92	16.92
Week 24 (Day 169)	0	25	83.3	23	92.0	9.42	15.75	2.61	16.23
Week 28 (Day 197)	0	25	83.3	23	92.0	7.25	12.13	2.00	12.49
Week 32 (Day 225)	0	20	66.7	16	80.0	15.63	17.71	6.19	25.06
Week 36 (Day 253)	0	18	60.0	11	61.1	10.61	13.48	1.55	19.66
Week 40 (Day 281)	0	16	53.3	11	68.8	18.18	22.92	2.79	33.58
Week 44 (Day 309)	0	15	50.0	12	80.0	19.44	32.44	-1.17	40.05
Week 48 (Day 337)	0	9	30.0	6	66.7	16.67	21.08	-5.46	38.79
Week 52 (Day 365)	0	9	30.0	3	33.3	11.11	19.25	-36.70	58.92
Week 56 (Day 393)	0	8	26.7	3	37.5	16.67	16.67	-24.74	58.07
Week 60 (Day 421)	0	5	16.7	1	20.0	33.33	NE	NE	NE
Week 64 (Day 449)	0	5	16.7	2	40.0	16.67	23.57	-195.10	228.44
Week 68 (Day 477)	0	3	10.0	1	33.3	16.67	NE	NE	NE
Week 72 (Day 505)	0	3	10.0	1	33.3	33.33	NE	NE	NE
Week 76 (Day 533)	0	3	10.0	1	33.3	16.67	NE	NE	NE
Week 80 (Day 561)	0	2	6.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	0	1	3.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	30	100.0	30	100.0	18.89	26.16	9.12	28.66
End of Study (LOCF)	0	30	100.0	30	100.0	16.11	21.21	8.19	24.03
Baseline	1	78	100.0	75	96.2	25.78	28.12	19.31	32.25
Week 4 (Day 29)	1	78	100.0	67	85.9	12.94	19.85	8.09	17.78

Week 8 (Day 57)	1	64	82.1	54	84.4	11.11	18.60	6.03	16.19
Week 12 (Day 85)	1	53	67.9	47	88.7	10.99	17.81	5.76	16.22
Week 16 (Day 113)	1	43	55.1	37	86.0	11.71	16.60	6.18	17.25
Week 20 (Day 141)	1	33	42.3	31	93.9	19.35	20.23	11.93	26.77
Week 24 (Day 169)	1	31	39.7	26	83.9	17.95	21.56	9.24	26.66
Week 28 (Day 197)	1	30	38.5	28	93.3	13.10	19.96	5.36	20.83
Week 32 (Day 225)	1	28	35.9	25	89.3	14.67	18.21	7.15	22.18
Week 36 (Day 253)	1	23	29.5	19	82.6	11.40	18.47	2.50	20.31
Week 40 (Day 281)	1	21	26.9	21	100.0	15.87	20.73	6.44	25.31
Week 44 (Day 309)	1	16	20.5	14	87.5	16.67	20.67	4.73	28.60
Week 48 (Day 337)	1	14	17.9	6	42.9	11.11	13.61	-3.17	25.39
Week 52 (Day 365)	1	10	12.8	1	10.0	16.67	NE	NE	NE
Week 56 (Day 393)	1	9	11.5	3	33.3	5.56	9.62	-18.35	29.46
Week 60 (Day 421)	1	6	7.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	5	6.4	1	20.0	0.00	NE	NE	NE
Week 68 (Day 477)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	3	3.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	78	100.0	78	100.0	12.39	19.08	8.09	16.69
End of Study (LOCF)	1	78	100.0	78	100.0	12.39	18.89	8.14	16.65
Geographic region									
Baseline	USA	21	100.0	19	90.5	16.67	20.03	7.01	26.32
Week 4 (Day 29)	USA	21	100.0	20	95.2	10.00	19.04	1.09	18.91
Week 8 (Day 57)	USA	21	100.0	19	90.5	10.53	15.92	2.85	18.20
Week 12 (Day 85)	USA	21	100.0	19	90.5	10.53	15.92	2.85	18.20
Week 16 (Day 113)	USA	21	100.0	16	76.2	10.42	14.75	2.56	18.28
Week 20 (Day 141)	USA	20	95.2	18	90.0	12.04	17.90	3.14	20.94
Week 24 (Day 169)	USA	20	95.2	19	95.0	10.53	18.60	1.56	19.49
Week 28 (Day 197)	USA	20	95.2	19	95.0	10.53	20.19	0.79	20.26
Week 32 (Day 225)	USA	17	81.0	15	88.2	17.78	18.33	7.63	27.93
Week 36 (Day 253)	USA	17	81.0	11	64.7	12.12	13.10	3.32	20.92
Week 40 (Day 281)	USA	15	71.4	12	80.0	20.83	24.75	5.11	36.56

Week 44 (Day 309)	USA	13	61.9	10	76.9	16.67	22.22	0.77	32.56
Week 48 (Day 337)	USA	8	38.1	5	62.5	6.67	9.13	-4.67	18.00
Week 52 (Day 365)	USA	6	28.6	1	16.7	0.00	NE	NE	NE
Week 56 (Day 393)	USA	6	28.6	3	50.0	11.11	9.62	-12.79	35.01
Week 60 (Day 421)	USA	5	23.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	4	19.0	1	25.0	0.00	NE	NE	NE
Week 68 (Day 477)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	21	100.0	21	100.0	10.32	17.85	2.19	18.44
End of Study (LOCF)	USA	21	100.0	21	100.0	11.11	17.74	3.03	19.19
Baseline	Europe (EU)	42	100.0	40	95.2	32.50	34.58	21.44	43.56
Week 4 (Day 29)	Europe (EU)	42	100.0	39	92.9	14.96	22.23	7.75	22.16
Week 8 (Day 57)	Europe (EU)	36	85.7	30	83.3	14.44	19.44	7.18	21.70
Week 12 (Day 85)	Europe (EU)	31	73.8	25	80.6	14.00	17.13	6.93	21.07
Week 16 (Day 113)	Europe (EU)	30	71.4	24	80.0	16.67	20.26	8.11	25.22
Week 20 (Day 141)	Europe (EU)	26	61.9	24	92.3	18.06	20.80	9.27	26.84
Week 24 (Day 169)	Europe (EU)	26	61.9	22	84.6	19.70	21.60	10.12	29.27
Week 28 (Day 197)	Europe (EU)	25	59.5	23	92.0	10.87	14.74	4.49	17.25
Week 32 (Day 225)	Europe (EU)	21	50.0	19	90.5	12.28	14.53	5.28	19.28
Week 36 (Day 253)	Europe (EU)	16	38.1	13	81.3	10.26	14.50	1.50	19.02
Week 40 (Day 281)	Europe (EU)	14	33.3	14	100.0	13.10	16.25	3.71	22.48
Week 44 (Day 309)	Europe (EU)	11	26.2	10	90.9	21.67	31.48	-0.85	44.18
Week 48 (Day 337)	Europe (EU)	8	19.0	6	75.0	22.22	20.18	1.04	43.40
Week 52 (Day 365)	Europe (EU)	6	14.3	3	50.0	16.67	16.67	-24.74	58.07
Week 56 (Day 393)	Europe (EU)	6	14.3	2	33.3	16.67	23.57	-195.10	228.44

Week 60 (Day 421)	Europe (EU)	4	9.5	1	25.0	33.33	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	4	9.5	2	50.0	16.67	23.57	-195.10	228.44
Week 68 (Day 477)	Europe (EU)	3	7.1	1	33.3	16.67	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	3	7.1	1	33.3	33.33	NE	NE	NE
Week 76 (Day 533)	Europe (EU)	3	7.1	1	33.3	16.67	NE	NE	NE
Week 80 (Day 561)	Europe (EU)	2	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Europe (EU)	42	100.0	42	100.0	17.06	23.71	9.67	24.45
End of Study (LOCF)	Europe (EU)	42	100.0	42	100.0	14.68	19.55	8.59	20.77
Baseline	Asia (AS)	45	100.0	45	100.0	24.07	26.25	16.19	31.96
Week 4 (Day 29)	Asia (AS)	45	100.0	37	82.2	13.06	20.84	6.12	20.01
Week 8 (Day 57)	Asia (AS)	35	77.8	30	85.7	10.00	20.34	2.40	17.60
Week 12 (Day 85)	Asia (AS)	27	60.0	27	100.0	6.79	15.51	0.65	12.93
Week 16 (Day 113)	Asia (AS)	18	40.0	18	100.0	5.56	8.08	1.54	9.58
Week 20 (Day 141)	Asia (AS)	13	28.9	13	100.0	15.38	15.90	5.78	24.99
Week 24 (Day 169)	Asia (AS)	10	22.2	8	80.0	6.25	8.63	-0.96	13.46
Week 28 (Day 197)	Asia (AS)	10	22.2	9	90.0	9.26	16.90	-3.73	22.25
Week 32 (Day 225)	Asia (AS)	10	22.2	7	70.0	16.67	25.46	-6.88	40.21
Week 36 (Day 253)	Asia (AS)	8	17.8	6	75.0	11.11	27.22	-17.45	39.67
Week 40 (Day 281)	Asia (AS)	8	17.8	6	75.0	16.67	25.82	-10.43	43.76
Week 44 (Day 309)	Asia (AS)	7	15.6	6	85.7	13.89	26.70	-14.13	41.91
Week 48 (Day 337)	Asia (AS)	7	15.6	1	14.3	0.00	NE	NE	NE
Week 52 (Day 365)	Asia (AS)	7	15.6	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Asia (AS)	5	11.1	1	20.0	0.00	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	45	100.0	45	100.0	13.33	20.60	7.15	19.52
End of Study (LOCF)	Asia (AS)	45	100.0	45	100.0	13.33	20.60	7.15	19.52

Race/ethnicity									
Baseline	Asian	48	100.0	48	100.0	22.57	26.07	15.00	30.14
Week 4 (Day 29)	Asian	48	100.0	40	83.3	12.50	20.24	6.03	18.97
Week 8 (Day 57)	Asian	38	79.2	31	81.6	10.75	20.43	3.26	18.25
Week 12 (Day 85)	Asian	30	62.5	30	100.0	7.22	15.59	1.40	13.04
Week 16 (Day 113)	Asian	21	43.8	21	100.0	5.56	8.05	1.89	9.22
Week 20 (Day 141)	Asian	16	33.3	15	93.8	15.56	16.02	6.68	24.43
Week 24 (Day 169)	Asian	13	27.1	11	84.6	7.58	11.46	-0.12	15.27
Week 28 (Day 197)	Asian	13	27.1	12	92.3	8.33	15.08	-1.25	17.91
Week 32 (Day 225)	Asian	12	25.0	9	75.0	18.52	25.61	-1.17	38.20
Week 36 (Day 253)	Asian	10	20.8	8	80.0	8.33	23.57	-11.37	28.04
Week 40 (Day 281)	Asian	10	20.8	8	80.0	18.75	22.60	-0.15	37.65
Week 44 (Day 309)	Asian	9	18.8	8	88.9	12.50	23.15	-6.85	31.85
Week 48 (Day 337)	Asian	9	18.8	2	22.2	0.00	0.00	NE	NE
Week 52 (Day 365)	Asian	9	18.8	1	11.1	0.00	NE	NE	NE
Week 56 (Day 393)	Asian	7	14.6	2	28.6	8.33	11.79	-97.55	114.22
Week 60 (Day 421)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	48	100.0	48	100.0	12.85	20.12	7.01	18.69
End of Study (LOCF)	Asian	48	100.0	48	100.0	12.85	20.12	7.01	18.69
Baseline	Non-Asian	54	100.0	52	96.3	28.85	30.63	20.32	37.37
Week 4 (Day 29)	Non-Asian	54	100.0	50	92.6	12.33	18.69	7.02	17.65
Week 8 (Day 57)	Non-Asian	49	90.7	44	89.8	11.36	18.25	5.82	16.91
Week 12 (Day 85)	Non-Asian	44	81.5	37	84.1	11.26	15.74	6.01	16.51
Week 16 (Day 113)	Non-Asian	43	79.6	34	79.1	12.75	17.91	6.50	19.00
Week 20 (Day 141)	Non-Asian	38	70.4	35	92.1	13.33	18.44	7.00	19.67
Week 24 (Day 169)	Non-Asian	38	70.4	34	89.5	14.71	20.83	7.44	21.97
Week 28 (Day 197)	Non-Asian	37	68.5	35	94.6	10.95	18.05	4.75	17.15
Week 32 (Day 225)	Non-Asian	32	59.3	28	87.5	14.29	15.53	8.27	20.31
Week 36 (Day 253)	Non-Asian	27	50.0	20	74.1	10.00	12.57	4.12	15.88

Week 40 (Day 281)	Non-Asian	23	42.6	21	91.3	13.49	20.83	4.01	22.97
Week 44 (Day 309)	Non-Asian	18	33.3	14	77.8	14.29	20.52	2.44	26.14
Week 48 (Day 337)	Non-Asian	12	22.2	9	75.0	14.81	17.57	1.31	28.32
Week 52 (Day 365)	Non-Asian	8	14.8	3	37.5	16.67	16.67	-24.74	58.07
Week 56 (Day 393)	Non-Asian	8	14.8	4	50.0	12.50	15.96	-12.89	37.89
Week 60 (Day 421)	Non-Asian	7	13.0	1	14.3	33.33	NE	NE	NE
Week 64 (Day 449)	Non-Asian	6	11.1	2	33.3	0.00	0.00	NE	NE
Week 68 (Day 477)	Non-Asian	3	5.6	1	33.3	16.67	NE	NE	NE
Week 72 (Day 505)	Non-Asian	3	5.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Non-Asian	3	5.6	1	33.3	16.67	NE	NE	NE
Week 80 (Day 561)	Non-Asian	2	3.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	54	100.0	54	100.0	13.58	19.98	8.13	19.03
End of Study (LOCF)	Non-Asian	54	100.0	54	100.0	13.27	19.53	7.94	18.60
Baseline	Unknown	6	100.0	4	66.7	29.17	47.87	-47.01	105.34
Week 4 (Day 29)	Unknown	6	100.0	6	100.0	25.00	39.09	-16.02	66.02
Week 8 (Day 57)	Unknown	5	83.3	4	80.0	25.00	9.62	9.69	40.31
Week 12 (Day 85)	Unknown	5	83.3	4	80.0	25.00	21.52	-9.24	59.24
Week 16 (Day 113)	Unknown	5	83.3	3	60.0	38.89	9.62	14.99	62.79
Week 20 (Day 141)	Unknown	5	83.3	5	100.0	30.00	24.72	-0.69	60.69
Week 24 (Day 169)	Unknown	5	83.3	4	80.0	25.00	21.52	-9.24	59.24
Week 28 (Day 197)	Unknown	5	83.3	4	80.0	12.50	15.96	-12.89	37.89
Week 32 (Day 225)	Unknown	4	66.7	4	100.0	12.50	15.96	-12.89	37.89
Week 36 (Day 253)	Unknown	4	66.7	2	50.0	33.33	0.00	NE	NE
Week 40 (Day 281)	Unknown	4	66.7	3	75.0	33.33	16.67	-8.07	74.74
Week 44 (Day 309)	Unknown	4	66.7	4	100.0	41.67	41.94	-25.07	108.41
Week 48 (Day 337)	Unknown	2	33.3	1	50.0	33.33	NE	NE	NE
Week 52 (Day 365)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 60 (Day 421)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE

Week 64 (Day 449)	Unknown	1	16.7	1	100.0	33.33	NE	NE	NE
Week 68 (Day 477)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	1	16.7	1	100.0	33.33	NE	NE	NE
Week 76 (Day 533)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	6	100.0	6	100.0	30.56	37.14	-8.42	69.54
End of Study (LOCF)	Unknown	6	100.0	6	100.0	19.44	16.39	2.25	36.64

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TN_QSC30PA_SG.xls
27OCT2021 7:39

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Pain
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	27	26.0	18.5	35.1
	Cycle 12 (LOCF)	n/a	104	96.3	14	13.5	8.2	21.3
	End of Study (LOCF)	n/a	104	96.3	14	13.5	8.2	21.3
Sex	All visits	Female	56	51.9	11	19.6	11.3	31.8
		Male	48	44.4	16	33.3	21.7	47.5
	Cycle 12 (LOCF)	Female	56	51.9	9	16.1	8.7	27.8
		Male	48	44.4	5	10.4	4.5	22.2
	End of Study (LOCF)	Female	56	51.9	9	16.1	8.7	27.8
		Male	48	44.4	5	10.4	4.5	22.2
Age	All visits	< 65	60	55.6	8	13.3	6.9	24.2
		>= 65	44	40.7	19	43.2	29.7	57.8
	Cycle 12 (LOCF)	< 65	60	55.6	4	6.7	2.6	15.9
		>= 65	44	40.7	10	22.7	12.8	37.0
	End of Study (LOCF)	< 65	60	55.6	4	6.7	2.6	15.9
		>= 65	44	40.7	10	22.7	12.8	37.0
ECOG performance status	All visits	0	29	26.9	11	37.9	22.7	56.0
		1	75	69.4	16	21.3	13.6	31.9
	Cycle 12 (LOCF)	0	29	26.9	6	20.7	9.8	38.4
		1	75	69.4	8	10.7	5.5	19.7
	End of Study (LOCF)	0	29	26.9	6	20.7	9.8	38.4
		1	75	69.4	8	10.7	5.5	19.7
Geographic region	All visits	USA	19	17.6	9	47.4	27.3	68.3
		Europe (EU)	40	37.0	11	27.5	16.1	42.8
		Asia (AS)	45	41.7	7	15.6	7.7	28.8
	Cycle 12 (LOCF)	USA	19	17.6	4	21.1	8.5	43.3
		Europe (EU)	40	37.0	5	12.5	5.5	26.1
		Asia (AS)	45	41.7	5	11.1	4.8	23.5
	End of Study (LOCF)	USA	19	17.6	4	21.1	8.5	43.3
		Europe (EU)	40	37.0	5	12.5	5.5	26.1
		Asia (AS)	45	41.7	5	11.1	4.8	23.5
Race/ethnicity	All visits	Asian	48	44.4	9	18.8	10.2	31.9
		Non-Asian	52	48.1	17	32.7	21.5	46.2
		Unknown	4	3.7	1	25.0	4.6	69.9
	Cycle 12 (LOCF)	Asian	48	44.4	6	12.5	5.9	24.7
		Non-Asian	52	48.1	7	13.5	6.7	25.3
		Unknown	4	3.7	1	25.0	4.6	69.9
	End of Study (LOCF)	Asian	48	44.4	6	12.5	5.9	24.7

		Non-Asian	52	48.1	7	13.5	6.7	25.3
		Unknown	4	3.7	1	25.0	4.6	69.9

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30PA_W10_SG.xls
15OCT2021 13:15

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Pain
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

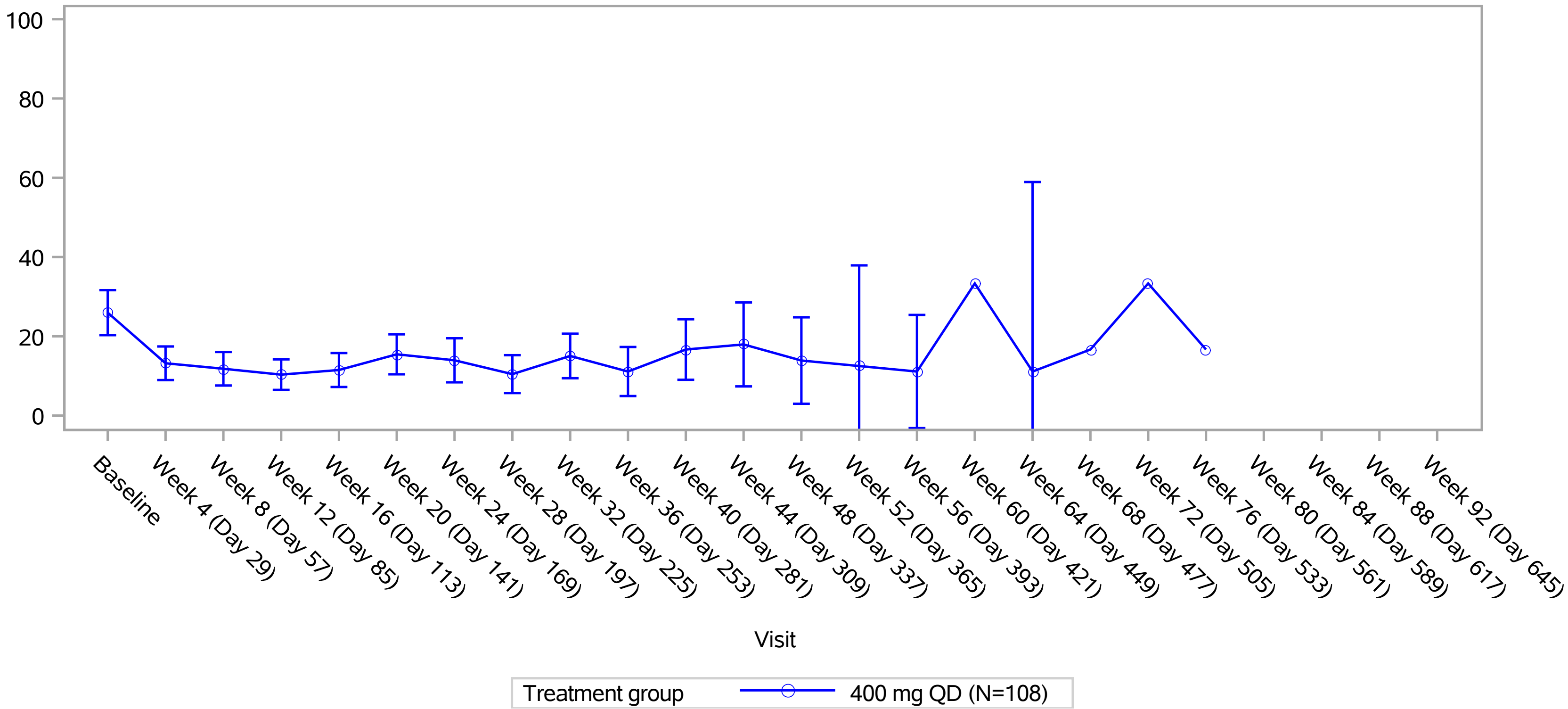
			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	27	26.0	18.5	35.1
	Cycle 12 (LOCF)	n/a	104	96.3	14	13.5	8.2	21.3
	End of Study (LOCF)	n/a	104	96.3	14	13.5	8.2	21.3
Sex	All visits	Female	56	51.9	11	19.6	11.3	31.8
		Male	48	44.4	16	33.3	21.7	47.5
	Cycle 12 (LOCF)	Female	56	51.9	9	16.1	8.7	27.8
		Male	48	44.4	5	10.4	4.5	22.2
	End of Study (LOCF)	Female	56	51.9	9	16.1	8.7	27.8
		Male	48	44.4	5	10.4	4.5	22.2
Age	All visits	< 65	60	55.6	8	13.3	6.9	24.2
		>= 65	44	40.7	19	43.2	29.7	57.8
	Cycle 12 (LOCF)	< 65	60	55.6	4	6.7	2.6	15.9
		>= 65	44	40.7	10	22.7	12.8	37.0
	End of Study (LOCF)	< 65	60	55.6	4	6.7	2.6	15.9
		>= 65	44	40.7	10	22.7	12.8	37.0
ECOG performance status	All visits	0	29	26.9	11	37.9	22.7	56.0
		1	75	69.4	16	21.3	13.6	31.9
	Cycle 12 (LOCF)	0	29	26.9	6	20.7	9.8	38.4
		1	75	69.4	8	10.7	5.5	19.7
	End of Study (LOCF)	0	29	26.9	6	20.7	9.8	38.4
		1	75	69.4	8	10.7	5.5	19.7
Geographic region	All visits	USA	19	17.6	9	47.4	27.3	68.3
		Europe (EU)	40	37.0	11	27.5	16.1	42.8
		Asia (AS)	45	41.7	7	15.6	7.7	28.8
	Cycle 12 (LOCF)	USA	19	17.6	4	21.1	8.5	43.3
		Europe (EU)	40	37.0	5	12.5	5.5	26.1
		Asia (AS)	45	41.7	5	11.1	4.8	23.5
	End of Study (LOCF)	USA	19	17.6	4	21.1	8.5	43.3
		Europe (EU)	40	37.0	5	12.5	5.5	26.1
		Asia (AS)	45	41.7	5	11.1	4.8	23.5
Race/ethnicity	All visits	Asian	48	44.4	9	18.8	10.2	31.9
		Non-Asian	52	48.1	17	32.7	21.5	46.2
		Unknown	4	3.7	1	25.0	4.6	69.9
	Cycle 12 (LOCF)	Asian	48	44.4	6	12.5	5.9	24.7
		Non-Asian	52	48.1	7	13.5	6.7	25.3
		Unknown	4	3.7	1	25.0	4.6	69.9
	End of Study (LOCF)	Asian	48	44.4	6	12.5	5.9	24.7

		Non-Asian	52	48.1	7	13.5	6.7	25.3
		Unknown	4	3.7	1	25.0	4.6	69.9

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30PA_W15_SG.xls
15OCT2021 13:05

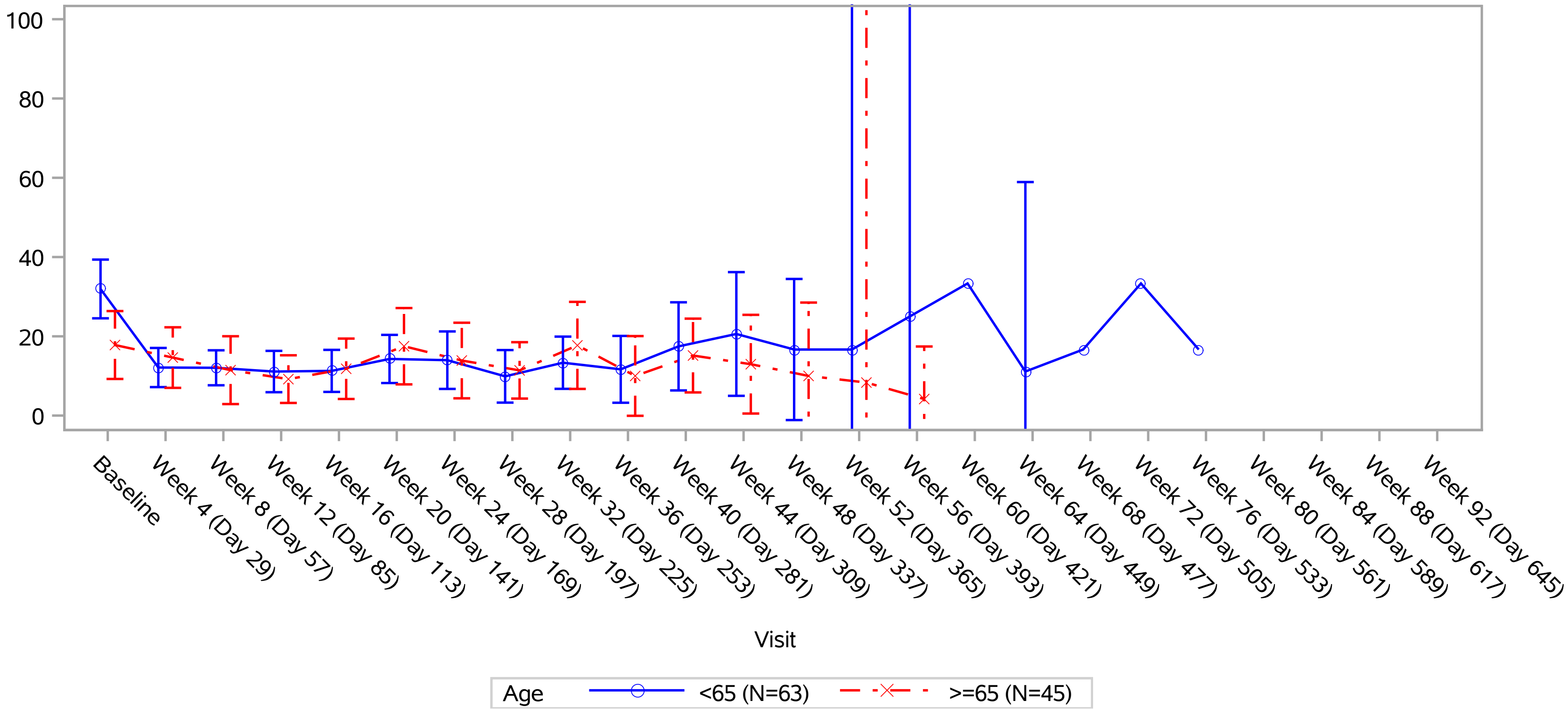
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Pain
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30PA.pdf
15OCT2021 17:28

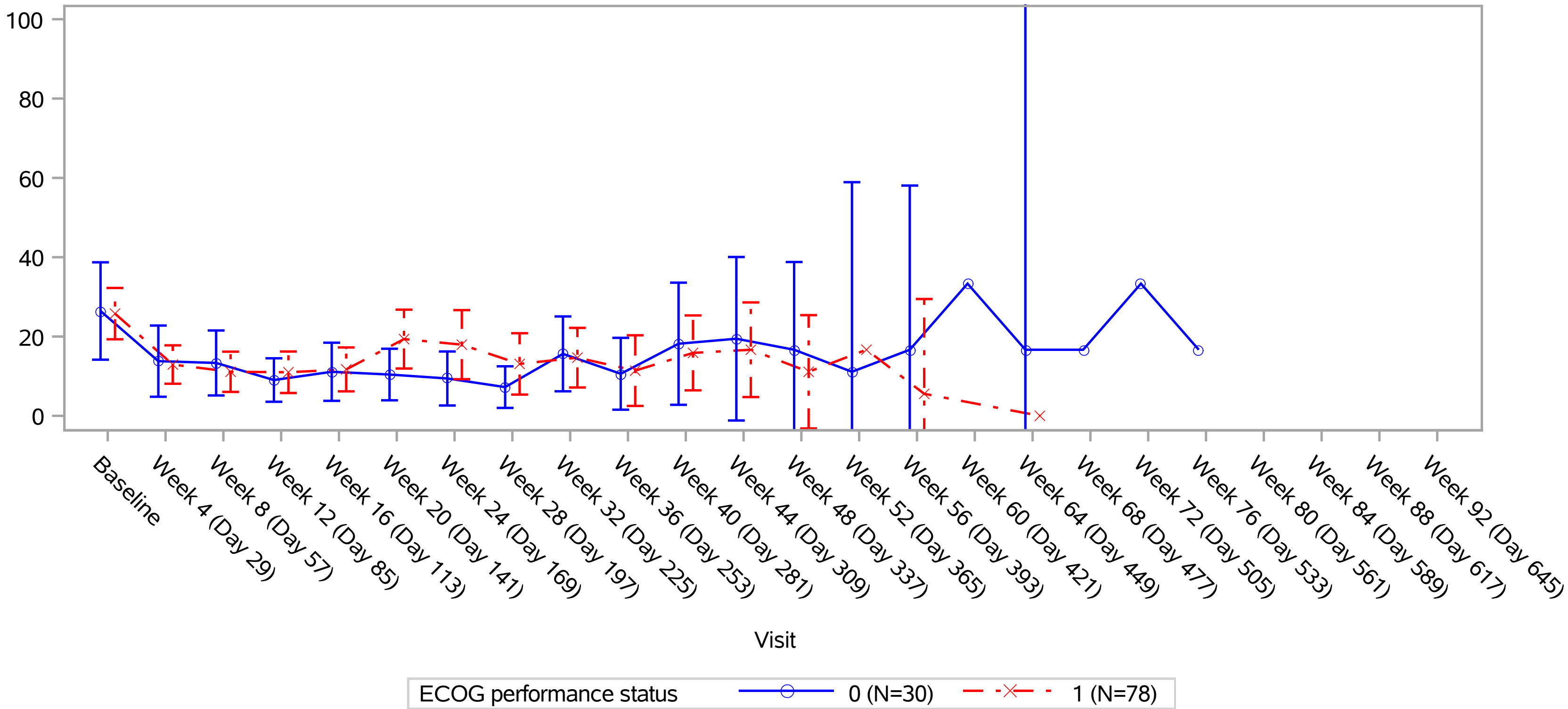
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Pain
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30PA_SGAGE65.pdf
15OCT2021 17:57

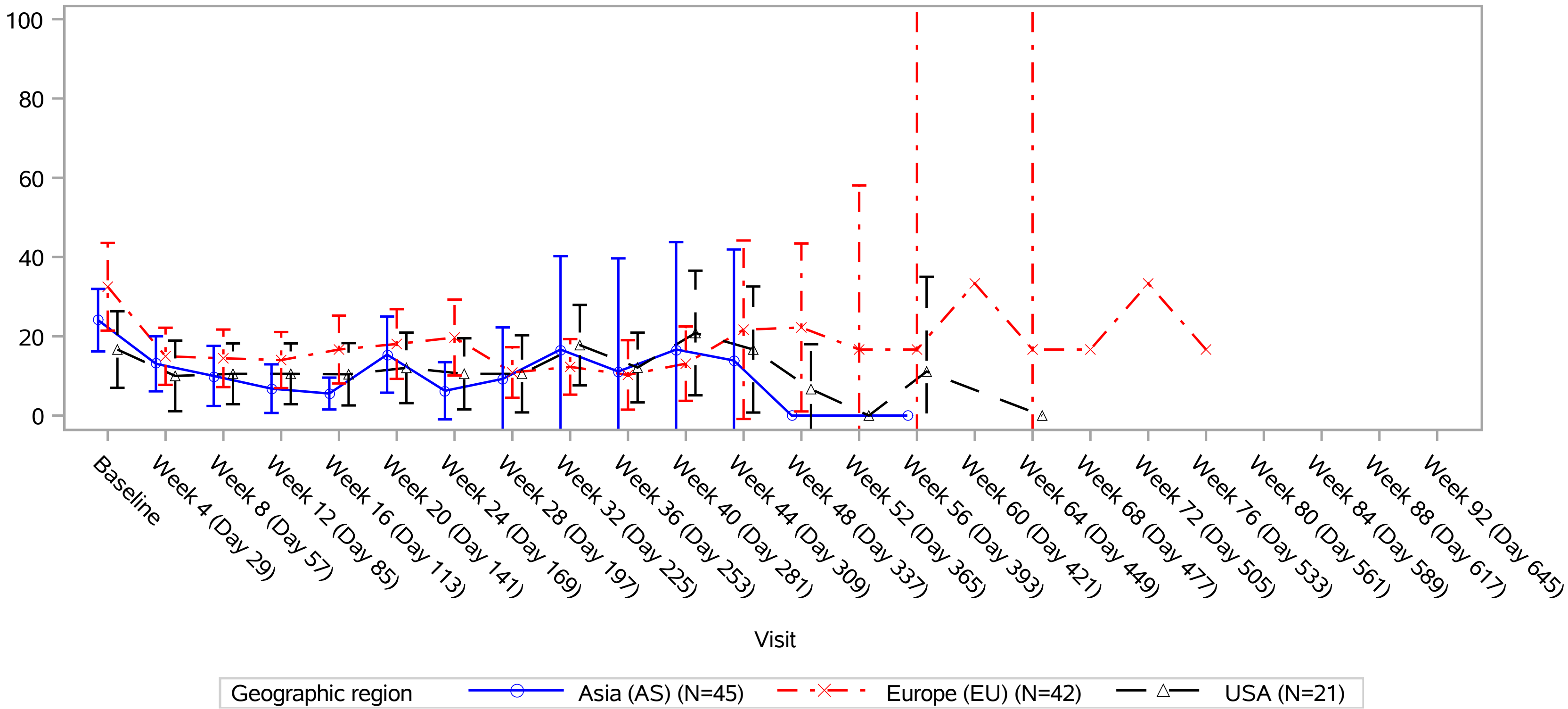
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Pain
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30PA_SGECOG.pdf
15OCT2021 18:28

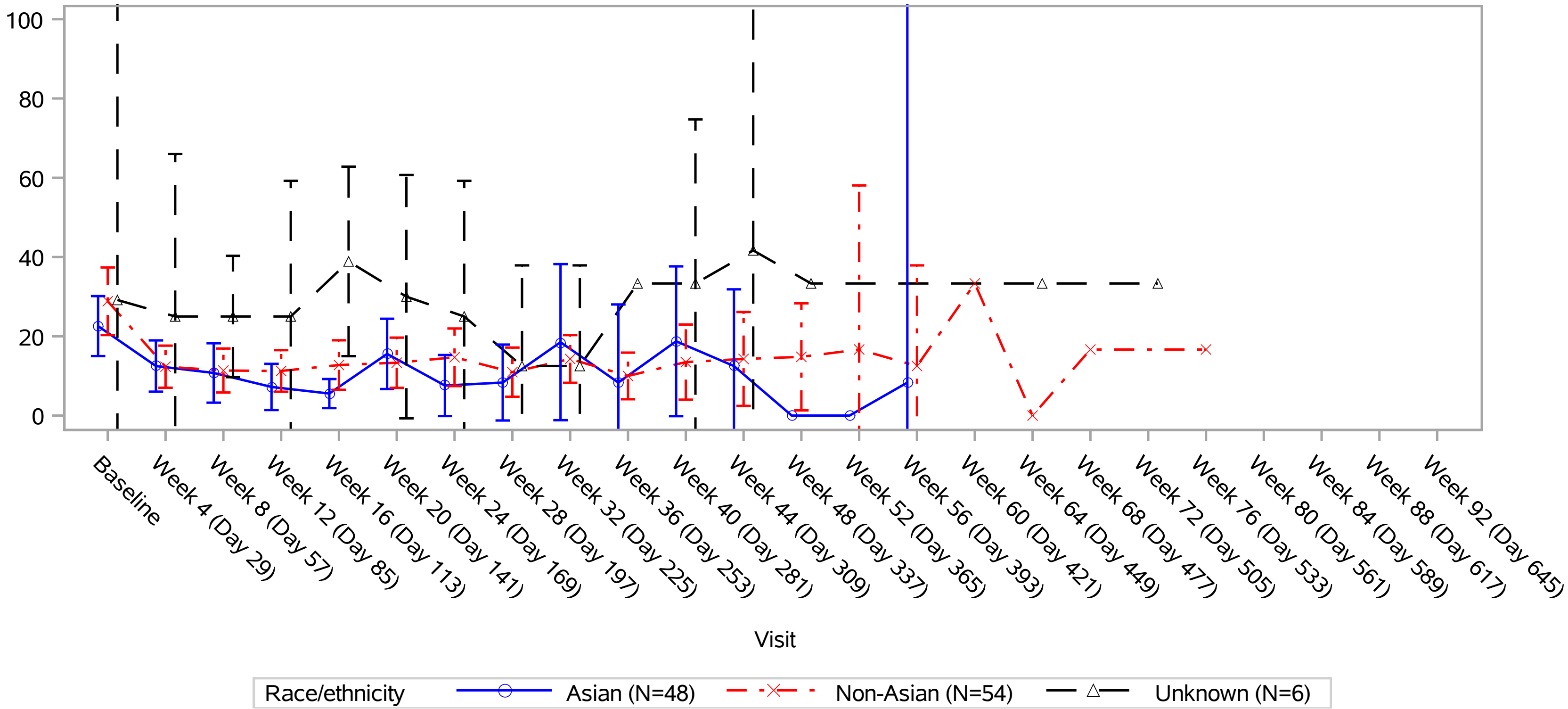
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Pain
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30PA_SGGEO.pdf
15OCT2021 18:58

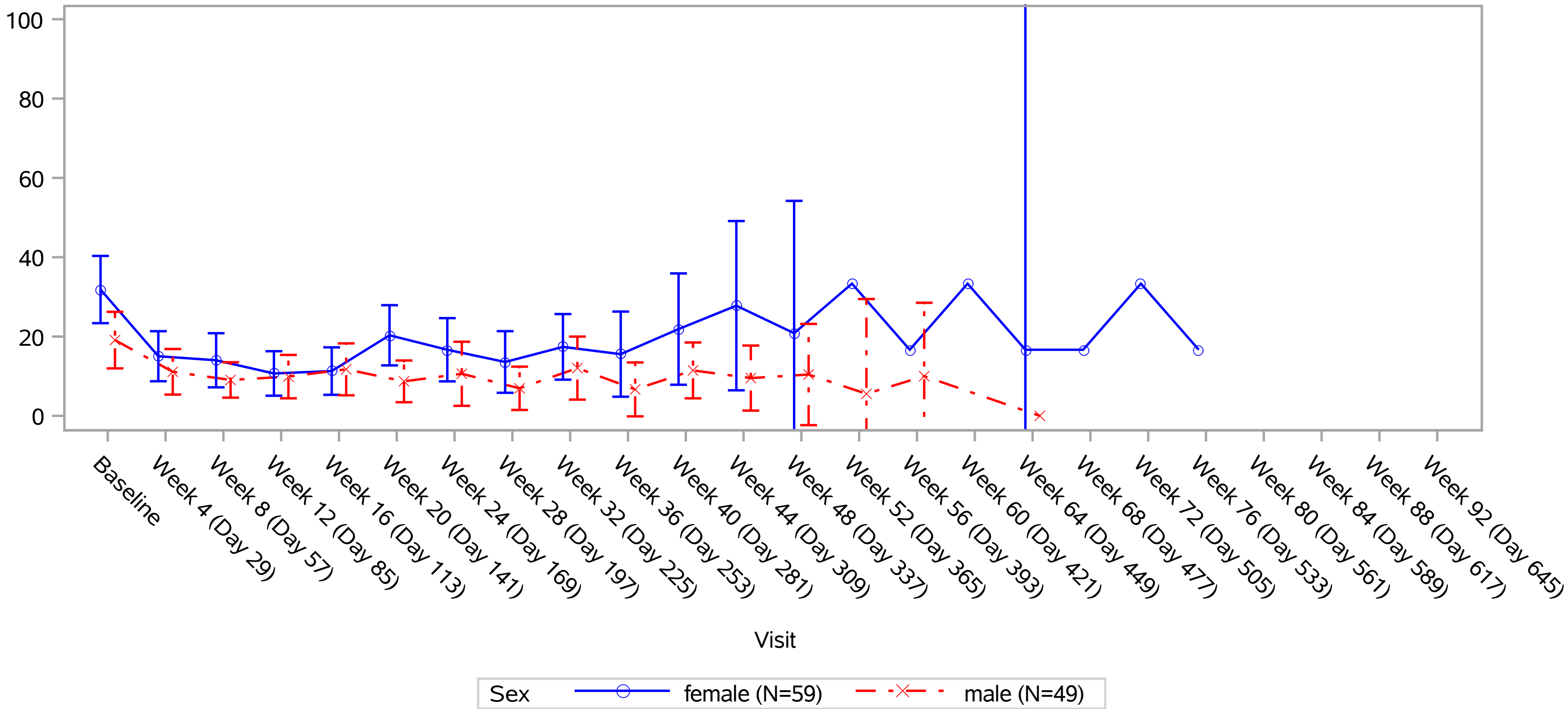
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Pain
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30PA_SGRE.pdf
15OCT2021 19:29

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Pain
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30PA_SGSEX.pdf
15OCT2021 19:59

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Physical functioning
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=108)							
		Patients				Statistics			
Name Visit	Level	in study¹	%	with value¹	%	mean²	SD	CI LL	CI UL
All									
Baseline	n/a	108	100.0	104	96.3	78.27	21.59	74.07	82.47
Week 4 (Day 29)	n/a	108	100.0	96	88.9	83.75	18.09	80.08	87.42
Week 8 (Day 57)	n/a	92	85.2	79	85.9	85.57	16.86	81.79	89.35
Week 12 (Day 85)	n/a	79	73.1	71	89.9	84.93	16.37	81.05	88.81
Week 16 (Day 113)	n/a	69	63.9	58	84.1	85.29	17.52	80.68	89.89
Week 20 (Day 141)	n/a	59	54.6	55	93.2	87.36	15.91	83.06	91.66
Week 24 (Day 169)	n/a	56	51.9	49	87.5	87.48	17.78	82.38	92.59
Week 28 (Day 197)	n/a	55	50.9	51	92.7	86.27	16.73	81.57	90.98
Week 32 (Day 225)	n/a	48	44.4	41	85.4	87.15	17.35	81.68	92.63
Week 36 (Day 253)	n/a	41	38.0	30	73.2	89.33	13.74	84.20	94.46
Week 40 (Day 281)	n/a	37	34.3	32	86.5	87.60	13.15	82.86	92.35
Week 44 (Day 309)	n/a	31	28.7	26	83.9	85.13	23.42	75.67	94.59
Week 48 (Day 337)	n/a	23	21.3	12	52.2	90.00	12.23	82.23	97.77
Week 52 (Day 365)	n/a	19	17.6	4	21.1	76.67	17.64	48.60	104.73
Week 56 (Day 393)	n/a	17	15.7	6	35.3	84.44	15.59	68.09	100.80
Week 60 (Day 421)	n/a	11	10.2	1	9.1	80.00	NE	NE	NE
Week 64 (Day 449)	n/a	10	9.3	3	30.0	82.22	7.70	63.10	101.35
Week 68 (Day 477)	n/a	6	5.6	1	16.7	80.00	NE	NE	NE
Week 72 (Day 505)	n/a	6	5.6	1	16.7	80.00	NE	NE	NE
Week 76 (Day 533)	n/a	6	5.6	1	16.7	80.00	NE	NE	NE
Week 80 (Day 561)	n/a	5	4.6	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	n/a	1	0.9	0	0.0	NE	NE	NE	NE

Cycle 12 (LOCF)	n/a	108	100.0	108	100.0	83.83	19.83	80.05	87.61
End of Study (LOCF)	n/a	108	100.0	108	100.0	84.20	18.31	80.70	87.69
Sex									
Baseline	Female	59	100.0	56	94.9	74.29	21.48	68.53	80.04
Week 4 (Day 29)	Female	59	100.0	51	86.4	80.00	17.64	75.04	84.96
Week 8 (Day 57)	Female	49	83.1	44	89.8	81.06	18.30	75.50	86.62
Week 12 (Day 85)	Female	44	74.6	39	88.6	80.21	17.72	74.47	85.96
Week 16 (Day 113)	Female	38	64.4	31	81.6	80.86	19.53	73.70	88.02
Week 20 (Day 141)	Female	33	55.9	32	97.0	82.03	17.94	75.56	88.50
Week 24 (Day 169)	Female	31	52.5	27	87.1	83.70	19.60	75.95	91.46
Week 28 (Day 197)	Female	30	50.8	27	90.0	81.23	19.04	73.70	88.77
Week 32 (Day 225)	Female	27	45.8	23	85.2	83.19	20.78	74.20	92.17
Week 36 (Day 253)	Female	22	37.3	15	68.2	85.78	16.30	76.75	94.81
Week 40 (Day 281)	Female	18	30.5	16	88.9	83.33	15.01	75.34	91.33
Week 44 (Day 309)	Female	15	25.4	12	80.0	77.22	31.59	57.15	97.29
Week 48 (Day 337)	Female	11	18.6	4	36.4	83.33	17.64	55.27	111.40
Week 52 (Day 365)	Female	9	15.3	1	11.1	80.00	NE	NE	NE
Week 56 (Day 393)	Female	7	11.9	1	14.3	86.67	NE	NE	NE
Week 60 (Day 421)	Female	5	8.5	1	20.0	80.00	NE	NE	NE
Week 64 (Day 449)	Female	4	6.8	2	50.0	80.00	9.43	-4.71	164.71
Week 68 (Day 477)	Female	3	5.1	1	33.3	80.00	NE	NE	NE
Week 72 (Day 505)	Female	3	5.1	1	33.3	80.00	NE	NE	NE
Week 76 (Day 533)	Female	3	5.1	1	33.3	80.00	NE	NE	NE
Week 80 (Day 561)	Female	2	3.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	59	100.0	59	100.0	80.00	21.58	74.37	85.63
End of Study (LOCF)	Female	59	100.0	59	100.0	80.90	18.92	75.97	85.83
Baseline	Male	49	100.0	48	98.0	82.92	20.99	76.82	89.01
Week 4 (Day 29)	Male	49	100.0	45	91.8	88.00	17.84	82.64	93.36
Week 8 (Day 57)	Male	43	87.8	35	81.4	91.24	13.01	86.77	95.71
Week 12 (Day 85)	Male	35	71.4	32	91.4	90.68	12.59	86.14	95.21
Week 16 (Day 113)	Male	31	63.3	27	87.1	90.37	13.50	85.03	95.71
Week 20 (Day 141)	Male	26	53.1	23	88.5	94.78	8.28	91.20	98.36
Week 24 (Day 169)	Male	25	51.0	22	88.0	92.12	14.35	85.76	98.48
Week 28 (Day 197)	Male	25	51.0	24	96.0	91.94	11.63	87.03	96.85

Week 32 (Day 225)	Male	21	42.9	18	85.7	92.22	10.03	87.23	97.21
Week 36 (Day 253)	Male	19	38.8	15	78.9	92.89	9.91	87.40	98.38
Week 40 (Day 281)	Male	19	38.8	16	84.2	91.87	9.66	86.73	97.02
Week 44 (Day 309)	Male	16	32.7	14	87.5	91.90	10.19	86.02	97.79
Week 48 (Day 337)	Male	12	24.5	8	66.7	93.33	7.97	86.67	99.99
Week 52 (Day 365)	Male	10	20.4	3	30.0	75.56	21.43	22.32	128.79
Week 56 (Day 393)	Male	10	20.4	5	50.0	84.00	17.38	62.41	105.59
Week 60 (Day 421)	Male	6	12.2	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Male	6	12.2	1	16.7	86.67	NE	NE	NE
Week 68 (Day 477)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	49	100.0	49	100.0	88.44	16.54	83.68	93.19
End of Study (LOCF)	Male	49	100.0	49	100.0	88.16	16.90	83.31	93.02
Age									
Baseline	< 65	63	100.0	60	95.2	76.89	22.18	71.16	82.62
Week 4 (Day 29)	< 65	63	100.0	55	87.3	86.30	16.65	81.80	90.80
Week 8 (Day 57)	< 65	54	85.7	47	87.0	88.09	13.04	84.26	91.91
Week 12 (Day 85)	< 65	47	74.6	42	89.4	87.02	14.24	82.59	91.46
Week 16 (Day 113)	< 65	39	61.9	34	87.2	88.24	15.14	82.95	93.52
Week 20 (Day 141)	< 65	35	55.6	35	100.0	88.95	12.93	84.51	93.39
Week 24 (Day 169)	< 65	34	54.0	31	91.2	88.17	16.30	82.19	94.15
Week 28 (Day 197)	< 65	33	52.4	32	97.0	89.38	12.31	84.94	93.81
Week 32 (Day 225)	< 65	30	47.6	25	83.3	92.80	8.80	89.17	96.43
Week 36 (Day 253)	< 65	25	39.7	20	80.0	92.00	7.98	88.27	95.73
Week 40 (Day 281)	< 65	23	36.5	21	91.3	88.89	11.61	83.60	94.17
Week 44 (Day 309)	< 65	19	30.2	17	89.5	86.27	24.77	73.54	99.01
Week 48 (Day 337)	< 65	14	22.2	7	50.0	89.52	14.84	75.80	103.24

Week 52 (Day 365)	< 65	12	19.0	2	16.7	70.00	14.14	-57.06	197.06
Week 56 (Day 393)	< 65	11	17.5	2	18.2	86.67	0.00	NE	NE
Week 60 (Day 421)	< 65	8	12.7	1	12.5	80.00	NE	NE	NE
Week 64 (Day 449)	< 65	7	11.1	3	42.9	82.22	7.70	63.10	101.35
Week 68 (Day 477)	< 65	4	6.3	1	25.0	80.00	NE	NE	NE
Week 72 (Day 505)	< 65	4	6.3	1	25.0	80.00	NE	NE	NE
Week 76 (Day 533)	< 65	4	6.3	1	25.0	80.00	NE	NE	NE
Week 80 (Day 561)	< 65	3	4.8	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	63	100.0	63	100.0	85.82	19.87	80.81	90.83
End of Study (LOCF)	< 65	63	100.0	63	100.0	86.67	16.85	82.42	90.91
Baseline	>= 65	45	100.0	44	97.8	80.15	20.86	73.81	86.49
Week 4 (Day 29)	>= 65	45	100.0	41	91.1	80.33	19.55	74.16	86.50
Week 8 (Day 57)	>= 65	38	84.4	32	84.2	81.87	20.96	74.32	89.43
Week 12 (Day 85)	>= 65	32	71.1	29	90.6	81.90	18.91	74.70	89.09
Week 16 (Day 113)	>= 65	30	66.7	24	80.0	81.11	20.02	72.66	89.56
Week 20 (Day 141)	>= 65	24	53.3	20	83.3	84.58	20.18	75.14	94.03
Week 24 (Day 169)	>= 65	22	48.9	18	81.8	86.30	20.51	76.10	96.50
Week 28 (Day 197)	>= 65	22	48.9	19	86.4	81.05	21.69	70.60	91.51
Week 32 (Day 225)	>= 65	18	40.0	16	88.9	78.33	23.29	65.93	90.74
Week 36 (Day 253)	>= 65	16	35.6	10	62.5	84.00	20.66	69.22	98.78
Week 40 (Day 281)	>= 65	14	31.1	11	78.6	85.15	16.01	74.39	95.91
Week 44 (Day 309)	>= 65	12	26.7	9	75.0	82.96	21.89	66.14	99.79
Week 48 (Day 337)	>= 65	9	20.0	5	55.6	90.67	8.94	79.56	101.77
Week 52 (Day 365)	>= 65	7	15.6	2	28.6	83.33	23.57	-128.44	295.10
Week 56 (Day 393)	>= 65	6	13.3	4	66.7	83.33	20.00	51.51	115.16
Week 60 (Day 421)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE

Week 76 (Day 533)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	45	100.0	45	100.0	81.04	19.64	75.14	86.94
End of Study (LOCF)	>= 65	45	100.0	45	100.0	80.74	19.86	74.77	86.71
ECOG performance status									
Baseline	0	30	100.0	29	96.7	81.61	20.60	73.77	89.44
Week 4 (Day 29)	0	30	100.0	29	96.7	86.90	16.18	80.74	93.05
Week 8 (Day 57)	0	28	93.3	25	89.3	84.80	21.13	76.08	93.52
Week 12 (Day 85)	0	26	86.7	24	92.3	87.92	14.13	81.95	93.88
Week 16 (Day 113)	0	26	86.7	21	80.8	88.89	13.55	82.72	95.06
Week 20 (Day 141)	0	26	86.7	24	92.3	89.17	14.95	82.85	95.48
Week 24 (Day 169)	0	25	83.3	23	92.0	90.72	16.05	83.79	97.66
Week 28 (Day 197)	0	25	83.3	23	92.0	91.01	11.12	86.21	95.82
Week 32 (Day 225)	0	20	66.7	16	80.0	93.33	10.04	87.99	98.68
Week 36 (Day 253)	0	18	60.0	11	61.1	92.73	10.94	85.38	100.07
Week 40 (Day 281)	0	16	53.3	11	68.8	84.85	14.01	75.43	94.26
Week 44 (Day 309)	0	15	50.0	12	80.0	85.56	29.38	66.89	104.22
Week 48 (Day 337)	0	9	30.0	6	66.7	95.56	8.07	87.08	104.03
Week 52 (Day 365)	0	9	30.0	3	33.3	80.00	20.00	30.32	129.68
Week 56 (Day 393)	0	8	26.7	3	37.5	95.56	7.70	76.43	114.68
Week 60 (Day 421)	0	5	16.7	1	20.0	80.00	NE	NE	NE
Week 64 (Day 449)	0	5	16.7	2	40.0	80.00	9.43	-4.71	164.71
Week 68 (Day 477)	0	3	10.0	1	33.3	80.00	NE	NE	NE
Week 72 (Day 505)	0	3	10.0	1	33.3	80.00	NE	NE	NE
Week 76 (Day 533)	0	3	10.0	1	33.3	80.00	NE	NE	NE
Week 80 (Day 561)	0	2	6.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	0	1	3.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	30	100.0	30	100.0	84.67	22.57	76.24	93.09
End of Study (LOCF)	0	30	100.0	30	100.0	87.11	16.04	81.12	93.10
Baseline	1	78	100.0	75	96.2	76.98	21.96	71.93	82.03
Week 4 (Day 29)	1	78	100.0	67	85.9	82.39	18.81	77.80	86.98

Week 8 (Day 57)	1	64	82.1	54	84.4	85.93	14.69	81.92	89.94
Week 12 (Day 85)	1	53	67.9	47	88.7	83.40	17.36	78.31	88.50
Week 16 (Day 113)	1	43	55.1	37	86.0	83.24	19.28	76.81	89.67
Week 20 (Day 141)	1	33	42.3	31	93.9	85.97	16.72	79.83	92.10
Week 24 (Day 169)	1	31	39.7	26	83.9	84.62	19.02	76.93	92.30
Week 28 (Day 197)	1	30	38.5	28	93.3	82.38	19.56	74.80	89.97
Week 32 (Day 225)	1	28	35.9	25	89.3	83.20	19.92	74.98	91.42
Week 36 (Day 253)	1	23	29.5	19	82.6	87.37	15.05	80.11	94.62
Week 40 (Day 281)	1	21	26.9	21	100.0	89.05	12.79	83.23	94.87
Week 44 (Day 309)	1	16	20.5	14	87.5	84.76	18.01	74.36	95.16
Week 48 (Day 337)	1	14	17.9	6	42.9	84.44	13.77	69.99	98.90
Week 52 (Day 365)	1	10	12.8	1	10.0	66.67	NE	NE	NE
Week 56 (Day 393)	1	9	11.5	3	33.3	73.33	13.33	40.21	106.46
Week 60 (Day 421)	1	6	7.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	5	6.4	1	20.0	86.67	NE	NE	NE
Week 68 (Day 477)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	3	3.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	78	100.0	78	100.0	83.50	18.82	79.26	87.75
End of Study (LOCF)	1	78	100.0	78	100.0	83.08	19.09	78.77	87.38
Geographic region									
Baseline	USA	21	100.0	19	90.5	86.67	18.99	77.52	95.82
Week 4 (Day 29)	USA	21	100.0	20	95.2	91.33	9.45	86.91	95.76
Week 8 (Day 57)	USA	21	100.0	19	90.5	87.72	15.60	80.20	95.24
Week 12 (Day 85)	USA	21	100.0	19	90.5	90.96	10.08	86.11	95.82
Week 16 (Day 113)	USA	21	100.0	16	76.2	90.42	9.10	85.57	95.26
Week 20 (Day 141)	USA	20	95.2	18	90.0	92.96	8.99	88.49	97.44
Week 24 (Day 169)	USA	20	95.2	19	95.0	90.88	12.21	84.99	96.76
Week 28 (Day 197)	USA	20	95.2	19	95.0	91.58	11.30	86.13	97.02
Week 32 (Day 225)	USA	17	81.0	15	88.2	90.22	10.04	84.66	95.78
Week 36 (Day 253)	USA	17	81.0	11	64.7	90.30	9.60	83.86	96.75
Week 40 (Day 281)	USA	15	71.4	12	80.0	90.28	9.37	84.32	96.23

Week 44 (Day 309)	USA	13	61.9	10	76.9	94.00	9.66	87.09	100.91
Week 48 (Day 337)	USA	8	38.1	5	62.5	98.67	2.98	94.96	102.37
Week 52 (Day 365)	USA	6	28.6	1	16.7	100.00	NE	NE	NE
Week 56 (Day 393)	USA	6	28.6	3	50.0	95.56	7.70	76.43	114.68
Week 60 (Day 421)	USA	5	23.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	4	19.0	1	25.0	86.67	NE	NE	NE
Week 68 (Day 477)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	21	100.0	21	100.0	93.33	8.94	89.26	97.40
End of Study (LOCF)	USA	21	100.0	21	100.0	93.02	9.06	88.89	97.14
Baseline	Europe (EU)	42	100.0	40	95.2	72.17	21.50	65.29	79.04
Week 4 (Day 29)	Europe (EU)	42	100.0	39	92.9	80.85	20.24	74.29	87.42
Week 8 (Day 57)	Europe (EU)	36	85.7	30	83.3	82.67	19.31	75.46	89.88
Week 12 (Day 85)	Europe (EU)	31	73.8	25	80.6	79.27	21.27	70.49	88.05
Week 16 (Day 113)	Europe (EU)	30	71.4	24	80.0	79.44	22.75	69.84	89.05
Week 20 (Day 141)	Europe (EU)	26	61.9	24	92.3	82.99	20.23	74.44	91.53
Week 24 (Day 169)	Europe (EU)	26	61.9	22	84.6	83.03	23.34	72.68	93.38
Week 28 (Day 197)	Europe (EU)	25	59.5	23	92.0	80.29	20.94	71.24	89.34
Week 32 (Day 225)	Europe (EU)	21	50.0	19	90.5	84.91	20.71	74.93	94.89
Week 36 (Day 253)	Europe (EU)	16	38.1	13	81.3	86.15	18.55	74.94	97.36
Week 40 (Day 281)	Europe (EU)	14	33.3	14	100.0	82.38	16.46	72.88	91.88
Week 44 (Day 309)	Europe (EU)	11	26.2	10	90.9	72.67	33.03	49.04	96.29
Week 48 (Day 337)	Europe (EU)	8	19.0	6	75.0	83.33	13.82	68.83	97.84
Week 52 (Day 365)	Europe (EU)	6	14.3	3	50.0	68.89	10.18	43.59	94.19
Week 56 (Day 393)	Europe (EU)	6	14.3	2	33.3	73.33	18.86	-96.08	242.75

Week 60 (Day 421)	Europe (EU)	4	9.5	1	25.0	80.00	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	4	9.5	2	50.0	80.00	9.43	-4.71	164.71
Week 68 (Day 477)	Europe (EU)	3	7.1	1	33.3	80.00	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	3	7.1	1	33.3	80.00	NE	NE	NE
Week 76 (Day 533)	Europe (EU)	3	7.1	1	33.3	80.00	NE	NE	NE
Week 80 (Day 561)	Europe (EU)	2	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Europe (EU)	42	100.0	42	100.0	78.25	22.96	71.10	85.41
End of Study (LOCF)	Europe (EU)	42	100.0	42	100.0	79.37	19.74	73.21	85.52
Baseline	Asia (AS)	45	100.0	45	100.0	80.15	21.58	73.67	86.63
Week 4 (Day 29)	Asia (AS)	45	100.0	37	82.2	82.70	18.49	76.54	88.87
Week 8 (Day 57)	Asia (AS)	35	77.8	30	85.7	87.11	15.05	81.49	92.73
Week 12 (Day 85)	Asia (AS)	27	60.0	27	100.0	85.93	13.25	80.69	91.17
Week 16 (Day 113)	Asia (AS)	18	40.0	18	100.0	88.52	13.10	82.01	95.03
Week 20 (Day 141)	Asia (AS)	13	28.9	13	100.0	87.69	12.43	80.18	95.20
Week 24 (Day 169)	Asia (AS)	10	22.2	8	80.0	91.67	5.91	86.73	96.61
Week 28 (Day 197)	Asia (AS)	10	22.2	9	90.0	90.37	8.24	84.04	96.70
Week 32 (Day 225)	Asia (AS)	10	22.2	7	70.0	86.67	21.08	67.17	106.16
Week 36 (Day 253)	Asia (AS)	8	17.8	6	75.0	94.44	5.02	89.18	99.71
Week 40 (Day 281)	Asia (AS)	8	17.8	6	75.0	94.44	5.02	89.18	99.71
Week 44 (Day 309)	Asia (AS)	7	15.6	6	85.7	91.11	10.04	80.58	101.64
Week 48 (Day 337)	Asia (AS)	7	15.6	1	14.3	86.67	NE	NE	NE
Week 52 (Day 365)	Asia (AS)	7	15.6	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Asia (AS)	5	11.1	1	20.0	73.33	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	45	100.0	45	100.0	84.59	18.85	78.93	90.25
End of Study (LOCF)	Asia (AS)	45	100.0	45	100.0	84.59	18.85	78.93	90.25

Race/ethnicity									
Baseline	Asian	48	100.0	48	100.0	80.14	22.07	73.73	86.55
Week 4 (Day 29)	Asian	48	100.0	40	83.3	83.50	18.18	77.69	89.31
Week 8 (Day 57)	Asian	38	79.2	31	81.6	87.10	14.80	81.67	92.53
Week 12 (Day 85)	Asian	30	62.5	30	100.0	85.61	13.18	80.69	90.53
Week 16 (Day 113)	Asian	21	43.8	21	100.0	89.21	12.73	83.41	95.00
Week 20 (Day 141)	Asian	16	33.3	15	93.8	88.00	12.14	81.28	94.72
Week 24 (Day 169)	Asian	13	27.1	11	84.6	92.12	7.19	87.29	96.95
Week 28 (Day 197)	Asian	13	27.1	12	92.3	91.11	8.68	85.59	96.63
Week 32 (Day 225)	Asian	12	25.0	9	75.0	86.67	19.44	71.73	101.61
Week 36 (Day 253)	Asian	10	20.8	8	80.0	93.33	7.13	87.38	99.29
Week 40 (Day 281)	Asian	10	20.8	8	80.0	93.75	6.28	88.50	99.00
Week 44 (Day 309)	Asian	9	18.8	8	88.9	90.83	10.04	82.44	99.23
Week 48 (Day 337)	Asian	9	18.8	2	22.2	93.33	9.43	8.63	178.04
Week 52 (Day 365)	Asian	9	18.8	1	11.1	100.00	NE	NE	NE
Week 56 (Day 393)	Asian	7	14.6	2	28.6	86.67	18.86	-82.75	256.08
Week 60 (Day 421)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	48	100.0	48	100.0	85.14	18.51	79.76	90.51
End of Study (LOCF)	Asian	48	100.0	48	100.0	85.14	18.51	79.76	90.51
Baseline	Non-Asian	54	100.0	52	96.3	77.05	21.02	71.20	82.90
Week 4 (Day 29)	Non-Asian	54	100.0	50	92.6	84.80	18.02	79.68	89.92
Week 8 (Day 57)	Non-Asian	49	90.7	44	89.8	83.94	18.76	78.23	89.64
Week 12 (Day 85)	Non-Asian	44	81.5	37	84.1	85.63	16.86	80.01	91.25
Week 16 (Day 113)	Non-Asian	43	79.6	34	79.1	83.92	19.36	77.17	90.68
Week 20 (Day 141)	Non-Asian	38	70.4	35	92.1	87.81	17.60	81.76	93.86
Week 24 (Day 169)	Non-Asian	38	70.4	34	89.5	85.88	20.68	78.67	93.10
Week 28 (Day 197)	Non-Asian	37	68.5	35	94.6	85.33	18.42	79.01	91.66
Week 32 (Day 225)	Non-Asian	32	59.3	28	87.5	89.05	14.65	83.37	94.73
Week 36 (Day 253)	Non-Asian	27	50.0	20	74.1	90.67	9.77	86.09	95.24

Week 40 (Day 281)	Non-Asian	23	42.6	21	91.3	88.25	11.53	83.01	93.50
Week 44 (Day 309)	Non-Asian	18	33.3	14	77.8	90.48	13.00	82.97	97.98
Week 48 (Day 337)	Non-Asian	12	22.2	9	75.0	89.63	13.79	79.03	100.23
Week 52 (Day 365)	Non-Asian	8	14.8	3	37.5	68.89	10.18	43.59	94.19
Week 56 (Day 393)	Non-Asian	8	14.8	4	50.0	83.33	16.78	56.64	110.03
Week 60 (Day 421)	Non-Asian	7	13.0	1	14.3	80.00	NE	NE	NE
Week 64 (Day 449)	Non-Asian	6	11.1	2	33.3	86.67	0.00	NE	NE
Week 68 (Day 477)	Non-Asian	3	5.6	1	33.3	80.00	NE	NE	NE
Week 72 (Day 505)	Non-Asian	3	5.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Non-Asian	3	5.6	1	33.3	80.00	NE	NE	NE
Week 80 (Day 561)	Non-Asian	2	3.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	54	100.0	54	100.0	84.81	17.35	80.08	89.55
End of Study (LOCF)	Non-Asian	54	100.0	54	100.0	84.07	17.82	79.21	88.94
Baseline	Unknown	6	100.0	4	66.7	71.67	26.87	28.90	114.43
Week 4 (Day 29)	Unknown	6	100.0	6	100.0	76.67	19.66	56.03	97.30
Week 8 (Day 57)	Unknown	5	83.3	4	80.0	91.67	6.38	81.51	101.82
Week 12 (Day 85)	Unknown	5	83.3	4	80.0	73.33	31.27	23.58	123.09
Week 16 (Day 113)	Unknown	5	83.3	3	60.0	73.33	23.09	15.96	130.70
Week 20 (Day 141)	Unknown	5	83.3	5	100.0	82.33	15.26	63.39	101.28
Week 24 (Day 169)	Unknown	5	83.3	4	80.0	88.33	8.39	74.99	101.68
Week 28 (Day 197)	Unknown	5	83.3	4	80.0	80.00	19.63	48.77	111.23
Week 32 (Day 225)	Unknown	4	66.7	4	100.0	75.00	29.00	28.86	121.14
Week 36 (Day 253)	Unknown	4	66.7	2	50.0	60.00	37.71	-278.83	398.83
Week 40 (Day 281)	Unknown	4	66.7	3	75.0	66.67	20.00	16.98	116.35
Week 44 (Day 309)	Unknown	4	66.7	4	100.0	55.00	46.63	-19.19	129.19
Week 48 (Day 337)	Unknown	2	33.3	1	50.0	86.67	NE	NE	NE
Week 52 (Day 365)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 60 (Day 421)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE

Week 64 (Day 449)	Unknown	1	16.7	1	100.0	73.33	NE	NE	NE
Week 68 (Day 477)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	1	16.7	1	100.0	80.00	NE	NE	NE
Week 76 (Day 533)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	6	100.0	6	100.0	64.44	39.03	23.49	105.40
End of Study (LOCF)	Unknown	6	100.0	6	100.0	77.78	22.97	53.68	101.88

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TN_QSC30PF_SG.xls
27OCT2021 7:39

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Physical functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	23	22.1	15.2	31.0
	Cycle 12 (LOCF)	n/a	104	96.3	10	9.6	5.3	16.8
	End of Study (LOCF)	n/a	104	96.3	11	10.6	6.0	18.0
Sex	All visits	Female	56	51.9	13	23.2	14.1	35.8
		Male	48	44.4	10	20.8	11.7	34.3
	Cycle 12 (LOCF)	Female	56	51.9	7	12.5	6.2	23.6
		Male	48	44.4	3	6.3	2.1	16.8
	End of Study (LOCF)	Female	56	51.9	8	14.3	7.4	25.7
		Male	48	44.4	3	6.3	2.1	16.8
Age	All visits	< 65	60	55.6	7	11.7	5.8	22.2
		>= 65	44	40.7	16	36.4	23.8	51.1
	Cycle 12 (LOCF)	< 65	60	55.6	3	5.0	1.7	13.7
		>= 65	44	40.7	7	15.9	7.9	29.4
	End of Study (LOCF)	< 65	60	55.6	4	6.7	2.6	15.9
		>= 65	44	40.7	7	15.9	7.9	29.4
ECOG performance status	All visits	0	29	26.9	8	27.6	14.7	45.7
		1	75	69.4	15	20.0	12.5	30.4
	Cycle 12 (LOCF)	0	29	26.9	3	10.3	3.6	26.4
		1	75	69.4	7	9.3	4.6	18.0
	End of Study (LOCF)	0	29	26.9	3	10.3	3.6	26.4
		1	75	69.4	8	10.7	5.5	19.7
Geographic region	All visits	USA	19	17.6	5	26.3	11.8	48.8
		Europe (EU)	40	37.0	11	27.5	16.1	42.8
		Asia (AS)	45	41.7	7	15.6	7.7	28.8
	Cycle 12 (LOCF)	USA	19	17.6	1	5.3	0.9	24.6
		Europe (EU)	40	37.0	5	12.5	5.5	26.1
		Asia (AS)	45	41.7	4	8.9	3.5	20.7
	End of Study (LOCF)	USA	19	17.6	1	5.3	0.9	24.6
		Europe (EU)	40	37.0	6	15.0	7.1	29.1
		Asia (AS)	45	41.7	4	8.9	3.5	20.7
Race/ethnicity	All visits	Asian	48	44.4	8	16.7	8.7	29.6
		Non-Asian	52	48.1	14	26.9	16.8	40.3
		Unknown	4	3.7	1	25.0	4.6	69.9
	Cycle 12 (LOCF)	Asian	48	44.4	4	8.3	3.3	19.6
		Non-Asian	52	48.1	5	9.6	4.2	20.6
		Unknown	4	3.7	1	25.0	4.6	69.9
	End of Study (LOCF)	Asian	48	44.4	4	8.3	3.3	19.6

		Non-Asian	52	48.1	6	11.5	5.4	23.0
		Unknown	4	3.7	1	25.0	4.6	69.9

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30PF_W10_SG.xls
15OCT2021 13:16

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Physical functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

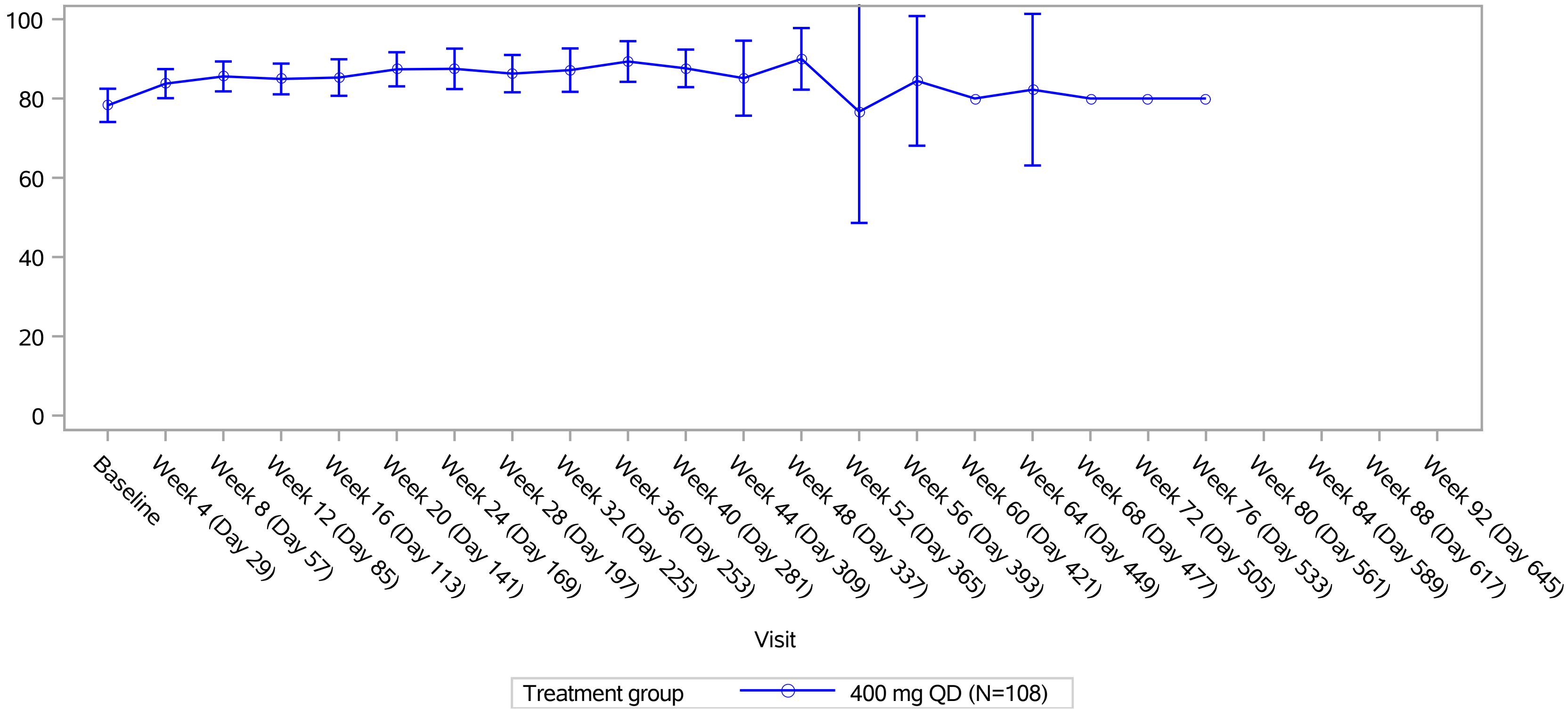
			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	12	11.5	6.7	19.1
	Cycle 12 (LOCF)	n/a	104	96.3	5	4.8	2.1	10.8
	End of Study (LOCF)	n/a	104	96.3	6	5.8	2.7	12.0
Sex	All visits	Female	56	51.9	6	10.7	5.0	21.5
		Male	48	44.4	6	12.5	5.9	24.7
	Cycle 12 (LOCF)	Female	56	51.9	4	7.1	2.8	17.0
		Male	48	44.4	1	2.1	0.4	10.9
	End of Study (LOCF)	Female	56	51.9	5	8.9	3.9	19.3
		Male	48	44.4	1	2.1	0.4	10.9
Age	All visits	< 65	60	55.6	3	5.0	1.7	13.7
		>= 65	44	40.7	9	20.5	11.2	34.5
	Cycle 12 (LOCF)	< 65	60	55.6	0	0.0	0.0	6.0
		>= 65	44	40.7	5	11.4	5.0	24.0
	End of Study (LOCF)	< 65	60	55.6	1	1.7	0.3	8.9
		>= 65	44	40.7	5	11.4	5.0	24.0
ECOG performance status	All visits	0	29	26.9	4	13.8	5.5	30.6
		1	75	69.4	8	10.7	5.5	19.7
	Cycle 12 (LOCF)	0	29	26.9	1	3.4	0.6	17.2
		1	75	69.4	4	5.3	2.1	12.9
	End of Study (LOCF)	0	29	26.9	1	3.4	0.6	17.2
		1	75	69.4	5	6.7	2.9	14.7
Geographic region	All visits	USA	19	17.6	2	10.5	2.9	31.4
		Europe (EU)	40	37.0	6	15.0	7.1	29.1
		Asia (AS)	45	41.7	4	8.9	3.5	20.7
	Cycle 12 (LOCF)	USA	19	17.6	1	5.3	0.9	24.6
		Europe (EU)	40	37.0	2	5.0	1.4	16.5
		Asia (AS)	45	41.7	2	4.4	1.2	14.8
	End of Study (LOCF)	USA	19	17.6	1	5.3	0.9	24.6
		Europe (EU)	40	37.0	3	7.5	2.6	19.9
		Asia (AS)	45	41.7	2	4.4	1.2	14.8
Race/ethnicity	All visits	Asian	48	44.4	5	10.4	4.5	22.2
		Non-Asian	52	48.1	6	11.5	5.4	23.0
		Unknown	4	3.7	1	25.0	4.6	69.9
	Cycle 12 (LOCF)	Asian	48	44.4	2	4.2	1.2	14.0
		Non-Asian	52	48.1	2	3.8	1.1	13.0
		Unknown	4	3.7	1	25.0	4.6	69.9
	End of Study (LOCF)	Asian	48	44.4	2	4.2	1.2	14.0

		Non-Asian	52	48.1	3	5.8	2.0	15.6
		Unknown	4	3.7	1	25.0	4.6	69.9

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30PF_W15_SG.xls
15OCT2021 13:06

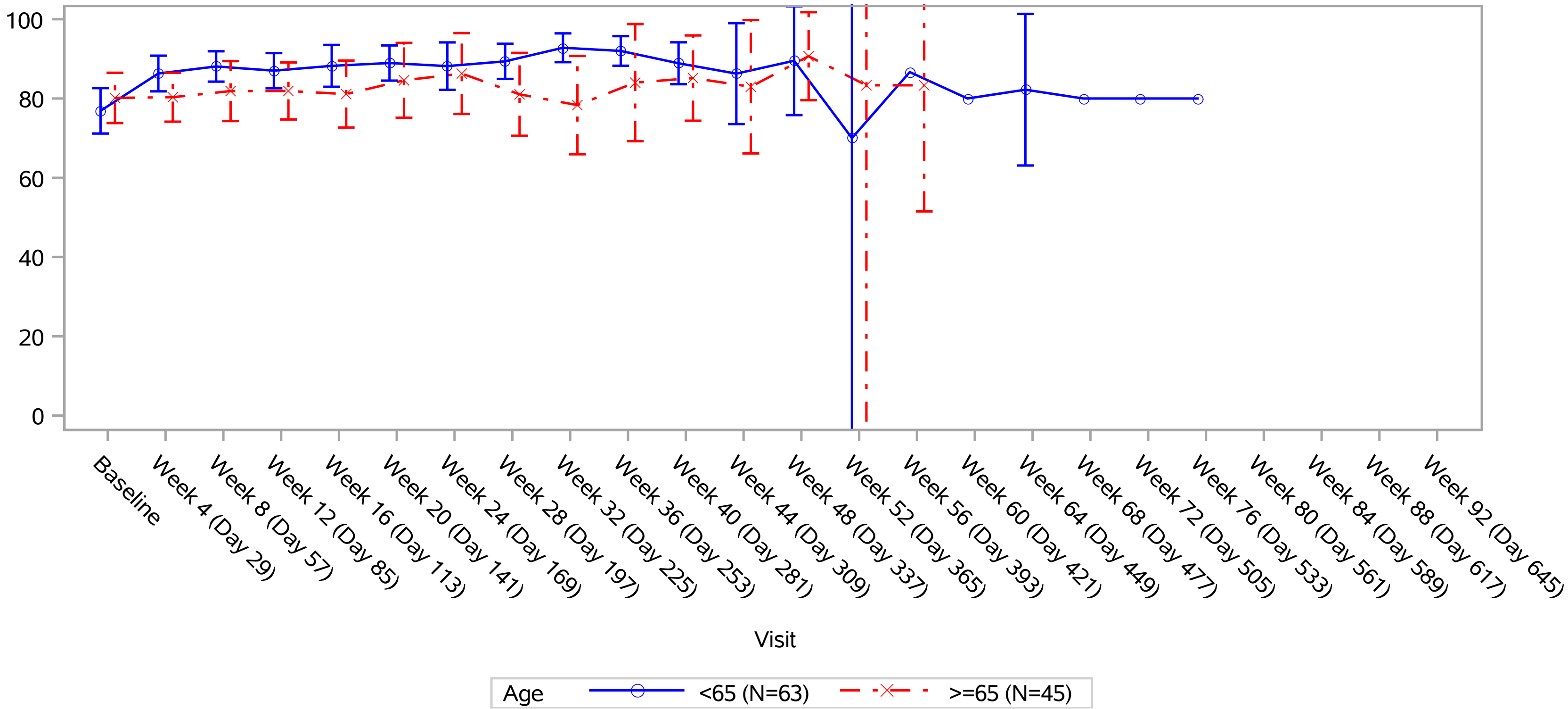
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Physical functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30PF.pdf
15OCT2021 17:28

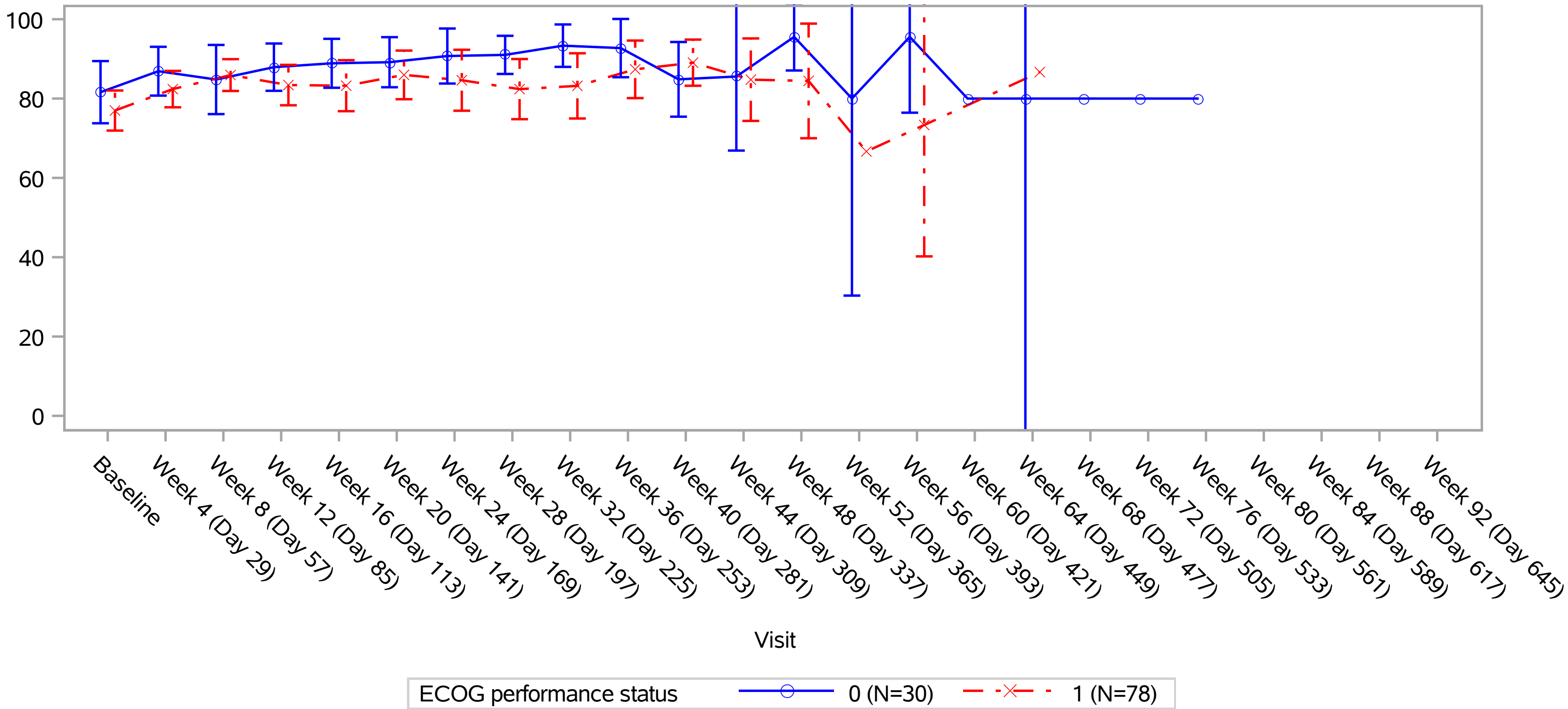
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Physical functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30PF_SGAGE65.pdf
15OCT2021 17:57

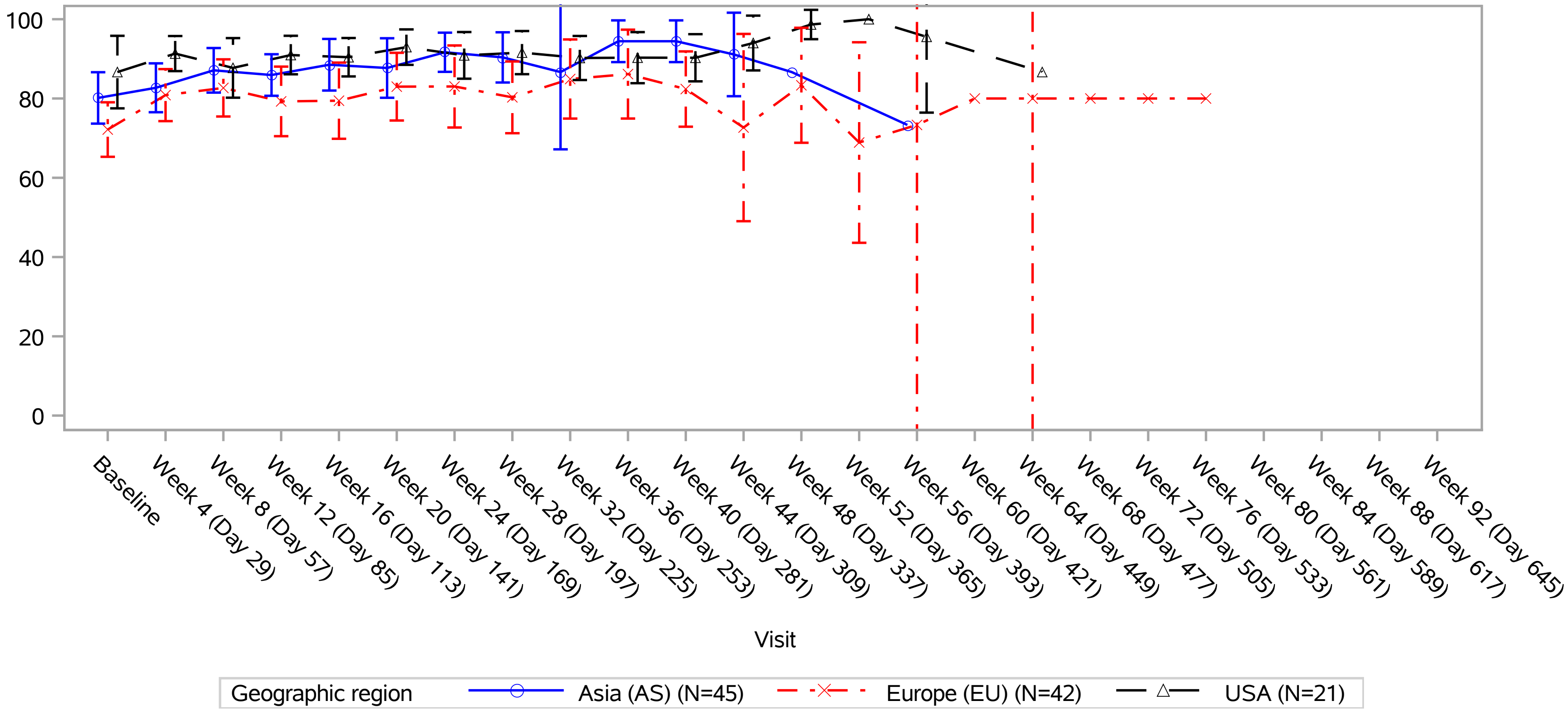
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Physical functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30PF_SGECOG.pdf
15OCT2021 18:28

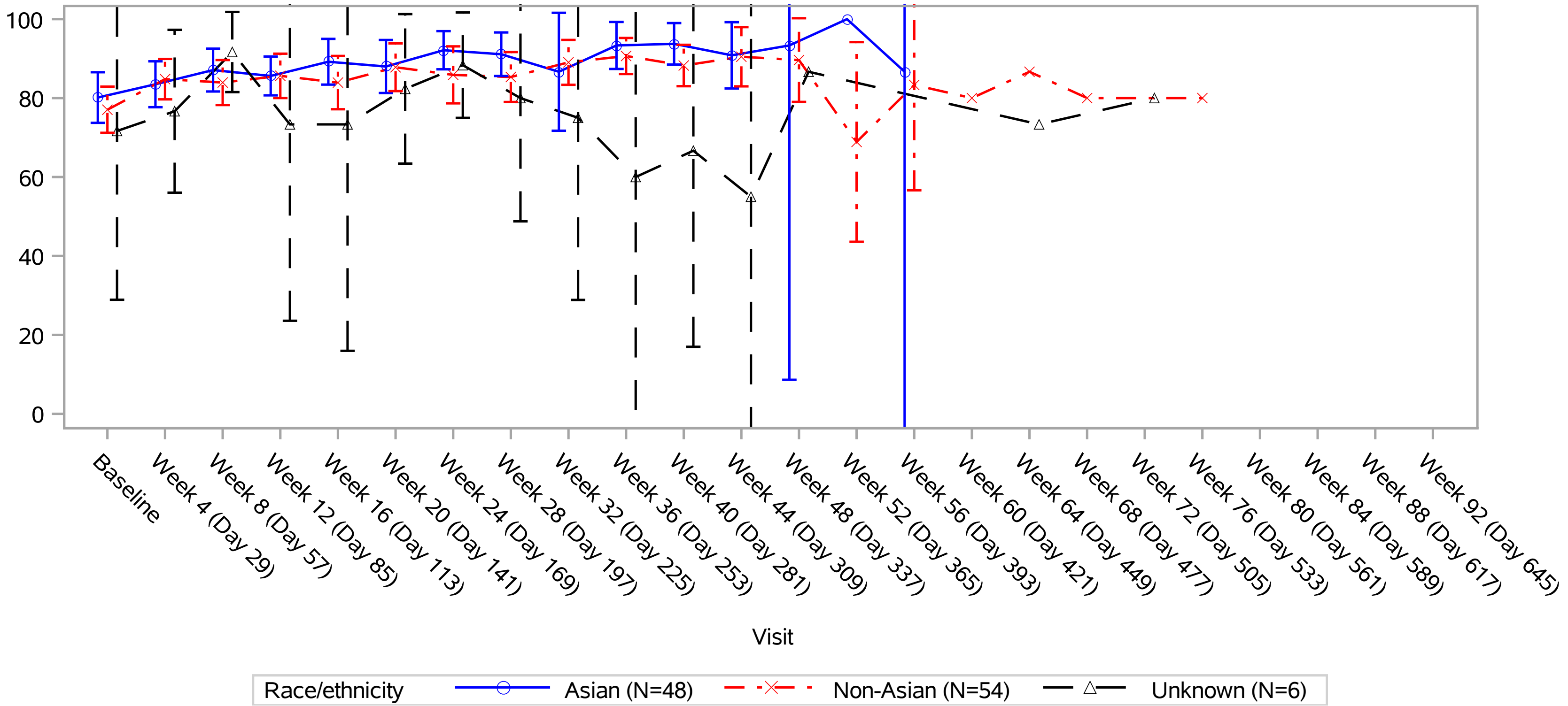
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Physical functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30PF_SGGEO.pdf
15OCT2021 18:59

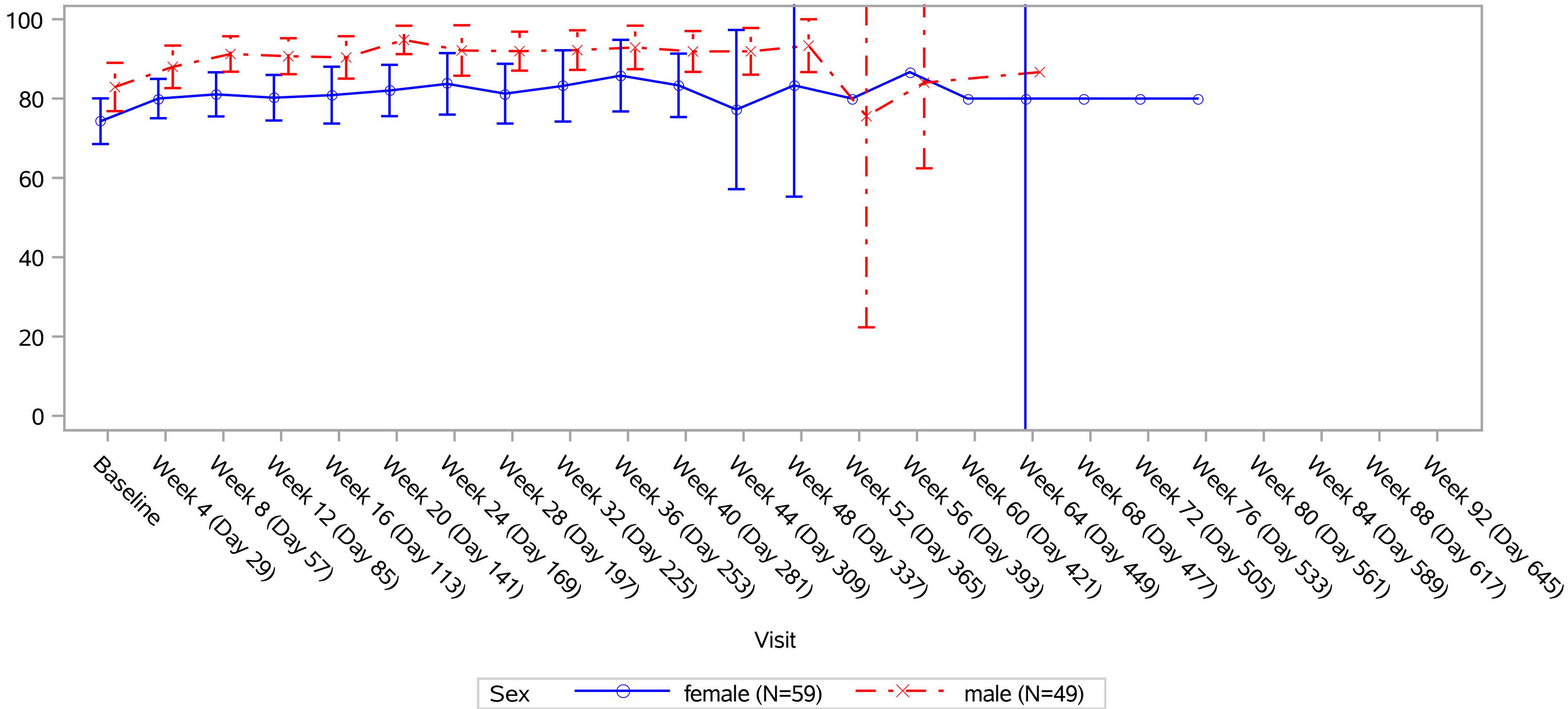
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Physical functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30PF_SGRE.pdf
15OCT2021 19:29

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Physical functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30PF_SGSEX.pdf
15OCT2021 20:00

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Global health status
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=108)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	108	100.0	104	96.3	64.90	23.56	60.32	69.49
Week 4 (Day 29)	n/a	108	100.0	96	88.9	71.70	21.17	67.41	75.99
Week 8 (Day 57)	n/a	92	85.2	79	85.9	74.05	19.20	69.75	78.35
Week 12 (Day 85)	n/a	79	73.1	70	88.6	75.60	17.96	71.31	79.88
Week 16 (Day 113)	n/a	69	63.9	58	84.1	75.57	18.92	70.60	80.55
Week 20 (Day 141)	n/a	59	54.6	55	93.2	73.33	18.10	68.44	78.23
Week 24 (Day 169)	n/a	56	51.9	49	87.5	74.83	19.21	69.31	80.35
Week 28 (Day 197)	n/a	55	50.9	51	92.7	75.00	17.40	70.11	79.89
Week 32 (Day 225)	n/a	48	44.4	41	85.4	75.00	17.97	69.33	80.67
Week 36 (Day 253)	n/a	41	38.0	30	73.2	78.06	17.57	71.49	84.62
Week 40 (Day 281)	n/a	37	34.3	32	86.5	70.05	19.27	63.11	77.00
Week 44 (Day 309)	n/a	31	28.7	26	83.9	70.19	23.47	60.71	79.67
Week 48 (Day 337)	n/a	23	21.3	12	52.2	78.47	13.04	70.19	86.75
Week 52 (Day 365)	n/a	19	17.6	4	21.1	72.92	20.83	39.77	106.07
Week 56 (Day 393)	n/a	17	15.7	6	35.3	73.61	11.08	61.99	85.24
Week 60 (Day 421)	n/a	11	10.2	1	9.1	66.67	NE	NE	NE
Week 64 (Day 449)	n/a	10	9.3	3	30.0	58.33	8.33	37.63	79.03
Week 68 (Day 477)	n/a	6	5.6	1	16.7	66.67	NE	NE	NE
Week 72 (Day 505)	n/a	6	5.6	1	16.7	41.67	NE	NE	NE
Week 76 (Day 533)	n/a	6	5.6	1	16.7	66.67	NE	NE	NE
Week 80 (Day 561)	n/a	5	4.6	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	n/a	1	0.9	0	0.0	NE	NE	NE	NE

Cycle 12 (LOCF)	n/a	108	100.0	108	100.0	70.52	20.49	66.62	74.43
End of Study (LOCF)	n/a	108	100.0	108	100.0	71.45	19.51	67.73	75.17
Sex									
Baseline	Female	59	100.0	56	94.9	62.05	26.20	55.04	69.07
Week 4 (Day 29)	Female	59	100.0	51	86.4	68.46	19.39	63.01	73.92
Week 8 (Day 57)	Female	49	83.1	44	89.8	69.89	21.28	63.42	76.36
Week 12 (Day 85)	Female	44	74.6	38	86.4	72.15	19.01	65.90	78.40
Week 16 (Day 113)	Female	38	64.4	31	81.6	75.54	18.75	68.66	82.42
Week 20 (Day 141)	Female	33	55.9	32	97.0	71.88	15.95	66.13	77.62
Week 24 (Day 169)	Female	31	52.5	27	87.1	70.68	19.39	63.01	78.35
Week 28 (Day 197)	Female	30	50.8	27	90.0	71.91	17.78	64.88	78.95
Week 32 (Day 225)	Female	27	45.8	23	85.2	69.57	19.24	61.25	77.88
Week 36 (Day 253)	Female	22	37.3	15	68.2	76.67	18.95	66.17	87.16
Week 40 (Day 281)	Female	18	30.5	16	88.9	62.50	19.72	51.99	73.01
Week 44 (Day 309)	Female	15	25.4	12	80.0	58.33	26.35	41.59	75.08
Week 48 (Day 337)	Female	11	18.6	4	36.4	66.67	0.00	NE	NE
Week 52 (Day 365)	Female	9	15.3	1	11.1	66.67	NE	NE	NE
Week 56 (Day 393)	Female	7	11.9	1	14.3	66.67	NE	NE	NE
Week 60 (Day 421)	Female	5	8.5	1	20.0	66.67	NE	NE	NE
Week 64 (Day 449)	Female	4	6.8	2	50.0	58.33	11.79	-47.55	164.22
Week 68 (Day 477)	Female	3	5.1	1	33.3	66.67	NE	NE	NE
Week 72 (Day 505)	Female	3	5.1	1	33.3	41.67	NE	NE	NE
Week 76 (Day 533)	Female	3	5.1	1	33.3	66.67	NE	NE	NE
Week 80 (Day 561)	Female	2	3.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	59	100.0	59	100.0	67.94	22.20	62.15	73.72
End of Study (LOCF)	Female	59	100.0	59	100.0	68.64	20.37	63.33	73.95
Baseline	Male	49	100.0	48	98.0	68.23	19.80	62.48	73.98
Week 4 (Day 29)	Male	49	100.0	45	91.8	75.37	22.68	68.56	82.18
Week 8 (Day 57)	Male	43	87.8	35	81.4	79.29	14.90	74.17	84.41
Week 12 (Day 85)	Male	35	71.4	32	91.4	79.69	15.97	73.93	85.45
Week 16 (Day 113)	Male	31	63.3	27	87.1	75.62	19.46	67.92	83.32
Week 20 (Day 141)	Male	26	53.1	23	88.5	75.36	20.94	66.31	84.42
Week 24 (Day 169)	Male	25	51.0	22	88.0	79.92	18.12	71.89	87.96
Week 28 (Day 197)	Male	25	51.0	24	96.0	78.47	16.65	71.44	85.50

Week 32 (Day 225)	Male	21	42.9	18	85.7	81.94	13.78	75.09	88.80
Week 36 (Day 253)	Male	19	38.8	15	78.9	79.44	16.63	70.24	88.65
Week 40 (Day 281)	Male	19	38.8	16	84.2	77.60	16.02	69.07	86.14
Week 44 (Day 309)	Male	16	32.7	14	87.5	80.36	15.19	71.58	89.13
Week 48 (Day 337)	Male	12	24.5	8	66.7	84.38	12.15	74.22	94.53
Week 52 (Day 365)	Male	10	20.4	3	30.0	75.00	25.00	12.90	137.10
Week 56 (Day 393)	Male	10	20.4	5	50.0	75.00	11.79	60.37	89.63
Week 60 (Day 421)	Male	6	12.2	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Male	6	12.2	1	16.7	58.33	NE	NE	NE
Week 68 (Day 477)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	49	100.0	49	100.0	73.64	17.95	68.48	78.80
End of Study (LOCF)	Male	49	100.0	49	100.0	74.83	18.04	69.65	80.01
Age									
Baseline	< 65	63	100.0	60	95.2	63.61	24.83	57.20	70.03
Week 4 (Day 29)	< 65	63	100.0	55	87.3	74.24	19.40	69.00	79.49
Week 8 (Day 57)	< 65	54	85.7	47	87.0	75.53	17.58	70.37	80.69
Week 12 (Day 85)	< 65	47	74.6	41	87.2	76.02	18.08	70.31	81.72
Week 16 (Day 113)	< 65	39	61.9	34	87.2	75.98	19.87	69.05	82.91
Week 20 (Day 141)	< 65	35	55.6	35	100.0	73.10	18.53	66.73	79.46
Week 24 (Day 169)	< 65	34	54.0	31	91.2	75.27	16.17	69.34	81.20
Week 28 (Day 197)	< 65	33	52.4	32	97.0	76.82	15.08	71.39	82.26
Week 32 (Day 225)	< 65	30	47.6	25	83.3	76.67	14.63	70.63	82.71
Week 36 (Day 253)	< 65	25	39.7	20	80.0	79.58	14.17	72.95	86.22
Week 40 (Day 281)	< 65	23	36.5	21	91.3	69.84	15.70	62.70	76.99
Week 44 (Day 309)	< 65	19	30.2	17	89.5	65.69	26.00	52.32	79.05
Week 48 (Day 337)	< 65	14	22.2	7	50.0	77.38	15.75	62.82	91.95

Week 52 (Day 365)	< 65	12	19.0	2	16.7	58.33	11.79	-47.55	164.22
Week 56 (Day 393)	< 65	11	17.5	2	18.2	66.67	0.00	NE	NE
Week 60 (Day 421)	< 65	8	12.7	1	12.5	66.67	NE	NE	NE
Week 64 (Day 449)	< 65	7	11.1	3	42.9	58.33	8.33	37.63	79.03
Week 68 (Day 477)	< 65	4	6.3	1	25.0	66.67	NE	NE	NE
Week 72 (Day 505)	< 65	4	6.3	1	25.0	41.67	NE	NE	NE
Week 76 (Day 533)	< 65	4	6.3	1	25.0	66.67	NE	NE	NE
Week 80 (Day 561)	< 65	3	4.8	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	63	100.0	63	100.0	71.16	21.52	65.74	76.58
End of Study (LOCF)	< 65	63	100.0	63	100.0	72.35	19.96	67.33	77.38
Baseline	>= 65	45	100.0	44	97.8	66.67	21.86	60.02	73.31
Week 4 (Day 29)	>= 65	45	100.0	41	91.1	68.29	23.14	60.99	75.60
Week 8 (Day 57)	>= 65	38	84.4	32	84.2	71.88	21.46	64.14	79.61
Week 12 (Day 85)	>= 65	32	71.1	29	90.6	75.00	18.09	68.12	81.88
Week 16 (Day 113)	>= 65	30	66.7	24	80.0	75.00	17.89	67.45	82.55
Week 20 (Day 141)	>= 65	24	53.3	20	83.3	73.75	17.79	65.43	82.07
Week 24 (Day 169)	>= 65	22	48.9	18	81.8	74.07	24.07	62.11	86.04
Week 28 (Day 197)	>= 65	22	48.9	19	86.4	71.93	20.83	61.89	81.97
Week 32 (Day 225)	>= 65	18	40.0	16	88.9	72.40	22.51	60.40	84.39
Week 36 (Day 253)	>= 65	16	35.6	10	62.5	75.00	23.57	58.14	91.86
Week 40 (Day 281)	>= 65	14	31.1	11	78.6	70.45	25.65	53.22	87.69
Week 44 (Day 309)	>= 65	12	26.7	9	75.0	78.70	15.65	66.67	90.73
Week 48 (Day 337)	>= 65	9	20.0	5	55.6	80.00	9.50	68.20	91.80
Week 52 (Day 365)	>= 65	7	15.6	2	28.6	87.50	17.68	-71.33	246.33
Week 56 (Day 393)	>= 65	6	13.3	4	66.7	77.08	12.50	57.19	96.97
Week 60 (Day 421)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE

Week 76 (Day 533)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	45	100.0	45	100.0	69.63	19.15	63.88	75.38
End of Study (LOCF)	>= 65	45	100.0	45	100.0	70.19	19.01	64.47	75.90
ECOG performance status									
Baseline	0	30	100.0	29	96.7	71.55	25.35	61.91	81.19
Week 4 (Day 29)	0	30	100.0	29	96.7	74.14	20.58	66.31	81.96
Week 8 (Day 57)	0	28	93.3	25	89.3	74.33	23.06	64.81	83.85
Week 12 (Day 85)	0	26	86.7	23	88.5	80.80	14.31	74.61	86.99
Week 16 (Day 113)	0	26	86.7	21	80.8	77.38	19.75	68.39	86.37
Week 20 (Day 141)	0	26	86.7	24	92.3	72.22	22.07	62.90	81.54
Week 24 (Day 169)	0	25	83.3	23	92.0	78.62	19.43	70.22	87.03
Week 28 (Day 197)	0	25	83.3	23	92.0	78.62	18.60	70.58	86.67
Week 32 (Day 225)	0	20	66.7	16	80.0	80.73	15.43	72.51	88.95
Week 36 (Day 253)	0	18	60.0	11	61.1	78.79	20.19	65.22	92.35
Week 40 (Day 281)	0	16	53.3	11	68.8	68.94	21.11	54.76	83.12
Week 44 (Day 309)	0	15	50.0	12	80.0	69.44	32.05	49.08	89.81
Week 48 (Day 337)	0	9	30.0	6	66.7	84.72	14.35	69.66	99.79
Week 52 (Day 365)	0	9	30.0	3	33.3	72.22	25.46	8.98	135.47
Week 56 (Day 393)	0	8	26.7	3	37.5	75.00	14.43	39.14	110.86
Week 60 (Day 421)	0	5	16.7	1	20.0	66.67	NE	NE	NE
Week 64 (Day 449)	0	5	16.7	2	40.0	54.17	5.89	1.22	107.11
Week 68 (Day 477)	0	3	10.0	1	33.3	66.67	NE	NE	NE
Week 72 (Day 505)	0	3	10.0	1	33.3	41.67	NE	NE	NE
Week 76 (Day 533)	0	3	10.0	1	33.3	66.67	NE	NE	NE
Week 80 (Day 561)	0	2	6.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	0	1	3.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	30	100.0	30	100.0	70.28	26.05	60.55	80.00
End of Study (LOCF)	0	30	100.0	30	100.0	72.78	23.66	63.94	81.61
Baseline	1	78	100.0	75	96.2	62.33	22.48	57.16	67.51
Week 4 (Day 29)	1	78	100.0	67	85.9	70.65	21.49	65.41	75.89

Week 8 (Day 57)	1	64	82.1	54	84.4	73.92	17.36	69.18	78.66
Week 12 (Day 85)	1	53	67.9	47	88.7	73.05	19.13	67.43	78.67
Week 16 (Day 113)	1	43	55.1	37	86.0	74.55	18.63	68.34	80.76
Week 20 (Day 141)	1	33	42.3	31	93.9	74.19	14.65	68.82	79.57
Week 24 (Day 169)	1	31	39.7	26	83.9	71.47	18.73	63.91	79.04
Week 28 (Day 197)	1	30	38.5	28	93.3	72.02	16.07	65.79	78.26
Week 32 (Day 225)	1	28	35.9	25	89.3	71.33	18.80	63.57	79.09
Week 36 (Day 253)	1	23	29.5	19	82.6	77.63	16.45	69.70	85.56
Week 40 (Day 281)	1	21	26.9	21	100.0	70.63	18.75	62.10	79.17
Week 44 (Day 309)	1	16	20.5	14	87.5	70.83	13.77	62.88	78.78
Week 48 (Day 337)	1	14	17.9	6	42.9	72.22	8.61	63.19	81.25
Week 52 (Day 365)	1	10	12.8	1	10.0	75.00	NE	NE	NE
Week 56 (Day 393)	1	9	11.5	3	33.3	72.22	9.62	48.32	96.13
Week 60 (Day 421)	1	6	7.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	5	6.4	1	20.0	66.67	NE	NE	NE
Week 68 (Day 477)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	3	3.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	78	100.0	78	100.0	70.62	18.10	66.54	74.70
End of Study (LOCF)	1	78	100.0	78	100.0	70.94	17.80	66.93	74.95
Geographic region									
Baseline	USA	21	100.0	19	90.5	74.12	23.22	62.93	85.32
Week 4 (Day 29)	USA	21	100.0	20	95.2	80.83	11.82	75.30	86.36
Week 8 (Day 57)	USA	21	100.0	19	90.5	77.19	15.67	69.64	84.75
Week 12 (Day 85)	USA	21	100.0	18	85.7	79.63	11.51	73.90	85.35
Week 16 (Day 113)	USA	21	100.0	16	76.2	77.60	17.41	68.33	86.88
Week 20 (Day 141)	USA	20	95.2	18	90.0	80.56	11.07	75.05	86.06
Week 24 (Day 169)	USA	20	95.2	19	95.0	82.89	16.07	75.15	90.64
Week 28 (Day 197)	USA	20	95.2	19	95.0	83.77	12.57	77.71	89.83
Week 32 (Day 225)	USA	17	81.0	15	88.2	78.89	14.73	70.73	87.05
Week 36 (Day 253)	USA	17	81.0	11	64.7	81.82	17.41	70.12	93.51
Week 40 (Day 281)	USA	15	71.4	12	80.0	73.61	15.82	63.56	83.67

Week 44 (Day 309)	USA	13	61.9	10	76.9	80.83	14.19	70.68	90.99
Week 48 (Day 337)	USA	8	38.1	5	62.5	80.00	15.14	61.20	98.80
Week 52 (Day 365)	USA	6	28.6	1	16.7	100.00	NE	NE	NE
Week 56 (Day 393)	USA	6	28.6	3	50.0	75.00	14.43	39.14	110.86
Week 60 (Day 421)	USA	5	23.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	4	19.0	1	25.0	66.67	NE	NE	NE
Week 68 (Day 477)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	21	100.0	21	100.0	78.17	15.92	70.93	85.42
End of Study (LOCF)	USA	21	100.0	21	100.0	78.17	16.77	70.54	85.81
Baseline	Europe (EU)	42	100.0	40	95.2	57.71	21.96	50.69	64.73
Week 4 (Day 29)	Europe (EU)	42	100.0	39	92.9	69.02	20.94	62.23	75.80
Week 8 (Day 57)	Europe (EU)	36	85.7	30	83.3	72.22	21.81	64.08	80.37
Week 12 (Day 85)	Europe (EU)	31	73.8	25	80.6	69.33	22.66	59.98	78.69
Week 16 (Day 113)	Europe (EU)	30	71.4	24	80.0	70.49	23.31	60.64	80.33
Week 20 (Day 141)	Europe (EU)	26	61.9	24	92.3	66.67	22.25	57.27	76.06
Week 24 (Day 169)	Europe (EU)	26	61.9	22	84.6	68.18	20.03	59.30	77.06
Week 28 (Day 197)	Europe (EU)	25	59.5	23	92.0	66.30	18.03	58.51	74.10
Week 32 (Day 225)	Europe (EU)	21	50.0	19	90.5	77.19	16.16	69.40	84.98
Week 36 (Day 253)	Europe (EU)	16	38.1	13	81.3	75.64	19.97	63.57	87.71
Week 40 (Day 281)	Europe (EU)	14	33.3	14	100.0	65.48	23.76	51.76	79.20
Week 44 (Day 309)	Europe (EU)	11	26.2	10	90.9	61.67	29.45	40.60	82.73
Week 48 (Day 337)	Europe (EU)	8	19.0	6	75.0	76.39	13.35	62.38	90.40
Week 52 (Day 365)	Europe (EU)	6	14.3	3	50.0	63.89	12.73	32.27	95.51
Week 56 (Day 393)	Europe (EU)	6	14.3	2	33.3	66.67	0.00	NE	NE

Week 60 (Day 421)	Europe (EU)	4	9.5	1	25.0	66.67	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	4	9.5	2	50.0	54.17	5.89	1.22	107.11
Week 68 (Day 477)	Europe (EU)	3	7.1	1	33.3	66.67	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	3	7.1	1	33.3	41.67	NE	NE	NE
Week 76 (Day 533)	Europe (EU)	3	7.1	1	33.3	66.67	NE	NE	NE
Week 80 (Day 561)	Europe (EU)	2	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Europe (EU)	42	100.0	42	100.0	65.87	20.73	59.41	72.33
End of Study (LOCF)	Europe (EU)	42	100.0	42	100.0	67.46	18.30	61.76	73.16
Baseline	Asia (AS)	45	100.0	45	100.0	67.41	23.69	60.29	74.53
Week 4 (Day 29)	Asia (AS)	45	100.0	37	82.2	69.59	24.23	61.51	77.67
Week 8 (Day 57)	Asia (AS)	35	77.8	30	85.7	73.89	18.79	66.87	80.91
Week 12 (Day 85)	Asia (AS)	27	60.0	27	100.0	78.70	15.39	72.62	84.79
Week 16 (Day 113)	Asia (AS)	18	40.0	18	100.0	80.56	11.43	74.87	86.24
Week 20 (Day 141)	Asia (AS)	13	28.9	13	100.0	75.64	13.38	67.56	83.72
Week 24 (Day 169)	Asia (AS)	10	22.2	8	80.0	73.96	18.60	58.41	89.51
Week 28 (Day 197)	Asia (AS)	10	22.2	9	90.0	78.70	15.09	67.11	90.30
Week 32 (Day 225)	Asia (AS)	10	22.2	7	70.0	60.71	23.92	38.59	82.84
Week 36 (Day 253)	Asia (AS)	8	17.8	6	75.0	76.39	13.35	62.38	90.40
Week 40 (Day 281)	Asia (AS)	8	17.8	6	75.0	73.61	13.35	59.60	87.62
Week 44 (Day 309)	Asia (AS)	7	15.6	6	85.7	66.67	21.08	44.54	88.79
Week 48 (Day 337)	Asia (AS)	7	15.6	1	14.3	83.33	NE	NE	NE
Week 52 (Day 365)	Asia (AS)	7	15.6	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Asia (AS)	5	11.1	1	20.0	83.33	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	45	100.0	45	100.0	71.30	21.36	64.88	77.71
End of Study (LOCF)	Asia (AS)	45	100.0	45	100.0	72.04	21.18	65.67	78.40

Race/ethnicity									
Baseline	Asian	48	100.0	48	100.0	67.71	23.55	60.87	74.55
Week 4 (Day 29)	Asian	48	100.0	40	83.3	70.63	23.64	63.06	78.19
Week 8 (Day 57)	Asian	38	79.2	31	81.6	73.66	18.52	66.86	80.45
Week 12 (Day 85)	Asian	30	62.5	30	100.0	78.06	14.92	72.48	83.63
Week 16 (Day 113)	Asian	21	43.8	21	100.0	80.16	11.02	75.14	85.17
Week 20 (Day 141)	Asian	16	33.3	15	93.8	75.00	12.60	68.02	81.98
Week 24 (Day 169)	Asian	13	27.1	11	84.6	77.27	16.70	66.05	88.49
Week 28 (Day 197)	Asian	13	27.1	12	92.3	79.17	13.99	70.28	88.06
Week 32 (Day 225)	Asian	12	25.0	9	75.0	62.04	22.48	44.76	79.32
Week 36 (Day 253)	Asian	10	20.8	8	80.0	79.17	14.09	67.39	90.94
Week 40 (Day 281)	Asian	10	20.8	8	80.0	73.96	12.15	63.80	84.11
Week 44 (Day 309)	Asian	9	18.8	8	88.9	71.88	20.38	54.84	88.91
Week 48 (Day 337)	Asian	9	18.8	2	22.2	87.50	5.89	34.56	140.44
Week 52 (Day 365)	Asian	9	18.8	1	11.1	100.00	NE	NE	NE
Week 56 (Day 393)	Asian	7	14.6	2	28.6	87.50	5.89	34.56	140.44
Week 60 (Day 421)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	48	100.0	48	100.0	71.88	20.96	65.79	77.96
End of Study (LOCF)	Asian	48	100.0	48	100.0	72.57	20.77	66.54	78.60
Baseline	Non-Asian	54	100.0	52	96.3	62.66	23.66	56.07	69.25
Week 4 (Day 29)	Non-Asian	54	100.0	50	92.6	73.67	19.00	68.27	79.07
Week 8 (Day 57)	Non-Asian	49	90.7	44	89.8	74.43	20.13	68.31	80.55
Week 12 (Day 85)	Non-Asian	44	81.5	36	81.8	75.00	18.90	68.61	81.39
Week 16 (Day 113)	Non-Asian	43	79.6	34	79.1	73.28	22.82	65.32	81.25
Week 20 (Day 141)	Non-Asian	38	70.4	35	92.1	73.81	19.61	67.07	80.55
Week 24 (Day 169)	Non-Asian	38	70.4	34	89.5	75.25	20.46	68.11	82.38
Week 28 (Day 197)	Non-Asian	37	68.5	35	94.6	74.29	18.12	68.06	80.51
Week 32 (Day 225)	Non-Asian	32	59.3	28	87.5	80.06	13.29	74.91	85.21
Week 36 (Day 253)	Non-Asian	27	50.0	20	74.1	80.83	16.24	73.23	88.44

Week 40 (Day 281)	Non-Asian	23	42.6	21	91.3	72.62	16.70	65.02	80.22
Week 44 (Day 309)	Non-Asian	18	33.3	14	77.8	72.02	19.50	60.76	83.29
Week 48 (Day 337)	Non-Asian	12	22.2	9	75.0	75.93	14.10	65.09	86.76
Week 52 (Day 365)	Non-Asian	8	14.8	3	37.5	63.89	12.73	32.27	95.51
Week 56 (Day 393)	Non-Asian	8	14.8	4	50.0	66.67	0.00	NE	NE
Week 60 (Day 421)	Non-Asian	7	13.0	1	14.3	66.67	NE	NE	NE
Week 64 (Day 449)	Non-Asian	6	11.1	2	33.3	62.50	5.89	9.56	115.44
Week 68 (Day 477)	Non-Asian	3	5.6	1	33.3	66.67	NE	NE	NE
Week 72 (Day 505)	Non-Asian	3	5.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Non-Asian	3	5.6	1	33.3	66.67	NE	NE	NE
Week 80 (Day 561)	Non-Asian	2	3.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	54	100.0	54	100.0	70.06	18.56	64.99	75.13
End of Study (LOCF)	Non-Asian	54	100.0	54	100.0	70.37	18.65	65.28	75.46
Baseline	Unknown	6	100.0	4	66.7	60.42	24.88	20.82	100.01
Week 4 (Day 29)	Unknown	6	100.0	6	100.0	62.50	21.57	39.86	85.14
Week 8 (Day 57)	Unknown	5	83.3	4	80.0	72.92	18.48	43.51	102.32
Week 12 (Day 85)	Unknown	5	83.3	4	80.0	62.50	28.46	17.21	107.79
Week 16 (Day 113)	Unknown	5	83.3	3	60.0	69.44	4.81	57.49	81.40
Week 20 (Day 141)	Unknown	5	83.3	5	100.0	65.00	22.36	37.24	92.76
Week 24 (Day 169)	Unknown	5	83.3	4	80.0	64.58	14.23	41.94	87.23
Week 28 (Day 197)	Unknown	5	83.3	4	80.0	68.75	21.92	33.88	103.62
Week 32 (Day 225)	Unknown	4	66.7	4	100.0	68.75	23.94	30.66	106.84
Week 36 (Day 253)	Unknown	4	66.7	2	50.0	45.83	17.68	-112.99	204.66
Week 40 (Day 281)	Unknown	4	66.7	3	75.0	41.67	33.33	-41.14	124.47
Week 44 (Day 309)	Unknown	4	66.7	4	100.0	60.42	42.70	-7.52	128.35
Week 48 (Day 337)	Unknown	2	33.3	1	50.0	83.33	NE	NE	NE
Week 52 (Day 365)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 60 (Day 421)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE

Week 64 (Day 449)	Unknown	1	16.7	1	100.0	50.00	NE	NE	NE
Week 68 (Day 477)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	1	16.7	1	100.0	41.67	NE	NE	NE
Week 76 (Day 533)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	6	100.0	6	100.0	63.89	33.61	28.62	99.16
End of Study (LOCF)	Unknown	6	100.0	6	100.0	72.22	19.48	51.77	92.67

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TN_QSC30QL_SG.xls
27OCT2021 7:40

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Global health status
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	38	36.5	27.9	46.1
	Cycle 12 (LOCF)	n/a	104	96.3	16	15.4	9.7	23.5
	End of Study (LOCF)	n/a	104	96.3	15	14.4	8.9	22.4
Sex	All visits	Female	56	51.9	21	37.5	26.0	50.6
		Male	48	44.4	17	35.4	23.4	49.6
	Cycle 12 (LOCF)	Female	56	51.9	8	14.3	7.4	25.7
		Male	48	44.4	8	16.7	8.7	29.6
	End of Study (LOCF)	Female	56	51.9	8	14.3	7.4	25.7
		Male	48	44.4	7	14.6	7.2	27.2
Age	All visits	< 65	60	55.6	17	28.3	18.5	40.8
		>= 65	44	40.7	21	47.7	33.8	62.1
	Cycle 12 (LOCF)	< 65	60	55.6	6	10.0	4.7	20.1
		>= 65	44	40.7	10	22.7	12.8	37.0
	End of Study (LOCF)	< 65	60	55.6	6	10.0	4.7	20.1
		>= 65	44	40.7	9	20.5	11.2	34.5
ECOG performance status	All visits	0	29	26.9	15	51.7	34.4	68.6
		1	75	69.4	23	30.7	21.4	41.8
	Cycle 12 (LOCF)	0	29	26.9	8	27.6	14.7	45.7
		1	75	69.4	8	10.7	5.5	19.7
	End of Study (LOCF)	0	29	26.9	8	27.6	14.7	45.7
		1	75	69.4	7	9.3	4.6	18.0
Geographic region	All visits	USA	19	17.6	9	47.4	27.3	68.3
		Europe (EU)	40	37.0	16	40.0	26.3	55.4
		Asia (AS)	45	41.7	13	28.9	17.7	43.4
	Cycle 12 (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	6	15.0	7.1	29.1
		Asia (AS)	45	41.7	7	15.6	7.7	28.8
	End of Study (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	6	15.0	7.1	29.1
		Asia (AS)	45	41.7	6	13.3	6.3	26.2
Race/ethnicity	All visits	Asian	48	44.4	14	29.2	18.2	43.2
		Non-Asian	52	48.1	23	44.2	31.6	57.7
		Unknown	4	3.7	1	25.0	4.6	69.9
	Cycle 12 (LOCF)	Asian	48	44.4	7	14.6	7.2	27.2
		Non-Asian	52	48.1	9	17.3	9.4	29.7
		Unknown	4	3.7	0	0.0	0.0	49.0
	End of Study (LOCF)	Asian	48	44.4	6	12.5	5.9	24.7

		Non-Asian	52	48.1	9	17.3	9.4	29.7
		Unknown	4	3.7	0	0.0	0.0	49.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30QL_W10_SG.xls
15OCT2021 13:17

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Global health status
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

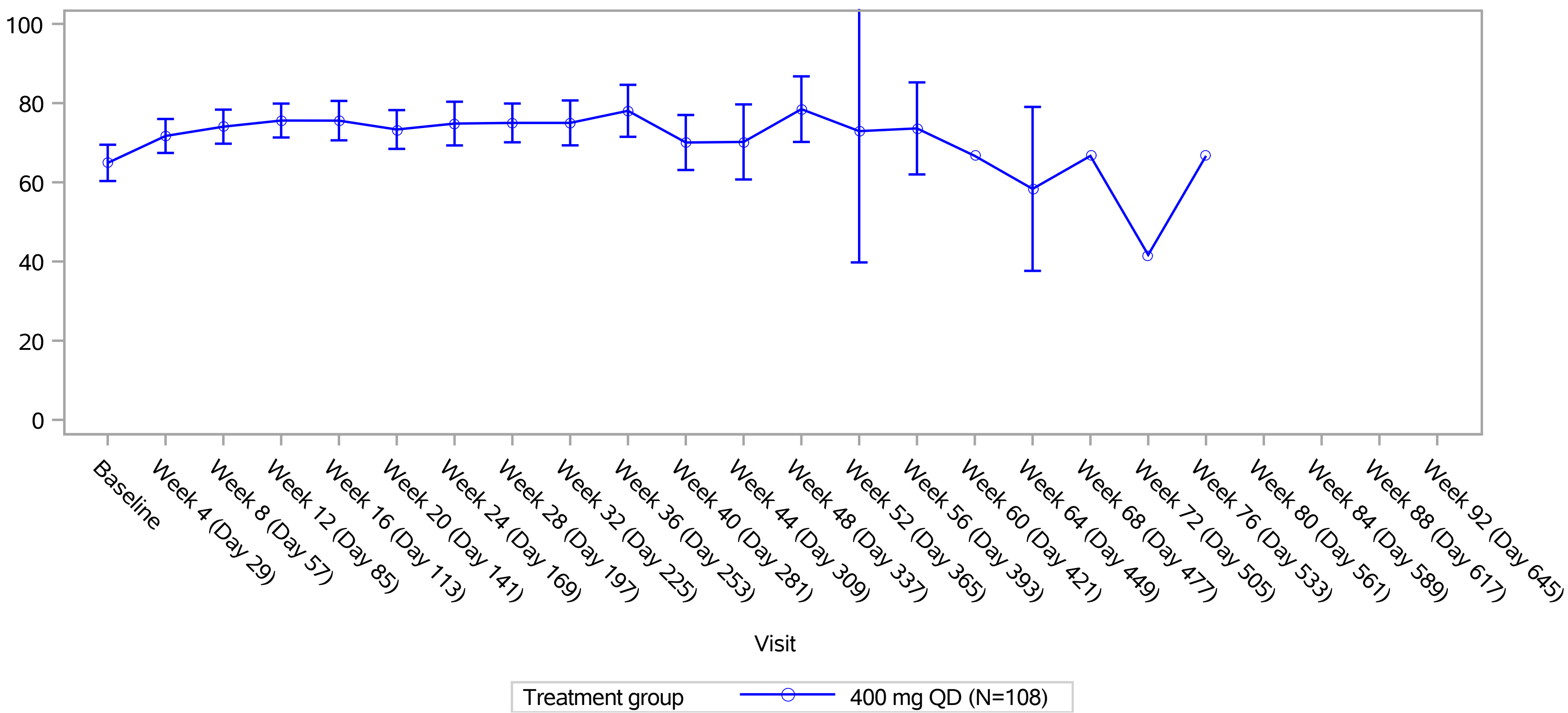
			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	38	36.5	27.9	46.1
	Cycle 12 (LOCF)	n/a	104	96.3	16	15.4	9.7	23.5
	End of Study (LOCF)	n/a	104	96.3	15	14.4	8.9	22.4
Sex	All visits	Female	56	51.9	21	37.5	26.0	50.6
		Male	48	44.4	17	35.4	23.4	49.6
	Cycle 12 (LOCF)	Female	56	51.9	8	14.3	7.4	25.7
		Male	48	44.4	8	16.7	8.7	29.6
	End of Study (LOCF)	Female	56	51.9	8	14.3	7.4	25.7
		Male	48	44.4	7	14.6	7.2	27.2
Age	All visits	< 65	60	55.6	17	28.3	18.5	40.8
		>= 65	44	40.7	21	47.7	33.8	62.1
	Cycle 12 (LOCF)	< 65	60	55.6	6	10.0	4.7	20.1
		>= 65	44	40.7	10	22.7	12.8	37.0
	End of Study (LOCF)	< 65	60	55.6	6	10.0	4.7	20.1
		>= 65	44	40.7	9	20.5	11.2	34.5
ECOG performance status	All visits	0	29	26.9	15	51.7	34.4	68.6
		1	75	69.4	23	30.7	21.4	41.8
	Cycle 12 (LOCF)	0	29	26.9	8	27.6	14.7	45.7
		1	75	69.4	8	10.7	5.5	19.7
	End of Study (LOCF)	0	29	26.9	8	27.6	14.7	45.7
		1	75	69.4	7	9.3	4.6	18.0
Geographic region	All visits	USA	19	17.6	9	47.4	27.3	68.3
		Europe (EU)	40	37.0	16	40.0	26.3	55.4
		Asia (AS)	45	41.7	13	28.9	17.7	43.4
	Cycle 12 (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	6	15.0	7.1	29.1
		Asia (AS)	45	41.7	7	15.6	7.7	28.8
	End of Study (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	6	15.0	7.1	29.1
		Asia (AS)	45	41.7	6	13.3	6.3	26.2
Race/ethnicity	All visits	Asian	48	44.4	14	29.2	18.2	43.2
		Non-Asian	52	48.1	23	44.2	31.6	57.7
		Unknown	4	3.7	1	25.0	4.6	69.9
	Cycle 12 (LOCF)	Asian	48	44.4	7	14.6	7.2	27.2
		Non-Asian	52	48.1	9	17.3	9.4	29.7
		Unknown	4	3.7	0	0.0	0.0	49.0
	End of Study (LOCF)	Asian	48	44.4	6	12.5	5.9	24.7

		Non-Asian	52	48.1	9	17.3	9.4	29.7
		Unknown	4	3.7	0	0.0	0.0	49.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30QL_W15_SG.xls
15OCT2021 13:06

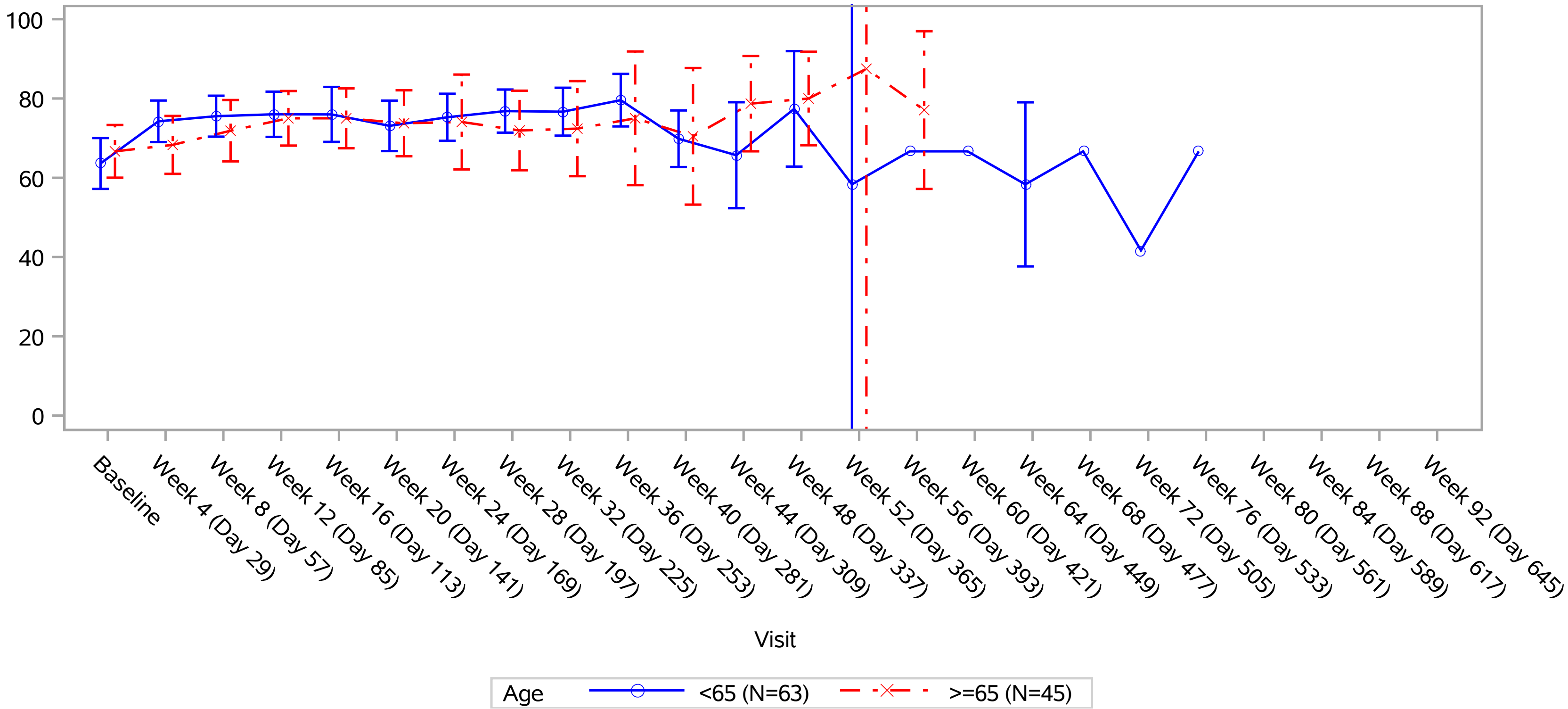
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Global health status
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30QL.pdf
15OCT2021 17:29

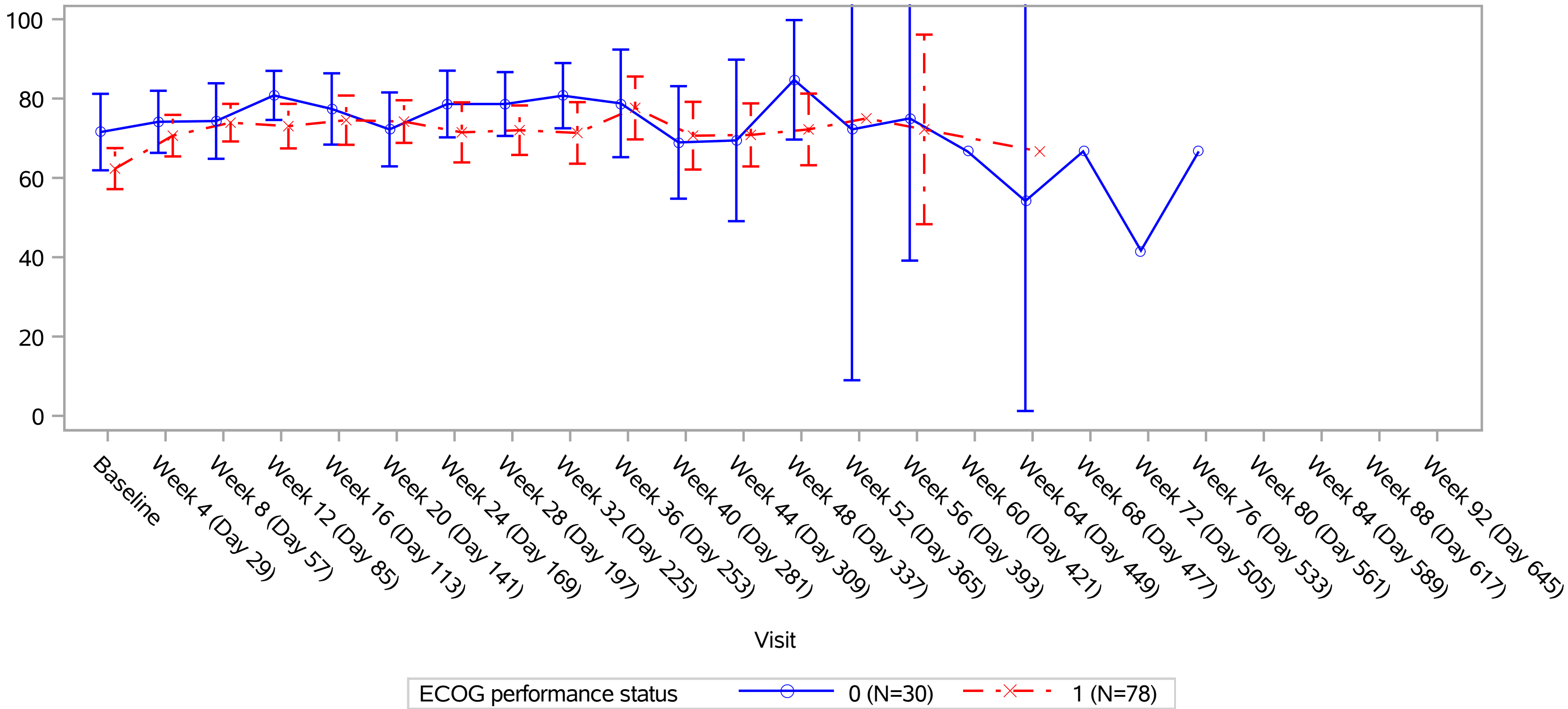
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Global health status
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30QL_SGAGE65.pdf
15OCT2021 17:58

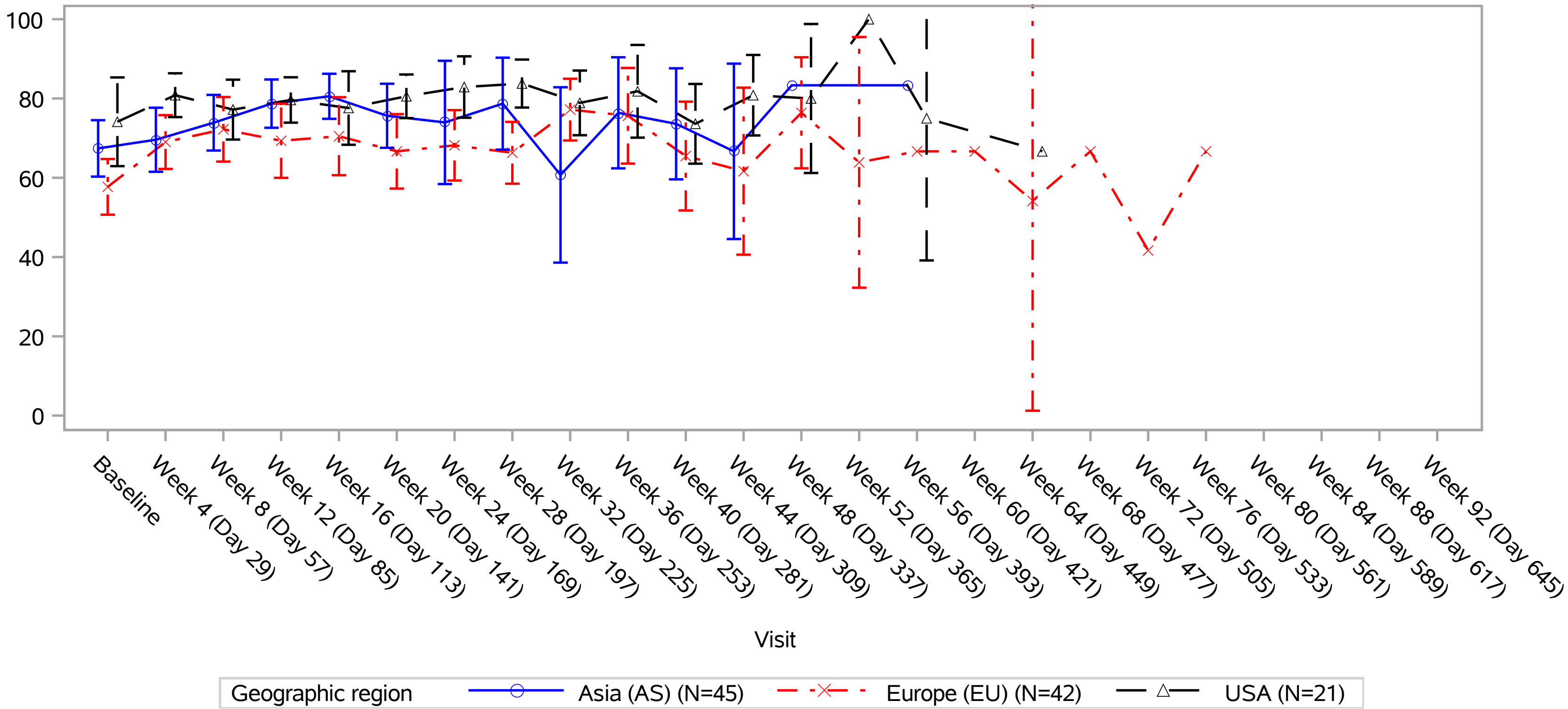
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Global health status
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30QL_SGECOG.pdf
15OCT2021 18:29

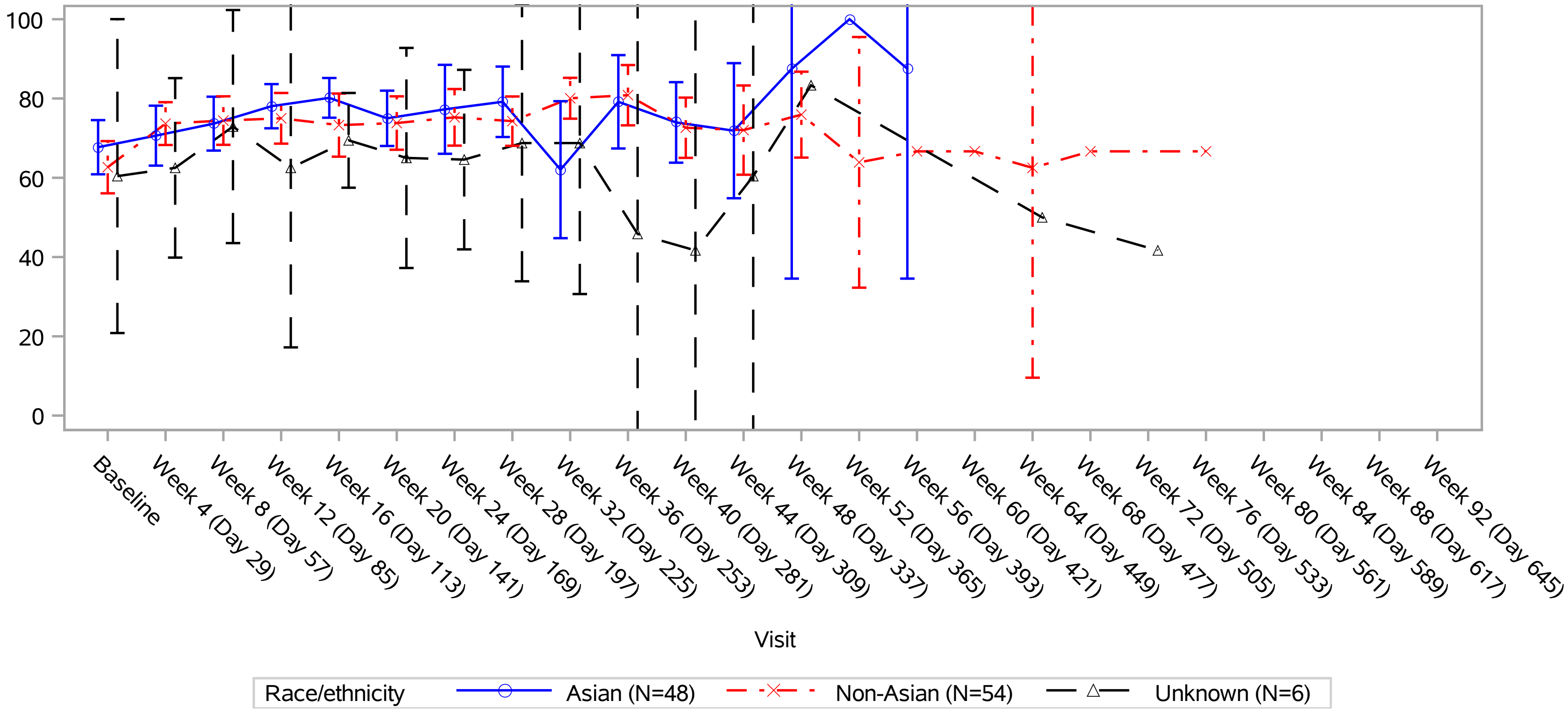
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Global health status
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30QL_SGGEO.pdf
15OCT2021 19:00

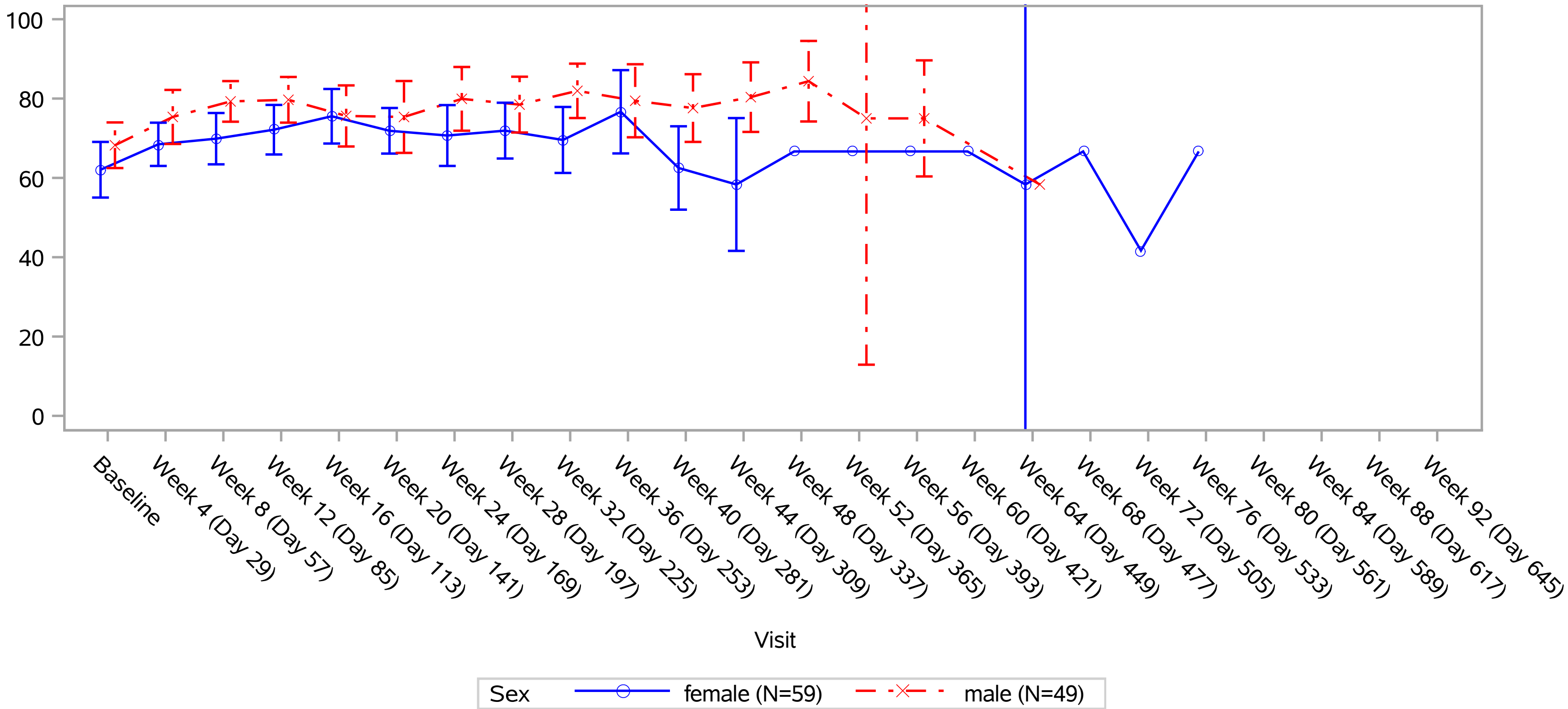
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Global health status
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30QL_SGRE.pdf
15OCT2021 19:30

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Global health status
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30QL_SGSEX.pdf
15OCT2021 20:01

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Role functioning
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=108)							
		Patients				Statistics			
Name Visit	Level	in study¹	%	with value¹	%	mean²	SD	CI LL	CI UL
All									
Baseline	n/a	108	100.0	104	96.3	75.96	30.88	69.96	81.97
Week 4 (Day 29)	n/a	108	100.0	96	88.9	78.82	25.65	73.62	84.02
Week 8 (Day 57)	n/a	92	85.2	79	85.9	82.70	25.66	76.95	88.45
Week 12 (Day 85)	n/a	79	73.1	71	89.9	83.10	23.32	77.58	88.62
Week 16 (Day 113)	n/a	69	63.9	58	84.1	81.32	24.40	74.91	87.74
Week 20 (Day 141)	n/a	59	54.6	55	93.2	81.52	22.83	75.34	87.69
Week 24 (Day 169)	n/a	56	51.9	49	87.5	81.29	26.27	73.75	88.84
Week 28 (Day 197)	n/a	55	50.9	51	92.7	81.37	22.52	75.04	87.71
Week 32 (Day 225)	n/a	48	44.4	41	85.4	81.71	24.67	73.92	89.49
Week 36 (Day 253)	n/a	41	38.0	30	73.2	82.22	24.34	73.13	91.31
Week 40 (Day 281)	n/a	37	34.3	32	86.5	81.25	21.48	73.50	89.00
Week 44 (Day 309)	n/a	31	28.7	26	83.9	76.92	27.92	65.65	88.20
Week 48 (Day 337)	n/a	23	21.3	12	52.2	86.11	18.58	74.31	97.91
Week 52 (Day 365)	n/a	19	17.6	4	21.1	66.67	30.43	18.25	115.09
Week 56 (Day 393)	n/a	17	15.7	6	35.3	88.89	17.21	70.82	106.95
Week 60 (Day 421)	n/a	11	10.2	1	9.1	50.00	NE	NE	NE
Week 64 (Day 449)	n/a	10	9.3	3	30.0	66.67	0.00	NE	NE
Week 68 (Day 477)	n/a	6	5.6	1	16.7	50.00	NE	NE	NE
Week 72 (Day 505)	n/a	6	5.6	1	16.7	50.00	NE	NE	NE
Week 76 (Day 533)	n/a	6	5.6	1	16.7	66.67	NE	NE	NE
Week 80 (Day 561)	n/a	5	4.6	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	n/a	1	0.9	0	0.0	NE	NE	NE	NE

Cycle 12 (LOCF)	n/a	108	100.0	108	100.0	79.48	25.33	74.64	84.31
End of Study (LOCF)	n/a	108	100.0	108	100.0	80.40	24.20	75.78	85.02
Sex									
Baseline	Female	59	100.0	56	94.9	73.81	32.08	65.22	82.40
Week 4 (Day 29)	Female	59	100.0	51	86.4	74.51	26.11	67.17	81.85
Week 8 (Day 57)	Female	49	83.1	44	89.8	79.55	29.17	70.68	88.41
Week 12 (Day 85)	Female	44	74.6	39	88.6	80.77	23.43	73.18	88.36
Week 16 (Day 113)	Female	38	64.4	31	81.6	77.42	27.74	67.24	87.59
Week 20 (Day 141)	Female	33	55.9	32	97.0	76.56	25.70	67.30	85.83
Week 24 (Day 169)	Female	31	52.5	27	87.1	75.93	27.48	65.06	86.80
Week 28 (Day 197)	Female	30	50.8	27	90.0	74.69	24.62	64.95	84.43
Week 32 (Day 225)	Female	27	45.8	23	85.2	74.64	26.53	63.17	86.11
Week 36 (Day 253)	Female	22	37.3	15	68.2	71.11	27.07	56.12	86.10
Week 40 (Day 281)	Female	18	30.5	16	88.9	71.88	22.54	59.86	83.89
Week 44 (Day 309)	Female	15	25.4	12	80.0	62.50	31.08	42.75	82.25
Week 48 (Day 337)	Female	11	18.6	4	36.4	75.00	21.52	40.76	109.24
Week 52 (Day 365)	Female	9	15.3	1	11.1	50.00	NE	NE	NE
Week 56 (Day 393)	Female	7	11.9	1	14.3	66.67	NE	NE	NE
Week 60 (Day 421)	Female	5	8.5	1	20.0	50.00	NE	NE	NE
Week 64 (Day 449)	Female	4	6.8	2	50.0	66.67	0.00	NE	NE
Week 68 (Day 477)	Female	3	5.1	1	33.3	50.00	NE	NE	NE
Week 72 (Day 505)	Female	3	5.1	1	33.3	50.00	NE	NE	NE
Week 76 (Day 533)	Female	3	5.1	1	33.3	66.67	NE	NE	NE
Week 80 (Day 561)	Female	2	3.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	59	100.0	59	100.0	76.84	25.90	70.09	83.58
End of Study (LOCF)	Female	59	100.0	59	100.0	77.68	24.09	71.40	83.96
Baseline	Male	49	100.0	48	98.0	78.47	29.57	69.89	87.06
Week 4 (Day 29)	Male	49	100.0	45	91.8	83.70	24.49	76.35	91.06
Week 8 (Day 57)	Male	43	87.8	35	81.4	86.67	20.13	79.75	93.58
Week 12 (Day 85)	Male	35	71.4	32	91.4	85.94	23.23	77.56	94.31
Week 16 (Day 113)	Male	31	63.3	27	87.1	85.80	19.45	78.11	93.50
Week 20 (Day 141)	Male	26	53.1	23	88.5	88.41	16.23	81.39	95.43
Week 24 (Day 169)	Male	25	51.0	22	88.0	87.88	23.67	77.38	98.37
Week 28 (Day 197)	Male	25	51.0	24	96.0	88.89	17.49	81.50	96.27

Week 32 (Day 225)	Male	21	42.9	18	85.7	90.74	19.15	81.22	100.26
Week 36 (Day 253)	Male	19	38.8	15	78.9	93.33	15.17	84.93	101.73
Week 40 (Day 281)	Male	19	38.8	16	84.2	90.63	16.07	82.06	99.19
Week 44 (Day 309)	Male	16	32.7	14	87.5	89.29	18.03	78.88	99.70
Week 48 (Day 337)	Male	12	24.5	8	66.7	91.67	15.43	78.77	104.57
Week 52 (Day 365)	Male	10	20.4	3	30.0	72.22	34.69	-13.96	158.41
Week 56 (Day 393)	Male	10	20.4	5	50.0	93.33	14.91	74.82	111.84
Week 60 (Day 421)	Male	6	12.2	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Male	6	12.2	1	16.7	66.67	NE	NE	NE
Week 68 (Day 477)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	49	100.0	49	100.0	82.65	24.52	75.61	89.70
End of Study (LOCF)	Male	49	100.0	49	100.0	83.67	24.17	76.73	90.62
Age									
Baseline	< 65	63	100.0	60	95.2	71.39	32.78	62.92	79.86
Week 4 (Day 29)	< 65	63	100.0	55	87.3	79.39	26.83	72.14	86.65
Week 8 (Day 57)	< 65	54	85.7	47	87.0	85.82	21.70	79.45	92.19
Week 12 (Day 85)	< 65	47	74.6	42	89.4	83.73	20.66	77.29	90.17
Week 16 (Day 113)	< 65	39	61.9	34	87.2	80.39	26.42	71.17	89.61
Week 20 (Day 141)	< 65	35	55.6	35	100.0	78.57	24.11	70.29	86.85
Week 24 (Day 169)	< 65	34	54.0	31	91.2	79.57	28.12	69.25	89.89
Week 28 (Day 197)	< 65	33	52.4	32	97.0	78.65	22.89	70.39	86.90
Week 32 (Day 225)	< 65	30	47.6	25	83.3	84.00	19.53	75.94	92.06
Week 36 (Day 253)	< 65	25	39.7	20	80.0	80.00	23.32	69.09	90.91
Week 40 (Day 281)	< 65	23	36.5	21	91.3	79.37	21.67	69.50	89.23
Week 44 (Day 309)	< 65	19	30.2	17	89.5	74.51	30.11	59.03	89.99
Week 48 (Day 337)	< 65	14	22.2	7	50.0	80.95	20.25	62.22	99.68

Week 52 (Day 365)	< 65	12	19.0	2	16.7	41.67	11.79	-64.22	147.55
Week 56 (Day 393)	< 65	11	17.5	2	18.2	66.67	0.00	NE	NE
Week 60 (Day 421)	< 65	8	12.7	1	12.5	50.00	NE	NE	NE
Week 64 (Day 449)	< 65	7	11.1	3	42.9	66.67	0.00	NE	NE
Week 68 (Day 477)	< 65	4	6.3	1	25.0	50.00	NE	NE	NE
Week 72 (Day 505)	< 65	4	6.3	1	25.0	50.00	NE	NE	NE
Week 76 (Day 533)	< 65	4	6.3	1	25.0	66.67	NE	NE	NE
Week 80 (Day 561)	< 65	3	4.8	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	63	100.0	63	100.0	79.63	26.34	73.00	86.26
End of Study (LOCF)	< 65	63	100.0	63	100.0	80.69	24.36	74.55	86.82
Baseline	>= 65	45	100.0	44	97.8	82.20	27.23	73.92	90.48
Week 4 (Day 29)	>= 65	45	100.0	41	91.1	78.05	24.28	70.39	85.71
Week 8 (Day 57)	>= 65	38	84.4	32	84.2	78.12	30.36	67.18	89.07
Week 12 (Day 85)	>= 65	32	71.1	29	90.6	82.18	27.07	71.89	92.48
Week 16 (Day 113)	>= 65	30	66.7	24	80.0	82.64	21.69	73.48	91.80
Week 20 (Day 141)	>= 65	24	53.3	20	83.3	86.67	19.94	77.33	96.00
Week 24 (Day 169)	>= 65	22	48.9	18	81.8	84.26	23.20	72.72	95.80
Week 28 (Day 197)	>= 65	22	48.9	19	86.4	85.96	21.70	75.50	96.43
Week 32 (Day 225)	>= 65	18	40.0	16	88.9	78.13	31.46	61.36	94.89
Week 36 (Day 253)	>= 65	16	35.6	10	62.5	86.67	26.99	67.36	105.97
Week 40 (Day 281)	>= 65	14	31.1	11	78.6	84.85	21.67	70.29	99.41
Week 44 (Day 309)	>= 65	12	26.7	9	75.0	81.48	24.22	62.87	100.10
Week 48 (Day 337)	>= 65	9	20.0	5	55.6	93.33	14.91	74.82	111.84
Week 52 (Day 365)	>= 65	7	15.6	2	28.6	91.67	11.79	-14.22	197.55
Week 56 (Day 393)	>= 65	6	13.3	4	66.7	100.00	0.00	NE	NE
Week 60 (Day 421)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE

Week 76 (Day 533)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	45	100.0	45	100.0	79.26	24.14	72.01	86.51
End of Study (LOCF)	>= 65	45	100.0	45	100.0	80.00	24.26	72.71	87.29
ECOG performance status									
Baseline	0	30	100.0	29	96.7	74.71	30.74	63.02	86.40
Week 4 (Day 29)	0	30	100.0	29	96.7	80.46	23.60	71.48	89.44
Week 8 (Day 57)	0	28	93.3	25	89.3	82.00	25.87	71.32	92.68
Week 12 (Day 85)	0	26	86.7	24	92.3	81.94	23.53	72.01	91.88
Week 16 (Day 113)	0	26	86.7	21	80.8	80.95	21.91	70.98	90.93
Week 20 (Day 141)	0	26	86.7	24	92.3	79.86	24.07	69.70	90.02
Week 24 (Day 169)	0	25	83.3	23	92.0	81.88	24.05	71.48	92.29
Week 28 (Day 197)	0	25	83.3	23	92.0	81.88	21.85	72.43	91.33
Week 32 (Day 225)	0	20	66.7	16	80.0	85.42	18.13	75.76	95.08
Week 36 (Day 253)	0	18	60.0	11	61.1	87.88	18.40	75.52	100.24
Week 40 (Day 281)	0	16	53.3	11	68.8	81.82	17.41	70.12	93.51
Week 44 (Day 309)	0	15	50.0	12	80.0	75.00	34.45	53.11	96.89
Week 48 (Day 337)	0	9	30.0	6	66.7	86.11	22.15	62.86	109.36
Week 52 (Day 365)	0	9	30.0	3	33.3	61.11	34.69	-25.07	147.30
Week 56 (Day 393)	0	8	26.7	3	37.5	88.89	19.25	41.08	136.70
Week 60 (Day 421)	0	5	16.7	1	20.0	50.00	NE	NE	NE
Week 64 (Day 449)	0	5	16.7	2	40.0	66.67	0.00	NE	NE
Week 68 (Day 477)	0	3	10.0	1	33.3	50.00	NE	NE	NE
Week 72 (Day 505)	0	3	10.0	1	33.3	50.00	NE	NE	NE
Week 76 (Day 533)	0	3	10.0	1	33.3	66.67	NE	NE	NE
Week 80 (Day 561)	0	2	6.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	0	1	3.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	30	100.0	30	100.0	80.56	25.92	70.88	90.24
End of Study (LOCF)	0	30	100.0	30	100.0	82.78	21.21	74.86	90.70
Baseline	1	78	100.0	75	96.2	76.44	31.13	69.28	83.61
Week 4 (Day 29)	1	78	100.0	67	85.9	78.11	26.62	71.62	84.60

Week 8 (Day 57)	1	64	82.1	54	84.4	83.02	25.80	75.98	90.07
Week 12 (Day 85)	1	53	67.9	47	88.7	83.69	23.44	76.81	90.57
Week 16 (Day 113)	1	43	55.1	37	86.0	81.53	25.99	72.86	90.20
Week 20 (Day 141)	1	33	42.3	31	93.9	82.80	22.15	74.67	90.92
Week 24 (Day 169)	1	31	39.7	26	83.9	80.77	28.55	69.24	92.30
Week 28 (Day 197)	1	30	38.5	28	93.3	80.95	23.45	71.86	90.04
Week 32 (Day 225)	1	28	35.9	25	89.3	79.33	28.17	67.71	90.96
Week 36 (Day 253)	1	23	29.5	19	82.6	78.95	27.13	65.87	92.02
Week 40 (Day 281)	1	21	26.9	21	100.0	80.95	23.74	70.15	91.76
Week 44 (Day 309)	1	16	20.5	14	87.5	78.57	22.10	65.81	91.33
Week 48 (Day 337)	1	14	17.9	6	42.9	86.11	16.39	68.91	103.31
Week 52 (Day 365)	1	10	12.8	1	10.0	83.33	NE	NE	NE
Week 56 (Day 393)	1	9	11.5	3	33.3	88.89	19.25	41.08	136.70
Week 60 (Day 421)	1	6	7.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	5	6.4	1	20.0	66.67	NE	NE	NE
Week 68 (Day 477)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	3	3.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	78	100.0	78	100.0	79.06	25.26	73.36	84.76
End of Study (LOCF)	1	78	100.0	78	100.0	79.49	25.33	73.78	85.20
Geographic region									
Baseline	USA	21	100.0	19	90.5	78.95	35.50	61.83	96.06
Week 4 (Day 29)	USA	21	100.0	20	95.2	85.83	17.33	77.72	93.95
Week 8 (Day 57)	USA	21	100.0	19	90.5	87.72	19.91	78.12	97.32
Week 12 (Day 85)	USA	21	100.0	19	90.5	83.33	20.79	73.31	93.35
Week 16 (Day 113)	USA	21	100.0	16	76.2	80.21	25.25	66.75	93.66
Week 20 (Day 141)	USA	20	95.2	18	90.0	81.48	17.04	73.01	89.96
Week 24 (Day 169)	USA	20	95.2	19	95.0	82.46	25.14	70.34	94.57
Week 28 (Day 197)	USA	20	95.2	19	95.0	85.96	18.64	76.98	94.95
Week 32 (Day 225)	USA	17	81.0	15	88.2	77.78	23.29	64.88	90.67
Week 36 (Day 253)	USA	17	81.0	11	64.7	80.30	22.13	65.43	95.17
Week 40 (Day 281)	USA	15	71.4	12	80.0	77.78	22.84	63.26	92.29

Week 44 (Day 309)	USA	13	61.9	10	76.9	81.67	21.44	66.33	97.01
Week 48 (Day 337)	USA	8	38.1	5	62.5	96.67	7.45	87.41	105.92
Week 52 (Day 365)	USA	6	28.6	1	16.7	100.00	NE	NE	NE
Week 56 (Day 393)	USA	6	28.6	3	50.0	88.89	19.25	41.08	136.70
Week 60 (Day 421)	USA	5	23.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	4	19.0	1	25.0	66.67	NE	NE	NE
Week 68 (Day 477)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	21	100.0	21	100.0	85.71	17.71	77.65	93.77
End of Study (LOCF)	USA	21	100.0	21	100.0	85.71	17.71	77.65	93.77
Baseline	Europe (EU)	42	100.0	40	95.2	62.50	29.90	52.94	72.06
Week 4 (Day 29)	Europe (EU)	42	100.0	39	92.9	75.21	25.04	67.10	83.33
Week 8 (Day 57)	Europe (EU)	36	85.7	30	83.3	76.11	28.26	65.56	86.66
Week 12 (Day 85)	Europe (EU)	31	73.8	25	80.6	73.33	27.64	61.92	84.74
Week 16 (Day 113)	Europe (EU)	30	71.4	24	80.0	74.31	27.79	62.57	86.04
Week 20 (Day 141)	Europe (EU)	26	61.9	24	92.3	75.69	28.65	63.60	87.79
Week 24 (Day 169)	Europe (EU)	26	61.9	22	84.6	76.52	30.28	63.09	89.94
Week 28 (Day 197)	Europe (EU)	25	59.5	23	92.0	72.46	25.43	61.47	83.46
Week 32 (Day 225)	Europe (EU)	21	50.0	19	90.5	82.46	26.34	69.76	95.15
Week 36 (Day 253)	Europe (EU)	16	38.1	13	81.3	80.77	26.22	64.93	96.61
Week 40 (Day 281)	Europe (EU)	14	33.3	14	100.0	78.57	22.10	65.81	91.33
Week 44 (Day 309)	Europe (EU)	11	26.2	10	90.9	65.00	35.53	39.58	90.42
Week 48 (Day 337)	Europe (EU)	8	19.0	6	75.0	75.00	20.41	53.58	96.42
Week 52 (Day 365)	Europe (EU)	6	14.3	3	50.0	55.56	25.46	-7.69	118.80
Week 56 (Day 393)	Europe (EU)	6	14.3	2	33.3	83.33	23.57	-128.44	295.10

Week 60 (Day 421)	Europe (EU)	4	9.5	1	25.0	50.00	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	4	9.5	2	50.0	66.67	0.00	NE	NE
Week 68 (Day 477)	Europe (EU)	3	7.1	1	33.3	50.00	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	3	7.1	1	33.3	50.00	NE	NE	NE
Week 76 (Day 533)	Europe (EU)	3	7.1	1	33.3	66.67	NE	NE	NE
Week 80 (Day 561)	Europe (EU)	2	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Europe (EU)	42	100.0	42	100.0	70.24	27.43	61.69	78.79
End of Study (LOCF)	Europe (EU)	42	100.0	42	100.0	71.83	25.10	64.00	79.65
Baseline	Asia (AS)	45	100.0	45	100.0	86.67	25.28	79.07	94.26
Week 4 (Day 29)	Asia (AS)	45	100.0	37	82.2	78.83	29.57	68.97	88.69
Week 8 (Day 57)	Asia (AS)	35	77.8	30	85.7	86.11	25.55	76.57	95.65
Week 12 (Day 85)	Asia (AS)	27	60.0	27	100.0	91.98	16.90	85.29	98.66
Week 16 (Day 113)	Asia (AS)	18	40.0	18	100.0	91.67	14.29	84.56	98.77
Week 20 (Day 141)	Asia (AS)	13	28.9	13	100.0	92.31	12.94	84.49	100.13
Week 24 (Day 169)	Asia (AS)	10	22.2	8	80.0	91.67	12.60	81.13	102.20
Week 28 (Day 197)	Asia (AS)	10	22.2	9	90.0	94.44	11.79	85.39	103.50
Week 32 (Day 225)	Asia (AS)	10	22.2	7	70.0	88.10	24.93	65.04	111.16
Week 36 (Day 253)	Asia (AS)	8	17.8	6	75.0	88.89	27.22	60.33	117.45
Week 40 (Day 281)	Asia (AS)	8	17.8	6	75.0	94.44	13.61	80.16	108.73
Week 44 (Day 309)	Asia (AS)	7	15.6	6	85.7	88.89	17.21	70.82	106.95
Week 48 (Day 337)	Asia (AS)	7	15.6	1	14.3	100.00	NE	NE	NE
Week 52 (Day 365)	Asia (AS)	7	15.6	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Asia (AS)	5	11.1	1	20.0	100.00	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	45	100.0	45	100.0	85.19	24.16	77.93	92.44
End of Study (LOCF)	Asia (AS)	45	100.0	45	100.0	85.93	24.09	78.69	93.16

Race/ethnicity									
Baseline	Asian	48	100.0	48	100.0	85.76	26.63	78.03	93.50
Week 4 (Day 29)	Asian	48	100.0	40	83.3	79.58	28.86	70.35	88.81
Week 8 (Day 57)	Asian	38	79.2	31	81.6	85.48	25.36	76.18	94.79
Week 12 (Day 85)	Asian	30	62.5	30	100.0	89.44	19.81	82.05	96.84
Week 16 (Day 113)	Asian	21	43.8	21	100.0	92.06	13.56	85.89	98.24
Week 20 (Day 141)	Asian	16	33.3	15	93.8	91.11	13.90	83.42	98.81
Week 24 (Day 169)	Asian	13	27.1	11	84.6	89.39	13.48	80.34	98.45
Week 28 (Day 197)	Asian	13	27.1	12	92.3	93.06	11.14	85.98	100.14
Week 32 (Day 225)	Asian	12	25.0	9	75.0	83.33	28.87	61.14	105.52
Week 36 (Day 253)	Asian	10	20.8	8	80.0	87.50	24.80	66.77	108.23
Week 40 (Day 281)	Asian	10	20.8	8	80.0	91.67	15.43	78.77	104.57
Week 44 (Day 309)	Asian	9	18.8	8	88.9	87.50	17.25	73.08	101.92
Week 48 (Day 337)	Asian	9	18.8	2	22.2	100.00	0.00	NE	NE
Week 52 (Day 365)	Asian	9	18.8	1	11.1	100.00	NE	NE	NE
Week 56 (Day 393)	Asian	7	14.6	2	28.6	100.00	0.00	NE	NE
Week 60 (Day 421)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	48	100.0	48	100.0	85.07	23.63	78.21	91.93
End of Study (LOCF)	Asian	48	100.0	48	100.0	85.76	23.57	78.92	92.61
Baseline	Non-Asian	54	100.0	52	96.3	67.31	31.13	58.64	75.97
Week 4 (Day 29)	Non-Asian	54	100.0	50	92.6	79.33	23.22	72.73	85.93
Week 8 (Day 57)	Non-Asian	49	90.7	44	89.8	81.44	26.71	73.32	89.56
Week 12 (Day 85)	Non-Asian	44	81.5	37	84.1	79.73	24.58	71.54	87.92
Week 16 (Day 113)	Non-Asian	43	79.6	34	79.1	76.47	27.86	66.75	86.19
Week 20 (Day 141)	Non-Asian	38	70.4	35	92.1	78.57	25.43	69.84	87.31
Week 24 (Day 169)	Non-Asian	38	70.4	34	89.5	80.39	30.00	69.92	90.86
Week 28 (Day 197)	Non-Asian	37	68.5	35	94.6	78.57	23.77	70.41	86.74
Week 32 (Day 225)	Non-Asian	32	59.3	28	87.5	84.52	19.21	77.08	91.97
Week 36 (Day 253)	Non-Asian	27	50.0	20	74.1	84.17	20.57	74.54	93.80

Week 40 (Day 281)	Non-Asian	23	42.6	21	91.3	80.95	21.27	71.27	90.63
Week 44 (Day 309)	Non-Asian	18	33.3	14	77.8	78.57	24.83	64.23	92.91
Week 48 (Day 337)	Non-Asian	12	22.2	9	75.0	85.19	19.44	70.24	100.13
Week 52 (Day 365)	Non-Asian	8	14.8	3	37.5	55.56	25.46	-7.69	118.80
Week 56 (Day 393)	Non-Asian	8	14.8	4	50.0	83.33	19.25	52.71	113.96
Week 60 (Day 421)	Non-Asian	7	13.0	1	14.3	50.00	NE	NE	NE
Week 64 (Day 449)	Non-Asian	6	11.1	2	33.3	66.67	0.00	NE	NE
Week 68 (Day 477)	Non-Asian	3	5.6	1	33.3	50.00	NE	NE	NE
Week 72 (Day 505)	Non-Asian	3	5.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Non-Asian	3	5.6	1	33.3	66.67	NE	NE	NE
Week 80 (Day 561)	Non-Asian	2	3.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	54	100.0	54	100.0	76.85	24.32	70.21	83.49
End of Study (LOCF)	Non-Asian	54	100.0	54	100.0	77.16	24.08	70.59	83.73
Baseline	Unknown	6	100.0	4	66.7	70.83	47.87	-5.34	147.01
Week 4 (Day 29)	Unknown	6	100.0	6	100.0	69.44	24.53	43.70	95.19
Week 8 (Day 57)	Unknown	5	83.3	4	80.0	75.00	16.67	48.48	101.52
Week 12 (Day 85)	Unknown	5	83.3	4	80.0	66.67	27.22	23.36	109.97
Week 16 (Day 113)	Unknown	5	83.3	3	60.0	61.11	9.62	37.21	85.01
Week 20 (Day 141)	Unknown	5	83.3	5	100.0	73.33	19.00	49.74	96.93
Week 24 (Day 169)	Unknown	5	83.3	4	80.0	66.67	0.00	NE	NE
Week 28 (Day 197)	Unknown	5	83.3	4	80.0	70.83	28.46	25.54	116.13
Week 32 (Day 225)	Unknown	4	66.7	4	100.0	58.33	41.94	-8.41	125.07
Week 36 (Day 253)	Unknown	4	66.7	2	50.0	41.67	35.36	-275.99	359.32
Week 40 (Day 281)	Unknown	4	66.7	3	75.0	55.56	19.25	7.75	103.36
Week 44 (Day 309)	Unknown	4	66.7	4	100.0	50.00	43.03	-18.48	118.48
Week 48 (Day 337)	Unknown	2	33.3	1	50.0	66.67	NE	NE	NE
Week 52 (Day 365)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 60 (Day 421)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE

Week 64 (Day 449)	Unknown	1	16.7	1	100.0	66.67	NE	NE	NE
Week 68 (Day 477)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	1	16.7	1	100.0	50.00	NE	NE	NE
Week 76 (Day 533)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	6	100.0	6	100.0	58.33	36.13	20.41	96.25
End of Study (LOCF)	Unknown	6	100.0	6	100.0	66.67	23.57	41.93	91.40

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TN_QSC30RF_SG.xls
27OCT2021 7:40

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Role functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	48	46.2	36.9	55.7
	Cycle 12 (LOCF)	n/a	104	96.3	25	24.0	16.8	33.1
	End of Study (LOCF)	n/a	104	96.3	23	22.1	15.2	31.0
Sex	All visits	Female	56	51.9	28	50.0	37.3	62.7
		Male	48	44.4	20	41.7	28.8	55.7
	Cycle 12 (LOCF)	Female	56	51.9	15	26.8	17.0	39.6
		Male	48	44.4	10	20.8	11.7	34.3
	End of Study (LOCF)	Female	56	51.9	15	26.8	17.0	39.6
		Male	48	44.4	8	16.7	8.7	29.6
Age	All visits	< 65	60	55.6	22	36.7	25.6	49.3
		>= 65	44	40.7	26	59.1	44.4	72.3
	Cycle 12 (LOCF)	< 65	60	55.6	9	15.0	8.1	26.1
		>= 65	44	40.7	16	36.4	23.8	51.1
	End of Study (LOCF)	< 65	60	55.6	8	13.3	6.9	24.2
		>= 65	44	40.7	15	34.1	21.9	48.9
ECOG performance status	All visits	0	29	26.9	18	62.1	44.0	77.3
		1	75	69.4	30	40.0	29.7	51.3
	Cycle 12 (LOCF)	0	29	26.9	5	17.2	7.6	34.5
		1	75	69.4	20	26.7	18.0	37.6
	End of Study (LOCF)	0	29	26.9	4	13.8	5.5	30.6
		1	75	69.4	19	25.3	16.9	36.2
Geographic region	All visits	USA	19	17.6	13	68.4	46.0	84.6
		Europe (EU)	40	37.0	19	47.5	32.9	62.5
		Asia (AS)	45	41.7	16	35.6	23.2	50.2
	Cycle 12 (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	12	30.0	18.1	45.4
		Asia (AS)	45	41.7	10	22.2	12.5	36.3
	End of Study (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	11	27.5	16.1	42.8
		Asia (AS)	45	41.7	9	20.0	10.9	33.8
Race/ethnicity	All visits	Asian	48	44.4	18	37.5	25.2	51.6
		Non-Asian	52	48.1	27	51.9	38.7	64.9
		Unknown	4	3.7	3	75.0	30.1	95.4
	Cycle 12 (LOCF)	Asian	48	44.4	11	22.9	13.3	36.5
		Non-Asian	52	48.1	12	23.1	13.7	36.1
		Unknown	4	3.7	2	50.0	15.0	85.0
	End of Study (LOCF)	Asian	48	44.4	10	20.8	11.7	34.3

		Non-Asian	52	48.1	11	21.2	12.2	34.0
		Unknown	4	3.7	2	50.0	15.0	85.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30RF_W10_SG.xls
15OCT2021 13:17

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Role functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

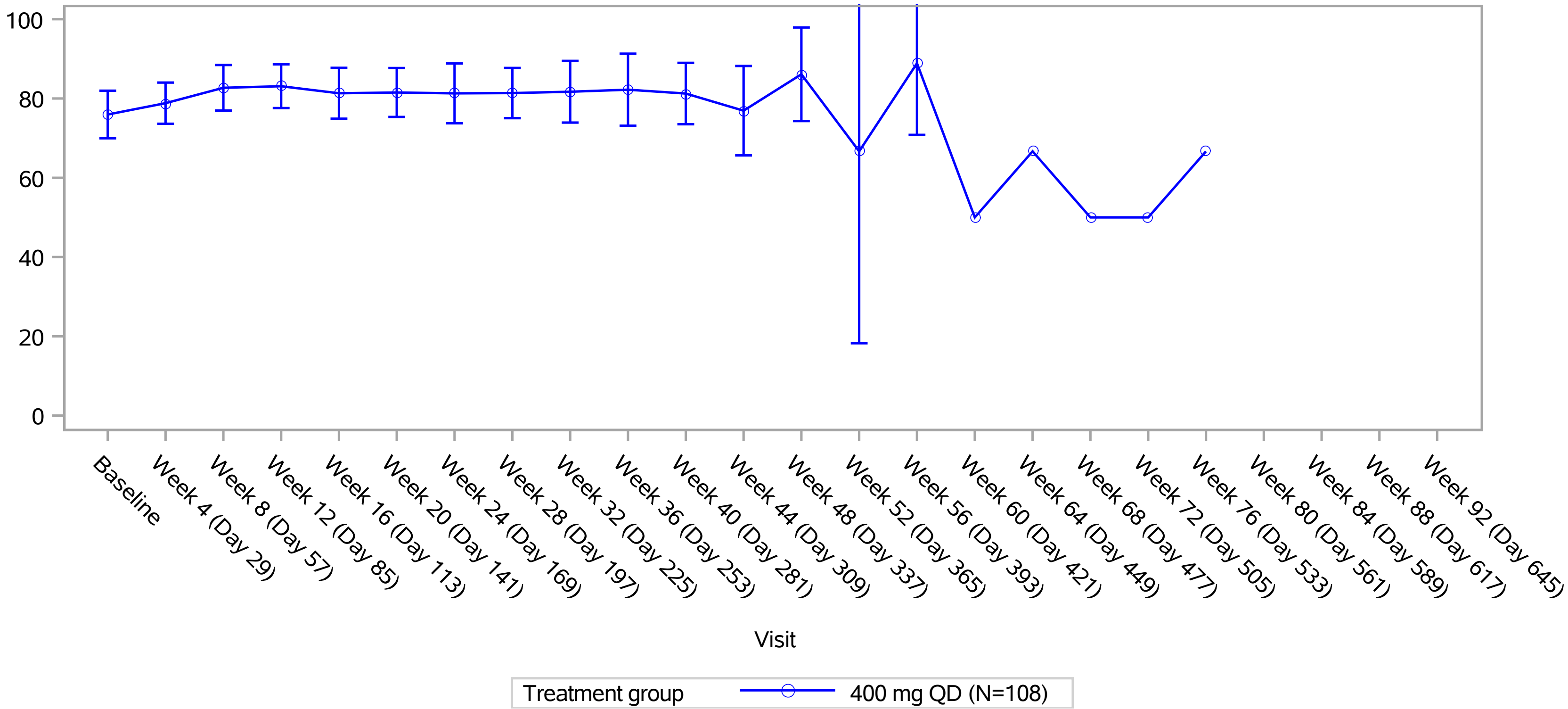
			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	48	46.2	36.9	55.7
	Cycle 12 (LOCF)	n/a	104	96.3	25	24.0	16.8	33.1
	End of Study (LOCF)	n/a	104	96.3	23	22.1	15.2	31.0
Sex	All visits	Female	56	51.9	28	50.0	37.3	62.7
		Male	48	44.4	20	41.7	28.8	55.7
	Cycle 12 (LOCF)	Female	56	51.9	15	26.8	17.0	39.6
		Male	48	44.4	10	20.8	11.7	34.3
	End of Study (LOCF)	Female	56	51.9	15	26.8	17.0	39.6
		Male	48	44.4	8	16.7	8.7	29.6
Age	All visits	< 65	60	55.6	22	36.7	25.6	49.3
		>= 65	44	40.7	26	59.1	44.4	72.3
	Cycle 12 (LOCF)	< 65	60	55.6	9	15.0	8.1	26.1
		>= 65	44	40.7	16	36.4	23.8	51.1
	End of Study (LOCF)	< 65	60	55.6	8	13.3	6.9	24.2
		>= 65	44	40.7	15	34.1	21.9	48.9
ECOG performance status	All visits	0	29	26.9	18	62.1	44.0	77.3
		1	75	69.4	30	40.0	29.7	51.3
	Cycle 12 (LOCF)	0	29	26.9	5	17.2	7.6	34.5
		1	75	69.4	20	26.7	18.0	37.6
	End of Study (LOCF)	0	29	26.9	4	13.8	5.5	30.6
		1	75	69.4	19	25.3	16.9	36.2
Geographic region	All visits	USA	19	17.6	13	68.4	46.0	84.6
		Europe (EU)	40	37.0	19	47.5	32.9	62.5
		Asia (AS)	45	41.7	16	35.6	23.2	50.2
	Cycle 12 (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	12	30.0	18.1	45.4
		Asia (AS)	45	41.7	10	22.2	12.5	36.3
	End of Study (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	11	27.5	16.1	42.8
		Asia (AS)	45	41.7	9	20.0	10.9	33.8
Race/ethnicity	All visits	Asian	48	44.4	18	37.5	25.2	51.6
		Non-Asian	52	48.1	27	51.9	38.7	64.9
		Unknown	4	3.7	3	75.0	30.1	95.4
	Cycle 12 (LOCF)	Asian	48	44.4	11	22.9	13.3	36.5
		Non-Asian	52	48.1	12	23.1	13.7	36.1
		Unknown	4	3.7	2	50.0	15.0	85.0
	End of Study (LOCF)	Asian	48	44.4	10	20.8	11.7	34.3

		Non-Asian	52	48.1	11	21.2	12.2	34.0
		Unknown	4	3.7	2	50.0	15.0	85.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30RF_W15_SG.xls
15OCT2021 13:07

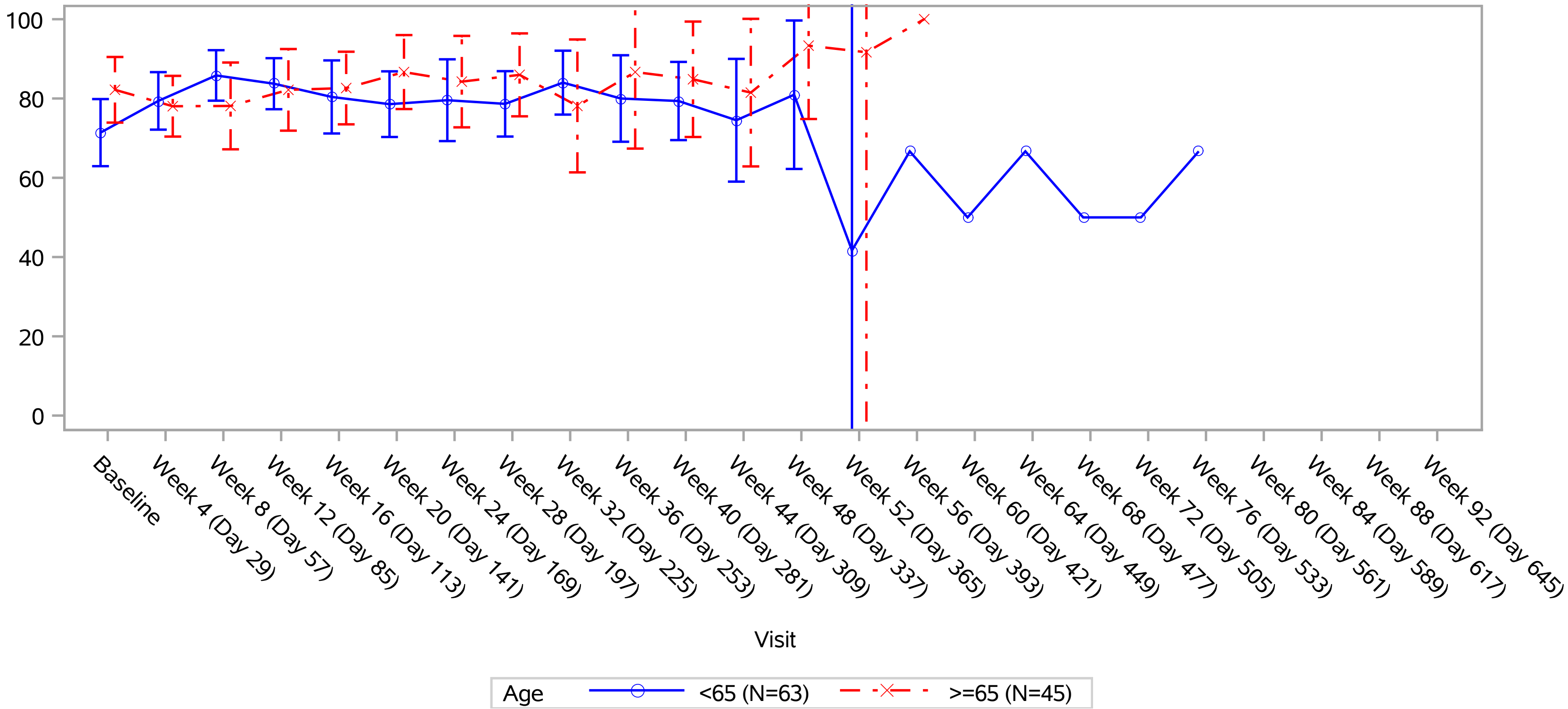
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Role functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30RF.pdf
15OCT2021 17:29

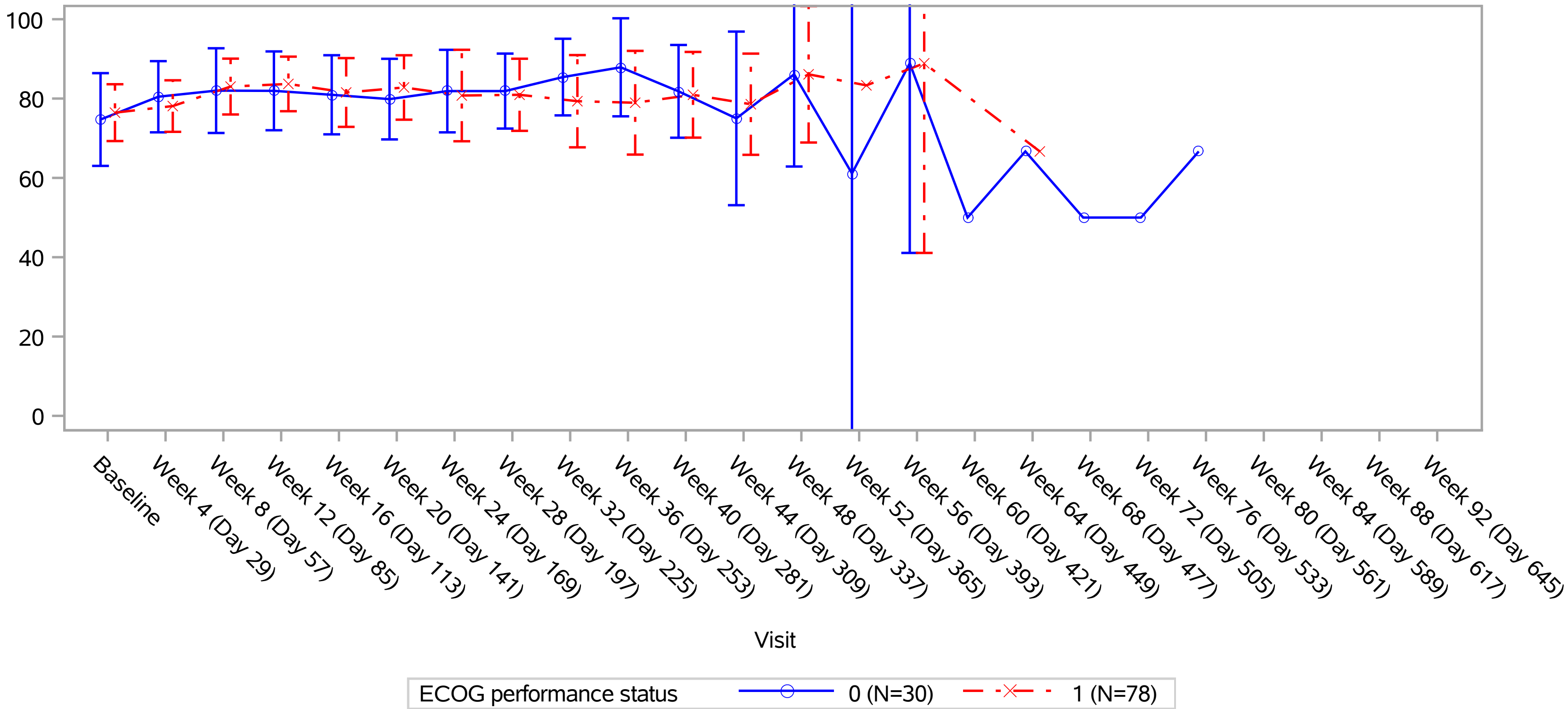
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Role functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30RF_SGAGE65.pdf
15OCT2021 17:59

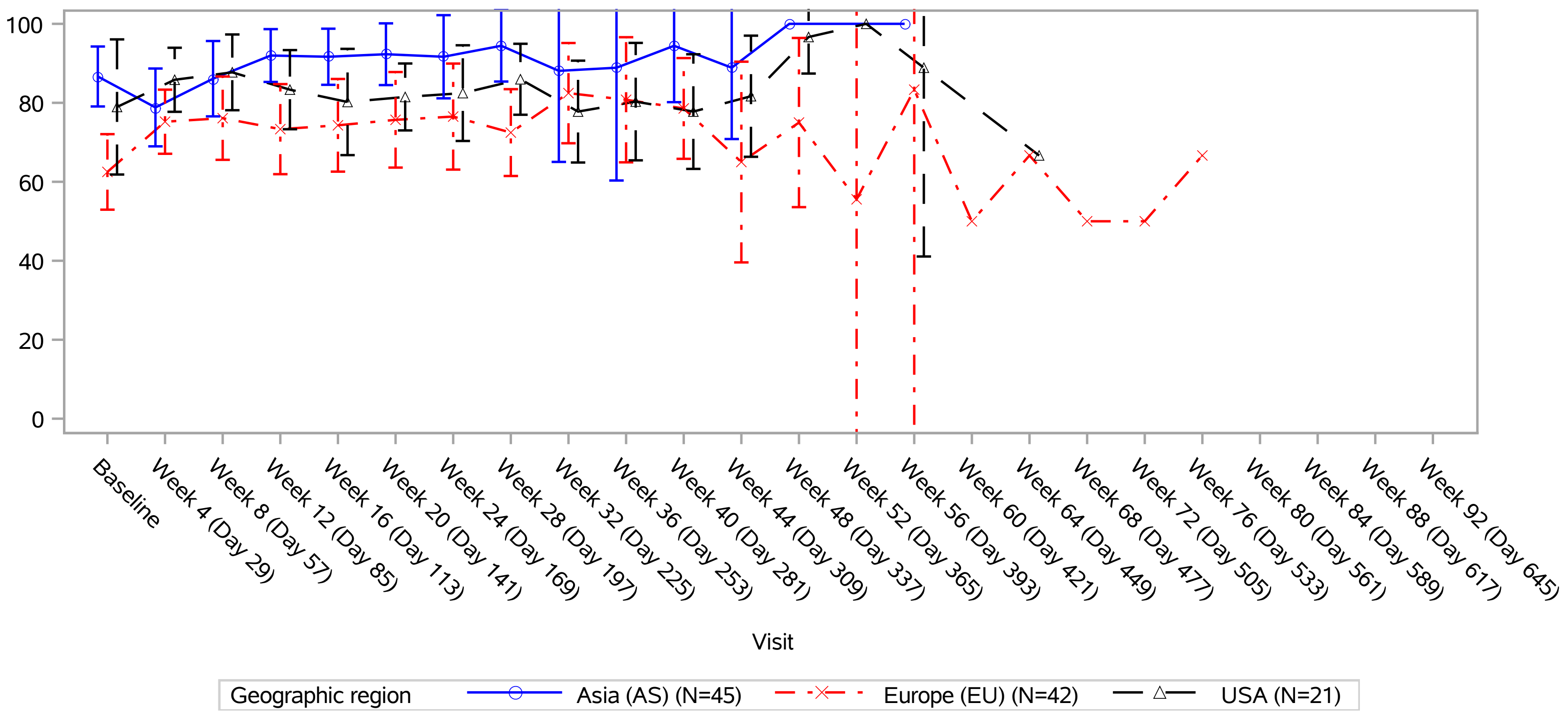
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Role functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30RF_SGECOG.pdf
15OCT2021 18:30

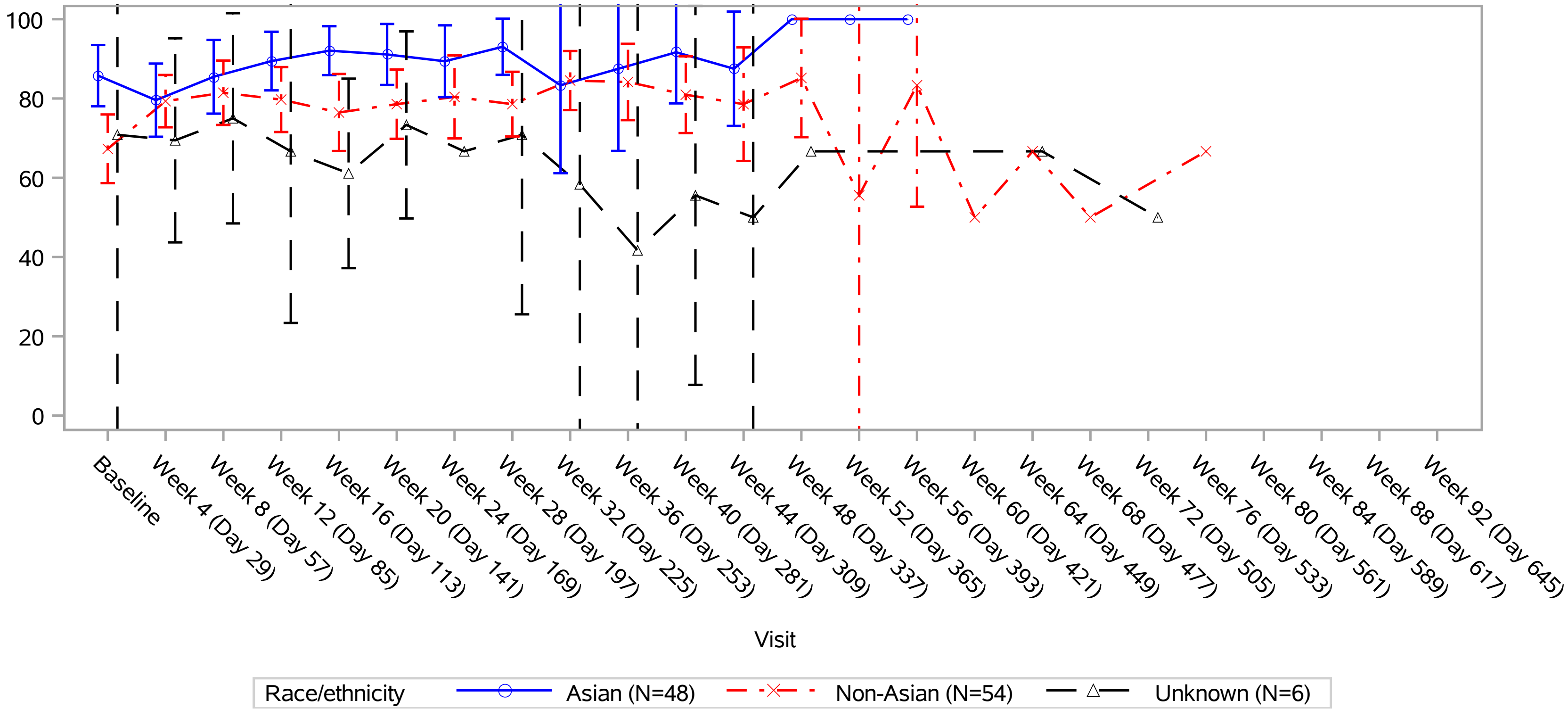
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Role functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30RF_SGGEO.pdf
15OCT2021 19:00

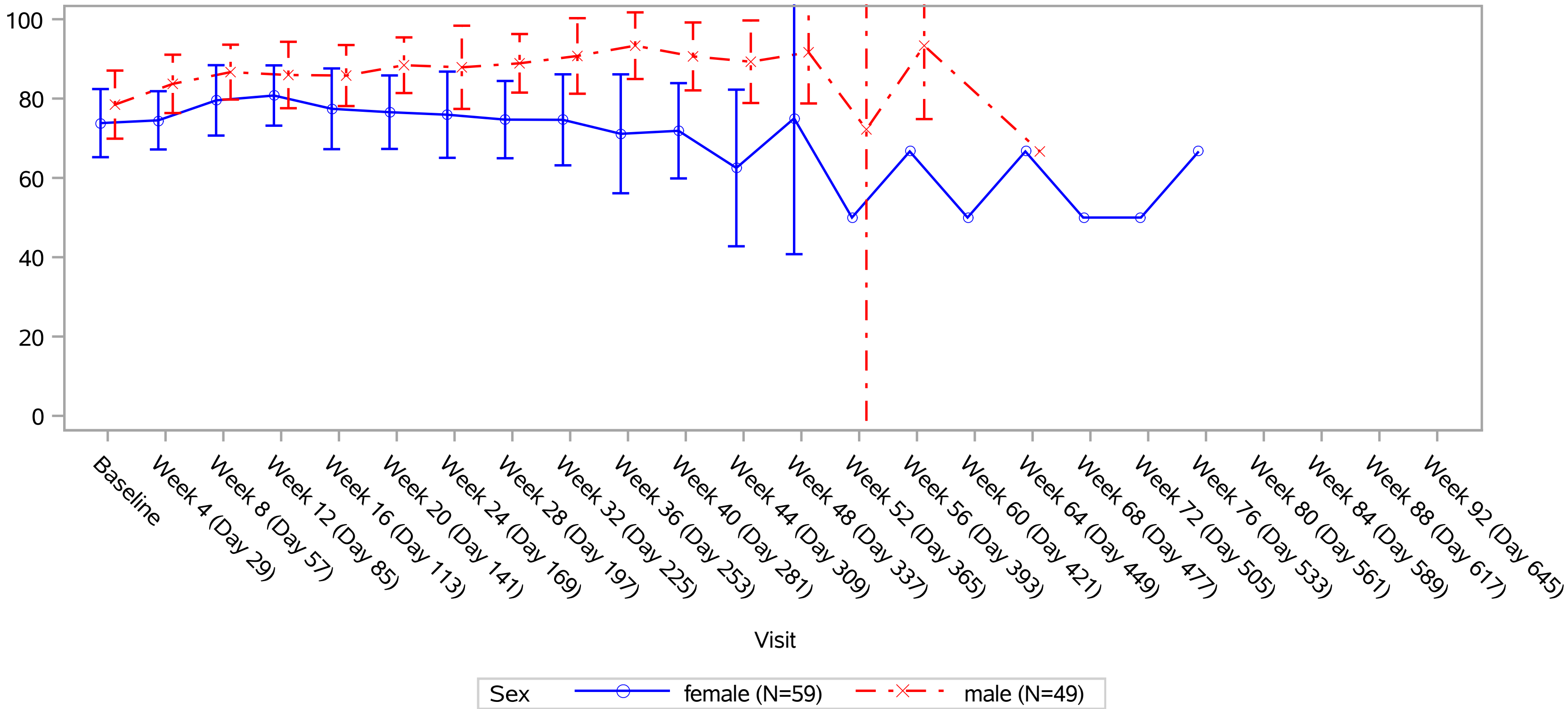
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Role functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30RF_SGRE.pdf
15OCT2021 19:31

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Role functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30RF_SGSEX.pdf
15OCT2021 20:01

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Social functioning
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=108)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	108	100.0	104	96.3	76.76	30.05	70.92	82.61
Week 4 (Day 29)	n/a	108	100.0	96	88.9	80.73	24.22	75.82	85.64
Week 8 (Day 57)	n/a	92	85.2	79	85.9	82.70	23.18	77.51	87.89
Week 12 (Day 85)	n/a	79	73.1	70	88.6	84.29	19.01	79.75	88.82
Week 16 (Day 113)	n/a	69	63.9	58	84.1	83.91	22.07	78.11	89.71
Week 20 (Day 141)	n/a	59	54.6	55	93.2	84.85	26.11	77.79	91.91
Week 24 (Day 169)	n/a	56	51.9	49	87.5	84.69	23.03	78.08	91.31
Week 28 (Day 197)	n/a	55	50.9	51	92.7	84.31	20.11	78.66	89.97
Week 32 (Day 225)	n/a	48	44.4	41	85.4	86.18	20.72	79.64	92.72
Week 36 (Day 253)	n/a	41	38.0	30	73.2	86.11	22.35	77.76	94.46
Week 40 (Day 281)	n/a	37	34.3	32	86.5	82.29	26.07	72.89	91.69
Week 44 (Day 309)	n/a	31	28.7	26	83.9	78.21	30.10	66.05	90.36
Week 48 (Day 337)	n/a	23	21.3	12	52.2	91.67	13.30	83.22	100.11
Week 52 (Day 365)	n/a	19	17.6	4	21.1	87.50	25.00	47.72	127.28
Week 56 (Day 393)	n/a	17	15.7	6	35.3	83.33	18.26	64.17	102.49
Week 60 (Day 421)	n/a	11	10.2	1	9.1	100.00	NE	NE	NE
Week 64 (Day 449)	n/a	10	9.3	3	30.0	77.78	19.25	29.97	125.59
Week 68 (Day 477)	n/a	6	5.6	1	16.7	100.00	NE	NE	NE
Week 72 (Day 505)	n/a	6	5.6	1	16.7	100.00	NE	NE	NE
Week 76 (Day 533)	n/a	6	5.6	1	16.7	100.00	NE	NE	NE
Week 80 (Day 561)	n/a	5	4.6	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	n/a	1	0.9	0	0.0	NE	NE	NE	NE

Cycle 12 (LOCF)	n/a	108	100.0	108	100.0	82.56	25.41	77.71	87.41
End of Study (LOCF)	n/a	108	100.0	108	100.0	83.95	23.45	79.48	88.42
Sex									
Baseline	Female	59	100.0	56	94.9	75.00	31.46	66.57	83.43
Week 4 (Day 29)	Female	59	100.0	51	86.4	78.43	24.79	71.46	85.40
Week 8 (Day 57)	Female	49	83.1	44	89.8	76.89	26.47	68.85	84.94
Week 12 (Day 85)	Female	44	74.6	38	86.4	80.70	20.33	74.02	87.38
Week 16 (Day 113)	Female	38	64.4	31	81.6	80.65	23.21	72.13	89.16
Week 20 (Day 141)	Female	33	55.9	32	97.0	81.77	29.74	71.05	92.49
Week 24 (Day 169)	Female	31	52.5	27	87.1	80.25	26.16	69.90	90.60
Week 28 (Day 197)	Female	30	50.8	27	90.0	79.63	21.85	70.99	88.27
Week 32 (Day 225)	Female	27	45.8	23	85.2	81.16	23.73	70.90	91.42
Week 36 (Day 253)	Female	22	37.3	15	68.2	77.78	27.22	62.71	92.85
Week 40 (Day 281)	Female	18	30.5	16	88.9	68.75	29.74	52.90	84.60
Week 44 (Day 309)	Female	15	25.4	12	80.0	62.50	34.91	40.32	84.68
Week 48 (Day 337)	Female	11	18.6	4	36.4	87.50	15.96	62.11	112.89
Week 52 (Day 365)	Female	9	15.3	1	11.1	100.00	NE	NE	NE
Week 56 (Day 393)	Female	7	11.9	1	14.3	66.67	NE	NE	NE
Week 60 (Day 421)	Female	5	8.5	1	20.0	100.00	NE	NE	NE
Week 64 (Day 449)	Female	4	6.8	2	50.0	83.33	23.57	-128.44	295.10
Week 68 (Day 477)	Female	3	5.1	1	33.3	100.00	NE	NE	NE
Week 72 (Day 505)	Female	3	5.1	1	33.3	100.00	NE	NE	NE
Week 76 (Day 533)	Female	3	5.1	1	33.3	100.00	NE	NE	NE
Week 80 (Day 561)	Female	2	3.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	59	100.0	59	100.0	79.66	26.81	72.67	86.65
End of Study (LOCF)	Female	59	100.0	59	100.0	82.20	23.95	75.96	88.44
Baseline	Male	49	100.0	48	98.0	78.82	28.50	70.54	87.10
Week 4 (Day 29)	Male	49	100.0	45	91.8	83.33	23.57	76.25	90.41
Week 8 (Day 57)	Male	43	87.8	35	81.4	90.00	15.76	84.59	95.41
Week 12 (Day 85)	Male	35	71.4	32	91.4	88.54	16.63	82.54	94.54
Week 16 (Day 113)	Male	31	63.3	27	87.1	87.65	20.46	79.56	95.75
Week 20 (Day 141)	Male	26	53.1	23	88.5	89.13	19.85	80.55	97.72
Week 24 (Day 169)	Male	25	51.0	22	88.0	90.15	17.56	82.36	97.94
Week 28 (Day 197)	Male	25	51.0	24	96.0	89.58	16.89	82.45	96.72

Week 32 (Day 225)	Male	21	42.9	18	85.7	92.59	14.26	85.50	99.68
Week 36 (Day 253)	Male	19	38.8	15	78.9	94.44	12.06	87.76	101.12
Week 40 (Day 281)	Male	19	38.8	16	84.2	95.83	11.39	89.77	101.90
Week 44 (Day 309)	Male	16	32.7	14	87.5	91.67	16.98	81.86	101.47
Week 48 (Day 337)	Male	12	24.5	8	66.7	93.75	12.40	83.38	104.12
Week 52 (Day 365)	Male	10	20.4	3	30.0	83.33	28.87	11.62	155.04
Week 56 (Day 393)	Male	10	20.4	5	50.0	86.67	18.26	64.00	109.34
Week 60 (Day 421)	Male	6	12.2	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Male	6	12.2	1	16.7	66.67	NE	NE	NE
Week 68 (Day 477)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	49	100.0	49	100.0	86.05	23.41	79.33	92.78
End of Study (LOCF)	Male	49	100.0	49	100.0	86.05	22.91	79.47	92.63
Age									
Baseline	< 65	63	100.0	60	95.2	68.33	31.99	60.07	76.60
Week 4 (Day 29)	< 65	63	100.0	55	87.3	77.27	25.73	70.32	84.23
Week 8 (Day 57)	< 65	54	85.7	47	87.0	81.56	23.11	74.77	88.35
Week 12 (Day 85)	< 65	47	74.6	41	87.2	80.89	18.84	74.95	86.84
Week 16 (Day 113)	< 65	39	61.9	34	87.2	77.94	24.86	69.27	86.62
Week 20 (Day 141)	< 65	35	55.6	35	100.0	80.48	28.15	70.81	90.15
Week 24 (Day 169)	< 65	34	54.0	31	91.2	81.72	24.85	72.60	90.84
Week 28 (Day 197)	< 65	33	52.4	32	97.0	83.33	20.30	76.01	90.65
Week 32 (Day 225)	< 65	30	47.6	25	83.3	85.33	21.15	76.60	94.06
Week 36 (Day 253)	< 65	25	39.7	20	80.0	83.33	25.36	71.46	95.20
Week 40 (Day 281)	< 65	23	36.5	21	91.3	76.19	29.14	62.93	89.46
Week 44 (Day 309)	< 65	19	30.2	17	89.5	73.53	33.88	56.11	90.95
Week 48 (Day 337)	< 65	14	22.2	7	50.0	88.10	15.85	73.43	102.76

Week 52 (Day 365)	< 65	12	19.0	2	16.7	75.00	35.36	-242.66	392.66
Week 56 (Day 393)	< 65	11	17.5	2	18.2	66.67	0.00	NE	NE
Week 60 (Day 421)	< 65	8	12.7	1	12.5	100.00	NE	NE	NE
Week 64 (Day 449)	< 65	7	11.1	3	42.9	77.78	19.25	29.97	125.59
Week 68 (Day 477)	< 65	4	6.3	1	25.0	100.00	NE	NE	NE
Week 72 (Day 505)	< 65	4	6.3	1	25.0	100.00	NE	NE	NE
Week 76 (Day 533)	< 65	4	6.3	1	25.0	100.00	NE	NE	NE
Week 80 (Day 561)	< 65	3	4.8	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	63	100.0	63	100.0	78.31	27.38	71.41	85.20
End of Study (LOCF)	< 65	63	100.0	63	100.0	80.69	24.90	74.42	86.96
Baseline	>= 65	45	100.0	44	97.8	88.26	22.90	81.30	95.22
Week 4 (Day 29)	>= 65	45	100.0	41	91.1	85.37	21.47	78.59	92.14
Week 8 (Day 57)	>= 65	38	84.4	32	84.2	84.38	23.55	75.89	92.86
Week 12 (Day 85)	>= 65	32	71.1	29	90.6	89.08	18.51	82.04	96.12
Week 16 (Day 113)	>= 65	30	66.7	24	80.0	92.36	13.88	86.50	98.22
Week 20 (Day 141)	>= 65	24	53.3	20	83.3	92.50	20.57	82.87	102.13
Week 24 (Day 169)	>= 65	22	48.9	18	81.8	89.81	19.08	80.33	99.30
Week 28 (Day 197)	>= 65	22	48.9	19	86.4	85.96	20.23	76.21	95.72
Week 32 (Day 225)	>= 65	18	40.0	16	88.9	87.50	20.64	76.50	98.50
Week 36 (Day 253)	>= 65	16	35.6	10	62.5	91.67	14.16	81.53	101.80
Week 40 (Day 281)	>= 65	14	31.1	11	78.6	93.94	13.48	84.88	103.00
Week 44 (Day 309)	>= 65	12	26.7	9	75.0	87.04	20.03	71.64	102.43
Week 48 (Day 337)	>= 65	9	20.0	5	55.6	96.67	7.45	87.41	105.92
Week 52 (Day 365)	>= 65	7	15.6	2	28.6	100.00	0.00	NE	NE
Week 56 (Day 393)	>= 65	6	13.3	4	66.7	91.67	16.67	65.15	118.19
Week 60 (Day 421)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE

Week 76 (Day 533)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	45	100.0	45	100.0	88.52	21.27	82.13	94.91
End of Study (LOCF)	>= 65	45	100.0	45	100.0	88.52	20.67	82.31	94.73
ECOG performance status									
Baseline	0	30	100.0	29	96.7	77.01	30.35	65.47	88.55
Week 4 (Day 29)	0	30	100.0	29	96.7	82.76	24.59	73.40	92.11
Week 8 (Day 57)	0	28	93.3	25	89.3	84.67	20.37	76.26	93.07
Week 12 (Day 85)	0	26	86.7	23	88.5	85.51	18.33	77.58	93.43
Week 16 (Day 113)	0	26	86.7	21	80.8	82.54	20.05	73.41	91.67
Week 20 (Day 141)	0	26	86.7	24	92.3	85.42	26.61	74.18	96.65
Week 24 (Day 169)	0	25	83.3	23	92.0	87.68	20.85	78.66	96.70
Week 28 (Day 197)	0	25	83.3	23	92.0	88.41	15.44	81.73	95.08
Week 32 (Day 225)	0	20	66.7	16	80.0	89.58	15.96	81.08	98.09
Week 36 (Day 253)	0	18	60.0	11	61.1	93.94	11.24	86.39	101.49
Week 40 (Day 281)	0	16	53.3	11	68.8	89.39	18.67	76.85	101.94
Week 44 (Day 309)	0	15	50.0	12	80.0	77.78	38.49	53.32	102.23
Week 48 (Day 337)	0	9	30.0	6	66.7	94.44	13.61	80.16	108.73
Week 52 (Day 365)	0	9	30.0	3	33.3	83.33	28.87	11.62	155.04
Week 56 (Day 393)	0	8	26.7	3	37.5	88.89	19.25	41.08	136.70
Week 60 (Day 421)	0	5	16.7	1	20.0	100.00	NE	NE	NE
Week 64 (Day 449)	0	5	16.7	2	40.0	83.33	23.57	-128.44	295.10
Week 68 (Day 477)	0	3	10.0	1	33.3	100.00	NE	NE	NE
Week 72 (Day 505)	0	3	10.0	1	33.3	100.00	NE	NE	NE
Week 76 (Day 533)	0	3	10.0	1	33.3	100.00	NE	NE	NE
Week 80 (Day 561)	0	2	6.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	0	1	3.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	30	100.0	30	100.0	83.89	30.16	72.63	95.15
End of Study (LOCF)	0	30	100.0	30	100.0	87.22	25.78	77.60	96.85
Baseline	1	78	100.0	75	96.2	76.67	30.14	69.73	83.60
Week 4 (Day 29)	1	78	100.0	67	85.9	79.85	24.19	73.95	85.75

Week 8 (Day 57)	1	64	82.1	54	84.4	81.79	24.50	75.10	88.48
Week 12 (Day 85)	1	53	67.9	47	88.7	83.69	19.50	77.96	89.41
Week 16 (Day 113)	1	43	55.1	37	86.0	84.68	23.37	76.89	92.48
Week 20 (Day 141)	1	33	42.3	31	93.9	84.41	26.15	74.82	94.00
Week 24 (Day 169)	1	31	39.7	26	83.9	82.05	24.91	71.99	92.11
Week 28 (Day 197)	1	30	38.5	28	93.3	80.95	23.00	72.03	89.87
Week 32 (Day 225)	1	28	35.9	25	89.3	84.00	23.31	74.38	93.62
Week 36 (Day 253)	1	23	29.5	19	82.6	81.58	26.00	69.05	94.11
Week 40 (Day 281)	1	21	26.9	21	100.0	78.57	28.94	65.40	91.74
Week 44 (Day 309)	1	16	20.5	14	87.5	78.57	22.10	65.81	91.33
Week 48 (Day 337)	1	14	17.9	6	42.9	88.89	13.61	74.61	103.17
Week 52 (Day 365)	1	10	12.8	1	10.0	100.00	NE	NE	NE
Week 56 (Day 393)	1	9	11.5	3	33.3	77.78	19.25	29.97	125.59
Week 60 (Day 421)	1	6	7.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	5	6.4	1	20.0	66.67	NE	NE	NE
Week 68 (Day 477)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	3	3.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	78	100.0	78	100.0	82.05	23.53	76.74	87.36
End of Study (LOCF)	1	78	100.0	78	100.0	82.69	22.54	77.61	87.78
Geographic region									
Baseline	USA	21	100.0	19	90.5	79.82	33.14	63.85	95.80
Week 4 (Day 29)	USA	21	100.0	20	95.2	84.17	17.50	75.98	92.36
Week 8 (Day 57)	USA	21	100.0	19	90.5	85.09	19.16	75.85	94.32
Week 12 (Day 85)	USA	21	100.0	18	85.7	85.19	17.04	76.71	93.66
Week 16 (Day 113)	USA	21	100.0	16	76.2	83.33	22.77	71.20	95.47
Week 20 (Day 141)	USA	20	95.2	18	90.0	88.89	18.08	79.90	97.88
Week 24 (Day 169)	USA	20	95.2	19	95.0	85.96	22.40	75.17	96.76
Week 28 (Day 197)	USA	20	95.2	19	95.0	85.96	14.97	78.75	93.18
Week 32 (Day 225)	USA	17	81.0	15	88.2	81.11	20.77	69.61	92.61
Week 36 (Day 253)	USA	17	81.0	11	64.7	83.33	18.26	71.07	95.60
Week 40 (Day 281)	USA	15	71.4	12	80.0	77.78	30.43	58.44	97.11

Week 44 (Day 309)	USA	13	61.9	10	76.9	85.00	16.57	73.14	96.86
Week 48 (Day 337)	USA	8	38.1	5	62.5	93.33	14.91	74.82	111.84
Week 52 (Day 365)	USA	6	28.6	1	16.7	100.00	NE	NE	NE
Week 56 (Day 393)	USA	6	28.6	3	50.0	88.89	19.25	41.08	136.70
Week 60 (Day 421)	USA	5	23.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	4	19.0	1	25.0	66.67	NE	NE	NE
Week 68 (Day 477)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	21	100.0	21	100.0	90.48	16.31	83.05	97.90
End of Study (LOCF)	USA	21	100.0	21	100.0	90.48	16.31	83.05	97.90
Baseline	Europe (EU)	42	100.0	40	95.2	70.42	31.91	60.21	80.62
Week 4 (Day 29)	Europe (EU)	42	100.0	39	92.9	81.20	25.70	72.87	89.53
Week 8 (Day 57)	Europe (EU)	36	85.7	30	83.3	85.00	22.04	76.77	93.23
Week 12 (Day 85)	Europe (EU)	31	73.8	25	80.6	79.33	22.71	69.96	88.71
Week 16 (Day 113)	Europe (EU)	30	71.4	24	80.0	81.25	23.22	71.45	91.05
Week 20 (Day 141)	Europe (EU)	26	61.9	24	92.3	82.64	27.13	71.18	94.10
Week 24 (Day 169)	Europe (EU)	26	61.9	22	84.6	81.82	24.07	71.14	92.49
Week 28 (Day 197)	Europe (EU)	25	59.5	23	92.0	81.88	22.98	71.95	91.82
Week 32 (Day 225)	Europe (EU)	21	50.0	19	90.5	92.98	13.96	86.25	99.71
Week 36 (Day 253)	Europe (EU)	16	38.1	13	81.3	92.31	12.94	84.49	100.13
Week 40 (Day 281)	Europe (EU)	14	33.3	14	100.0	85.71	22.51	72.72	98.71
Week 44 (Day 309)	Europe (EU)	11	26.2	10	90.9	73.33	40.98	44.02	102.65
Week 48 (Day 337)	Europe (EU)	8	19.0	6	75.0	88.89	13.61	74.61	103.17
Week 52 (Day 365)	Europe (EU)	6	14.3	3	50.0	83.33	28.87	11.62	155.04
Week 56 (Day 393)	Europe (EU)	6	14.3	2	33.3	83.33	23.57	-128.44	295.10

Week 60 (Day 421)	Europe (EU)	4	9.5	1	25.0	100.00	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	4	9.5	2	50.0	83.33	23.57	-128.44	295.10
Week 68 (Day 477)	Europe (EU)	3	7.1	1	33.3	100.00	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	3	7.1	1	33.3	100.00	NE	NE	NE
Week 76 (Day 533)	Europe (EU)	3	7.1	1	33.3	100.00	NE	NE	NE
Week 80 (Day 561)	Europe (EU)	2	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Europe (EU)	42	100.0	42	100.0	81.75	27.25	73.25	90.24
End of Study (LOCF)	Europe (EU)	42	100.0	42	100.0	84.92	22.63	77.87	91.97
Baseline	Asia (AS)	45	100.0	45	100.0	81.11	26.50	73.15	89.07
Week 4 (Day 29)	Asia (AS)	45	100.0	37	82.2	78.38	26.02	69.70	87.05
Week 8 (Day 57)	Asia (AS)	35	77.8	30	85.7	78.89	26.60	68.96	88.82
Week 12 (Day 85)	Asia (AS)	27	60.0	27	100.0	88.27	15.89	81.99	94.56
Week 16 (Day 113)	Asia (AS)	18	40.0	18	100.0	87.96	20.46	77.79	98.14
Week 20 (Day 141)	Asia (AS)	13	28.9	13	100.0	83.33	34.02	62.77	103.89
Week 24 (Day 169)	Asia (AS)	10	22.2	8	80.0	89.58	23.46	69.97	109.20
Week 28 (Day 197)	Asia (AS)	10	22.2	9	90.0	87.04	23.24	69.17	104.90
Week 32 (Day 225)	Asia (AS)	10	22.2	7	70.0	78.57	31.50	49.44	107.70
Week 36 (Day 253)	Asia (AS)	8	17.8	6	75.0	77.78	40.37	35.41	120.14
Week 40 (Day 281)	Asia (AS)	8	17.8	6	75.0	83.33	27.89	54.07	112.60
Week 44 (Day 309)	Asia (AS)	7	15.6	6	85.7	75.00	29.34	44.20	105.80
Week 48 (Day 337)	Asia (AS)	7	15.6	1	14.3	100.00	NE	NE	NE
Week 52 (Day 365)	Asia (AS)	7	15.6	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Asia (AS)	5	11.1	1	20.0	66.67	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	45	100.0	45	100.0	79.63	26.80	71.58	87.68
End of Study (LOCF)	Asia (AS)	45	100.0	45	100.0	80.00	26.50	72.04	87.96

Race/ethnicity									
Baseline	Asian	48	100.0	48	100.0	80.21	28.49	71.94	88.48
Week 4 (Day 29)	Asian	48	100.0	40	83.3	77.50	26.30	69.09	85.91
Week 8 (Day 57)	Asian	38	79.2	31	81.6	78.49	26.24	68.87	88.12
Week 12 (Day 85)	Asian	30	62.5	30	100.0	87.22	16.19	81.18	93.27
Week 16 (Day 113)	Asian	21	43.8	21	100.0	87.30	19.65	78.36	96.25
Week 20 (Day 141)	Asian	16	33.3	15	93.8	83.33	32.12	65.55	101.12
Week 24 (Day 169)	Asian	13	27.1	11	84.6	86.36	22.13	71.49	101.23
Week 28 (Day 197)	Asian	13	27.1	12	92.3	84.72	21.86	70.84	98.61
Week 32 (Day 225)	Asian	12	25.0	9	75.0	75.93	27.78	54.57	97.28
Week 36 (Day 253)	Asian	10	20.8	8	80.0	77.08	34.43	48.30	105.87
Week 40 (Day 281)	Asian	10	20.8	8	80.0	83.33	25.20	62.27	104.40
Week 44 (Day 309)	Asian	9	18.8	8	88.9	77.08	26.63	54.82	99.35
Week 48 (Day 337)	Asian	9	18.8	2	22.2	100.00	0.00	NE	NE
Week 52 (Day 365)	Asian	9	18.8	1	11.1	100.00	NE	NE	NE
Week 56 (Day 393)	Asian	7	14.6	2	28.6	83.33	23.57	-128.44	295.10
Week 60 (Day 421)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	48	100.0	48	100.0	80.21	26.33	72.56	87.85
End of Study (LOCF)	Asian	48	100.0	48	100.0	80.56	26.03	73.00	88.11
Baseline	Non-Asian	54	100.0	52	96.3	73.72	30.13	65.33	82.11
Week 4 (Day 29)	Non-Asian	54	100.0	50	92.6	83.67	21.95	77.43	89.90
Week 8 (Day 57)	Non-Asian	49	90.7	44	89.8	84.85	21.21	78.40	91.30
Week 12 (Day 85)	Non-Asian	44	81.5	36	81.8	82.41	20.68	75.41	89.40
Week 16 (Day 113)	Non-Asian	43	79.6	34	79.1	81.86	24.05	73.47	90.26
Week 20 (Day 141)	Non-Asian	38	70.4	35	92.1	85.71	24.96	77.14	94.29
Week 24 (Day 169)	Non-Asian	38	70.4	34	89.5	84.31	24.60	75.73	92.90
Week 28 (Day 197)	Non-Asian	37	68.5	35	94.6	84.29	20.19	77.35	91.22
Week 32 (Day 225)	Non-Asian	32	59.3	28	87.5	88.69	18.17	81.64	95.74
Week 36 (Day 253)	Non-Asian	27	50.0	20	74.1	90.83	15.74	83.47	98.20

Week 40 (Day 281)	Non-Asian	23	42.6	21	91.3	80.95	28.03	68.19	93.71
Week 44 (Day 309)	Non-Asian	18	33.3	14	77.8	82.14	28.09	65.92	98.36
Week 48 (Day 337)	Non-Asian	12	22.2	9	75.0	90.74	14.70	79.44	102.04
Week 52 (Day 365)	Non-Asian	8	14.8	3	37.5	83.33	28.87	11.62	155.04
Week 56 (Day 393)	Non-Asian	8	14.8	4	50.0	83.33	19.25	52.71	113.96
Week 60 (Day 421)	Non-Asian	7	13.0	1	14.3	100.00	NE	NE	NE
Week 64 (Day 449)	Non-Asian	6	11.1	2	33.3	66.67	0.00	NE	NE
Week 68 (Day 477)	Non-Asian	3	5.6	1	33.3	100.00	NE	NE	NE
Week 72 (Day 505)	Non-Asian	3	5.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Non-Asian	3	5.6	1	33.3	100.00	NE	NE	NE
Week 80 (Day 561)	Non-Asian	2	3.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	54	100.0	54	100.0	86.11	22.84	79.88	92.34
End of Study (LOCF)	Non-Asian	54	100.0	54	100.0	87.04	21.64	81.13	92.94
Baseline	Unknown	6	100.0	4	66.7	75.00	50.00	-4.56	154.56
Week 4 (Day 29)	Unknown	6	100.0	6	100.0	77.78	29.19	47.15	108.41
Week 8 (Day 57)	Unknown	5	83.3	4	80.0	91.67	16.67	65.15	118.19
Week 12 (Day 85)	Unknown	5	83.3	4	80.0	79.17	25.00	39.39	118.95
Week 16 (Day 113)	Unknown	5	83.3	3	60.0	83.33	16.67	41.93	124.74
Week 20 (Day 141)	Unknown	5	83.3	5	100.0	83.33	16.67	62.64	104.03
Week 24 (Day 169)	Unknown	5	83.3	4	80.0	83.33	13.61	61.68	104.99
Week 28 (Day 197)	Unknown	5	83.3	4	80.0	83.33	19.25	52.71	113.96
Week 32 (Day 225)	Unknown	4	66.7	4	100.0	91.67	16.67	65.15	118.19
Week 36 (Day 253)	Unknown	4	66.7	2	50.0	75.00	11.79	-30.89	180.89
Week 40 (Day 281)	Unknown	4	66.7	3	75.0	88.89	19.25	41.08	136.70
Week 44 (Day 309)	Unknown	4	66.7	4	100.0	66.67	47.14	-8.34	141.68
Week 48 (Day 337)	Unknown	2	33.3	1	50.0	83.33	NE	NE	NE
Week 52 (Day 365)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 60 (Day 421)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE

Week 64 (Day 449)	Unknown	1	16.7	1	100.0	100.00	NE	NE	NE
Week 68 (Day 477)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	1	16.7	1	100.0	100.00	NE	NE	NE
Week 76 (Day 533)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	6	100.0	6	100.0	69.44	37.14	30.46	108.42
End of Study (LOCF)	Unknown	6	100.0	6	100.0	83.33	14.91	67.69	98.98

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TN_QSC30SF_SG.xls
27OCT2021 7:41

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Social functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	41	39.4	30.6	49.0
	Cycle 12 (LOCF)	n/a	104	96.3	18	17.3	11.2	25.7
	End of Study (LOCF)	n/a	104	96.3	16	15.4	9.7	23.5
Sex	All visits	Female	56	51.9	26	46.4	34.0	59.3
		Male	48	44.4	15	31.3	19.9	45.3
	Cycle 12 (LOCF)	Female	56	51.9	11	19.6	11.3	31.8
		Male	48	44.4	7	14.6	7.2	27.2
	End of Study (LOCF)	Female	56	51.9	10	17.9	10.0	29.8
		Male	48	44.4	6	12.5	5.9	24.7
Age	All visits	< 65	60	55.6	18	30.0	19.9	42.5
		>= 65	44	40.7	23	52.3	37.9	66.2
	Cycle 12 (LOCF)	< 65	60	55.6	9	15.0	8.1	26.1
		>= 65	44	40.7	9	20.5	11.2	34.5
	End of Study (LOCF)	< 65	60	55.6	8	13.3	6.9	24.2
		>= 65	44	40.7	8	18.2	9.5	32.0
ECOG performance status	All visits	0	29	26.9	13	44.8	28.4	62.5
		1	75	69.4	28	37.3	27.3	48.6
	Cycle 12 (LOCF)	0	29	26.9	3	10.3	3.6	26.4
		1	75	69.4	15	20.0	12.5	30.4
	End of Study (LOCF)	0	29	26.9	3	10.3	3.6	26.4
		1	75	69.4	13	17.3	10.4	27.4
Geographic region	All visits	USA	19	17.6	9	47.4	27.3	68.3
		Europe (EU)	40	37.0	16	40.0	26.3	55.4
		Asia (AS)	45	41.7	16	35.6	23.2	50.2
	Cycle 12 (LOCF)	USA	19	17.6	0	0.0	0.0	16.8
		Europe (EU)	40	37.0	7	17.5	8.7	31.9
		Asia (AS)	45	41.7	11	24.4	14.2	38.7
	End of Study (LOCF)	USA	19	17.6	0	0.0	0.0	16.8
		Europe (EU)	40	37.0	6	15.0	7.1	29.1
		Asia (AS)	45	41.7	10	22.2	12.5	36.3
Race/ethnicity	All visits	Asian	48	44.4	17	35.4	23.4	49.6
		Non-Asian	52	48.1	22	42.3	29.9	55.8
		Unknown	4	3.7	2	50.0	15.0	85.0
	Cycle 12 (LOCF)	Asian	48	44.4	11	22.9	13.3	36.5
		Non-Asian	52	48.1	5	9.6	4.2	20.6
		Unknown	4	3.7	2	50.0	15.0	85.0
	End of Study (LOCF)	Asian	48	44.4	10	20.8	11.7	34.3

		Non-Asian	52	48.1	4	7.7	3.0	18.2
		Unknown	4	3.7	2	50.0	15.0	85.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30SF_W10_SG.xls
15OCT2021 13:18

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Social functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

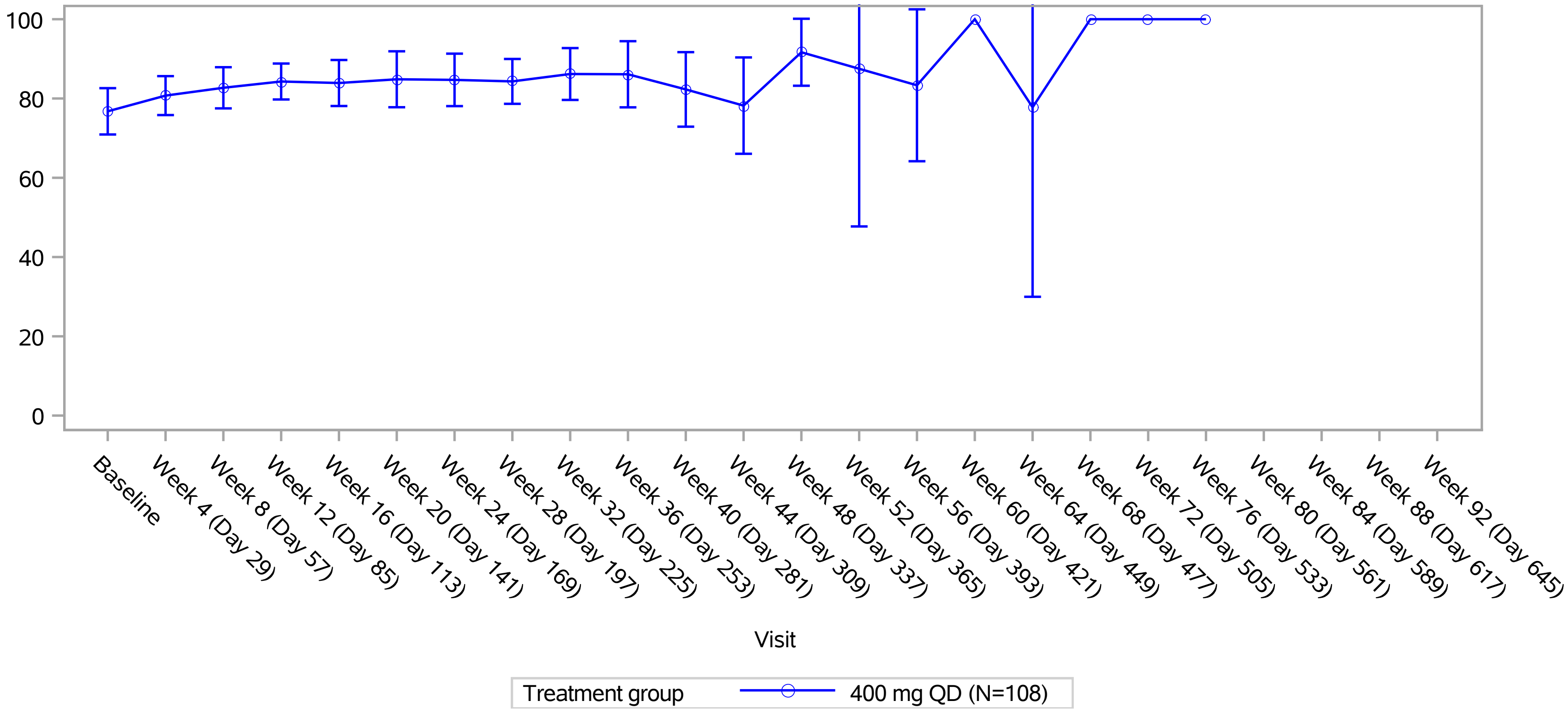
			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	41	39.4	30.6	49.0
	Cycle 12 (LOCF)	n/a	104	96.3	18	17.3	11.2	25.7
	End of Study (LOCF)	n/a	104	96.3	16	15.4	9.7	23.5
Sex	All visits	Female	56	51.9	26	46.4	34.0	59.3
		Male	48	44.4	15	31.3	19.9	45.3
	Cycle 12 (LOCF)	Female	56	51.9	11	19.6	11.3	31.8
		Male	48	44.4	7	14.6	7.2	27.2
	End of Study (LOCF)	Female	56	51.9	10	17.9	10.0	29.8
		Male	48	44.4	6	12.5	5.9	24.7
Age	All visits	< 65	60	55.6	18	30.0	19.9	42.5
		>= 65	44	40.7	23	52.3	37.9	66.2
	Cycle 12 (LOCF)	< 65	60	55.6	9	15.0	8.1	26.1
		>= 65	44	40.7	9	20.5	11.2	34.5
	End of Study (LOCF)	< 65	60	55.6	8	13.3	6.9	24.2
		>= 65	44	40.7	8	18.2	9.5	32.0
ECOG performance status	All visits	0	29	26.9	13	44.8	28.4	62.5
		1	75	69.4	28	37.3	27.3	48.6
	Cycle 12 (LOCF)	0	29	26.9	3	10.3	3.6	26.4
		1	75	69.4	15	20.0	12.5	30.4
	End of Study (LOCF)	0	29	26.9	3	10.3	3.6	26.4
		1	75	69.4	13	17.3	10.4	27.4
Geographic region	All visits	USA	19	17.6	9	47.4	27.3	68.3
		Europe (EU)	40	37.0	16	40.0	26.3	55.4
		Asia (AS)	45	41.7	16	35.6	23.2	50.2
	Cycle 12 (LOCF)	USA	19	17.6	0	0.0	0.0	16.8
		Europe (EU)	40	37.0	7	17.5	8.7	31.9
		Asia (AS)	45	41.7	11	24.4	14.2	38.7
	End of Study (LOCF)	USA	19	17.6	0	0.0	0.0	16.8
		Europe (EU)	40	37.0	6	15.0	7.1	29.1
		Asia (AS)	45	41.7	10	22.2	12.5	36.3
Race/ethnicity	All visits	Asian	48	44.4	17	35.4	23.4	49.6
		Non-Asian	52	48.1	22	42.3	29.9	55.8
		Unknown	4	3.7	2	50.0	15.0	85.0
	Cycle 12 (LOCF)	Asian	48	44.4	11	22.9	13.3	36.5
		Non-Asian	52	48.1	5	9.6	4.2	20.6
		Unknown	4	3.7	2	50.0	15.0	85.0
	End of Study (LOCF)	Asian	48	44.4	10	20.8	11.7	34.3

		Non-Asian	52	48.1	4	7.7	3.0	18.2
		Unknown	4	3.7	2	50.0	15.0	85.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30SF_W15_SG.xls
15OCT2021 13:08

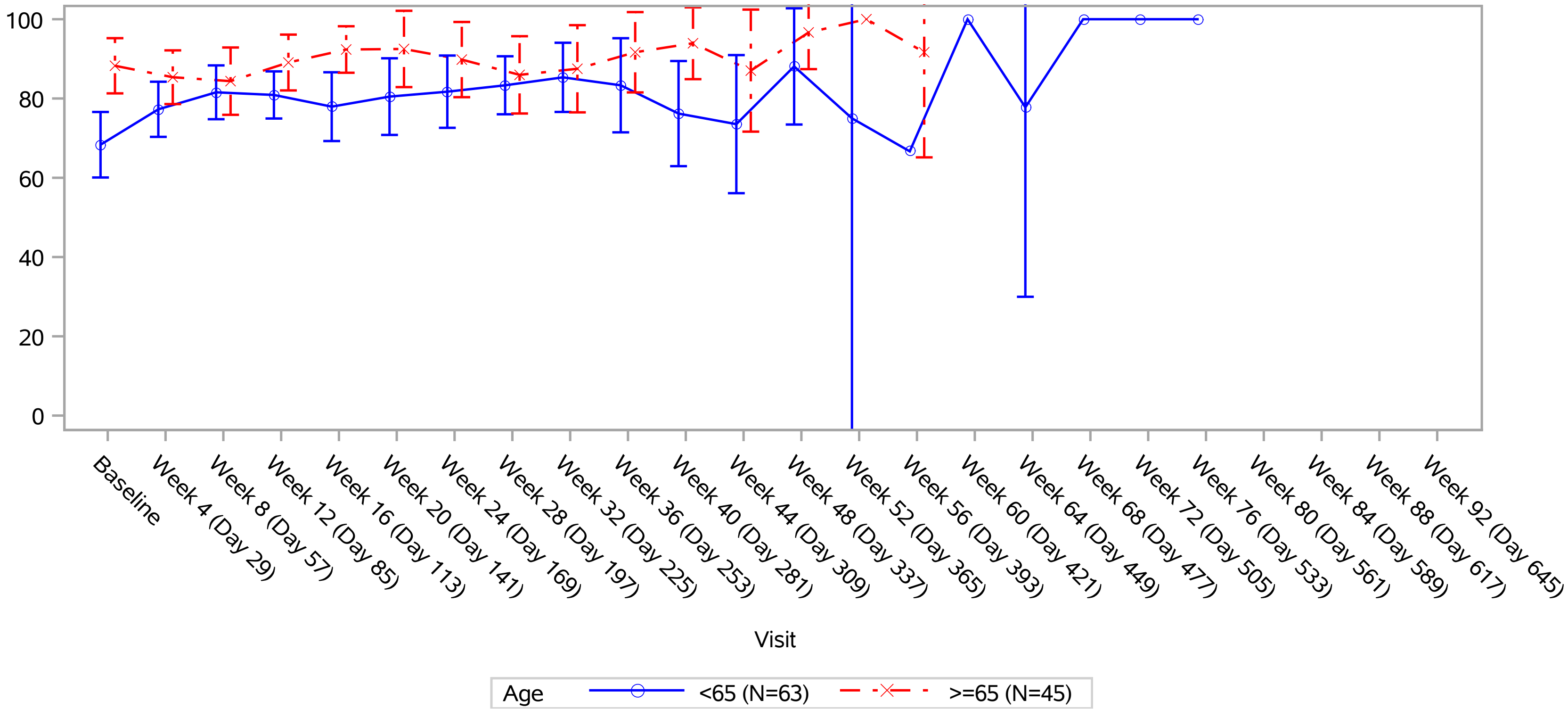
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Social functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30SF.pdf
15OCT2021 17:30

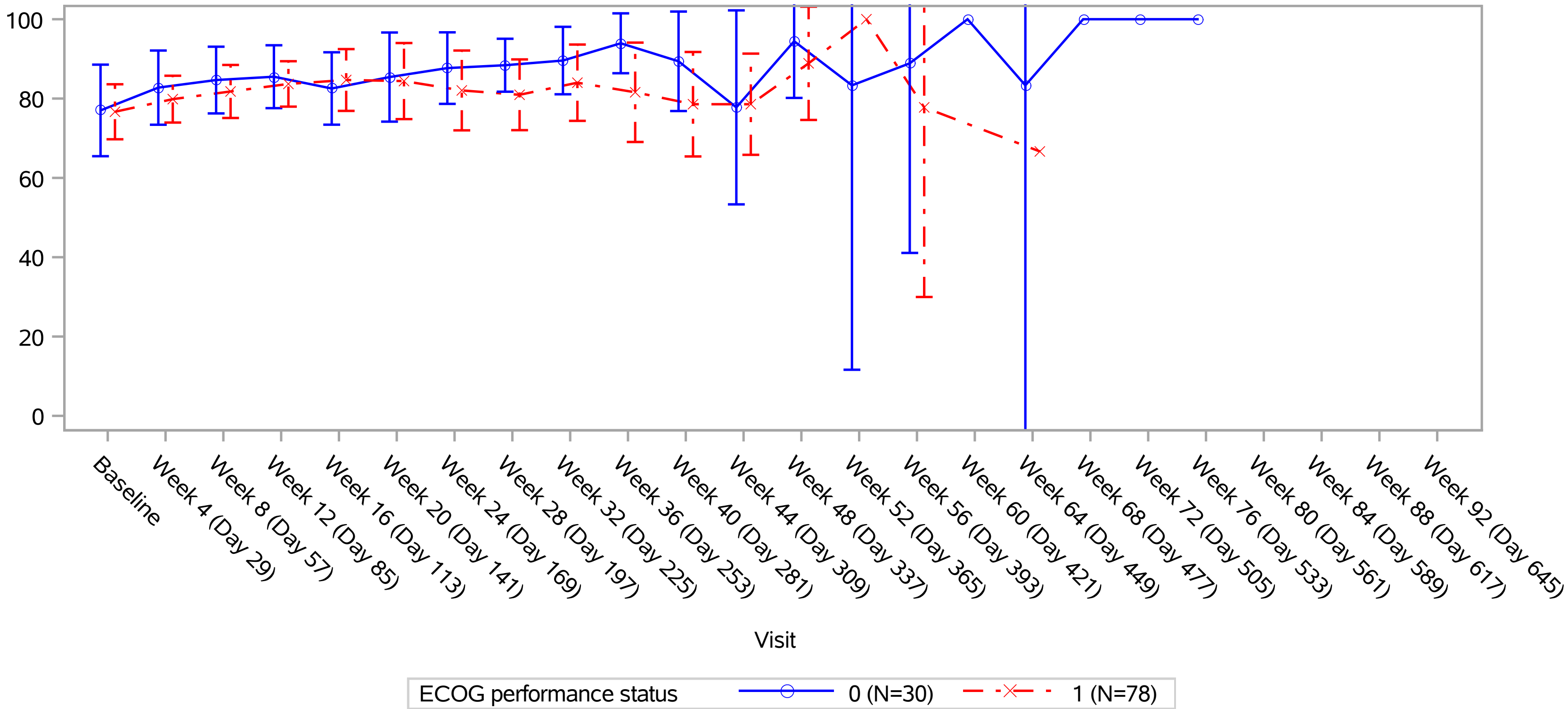
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Social functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30SF_SGAGE65.pdf
15OCT2021 17:59

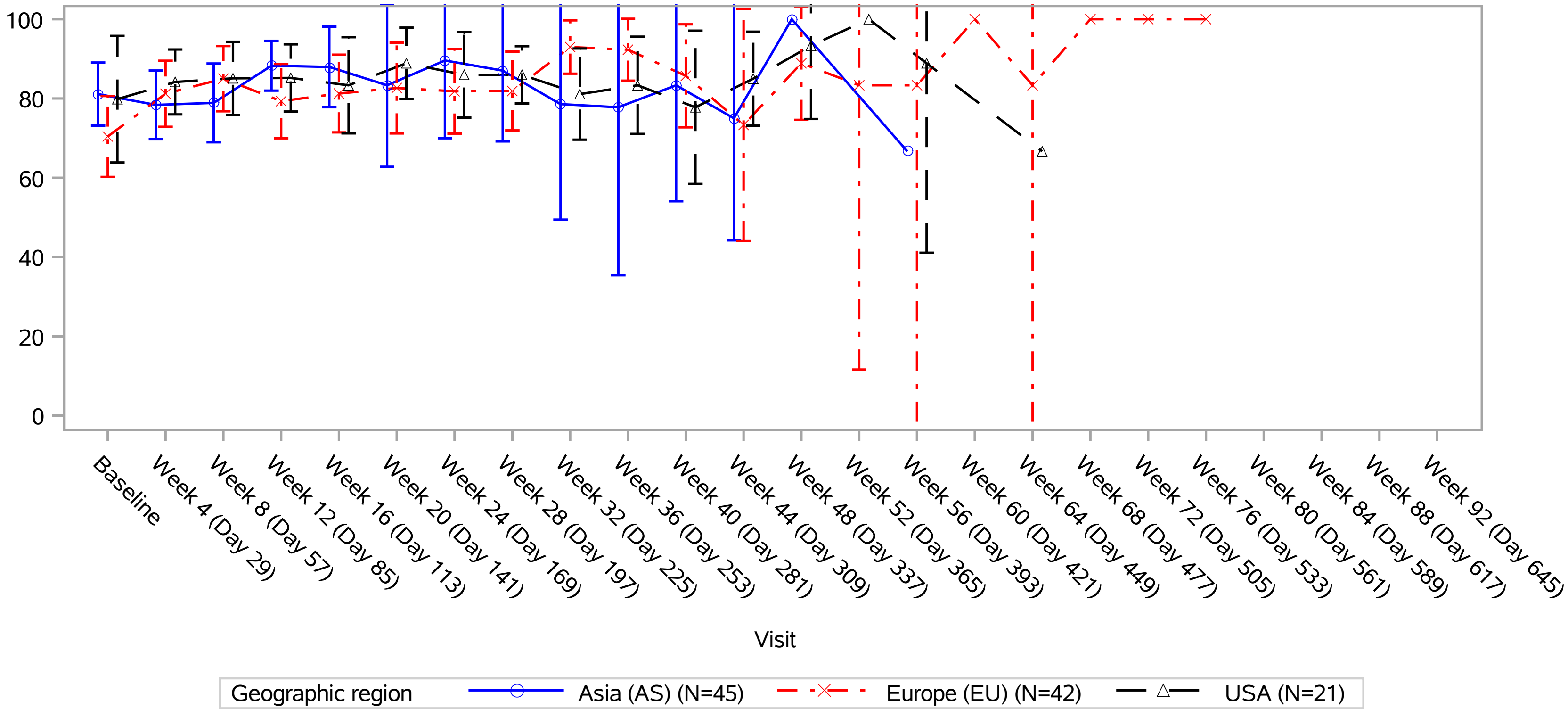
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Social functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30SF_SGECOG.pdf
15OCT2021 18:30

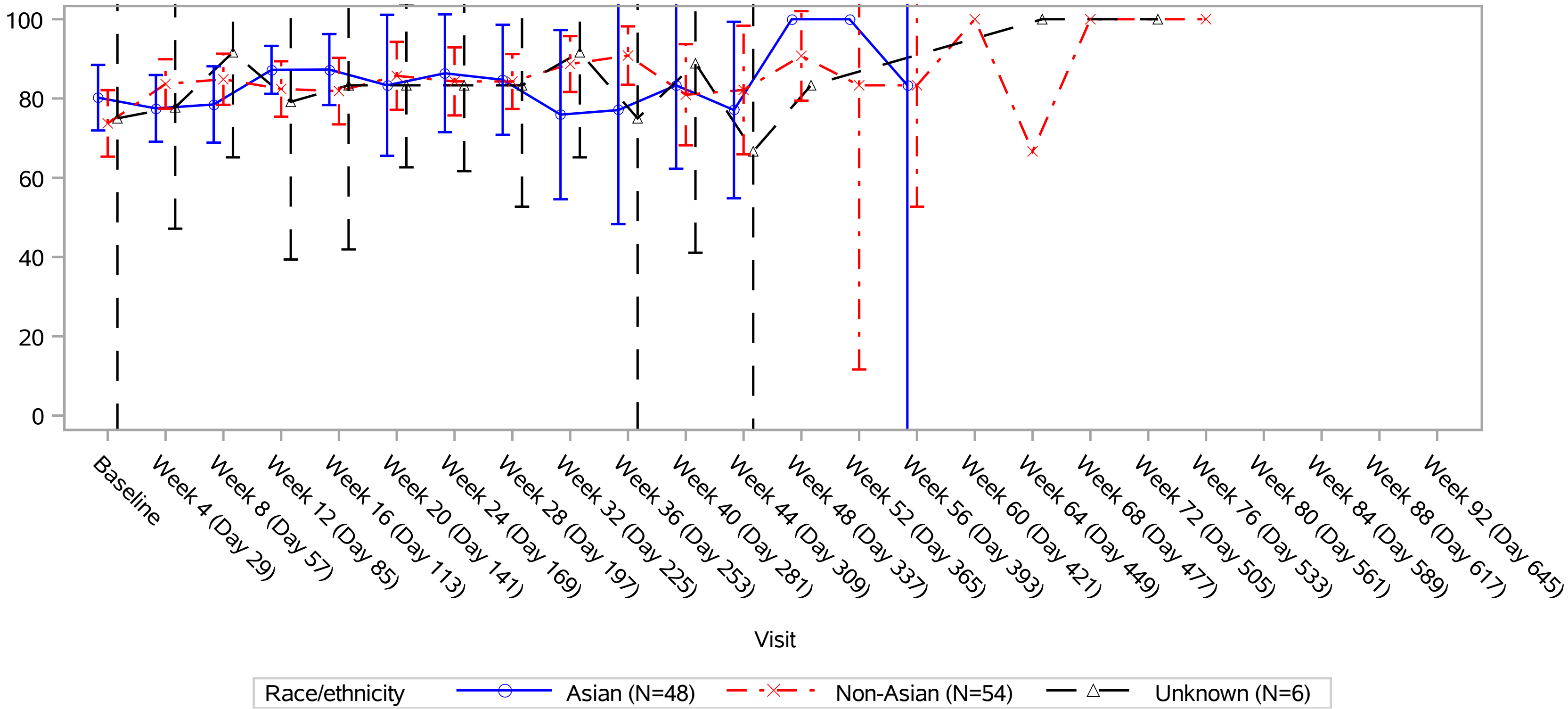
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Social functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30SF_SGGEO.pdf
15OCT2021 19:01

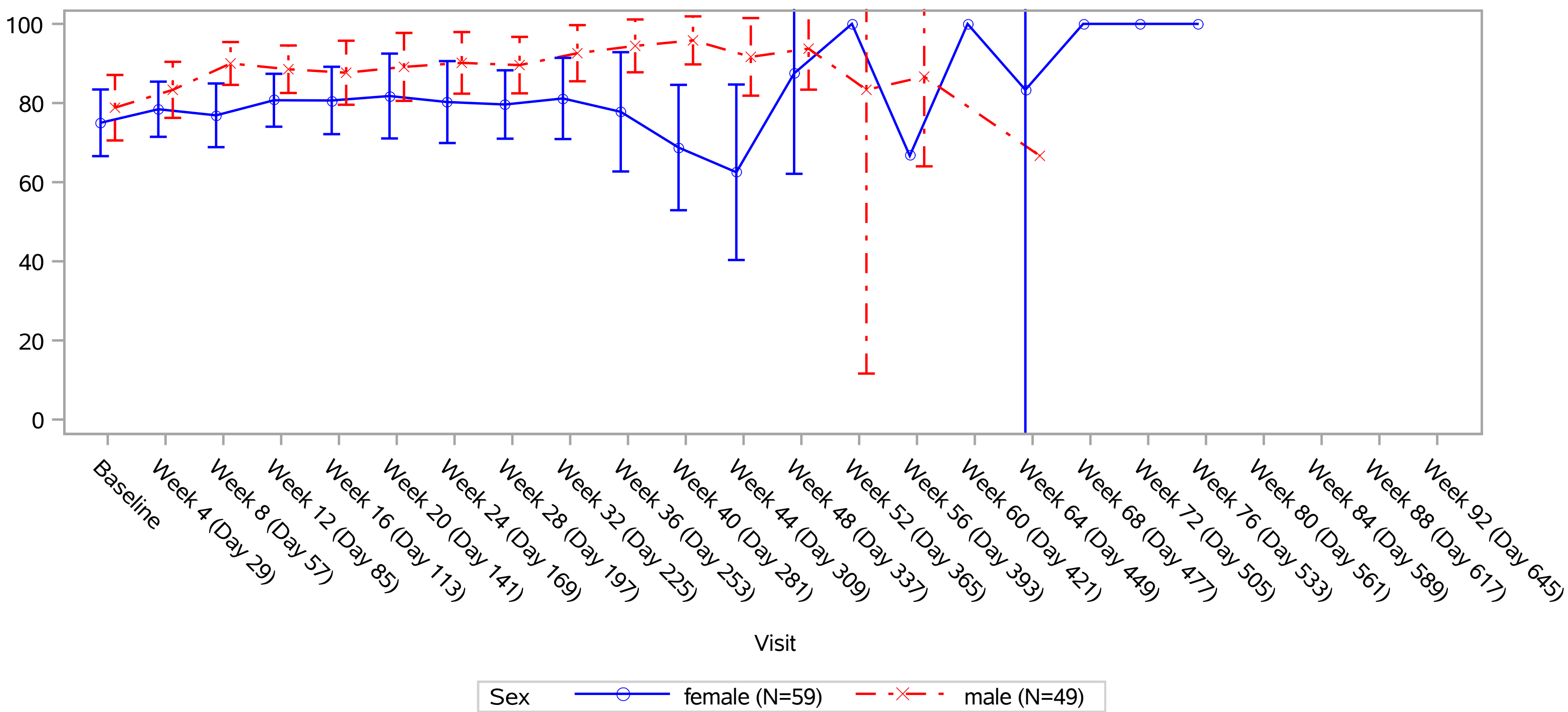
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Social functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30SF_SGRE.pdf
15OCT2021 19:31

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Social functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30SF_SGSEX.pdf
15OCT2021 20:02

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Insomnia
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=108)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	108	100.0	104	96.3	26.60	30.94	20.58	32.62
Week 4 (Day 29)	n/a	108	100.0	95	88.0	14.39	22.10	9.88	18.89
Week 8 (Day 57)	n/a	92	85.2	79	85.9	13.08	23.52	7.81	18.35
Week 12 (Day 85)	n/a	79	73.1	70	88.6	10.95	19.43	6.32	15.59
Week 16 (Day 113)	n/a	69	63.9	58	84.1	17.24	22.72	11.27	23.22
Week 20 (Day 141)	n/a	59	54.6	55	93.2	21.21	25.95	14.20	28.23
Week 24 (Day 169)	n/a	56	51.9	49	87.5	15.65	24.63	8.57	22.72
Week 28 (Day 197)	n/a	55	50.9	51	92.7	15.03	24.33	8.19	21.87
Week 32 (Day 225)	n/a	48	44.4	41	85.4	17.07	27.00	8.55	25.60
Week 36 (Day 253)	n/a	41	38.0	30	73.2	10.00	17.83	3.34	16.66
Week 40 (Day 281)	n/a	37	34.3	32	86.5	16.67	26.77	7.01	26.32
Week 44 (Day 309)	n/a	31	28.7	26	83.9	28.21	36.14	13.61	42.80
Week 48 (Day 337)	n/a	23	21.3	12	52.2	22.22	29.59	3.42	41.02
Week 52 (Day 365)	n/a	19	17.6	4	21.1	25.00	50.00	-54.56	104.56
Week 56 (Day 393)	n/a	17	15.7	6	35.3	16.67	18.26	-2.49	35.83
Week 60 (Day 421)	n/a	11	10.2	1	9.1	100.00	NE	NE	NE
Week 64 (Day 449)	n/a	10	9.3	3	30.0	22.22	19.25	-25.59	70.03
Week 68 (Day 477)	n/a	6	5.6	1	16.7	100.00	NE	NE	NE
Week 72 (Day 505)	n/a	6	5.6	1	16.7	66.67	NE	NE	NE
Week 76 (Day 533)	n/a	6	5.6	1	16.7	100.00	NE	NE	NE
Week 80 (Day 561)	n/a	5	4.6	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	n/a	1	0.9	0	0.0	NE	NE	NE	NE

Cycle 12 (LOCF)	n/a	108	100.0	108	100.0	16.98	26.38	11.94	22.01
End of Study (LOCF)	n/a	108	100.0	108	100.0	16.67	24.75	11.95	21.39
Sex									
Baseline	Female	59	100.0	56	94.9	33.33	35.39	23.86	42.81
Week 4 (Day 29)	Female	59	100.0	51	86.4	13.73	22.29	7.46	19.99
Week 8 (Day 57)	Female	49	83.1	44	89.8	14.39	27.28	6.10	22.69
Week 12 (Day 85)	Female	44	74.6	39	88.6	11.97	22.28	4.74	19.19
Week 16 (Day 113)	Female	38	64.4	31	81.6	21.51	26.59	11.75	31.26
Week 20 (Day 141)	Female	33	55.9	32	97.0	22.92	29.86	12.15	33.68
Week 24 (Day 169)	Female	31	52.5	27	87.1	18.52	28.24	7.35	29.69
Week 28 (Day 197)	Female	30	50.8	27	90.0	22.22	27.74	11.25	33.19
Week 32 (Day 225)	Female	27	45.8	23	85.2	23.19	32.47	9.15	37.23
Week 36 (Day 253)	Female	22	37.3	15	68.2	11.11	20.57	-0.28	22.50
Week 40 (Day 281)	Female	18	30.5	16	88.9	27.08	32.70	9.66	44.51
Week 44 (Day 309)	Female	15	25.4	12	80.0	44.44	43.42	16.86	72.03
Week 48 (Day 337)	Female	11	18.6	4	36.4	50.00	33.33	-3.04	103.04
Week 52 (Day 365)	Female	9	15.3	1	11.1	100.00	NE	NE	NE
Week 56 (Day 393)	Female	7	11.9	1	14.3	33.33	NE	NE	NE
Week 60 (Day 421)	Female	5	8.5	1	20.0	100.00	NE	NE	NE
Week 64 (Day 449)	Female	4	6.8	2	50.0	33.33	0.00	NE	NE
Week 68 (Day 477)	Female	3	5.1	1	33.3	100.00	NE	NE	NE
Week 72 (Day 505)	Female	3	5.1	1	33.3	66.67	NE	NE	NE
Week 76 (Day 533)	Female	3	5.1	1	33.3	100.00	NE	NE	NE
Week 80 (Day 561)	Female	2	3.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	59	100.0	59	100.0	22.60	31.22	14.46	30.74
End of Study (LOCF)	Female	59	100.0	59	100.0	22.03	29.43	14.36	29.70
Baseline	Male	49	100.0	48	98.0	18.75	22.71	12.16	25.34
Week 4 (Day 29)	Male	49	100.0	44	89.8	15.15	22.10	8.43	21.87
Week 8 (Day 57)	Male	43	87.8	35	81.4	11.43	17.97	5.25	17.60
Week 12 (Day 85)	Male	35	71.4	31	88.6	9.68	15.38	4.04	15.32
Week 16 (Day 113)	Male	31	63.3	27	87.1	12.35	16.40	5.86	18.83
Week 20 (Day 141)	Male	26	53.1	23	88.5	18.84	19.66	10.34	27.34
Week 24 (Day 169)	Male	25	51.0	22	88.0	12.12	19.37	3.53	20.71
Week 28 (Day 197)	Male	25	51.0	24	96.0	6.94	16.97	-0.22	14.11

Week 32 (Day 225)	Male	21	42.9	18	85.7	9.26	15.36	1.62	16.90
Week 36 (Day 253)	Male	19	38.8	15	78.9	8.89	15.26	0.44	17.34
Week 40 (Day 281)	Male	19	38.8	16	84.2	6.25	13.44	-0.91	13.41
Week 44 (Day 309)	Male	16	32.7	14	87.5	14.29	21.54	1.85	26.72
Week 48 (Day 337)	Male	12	24.5	8	66.7	8.33	15.43	-4.57	21.23
Week 52 (Day 365)	Male	10	20.4	3	30.0	0.00	0.00	NE	NE
Week 56 (Day 393)	Male	10	20.4	5	50.0	13.33	18.26	-9.34	36.00
Week 60 (Day 421)	Male	6	12.2	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Male	6	12.2	1	16.7	0.00	NE	NE	NE
Week 68 (Day 477)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	3	6.1	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Male	1	2.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	49	100.0	49	100.0	10.20	16.95	5.34	15.07
End of Study (LOCF)	Male	49	100.0	49	100.0	10.20	15.52	5.75	14.66
Age									
Baseline	< 65	63	100.0	60	95.2	33.89	32.76	25.43	42.35
Week 4 (Day 29)	< 65	63	100.0	55	87.3	15.76	23.00	9.54	21.98
Week 8 (Day 57)	< 65	54	85.7	47	87.0	14.18	23.82	7.19	21.18
Week 12 (Day 85)	< 65	47	74.6	42	89.4	11.90	21.87	5.09	18.72
Week 16 (Day 113)	< 65	39	61.9	34	87.2	21.57	24.46	13.04	30.10
Week 20 (Day 141)	< 65	35	55.6	35	100.0	24.76	29.53	14.62	34.91
Week 24 (Day 169)	< 65	34	54.0	31	91.2	20.43	28.12	10.11	30.75
Week 28 (Day 197)	< 65	33	52.4	32	97.0	19.79	26.59	10.21	29.38
Week 32 (Day 225)	< 65	30	47.6	25	83.3	21.33	27.01	10.18	32.48
Week 36 (Day 253)	< 65	25	39.7	20	80.0	13.33	19.94	4.00	22.67
Week 40 (Day 281)	< 65	23	36.5	21	91.3	23.81	30.08	10.12	37.50
Week 44 (Day 309)	< 65	19	30.2	17	89.5	35.29	39.91	14.77	55.82
Week 48 (Day 337)	< 65	14	22.2	7	50.0	33.33	33.33	2.51	64.16

Week 52 (Day 365)	< 65	12	19.0	2	16.7	50.00	70.71	-585.31	685.31
Week 56 (Day 393)	< 65	11	17.5	2	18.2	16.67	23.57	-195.10	228.44
Week 60 (Day 421)	< 65	8	12.7	1	12.5	100.00	NE	NE	NE
Week 64 (Day 449)	< 65	7	11.1	3	42.9	22.22	19.25	-25.59	70.03
Week 68 (Day 477)	< 65	4	6.3	1	25.0	100.00	NE	NE	NE
Week 72 (Day 505)	< 65	4	6.3	1	25.0	66.67	NE	NE	NE
Week 76 (Day 533)	< 65	4	6.3	1	25.0	100.00	NE	NE	NE
Week 80 (Day 561)	< 65	3	4.8	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	< 65	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	63	100.0	63	100.0	20.63	28.35	13.49	27.78
End of Study (LOCF)	< 65	63	100.0	63	100.0	20.11	26.46	13.44	26.77
Baseline	>= 65	45	100.0	44	97.8	16.67	25.42	8.94	24.39
Week 4 (Day 29)	>= 65	45	100.0	40	88.9	12.50	20.93	5.81	19.19
Week 8 (Day 57)	>= 65	38	84.4	32	84.2	11.46	23.36	3.04	19.88
Week 12 (Day 85)	>= 65	32	71.1	28	87.5	9.52	15.33	3.58	15.47
Week 16 (Day 113)	>= 65	30	66.7	24	80.0	11.11	18.82	3.16	19.06
Week 20 (Day 141)	>= 65	24	53.3	20	83.3	15.00	17.01	7.04	22.96
Week 24 (Day 169)	>= 65	22	48.9	18	81.8	7.41	14.26	0.32	14.50
Week 28 (Day 197)	>= 65	22	48.9	19	86.4	7.02	17.84	-1.58	15.62
Week 32 (Day 225)	>= 65	18	40.0	16	88.9	10.42	26.44	-3.67	24.51
Week 36 (Day 253)	>= 65	16	35.6	10	62.5	3.33	10.54	-4.21	10.87
Week 40 (Day 281)	>= 65	14	31.1	11	78.6	3.03	10.05	-3.72	9.78
Week 44 (Day 309)	>= 65	12	26.7	9	75.0	14.81	24.22	-3.80	33.43
Week 48 (Day 337)	>= 65	9	20.0	5	55.6	6.67	14.91	-11.84	25.18
Week 52 (Day 365)	>= 65	7	15.6	2	28.6	0.00	0.00	NE	NE
Week 56 (Day 393)	>= 65	6	13.3	4	66.7	16.67	19.25	-13.96	47.29
Week 60 (Day 421)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	3	6.7	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE

Week 76 (Day 533)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	2	4.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	45	100.0	45	100.0	11.85	22.65	5.05	18.66
End of Study (LOCF)	>= 65	45	100.0	45	100.0	11.85	21.50	5.39	18.31
ECOG performance status									
Baseline	0	30	100.0	29	96.7	31.03	32.04	18.85	43.22
Week 4 (Day 29)	0	30	100.0	29	96.7	17.24	21.12	9.21	25.28
Week 8 (Day 57)	0	28	93.3	25	89.3	18.67	21.69	9.71	27.62
Week 12 (Day 85)	0	26	86.7	23	88.5	14.49	16.90	7.19	21.80
Week 16 (Day 113)	0	26	86.7	21	80.8	15.87	17.06	8.11	23.64
Week 20 (Day 141)	0	26	86.7	24	92.3	23.61	25.02	13.05	34.18
Week 24 (Day 169)	0	25	83.3	23	92.0	15.94	24.35	5.41	26.47
Week 28 (Day 197)	0	25	83.3	23	92.0	8.70	18.03	0.90	16.49
Week 32 (Day 225)	0	20	66.7	16	80.0	16.67	21.08	5.43	27.90
Week 36 (Day 253)	0	18	60.0	11	61.1	12.12	22.47	-2.98	27.22
Week 40 (Day 281)	0	16	53.3	11	68.8	18.18	22.92	2.79	33.58
Week 44 (Day 309)	0	15	50.0	12	80.0	33.33	40.20	7.79	58.88
Week 48 (Day 337)	0	9	30.0	6	66.7	27.78	38.97	-13.12	68.67
Week 52 (Day 365)	0	9	30.0	3	33.3	33.33	57.74	-110.09	176.76
Week 56 (Day 393)	0	8	26.7	3	37.5	11.11	19.25	-36.70	58.92
Week 60 (Day 421)	0	5	16.7	1	20.0	100.00	NE	NE	NE
Week 64 (Day 449)	0	5	16.7	2	40.0	16.67	23.57	-195.10	228.44
Week 68 (Day 477)	0	3	10.0	1	33.3	100.00	NE	NE	NE
Week 72 (Day 505)	0	3	10.0	1	33.3	66.67	NE	NE	NE
Week 76 (Day 533)	0	3	10.0	1	33.3	100.00	NE	NE	NE
Week 80 (Day 561)	0	2	6.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	1	3.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	0	1	3.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	30	100.0	30	100.0	22.22	30.74	10.74	33.70
End of Study (LOCF)	0	30	100.0	30	100.0	22.22	28.14	11.71	32.73
Baseline	1	78	100.0	75	96.2	24.89	30.56	17.86	31.92
Week 4 (Day 29)	1	78	100.0	66	84.6	13.13	22.55	7.59	18.68

Week 8 (Day 57)	1	64	82.1	54	84.4	10.49	24.08	3.92	17.07
Week 12 (Day 85)	1	53	67.9	47	88.7	9.22	20.50	3.20	15.24
Week 16 (Day 113)	1	43	55.1	37	86.0	18.02	25.57	9.49	26.54
Week 20 (Day 141)	1	33	42.3	31	93.9	19.35	26.91	9.49	29.22
Week 24 (Day 169)	1	31	39.7	26	83.9	15.38	25.35	5.14	25.62
Week 28 (Day 197)	1	30	38.5	28	93.3	20.24	27.72	9.49	30.99
Week 32 (Day 225)	1	28	35.9	25	89.3	17.33	30.61	4.70	29.97
Week 36 (Day 253)	1	23	29.5	19	82.6	8.77	15.08	1.50	16.04
Week 40 (Day 281)	1	21	26.9	21	100.0	15.87	29.10	2.63	29.12
Week 44 (Day 309)	1	16	20.5	14	87.5	23.81	33.15	4.67	42.95
Week 48 (Day 337)	1	14	17.9	6	42.9	16.67	18.26	-2.49	35.83
Week 52 (Day 365)	1	10	12.8	1	10.0	0.00	NE	NE	NE
Week 56 (Day 393)	1	9	11.5	3	33.3	22.22	19.25	-25.59	70.03
Week 60 (Day 421)	1	6	7.7	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	5	6.4	1	20.0	33.33	NE	NE	NE
Week 68 (Day 477)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	3	3.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	78	100.0	78	100.0	14.96	24.41	9.45	20.46
End of Study (LOCF)	1	78	100.0	78	100.0	14.53	23.16	9.31	19.75
Geographic region									
Baseline	USA	21	100.0	19	90.5	26.32	26.24	13.67	38.97
Week 4 (Day 29)	USA	21	100.0	20	95.2	15.00	17.01	7.04	22.96
Week 8 (Day 57)	USA	21	100.0	19	90.5	10.53	19.41	1.17	19.88
Week 12 (Day 85)	USA	21	100.0	18	85.7	11.11	19.80	1.26	20.96
Week 16 (Day 113)	USA	21	100.0	16	76.2	20.83	20.64	9.84	31.83
Week 20 (Day 141)	USA	20	95.2	18	90.0	20.37	25.92	7.48	33.26
Week 24 (Day 169)	USA	20	95.2	19	95.0	12.28	16.52	4.32	20.24
Week 28 (Day 197)	USA	20	95.2	19	95.0	10.53	19.41	1.17	19.88
Week 32 (Day 225)	USA	17	81.0	15	88.2	15.56	21.33	3.74	27.37
Week 36 (Day 253)	USA	17	81.0	11	64.7	6.06	13.48	-3.00	15.12
Week 40 (Day 281)	USA	15	71.4	12	80.0	8.33	20.72	-4.83	21.50

Week 44 (Day 309)	USA	13	61.9	10	76.9	26.67	26.29	7.86	45.48
Week 48 (Day 337)	USA	8	38.1	5	62.5	26.67	14.91	8.16	45.18
Week 52 (Day 365)	USA	6	28.6	1	16.7	0.00	NE	NE	NE
Week 56 (Day 393)	USA	6	28.6	3	50.0	22.22	19.25	-25.59	70.03
Week 60 (Day 421)	USA	5	23.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	4	19.0	1	25.0	33.33	NE	NE	NE
Week 68 (Day 477)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	2	9.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	1	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	21	100.0	21	100.0	14.29	22.54	4.03	24.54
End of Study (LOCF)	USA	21	100.0	21	100.0	17.46	22.65	7.15	27.77
Baseline	Europe (EU)	42	100.0	40	95.2	31.67	32.86	21.16	42.18
Week 4 (Day 29)	Europe (EU)	42	100.0	38	90.5	13.16	22.65	5.71	20.60
Week 8 (Day 57)	Europe (EU)	36	85.7	30	83.3	14.44	22.63	5.99	22.89
Week 12 (Day 85)	Europe (EU)	31	73.8	25	80.6	13.33	16.67	6.45	20.21
Week 16 (Day 113)	Europe (EU)	30	71.4	24	80.0	19.44	21.80	10.24	28.65
Week 20 (Day 141)	Europe (EU)	26	61.9	24	92.3	25.00	24.57	14.62	35.38
Week 24 (Day 169)	Europe (EU)	26	61.9	22	84.6	16.67	24.67	5.73	27.60
Week 28 (Day 197)	Europe (EU)	25	59.5	23	92.0	15.94	22.18	6.35	25.53
Week 32 (Day 225)	Europe (EU)	21	50.0	19	90.5	12.28	19.91	2.68	21.88
Week 36 (Day 253)	Europe (EU)	16	38.1	13	81.3	12.82	21.68	-0.28	25.92
Week 40 (Day 281)	Europe (EU)	14	33.3	14	100.0	21.43	24.83	7.09	35.77
Week 44 (Day 309)	Europe (EU)	11	26.2	10	90.9	26.67	43.89	-4.73	58.06
Week 48 (Day 337)	Europe (EU)	8	19.0	6	75.0	22.22	40.37	-20.14	64.59
Week 52 (Day 365)	Europe (EU)	6	14.3	3	50.0	33.33	57.74	-110.09	176.76
Week 56 (Day 393)	Europe (EU)	6	14.3	2	33.3	0.00	0.00	NE	NE

Week 60 (Day 421)	Europe (EU)	4	9.5	1	25.0	100.00	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	4	9.5	2	50.0	16.67	23.57	-195.10	228.44
Week 68 (Day 477)	Europe (EU)	3	7.1	1	33.3	100.00	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	3	7.1	1	33.3	66.67	NE	NE	NE
Week 76 (Day 533)	Europe (EU)	3	7.1	1	33.3	100.00	NE	NE	NE
Week 80 (Day 561)	Europe (EU)	2	4.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Europe (EU)	42	100.0	42	100.0	22.22	28.19	13.44	31.01
End of Study (LOCF)	Europe (EU)	42	100.0	42	100.0	20.63	25.45	12.70	28.57
Baseline	Asia (AS)	45	100.0	45	100.0	22.22	30.98	12.92	31.53
Week 4 (Day 29)	Asia (AS)	45	100.0	37	82.2	15.32	24.34	7.20	23.43
Week 8 (Day 57)	Asia (AS)	35	77.8	30	85.7	13.33	27.12	3.21	23.46
Week 12 (Day 85)	Asia (AS)	27	60.0	27	100.0	8.64	21.86	-0.01	17.29
Week 16 (Day 113)	Asia (AS)	18	40.0	18	100.0	11.11	25.57	-1.60	23.82
Week 20 (Day 141)	Asia (AS)	13	28.9	13	100.0	15.38	29.24	-2.28	33.05
Week 24 (Day 169)	Asia (AS)	10	22.2	8	80.0	20.83	39.59	-12.27	53.93
Week 28 (Day 197)	Asia (AS)	10	22.2	9	90.0	22.22	37.27	-6.42	50.87
Week 32 (Day 225)	Asia (AS)	10	22.2	7	70.0	33.33	47.14	-10.26	76.93
Week 36 (Day 253)	Asia (AS)	8	17.8	6	75.0	11.11	17.21	-6.95	29.18
Week 40 (Day 281)	Asia (AS)	8	17.8	6	75.0	22.22	40.37	-20.14	64.59
Week 44 (Day 309)	Asia (AS)	7	15.6	6	85.7	33.33	42.16	-10.91	77.58
Week 48 (Day 337)	Asia (AS)	7	15.6	1	14.3	0.00	NE	NE	NE
Week 52 (Day 365)	Asia (AS)	7	15.6	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Asia (AS)	5	11.1	1	20.0	33.33	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	2	4.4	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	45	100.0	45	100.0	13.33	26.01	5.52	21.15
End of Study (LOCF)	Asia (AS)	45	100.0	45	100.0	12.59	24.91	5.11	20.08

Race/ethnicity									
Baseline	Asian	48	100.0	48	100.0	22.92	30.10	14.18	31.66
Week 4 (Day 29)	Asian	48	100.0	40	83.3	15.00	23.81	7.38	22.62
Week 8 (Day 57)	Asian	38	79.2	31	81.6	12.90	26.77	3.08	22.72
Week 12 (Day 85)	Asian	30	62.5	29	96.7	8.05	21.19	-0.01	16.10
Week 16 (Day 113)	Asian	21	43.8	21	100.0	11.11	24.34	0.03	22.19
Week 20 (Day 141)	Asian	16	33.3	15	93.8	15.56	27.79	0.16	30.95
Week 24 (Day 169)	Asian	13	27.1	11	84.6	18.18	34.52	-5.01	41.38
Week 28 (Day 197)	Asian	13	27.1	12	92.3	19.44	33.21	-1.65	40.54
Week 32 (Day 225)	Asian	12	25.0	9	75.0	25.93	43.39	-7.43	59.28
Week 36 (Day 253)	Asian	10	20.8	8	80.0	8.33	15.43	-4.57	21.23
Week 40 (Day 281)	Asian	10	20.8	8	80.0	16.67	35.63	-13.12	46.46
Week 44 (Day 309)	Asian	9	18.8	8	88.9	25.00	38.83	-7.46	57.46
Week 48 (Day 337)	Asian	9	18.8	2	22.2	0.00	0.00	NE	NE
Week 52 (Day 365)	Asian	9	18.8	1	11.1	0.00	NE	NE	NE
Week 56 (Day 393)	Asian	7	14.6	2	28.6	16.67	23.57	-195.10	228.44
Week 60 (Day 421)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	3	6.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	2	4.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	48	100.0	48	100.0	13.19	25.49	5.79	20.60
End of Study (LOCF)	Asian	48	100.0	48	100.0	12.50	24.43	5.41	19.59
Baseline	Non-Asian	54	100.0	52	96.3	30.13	31.84	21.27	38.99
Week 4 (Day 29)	Non-Asian	54	100.0	49	90.7	14.29	21.52	8.11	20.47
Week 8 (Day 57)	Non-Asian	49	90.7	44	89.8	12.12	20.45	5.90	18.34
Week 12 (Day 85)	Non-Asian	44	81.5	37	84.1	12.61	18.17	6.55	18.67
Week 16 (Day 113)	Non-Asian	43	79.6	34	79.1	20.59	21.73	13.00	28.17
Week 20 (Day 141)	Non-Asian	38	70.4	35	92.1	22.86	26.53	13.74	31.97
Week 24 (Day 169)	Non-Asian	38	70.4	34	89.5	13.73	21.89	6.09	21.36
Week 28 (Day 197)	Non-Asian	37	68.5	35	94.6	12.38	19.94	5.53	19.23
Week 32 (Day 225)	Non-Asian	32	59.3	28	87.5	14.29	21.14	6.09	22.48
Week 36 (Day 253)	Non-Asian	27	50.0	20	74.1	11.67	19.57	2.51	20.83

Week 40 (Day 281)	Non-Asian	23	42.6	21	91.3	15.87	24.99	4.50	27.25
Week 44 (Day 309)	Non-Asian	18	33.3	14	77.8	28.57	34.24	8.80	48.34
Week 48 (Day 337)	Non-Asian	12	22.2	9	75.0	29.63	30.93	5.85	53.41
Week 52 (Day 365)	Non-Asian	8	14.8	3	37.5	33.33	57.74	-110.09	176.76
Week 56 (Day 393)	Non-Asian	8	14.8	4	50.0	16.67	19.25	-13.96	47.29
Week 60 (Day 421)	Non-Asian	7	13.0	1	14.3	100.00	NE	NE	NE
Week 64 (Day 449)	Non-Asian	6	11.1	2	33.3	16.67	23.57	-195.10	228.44
Week 68 (Day 477)	Non-Asian	3	5.6	1	33.3	100.00	NE	NE	NE
Week 72 (Day 505)	Non-Asian	3	5.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Non-Asian	3	5.6	1	33.3	100.00	NE	NE	NE
Week 80 (Day 561)	Non-Asian	2	3.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Non-Asian	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	54	100.0	54	100.0	19.14	25.58	12.15	26.12
End of Study (LOCF)	Non-Asian	54	100.0	54	100.0	19.75	24.67	13.02	26.49
Baseline	Unknown	6	100.0	4	66.7	25.00	31.91	-25.78	75.78
Week 4 (Day 29)	Unknown	6	100.0	6	100.0	11.11	17.21	-6.95	29.18
Week 8 (Day 57)	Unknown	5	83.3	4	80.0	25.00	31.91	-25.78	75.78
Week 12 (Day 85)	Unknown	5	83.3	4	80.0	16.67	19.25	-13.96	47.29
Week 16 (Day 113)	Unknown	5	83.3	3	60.0	22.22	19.25	-25.59	70.03
Week 20 (Day 141)	Unknown	5	83.3	5	100.0	26.67	14.91	8.16	45.18
Week 24 (Day 169)	Unknown	5	83.3	4	80.0	25.00	16.67	-1.52	51.52
Week 28 (Day 197)	Unknown	5	83.3	4	80.0	25.00	31.91	-25.78	75.78
Week 32 (Day 225)	Unknown	4	66.7	4	100.0	16.67	19.25	-13.96	47.29
Week 36 (Day 253)	Unknown	4	66.7	2	50.0	0.00	0.00	NE	NE
Week 40 (Day 281)	Unknown	4	66.7	3	75.0	22.22	19.25	-25.59	70.03
Week 44 (Day 309)	Unknown	4	66.7	4	100.0	33.33	47.14	-41.68	108.34
Week 48 (Day 337)	Unknown	2	33.3	1	50.0	0.00	NE	NE	NE
Week 52 (Day 365)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	2	33.3	0	0.0	NE	NE	NE	NE
Week 60 (Day 421)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE

Week 64 (Day 449)	Unknown	1	16.7	1	100.0	33.33	NE	NE	NE
Week 68 (Day 477)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	1	16.7	1	100.0	66.67	NE	NE	NE
Week 76 (Day 533)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	1	16.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	6	100.0	6	100.0	27.78	38.97	-13.12	68.67
End of Study (LOCF)	Unknown	6	100.0	6	100.0	22.22	27.22	-6.34	50.78

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TN_QSC30SL_SG.xls
27OCT2021 7:41

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Insomnia
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	29	27.9	20.2	37.2
	Cycle 12 (LOCF)	n/a	104	96.3	12	11.5	6.7	19.1
	End of Study (LOCF)	n/a	104	96.3	11	10.6	6.0	18.0
Sex	All visits	Female	56	51.9	14	25.0	15.5	37.7
		Male	48	44.4	15	31.3	19.9	45.3
	Cycle 12 (LOCF)	Female	56	51.9	7	12.5	6.2	23.6
		Male	48	44.4	5	10.4	4.5	22.2
	End of Study (LOCF)	Female	56	51.9	6	10.7	5.0	21.5
		Male	48	44.4	5	10.4	4.5	22.2
Age	All visits	< 65	60	55.6	13	21.7	13.1	33.6
		>= 65	44	40.7	16	36.4	23.8	51.1
	Cycle 12 (LOCF)	< 65	60	55.6	7	11.7	5.8	22.2
		>= 65	44	40.7	5	11.4	5.0	24.0
	End of Study (LOCF)	< 65	60	55.6	6	10.0	4.7	20.1
		>= 65	44	40.7	5	11.4	5.0	24.0
ECOG performance status	All visits	0	29	26.9	10	34.5	19.9	52.7
		1	75	69.4	19	25.3	16.9	36.2
	Cycle 12 (LOCF)	0	29	26.9	5	17.2	7.6	34.5
		1	75	69.4	7	9.3	4.6	18.0
	End of Study (LOCF)	0	29	26.9	6	20.7	9.8	38.4
		1	75	69.4	5	6.7	2.9	14.7
Geographic region	All visits	USA	19	17.6	6	31.6	15.4	54.0
		Europe (EU)	40	37.0	13	32.5	20.1	48.0
		Asia (AS)	45	41.7	10	22.2	12.5	36.3
	Cycle 12 (LOCF)	USA	19	17.6	2	10.5	2.9	31.4
		Europe (EU)	40	37.0	4	10.0	4.0	23.1
		Asia (AS)	45	41.7	6	13.3	6.3	26.2
	End of Study (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	3	7.5	2.6	19.9
		Asia (AS)	45	41.7	5	11.1	4.8	23.5
Race/ethnicity	All visits	Asian	48	44.4	10	20.8	11.7	34.3
		Non-Asian	52	48.1	18	34.6	23.2	48.2
		Unknown	4	3.7	1	25.0	4.6	69.9
	Cycle 12 (LOCF)	Asian	48	44.4	6	12.5	5.9	24.7
		Non-Asian	52	48.1	6	11.5	5.4	23.0
		Unknown	4	3.7	0	0.0	0.0	49.0
	End of Study (LOCF)	Asian	48	44.4	5	10.4	4.5	22.2

		Non-Asian	52	48.1	6	11.5	5.4	23.0
		Unknown	4	3.7	0	0.0	0.0	49.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30SL_W10_SG.xls
15OCT2021 13:19

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Insomnia
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

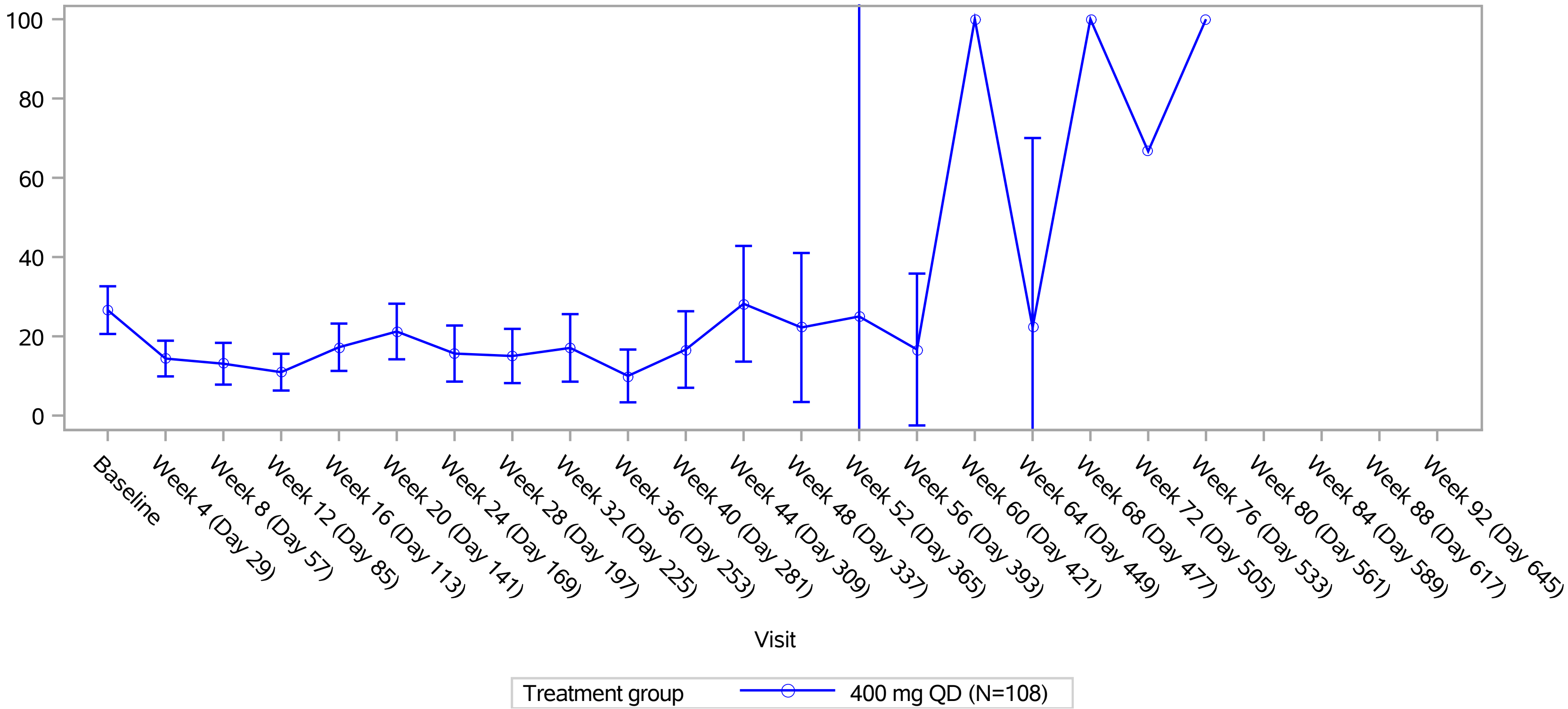
			400 mg QD (N=108)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	104	96.3	29	27.9	20.2	37.2
	Cycle 12 (LOCF)	n/a	104	96.3	12	11.5	6.7	19.1
	End of Study (LOCF)	n/a	104	96.3	11	10.6	6.0	18.0
Sex	All visits	Female	56	51.9	14	25.0	15.5	37.7
		Male	48	44.4	15	31.3	19.9	45.3
	Cycle 12 (LOCF)	Female	56	51.9	7	12.5	6.2	23.6
		Male	48	44.4	5	10.4	4.5	22.2
	End of Study (LOCF)	Female	56	51.9	6	10.7	5.0	21.5
		Male	48	44.4	5	10.4	4.5	22.2
Age	All visits	< 65	60	55.6	13	21.7	13.1	33.6
		>= 65	44	40.7	16	36.4	23.8	51.1
	Cycle 12 (LOCF)	< 65	60	55.6	7	11.7	5.8	22.2
		>= 65	44	40.7	5	11.4	5.0	24.0
	End of Study (LOCF)	< 65	60	55.6	6	10.0	4.7	20.1
		>= 65	44	40.7	5	11.4	5.0	24.0
ECOG performance status	All visits	0	29	26.9	10	34.5	19.9	52.7
		1	75	69.4	19	25.3	16.9	36.2
	Cycle 12 (LOCF)	0	29	26.9	5	17.2	7.6	34.5
		1	75	69.4	7	9.3	4.6	18.0
	End of Study (LOCF)	0	29	26.9	6	20.7	9.8	38.4
		1	75	69.4	5	6.7	2.9	14.7
Geographic region	All visits	USA	19	17.6	6	31.6	15.4	54.0
		Europe (EU)	40	37.0	13	32.5	20.1	48.0
		Asia (AS)	45	41.7	10	22.2	12.5	36.3
	Cycle 12 (LOCF)	USA	19	17.6	2	10.5	2.9	31.4
		Europe (EU)	40	37.0	4	10.0	4.0	23.1
		Asia (AS)	45	41.7	6	13.3	6.3	26.2
	End of Study (LOCF)	USA	19	17.6	3	15.8	5.5	37.6
		Europe (EU)	40	37.0	3	7.5	2.6	19.9
		Asia (AS)	45	41.7	5	11.1	4.8	23.5
Race/ethnicity	All visits	Asian	48	44.4	10	20.8	11.7	34.3
		Non-Asian	52	48.1	18	34.6	23.2	48.2
		Unknown	4	3.7	1	25.0	4.6	69.9
	Cycle 12 (LOCF)	Asian	48	44.4	6	12.5	5.9	24.7
		Non-Asian	52	48.1	6	11.5	5.4	23.0
		Unknown	4	3.7	0	0.0	0.0	49.0
	End of Study (LOCF)	Asian	48	44.4	5	10.4	4.5	22.2

		Non-Asian	52	48.1	6	11.5	5.4	23.0
		Unknown	4	3.7	0	0.0	0.0	49.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TN_QSC30SL_W15_SG.xls
15OCT2021 13:09

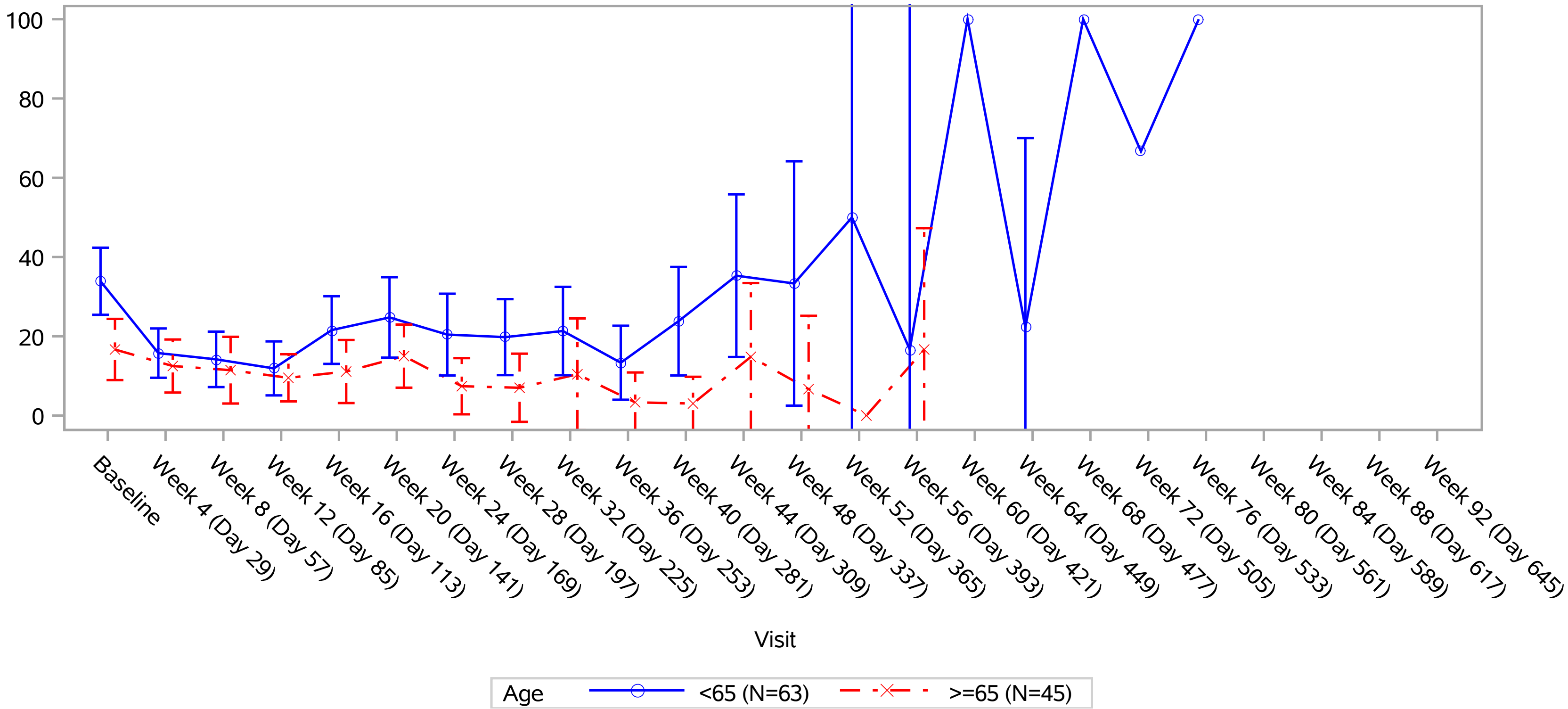
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Insomnia
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30SL.pdf
15OCT2021 17:31

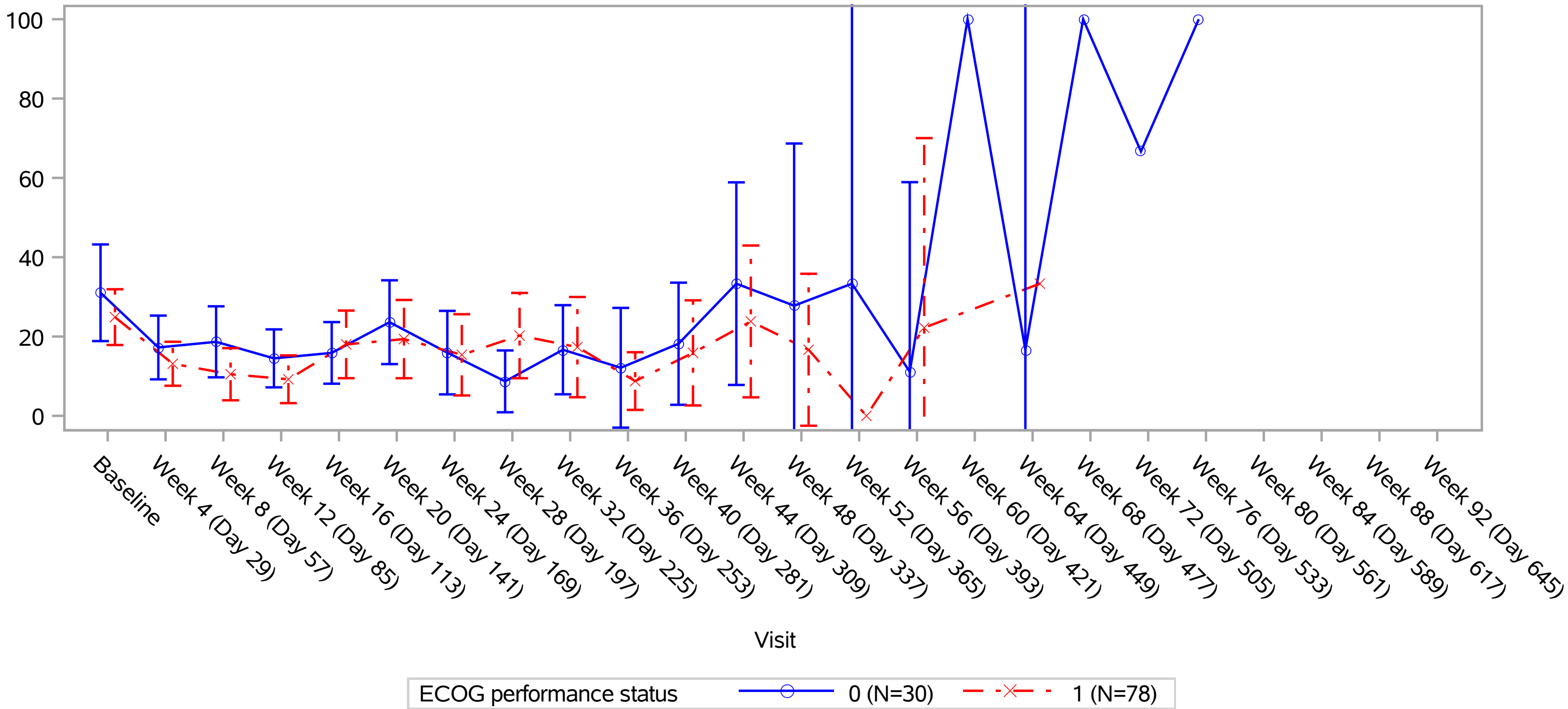
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Insomnia
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30SL_SGAGE65.pdf
15OCT2021 18:00

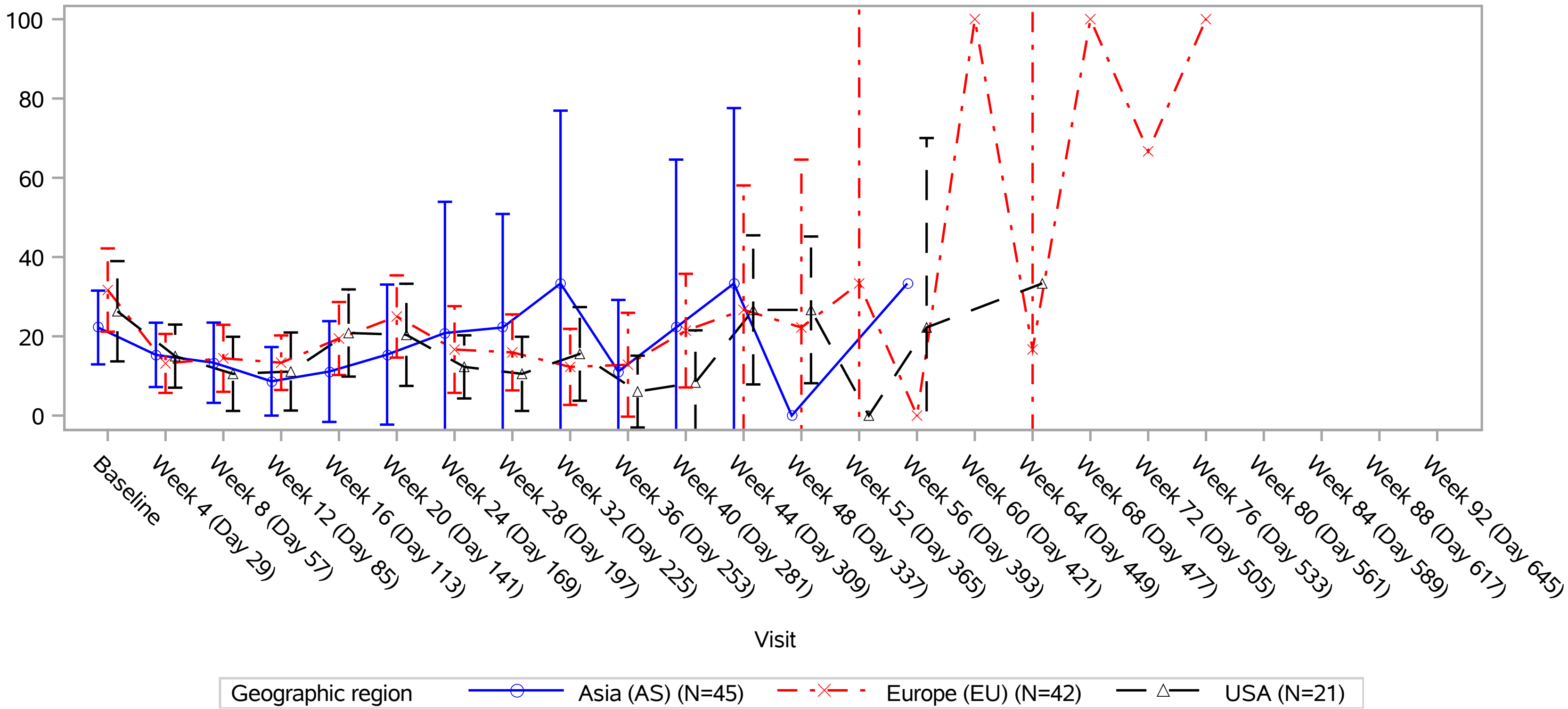
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Insomnia
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30SL_SGECOG.pdf
15OCT2021 18:31

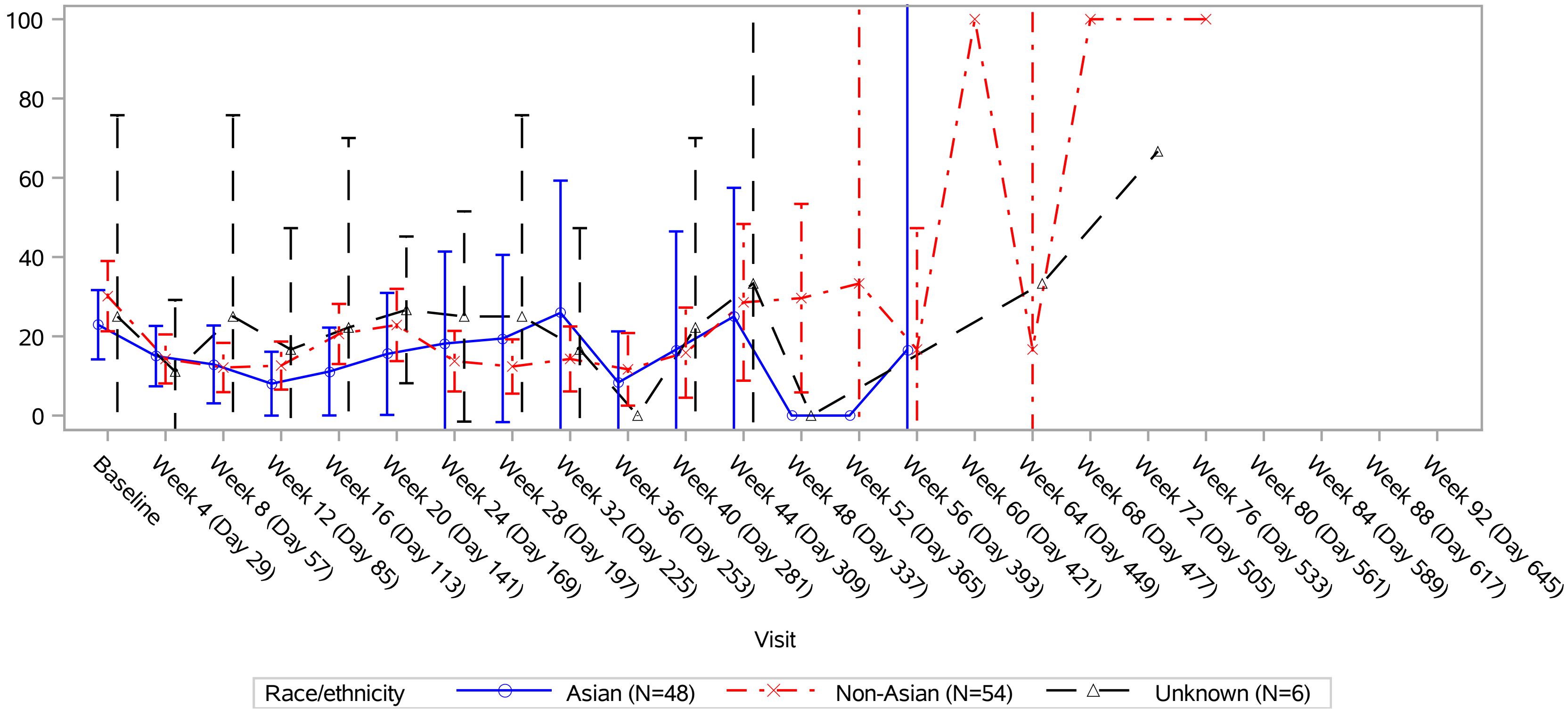
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Insomnia
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30SL_SGGEO.pdf
15OCT2021 19:02

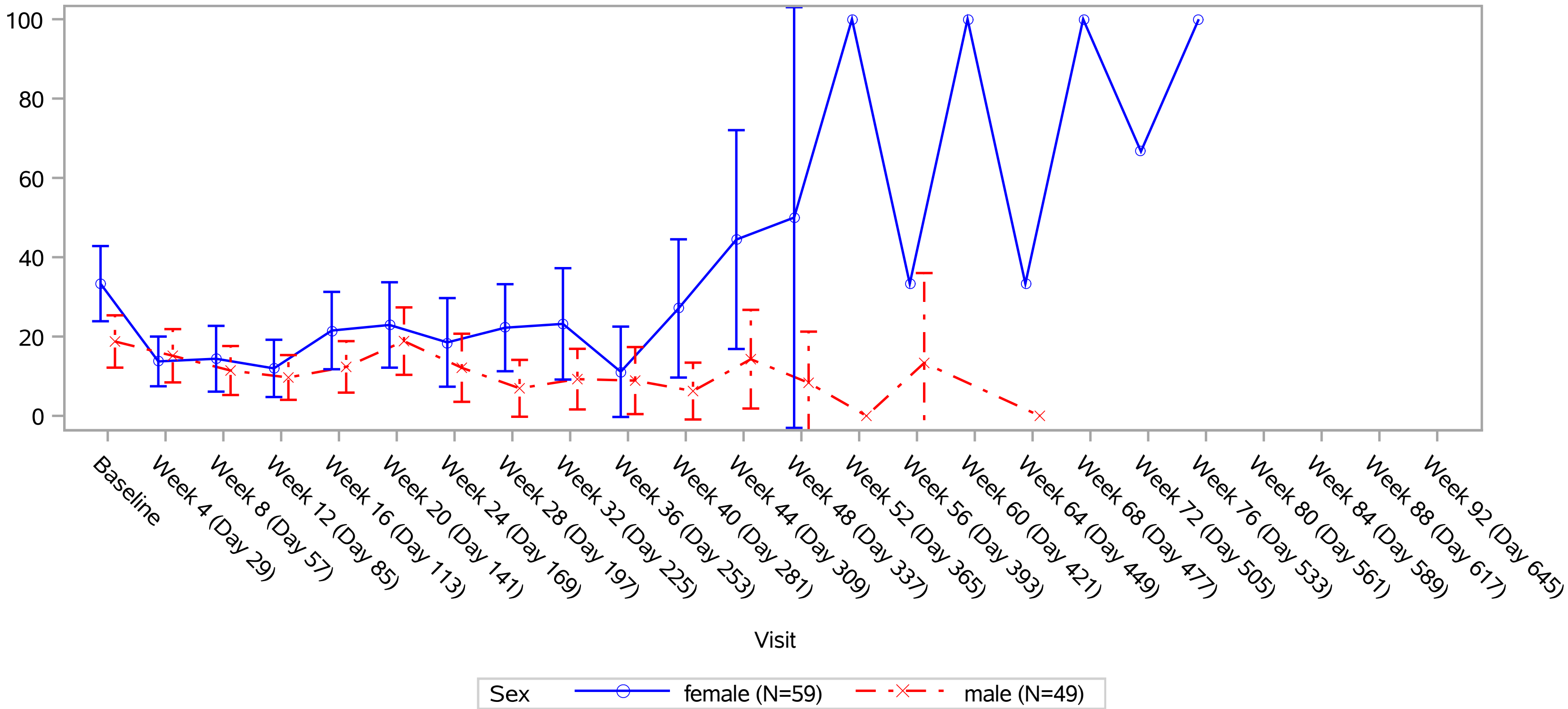
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Insomnia
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30SL_SGRE.pdf
15OCT2021 19:32

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Treatment-Naive Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Insomnia
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TN_QSC30SL_SGSEX.pdf
15OCT2021 20:03

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Appetite Loss
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=113)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	113	100.0	108	95.6	21.91	29.94	16.20	27.62
Week 4 (Day 29)	n/a	113	100.0	94	83.2	12.06	21.78	7.60	16.52
Week 8 (Day 57)	n/a	101	89.4	92	91.1	9.78	21.28	5.38	14.19
Week 12 (Day 85)	n/a	97	85.8	90	92.8	6.67	15.16	3.49	9.84
Week 16 (Day 113)	n/a	95	84.1	85	89.5	9.80	16.92	6.15	13.45
Week 20 (Day 141)	n/a	89	78.8	83	93.3	9.24	21.03	4.65	13.83
Week 24 (Day 169)	n/a	81	71.7	73	90.1	7.76	18.02	3.56	11.97
Week 28 (Day 197)	n/a	74	65.5	69	93.2	6.76	17.69	2.51	11.01
Week 32 (Day 225)	n/a	71	62.8	63	88.7	7.41	19.35	2.53	12.28
Week 36 (Day 253)	n/a	71	62.8	65	91.5	8.72	17.95	4.27	13.17
Week 40 (Day 281)	n/a	67	59.3	59	88.1	7.91	17.87	3.25	12.57
Week 44 (Day 309)	n/a	64	56.6	58	90.6	8.05	19.05	3.04	13.06
Week 48 (Day 337)	n/a	58	51.3	33	56.9	5.05	14.72	-0.17	10.27
Week 52 (Day 365)	n/a	45	39.8	7	15.6	4.76	12.60	-6.89	16.41
Week 56 (Day 393)	n/a	37	32.7	12	32.4	2.78	9.62	-3.34	8.89
Week 60 (Day 421)	n/a	32	28.3	1	3.1	0.00	NE	NE	NE
Week 64 (Day 449)	n/a	31	27.4	9	29.0	0.00	0.00	NE	NE
Week 68 (Day 477)	n/a	28	24.8	1	3.6	0.00	NE	NE	NE
Week 72 (Day 505)	n/a	28	24.8	4	14.3	0.00	0.00	NE	NE
Week 76 (Day 533)	n/a	25	22.1	2	8.0	0.00	0.00	NE	NE
Week 80 (Day 561)	n/a	25	22.1	6	24.0	16.67	40.82	-26.18	59.51
Week 84 (Day 589)	n/a	18	15.9	1	5.6	0.00	NE	NE	NE
Week 88 (Day 617)	n/a	14	12.4	2	14.3	0.00	0.00	NE	NE
Week 92 (Day 645)	n/a	7	6.2	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	5.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	2.7	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	113	100.0	111	98.2	14.71	26.09	9.81	19.62
End of Study (LOCF)	n/a	113	100.0	111	98.2	14.11	26.03	9.22	19.01
Sex									
Baseline	Female	69	100.0	67	97.1	22.89	31.36	15.24	30.53
Week 4 (Day 29)	Female	69	100.0	54	78.3	13.58	21.98	7.58	19.58
Week 8 (Day 57)	Female	63	91.3	54	85.7	14.20	25.58	7.22	21.18
Week 12 (Day 85)	Female	60	87.0	56	93.3	8.33	17.12	3.75	12.92
Week 16 (Day 113)	Female	58	84.1	50	86.2	12.67	17.68	7.64	17.69
Week 20 (Day 141)	Female	53	76.8	48	90.6	11.11	24.15	4.10	18.12
Week 24 (Day 169)	Female	47	68.1	40	85.1	10.00	21.62	3.09	16.91
Week 28 (Day 197)	Female	42	60.9	38	90.5	8.77	21.48	1.71	15.83
Week 32 (Day 225)	Female	42	60.9	35	83.3	9.52	22.25	1.88	17.17
Week 36 (Day 253)	Female	42	60.9	37	88.1	8.11	19.88	1.48	14.74
Week 40 (Day 281)	Female	41	59.4	37	90.2	7.21	17.80	1.27	13.14
Week 44 (Day 309)	Female	41	59.4	35	85.4	9.52	20.72	2.40	16.64
Week 48 (Day 337)	Female	37	53.6	22	59.5	4.55	15.59	-2.36	11.46
Week 52 (Day 365)	Female	29	42.0	5	17.2	6.67	14.91	-11.84	25.18
Week 56 (Day 393)	Female	24	34.8	8	33.3	4.17	11.79	-5.69	14.02
Week 60 (Day 421)	Female	22	31.9	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Female	22	31.9	6	27.3	0.00	0.00	NE	NE
Week 68 (Day 477)	Female	20	29.0	1	5.0	0.00	NE	NE	NE
Week 72 (Day 505)	Female	20	29.0	2	10.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Female	18	26.1	2	11.1	0.00	0.00	NE	NE
Week 80 (Day 561)	Female	18	26.1	5	27.8	20.00	44.72	-35.53	75.53
Week 84 (Day 589)	Female	12	17.4	1	8.3	0.00	NE	NE	NE
Week 88 (Day 617)	Female	9	13.0	1	11.1	0.00	NE	NE	NE
Week 92 (Day 645)	Female	6	8.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	7.2	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	2.9	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	1.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	69	100.0	68	98.6	17.16	28.50	10.26	24.06
End of Study (LOCF)	Female	69	100.0	68	98.6	16.67	29.08	9.63	23.71
Baseline	Male	44	100.0	41	93.2	20.33	27.77	11.56	29.09
Week 4 (Day 29)	Male	44	100.0	40	90.9	10.00	21.62	3.09	16.91
Week 8 (Day 57)	Male	38	86.4	38	100.0	3.51	10.37	0.10	6.92
Week 12 (Day 85)	Male	37	84.1	34	91.9	3.92	10.90	0.12	7.73
Week 16 (Day 113)	Male	37	84.1	35	94.6	5.71	15.09	0.53	10.90
Week 20 (Day 141)	Male	36	81.8	35	97.2	6.67	15.76	1.25	12.08
Week 24 (Day 169)	Male	34	77.3	33	97.1	5.05	12.14	0.75	9.35
Week 28 (Day 197)	Male	32	72.7	31	96.9	4.30	11.36	0.13	8.47
Week 32 (Day 225)	Male	29	65.9	28	96.6	4.76	14.95	-1.03	10.56
Week 36 (Day 253)	Male	29	65.9	28	96.6	9.52	15.33	3.58	15.47
Week 40 (Day 281)	Male	26	59.1	22	84.6	9.09	18.35	0.96	17.23
Week 44 (Day 309)	Male	23	52.3	23	100.0	5.80	16.37	-1.28	12.87
Week 48 (Day 337)	Male	21	47.7	11	52.4	6.06	13.48	-3.00	15.12
Week 52 (Day 365)	Male	16	36.4	2	12.5	0.00	0.00	NE	NE
Week 56 (Day 393)	Male	13	29.5	4	30.8	0.00	0.00	NE	NE
Week 60 (Day 421)	Male	10	22.7	1	10.0	0.00	NE	NE	NE
Week 64 (Day 449)	Male	9	20.5	3	33.3	0.00	0.00	NE	NE
Week 68 (Day 477)	Male	8	18.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	8	18.2	2	25.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Male	7	15.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	7	15.9	1	14.3	0.00	NE	NE	NE
Week 84 (Day 589)	Male	6	13.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	5	11.4	1	20.0	0.00	NE	NE	NE
Week 92 (Day 645)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	44	100.0	43	97.7	10.85	21.48	4.24	17.46
End of Study (LOCF)	Male	44	100.0	43	97.7	10.08	19.97	3.93	16.22
Age									

Baseline	< 65	78	100.0	73	93.6	21.00	30.18	13.96	28.05
Week 4 (Day 29)	< 65	78	100.0	68	87.2	10.78	20.31	5.87	15.70
Week 8 (Day 57)	< 65	73	93.6	66	90.4	7.58	18.30	3.08	12.07
Week 12 (Day 85)	< 65	71	91.0	64	90.1	4.69	11.68	1.77	7.60
Week 16 (Day 113)	< 65	69	88.5	59	85.5	8.47	14.64	4.66	12.29
Week 20 (Day 141)	< 65	65	83.3	62	95.4	8.60	20.85	3.31	13.90
Week 24 (Day 169)	< 65	59	75.6	55	93.2	7.27	18.91	2.16	12.39
Week 28 (Day 197)	< 65	55	70.5	51	92.7	5.88	17.26	1.03	10.74
Week 32 (Day 225)	< 65	53	67.9	48	90.6	4.86	15.36	0.40	9.32
Week 36 (Day 253)	< 65	53	67.9	50	94.3	5.33	14.06	1.34	9.33
Week 40 (Day 281)	< 65	52	66.7	48	92.3	4.86	13.73	0.87	8.85
Week 44 (Day 309)	< 65	52	66.7	48	92.3	6.94	16.78	2.07	11.82
Week 48 (Day 337)	< 65	47	60.3	26	55.3	3.85	10.86	-0.54	8.23
Week 52 (Day 365)	< 65	36	46.2	4	11.1	0.00	0.00	NE	NE
Week 56 (Day 393)	< 65	30	38.5	9	30.0	3.70	11.11	-4.84	12.24
Week 60 (Day 421)	< 65	25	32.1	1	4.0	0.00	NE	NE	NE
Week 64 (Day 449)	< 65	24	30.8	7	29.2	0.00	0.00	NE	NE
Week 68 (Day 477)	< 65	22	28.2	1	4.5	0.00	NE	NE	NE
Week 72 (Day 505)	< 65	22	28.2	4	18.2	0.00	0.00	NE	NE
Week 76 (Day 533)	< 65	21	26.9	2	9.5	0.00	0.00	NE	NE
Week 80 (Day 561)	< 65	21	26.9	5	23.8	20.00	44.72	-35.53	75.53
Week 84 (Day 589)	< 65	15	19.2	1	6.7	0.00	NE	NE	NE
Week 88 (Day 617)	< 65	12	15.4	2	16.7	0.00	0.00	NE	NE
Week 92 (Day 645)	< 65	6	7.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	6.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	78	100.0	76	97.4	14.47	26.85	8.34	20.61
End of Study (LOCF)	< 65	78	100.0	76	97.4	14.04	27.36	7.78	20.29
Baseline	>= 65	35	100.0	35	100.0	23.81	29.78	13.58	34.04
Week 4 (Day 29)	>= 65	35	100.0	26	74.3	15.38	25.35	5.14	25.62
Week 8 (Day 57)	>= 65	28	80.0	26	92.9	15.38	27.05	4.46	26.31
Week 12 (Day 85)	>= 65	26	74.3	26	100.0	11.54	20.96	3.07	20.00

Week 16 (Day 113)	>= 65	26	74.3	26	100.0	12.82	21.24	4.24	21.40
Week 20 (Day 141)	>= 65	24	68.6	21	87.5	11.11	21.94	1.12	21.10
Week 24 (Day 169)	>= 65	22	62.9	18	81.8	9.26	15.36	1.62	16.90
Week 28 (Day 197)	>= 65	19	54.3	18	94.7	9.26	19.15	-0.26	18.78
Week 32 (Day 225)	>= 65	18	51.4	15	83.3	15.56	27.79	0.16	30.95
Week 36 (Day 253)	>= 65	18	51.4	15	83.3	20.00	24.56	6.40	33.60
Week 40 (Day 281)	>= 65	15	42.9	11	73.3	21.21	26.97	3.09	39.33
Week 44 (Day 309)	>= 65	12	34.3	10	83.3	13.33	28.11	-6.77	33.44
Week 48 (Day 337)	>= 65	11	31.4	7	63.6	9.52	25.20	-13.78	32.83
Week 52 (Day 365)	>= 65	9	25.7	3	33.3	11.11	19.25	-36.70	58.92
Week 56 (Day 393)	>= 65	7	20.0	3	42.9	0.00	0.00	NE	NE
Week 60 (Day 421)	>= 65	7	20.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	7	20.0	2	28.6	0.00	0.00	NE	NE
Week 68 (Day 477)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	4	11.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	4	11.4	1	25.0	0.00	NE	NE	NE
Week 84 (Day 589)	>= 65	3	8.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	5.7	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	35	100.0	35	100.0	15.24	24.71	6.75	23.73
End of Study (LOCF)	>= 65	35	100.0	35	100.0	14.29	23.27	6.29	22.28
ECOG performance status									
Baseline	0	33	100.0	31	93.9	22.58	35.89	9.42	35.74
Week 4 (Day 29)	0	33	100.0	27	81.8	19.75	32.37	6.95	32.56
Week 8 (Day 57)	0	30	90.9	27	90.0	13.58	31.02	1.31	25.85
Week 12 (Day 85)	0	29	87.9	26	89.7	10.26	20.59	1.94	18.57
Week 16 (Day 113)	0	28	84.8	24	85.7	11.11	16.05	4.33	17.89
Week 20 (Day 141)	0	26	78.8	24	92.3	13.89	25.85	2.97	24.80
Week 24 (Day 169)	0	24	72.7	20	83.3	5.00	16.31	-2.63	12.63
Week 28 (Day 197)	0	21	63.6	19	90.5	10.53	27.34	-2.65	23.70

Week 32 (Day 225)	0	21	63.6	18	85.7	5.56	23.57	-6.17	17.28
Week 36 (Day 253)	0	21	63.6	20	95.2	6.67	17.44	-1.49	14.83
Week 40 (Day 281)	0	21	63.6	19	90.5	8.77	18.73	-0.26	17.80
Week 44 (Day 309)	0	21	63.6	17	81.0	9.80	19.60	-0.27	19.88
Week 48 (Day 337)	0	19	57.6	12	63.2	8.33	20.72	-4.83	21.50
Week 52 (Day 365)	0	18	54.5	3	16.7	0.00	0.00	NE	NE
Week 56 (Day 393)	0	16	48.5	5	31.3	0.00	0.00	NE	NE
Week 60 (Day 421)	0	16	48.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	0	16	48.5	5	31.3	0.00	0.00	NE	NE
Week 68 (Day 477)	0	14	42.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	0	14	42.4	1	7.1	0.00	NE	NE	NE
Week 76 (Day 533)	0	12	36.4	1	8.3	0.00	NE	NE	NE
Week 80 (Day 561)	0	12	36.4	1	8.3	0.00	NE	NE	NE
Week 84 (Day 589)	0	10	30.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	9	27.3	1	11.1	0.00	NE	NE	NE
Week 92 (Day 645)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	9.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	3.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	33	100.0	33	100.0	21.21	32.08	9.84	32.59
End of Study (LOCF)	0	33	100.0	33	100.0	19.19	32.31	7.74	30.65
Baseline	1	79	100.0	76	96.2	21.93	27.52	15.64	28.22
Week 4 (Day 29)	1	79	100.0	66	83.5	9.09	14.96	5.41	12.77
Week 8 (Day 57)	1	70	88.6	65	92.9	8.21	15.62	4.33	12.08
Week 12 (Day 85)	1	68	86.1	64	94.1	5.21	12.20	2.16	8.26
Week 16 (Day 113)	1	67	84.8	61	91.0	9.29	17.35	4.85	13.73
Week 20 (Day 141)	1	63	79.7	59	93.7	7.34	18.64	2.49	12.20
Week 24 (Day 169)	1	57	72.2	53	93.0	8.81	18.66	3.66	13.95
Week 28 (Day 197)	1	53	67.1	50	94.3	5.33	12.34	1.83	8.84
Week 32 (Day 225)	1	50	63.3	45	90.0	8.15	17.63	2.85	13.45
Week 36 (Day 253)	1	50	63.3	45	90.0	9.63	18.29	4.14	15.12
Week 40 (Day 281)	1	46	58.2	40	87.0	7.50	17.68	1.84	13.16

Week 44 (Day 309)	1	43	54.4	41	95.3	7.32	19.02	1.31	13.32
Week 48 (Day 337)	1	39	49.4	21	53.8	3.17	10.03	-1.39	7.74
Week 52 (Day 365)	1	27	34.2	4	14.8	8.33	16.67	-18.19	34.85
Week 56 (Day 393)	1	21	26.6	7	33.3	4.76	12.60	-6.89	16.41
Week 60 (Day 421)	1	16	20.3	1	6.3	0.00	NE	NE	NE
Week 64 (Day 449)	1	15	19.0	4	26.7	0.00	0.00	NE	NE
Week 68 (Day 477)	1	14	17.7	1	7.1	0.00	NE	NE	NE
Week 72 (Day 505)	1	14	17.7	3	21.4	0.00	0.00	NE	NE
Week 76 (Day 533)	1	13	16.5	1	7.7	0.00	NE	NE	NE
Week 80 (Day 561)	1	13	16.5	5	38.5	20.00	44.72	-35.53	75.53
Week 84 (Day 589)	1	8	10.1	1	12.5	0.00	NE	NE	NE
Week 88 (Day 617)	1	5	6.3	1	20.0	0.00	NE	NE	NE
Week 92 (Day 645)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	2.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	79	100.0	77	97.5	12.12	22.88	6.93	17.32
End of Study (LOCF)	1	79	100.0	77	97.5	12.12	22.88	6.93	17.32
Baseline	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Geographic region									
Baseline	USA	22	100.0	22	100.0	19.70	30.27	6.28	33.12
Week 4 (Day 29)	USA	22	100.0	17	77.3	3.92	11.07	-1.77	9.61
Week 8 (Day 57)	USA	20	90.9	18	90.0	5.56	12.78	-0.80	11.91
Week 12 (Day 85)	USA	20	90.9	19	95.0	5.26	12.49	-0.76	11.28
Week 16 (Day 113)	USA	19	86.4	17	89.5	7.84	14.57	0.35	15.34
Week 20 (Day 141)	USA	19	86.4	17	89.5	5.88	13.10	-0.85	12.62
Week 24 (Day 169)	USA	16	72.7	14	87.5	4.76	12.10	-2.23	11.75
Week 28 (Day 197)	USA	15	68.2	12	80.0	2.78	9.62	-3.34	8.89
Week 32 (Day 225)	USA	15	68.2	13	86.7	7.69	19.97	-4.38	19.76
Week 36 (Day 253)	USA	15	68.2	13	86.7	0.00	0.00	NE	NE
Week 40 (Day 281)	USA	14	63.6	11	78.6	12.12	22.47	-2.98	27.22

Week 44 (Day 309)	USA	13	59.1	11	84.6	12.12	22.47	-2.98	27.22
Week 48 (Day 337)	USA	13	59.1	10	76.9	3.33	10.54	-4.21	10.87
Week 52 (Day 365)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	USA	12	54.5	6	50.0	5.56	13.61	-8.73	19.84
Week 60 (Day 421)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	11	50.0	4	36.4	0.00	0.00	NE	NE
Week 68 (Day 477)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	10	45.5	1	10.0	0.00	NE	NE	NE
Week 76 (Day 533)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	10	45.5	2	20.0	50.00	70.71	-585.31	685.31
Week 84 (Day 589)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	13.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	4.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	22	100.0	22	100.0	7.58	17.61	-0.23	15.39
End of Study (LOCF)	USA	22	100.0	22	100.0	7.58	22.84	-2.55	17.70
Baseline	Europe (EU)	32	100.0	29	90.6	18.39	27.58	7.90	28.88
Week 4 (Day 29)	Europe (EU)	32	100.0	25	78.1	17.33	27.42	6.01	28.65
Week 8 (Day 57)	Europe (EU)	29	90.6	25	86.2	13.33	27.22	2.10	24.57
Week 12 (Day 85)	Europe (EU)	26	81.3	24	92.3	6.94	16.97	-0.22	14.11
Week 16 (Day 113)	Europe (EU)	25	78.1	20	80.0	10.00	15.67	2.67	17.33
Week 20 (Day 141)	Europe (EU)	23	71.9	22	95.7	13.64	26.55	1.87	25.41
Week 24 (Day 169)	Europe (EU)	21	65.6	20	95.2	8.33	18.34	-0.25	16.92
Week 28 (Day 197)	Europe (EU)	20	62.5	20	100.0	10.00	24.42	-1.43	21.43
Week 32 (Day 225)	Europe (EU)	18	56.3	16	88.9	4.17	11.39	-1.90	10.23
Week 36 (Day 253)	Europe (EU)	18	56.3	17	94.4	3.92	11.07	-1.77	9.61
Week 40 (Day 281)	Europe (EU)	17	53.1	16	94.1	2.08	8.33	-2.36	6.52
Week 44 (Day 309)	Europe (EU)	17	53.1	14	82.4	7.14	19.30	-4.00	18.29

Week 48 (Day 337)	Europe (EU)	14	43.8	10	71.4	3.33	10.54	-4.21	10.87
Week 52 (Day 365)	Europe (EU)	13	40.6	3	23.1	0.00	0.00	NE	NE
Week 56 (Day 393)	Europe (EU)	11	34.4	5	45.5	0.00	0.00	NE	NE
Week 60 (Day 421)	Europe (EU)	11	34.4	1	9.1	0.00	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	11	34.4	5	45.5	0.00	0.00	NE	NE
Week 68 (Day 477)	Europe (EU)	10	31.3	1	10.0	0.00	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	10	31.3	3	30.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Europe (EU)	8	25.0	2	25.0	0.00	0.00	NE	NE
Week 80 (Day 561)	Europe (EU)	8	25.0	4	50.0	0.00	0.00	NE	NE
Week 84 (Day 589)	Europe (EU)	6	18.8	1	16.7	0.00	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	9.4	2	66.7	0.00	0.00	NE	NE
Cycle 12 (LOCF)	Europe (EU)	32	100.0	31	96.9	15.05	25.59	5.67	24.44
End of Study (LOCF)	Europe (EU)	32	100.0	31	96.9	13.98	24.00	5.18	22.78
Baseline	Asia (AS)	59	100.0	57	96.6	24.56	31.20	16.28	32.84
Week 4 (Day 29)	Asia (AS)	59	100.0	52	88.1	12.18	20.90	6.36	18.00
Week 8 (Day 57)	Asia (AS)	52	88.1	49	94.2	9.52	20.41	3.66	15.39
Week 12 (Day 85)	Asia (AS)	51	86.4	47	92.2	7.09	15.44	2.56	11.63
Week 16 (Day 113)	Asia (AS)	51	86.4	48	94.1	10.42	18.39	5.08	15.76
Week 20 (Day 141)	Asia (AS)	47	79.7	44	93.6	8.33	20.49	2.10	14.56
Week 24 (Day 169)	Asia (AS)	44	74.6	39	88.6	8.55	19.82	2.12	14.97
Week 28 (Day 197)	Asia (AS)	39	66.1	37	94.9	6.31	15.39	1.17	11.44
Week 32 (Day 225)	Asia (AS)	38	64.4	34	89.5	8.82	22.19	1.08	16.56
Week 36 (Day 253)	Asia (AS)	38	64.4	35	92.1	14.29	21.82	6.79	21.78
Week 40 (Day 281)	Asia (AS)	36	61.0	32	88.9	9.38	19.37	2.39	16.36
Week 44 (Day 309)	Asia (AS)	34	57.6	33	97.1	7.07	18.18	0.63	13.52
Week 48 (Day 337)	Asia (AS)	31	52.5	13	41.9	7.69	19.97	-4.38	19.76
Week 52 (Day 365)	Asia (AS)	20	33.9	4	20.0	8.33	16.67	-18.19	34.85
Week 56 (Day 393)	Asia (AS)	14	23.7	1	7.1	0.00	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	10.2	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	8.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	3.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	59	100.0	58	98.3	17.24	28.78	9.67	24.81
End of Study (LOCF)	Asia (AS)	59	100.0	58	98.3	16.67	28.10	9.28	24.05
Race/ethnicity									
Baseline	Asian	61	100.0	58	95.1	24.71	30.94	16.58	32.85
Week 4 (Day 29)	Asian	61	100.0	52	85.2	12.18	20.90	6.36	18.00
Week 8 (Day 57)	Asian	53	86.9	49	92.5	9.52	20.41	3.66	15.39
Week 12 (Day 85)	Asian	52	85.2	48	92.3	6.94	15.31	2.50	11.39
Week 16 (Day 113)	Asian	52	85.2	49	94.2	10.20	18.26	4.96	15.45
Week 20 (Day 141)	Asian	48	78.7	45	93.8	8.89	20.60	2.70	15.08
Week 24 (Day 169)	Asian	44	72.1	39	88.6	8.55	19.82	2.12	14.97
Week 28 (Day 197)	Asian	39	63.9	37	94.9	6.31	15.39	1.17	11.44
Week 32 (Day 225)	Asian	38	62.3	34	89.5	8.82	22.19	1.08	16.56
Week 36 (Day 253)	Asian	38	62.3	35	92.1	14.29	21.82	6.79	21.78
Week 40 (Day 281)	Asian	36	59.0	32	88.9	9.38	19.37	2.39	16.36
Week 44 (Day 309)	Asian	34	55.7	33	97.1	7.07	18.18	0.63	13.52
Week 48 (Day 337)	Asian	31	50.8	13	41.9	7.69	19.97	-4.38	19.76
Week 52 (Day 365)	Asian	20	32.8	4	20.0	8.33	16.67	-18.19	34.85
Week 56 (Day 393)	Asian	14	23.0	1	7.1	0.00	NE	NE	NE
Week 60 (Day 421)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	9.8	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	8.2	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	3.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	61	100.0	59	96.7	17.51	28.60	10.06	24.97
End of Study (LOCF)	Asian	61	100.0	59	96.7	16.95	27.94	9.67	24.23
Baseline	Non-Asian	45	100.0	44	97.8	18.18	27.33	9.87	26.49
Week 4 (Day 29)	Non-Asian	45	100.0	38	84.4	8.77	18.48	2.70	14.85
Week 8 (Day 57)	Non-Asian	42	93.3	38	90.5	11.40	23.60	3.65	19.16
Week 12 (Day 85)	Non-Asian	39	86.7	37	94.9	6.31	15.39	1.17	11.44
Week 16 (Day 113)	Non-Asian	37	82.2	34	91.9	9.80	15.42	4.42	15.18
Week 20 (Day 141)	Non-Asian	36	80.0	34	94.4	10.78	22.80	2.83	18.74
Week 24 (Day 169)	Non-Asian	32	71.1	31	96.9	7.53	16.58	1.45	13.61
Week 28 (Day 197)	Non-Asian	30	66.7	28	93.3	4.76	11.88	0.16	9.37
Week 32 (Day 225)	Non-Asian	28	62.2	25	89.3	6.67	16.67	-0.21	13.55
Week 36 (Day 253)	Non-Asian	28	62.2	26	92.9	1.28	6.54	-1.36	3.92
Week 40 (Day 281)	Non-Asian	26	57.8	23	88.5	7.25	17.28	-0.23	14.72
Week 44 (Day 309)	Non-Asian	25	55.6	21	84.0	9.52	21.46	-0.24	19.29
Week 48 (Day 337)	Non-Asian	23	51.1	17	73.9	3.92	11.07	-1.77	9.61
Week 52 (Day 365)	Non-Asian	21	46.7	3	14.3	0.00	0.00	NE	NE
Week 56 (Day 393)	Non-Asian	19	42.2	10	52.6	3.33	10.54	-4.21	10.87
Week 60 (Day 421)	Non-Asian	19	42.2	1	5.3	0.00	NE	NE	NE
Week 64 (Day 449)	Non-Asian	18	40.0	7	38.9	0.00	0.00	NE	NE
Week 68 (Day 477)	Non-Asian	17	37.8	1	5.9	0.00	NE	NE	NE
Week 72 (Day 505)	Non-Asian	17	37.8	3	17.6	0.00	0.00	NE	NE
Week 76 (Day 533)	Non-Asian	15	33.3	2	13.3	0.00	0.00	NE	NE
Week 80 (Day 561)	Non-Asian	15	33.3	5	33.3	20.00	44.72	-35.53	75.53
Week 84 (Day 589)	Non-Asian	10	22.2	1	10.0	0.00	NE	NE	NE
Week 88 (Day 617)	Non-Asian	7	15.6	2	28.6	0.00	0.00	NE	NE
Week 92 (Day 645)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	45	100.0	45	100.0	11.85	23.74	4.72	18.98

End of Study (LOCF)	Non-Asian	45	100.0	45	100.0	11.85	24.78	4.41	19.30
Baseline	Unknown	7	100.0	6	85.7	22.22	40.37	-20.14	64.59
Week 4 (Day 29)	Unknown	7	100.0	4	57.1	41.67	41.94	-25.07	108.41
Week 8 (Day 57)	Unknown	6	85.7	5	83.3	0.00	0.00	NE	NE
Week 12 (Day 85)	Unknown	6	85.7	5	83.3	6.67	14.91	-11.84	25.18
Week 16 (Day 113)	Unknown	6	85.7	2	33.3	0.00	0.00	NE	NE
Week 20 (Day 141)	Unknown	5	71.4	4	80.0	0.00	0.00	NE	NE
Week 24 (Day 169)	Unknown	5	71.4	3	60.0	0.00	0.00	NE	NE
Week 28 (Day 197)	Unknown	5	71.4	4	80.0	25.00	50.00	-54.56	104.56
Week 32 (Day 225)	Unknown	5	71.4	4	80.0	0.00	0.00	NE	NE
Week 36 (Day 253)	Unknown	5	71.4	4	80.0	8.33	16.67	-18.19	34.85
Week 40 (Day 281)	Unknown	5	71.4	4	80.0	0.00	0.00	NE	NE
Week 44 (Day 309)	Unknown	5	71.4	4	80.0	8.33	16.67	-18.19	34.85
Week 48 (Day 337)	Unknown	4	57.1	3	75.0	0.00	0.00	NE	NE
Week 52 (Day 365)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	4	57.1	1	25.0	0.00	NE	NE	NE
Week 60 (Day 421)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	4	57.1	2	50.0	0.00	0.00	NE	NE
Week 68 (Day 477)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	3	42.9	1	33.3	0.00	NE	NE	NE
Week 76 (Day 533)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	3	42.9	1	33.3	0.00	NE	NE	NE
Week 84 (Day 589)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	14.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	7	100.0	7	100.0	9.52	16.27	-5.52	24.57
End of Study (LOCF)	Unknown	7	100.0	7	100.0	4.76	12.60	-6.89	16.41
Number of prior antineoplastic systemic therapy lines I									
Baseline	1	60	100.0	57	95.0	22.81	30.96	14.59	31.02

Week 4 (Day 29)	1	60	100.0	49	81.7	11.56	21.03	5.52	17.60
Week 8 (Day 57)	1	54	90.0	49	90.7	10.20	19.49	4.61	15.80
Week 12 (Day 85)	1	52	86.7	48	92.3	6.94	15.31	2.50	11.39
Week 16 (Day 113)	1	51	85.0	46	90.2	10.87	17.29	5.73	16.00
Week 20 (Day 141)	1	48	80.0	43	89.6	9.30	20.99	2.84	15.76
Week 24 (Day 169)	1	43	71.7	39	90.7	5.98	12.96	1.78	10.18
Week 28 (Day 197)	1	38	63.3	34	89.5	7.84	20.20	0.80	14.89
Week 32 (Day 225)	1	35	58.3	29	82.9	5.75	15.61	-0.19	11.68
Week 36 (Day 253)	1	35	58.3	31	88.6	8.60	17.14	2.31	14.89
Week 40 (Day 281)	1	32	53.3	27	84.4	6.17	16.11	-0.20	12.55
Week 44 (Day 309)	1	32	53.3	27	84.4	11.11	22.65	2.15	20.07
Week 48 (Day 337)	1	27	45.0	16	59.3	6.25	13.44	-0.91	13.41
Week 52 (Day 365)	1	23	38.3	5	21.7	6.67	14.91	-11.84	25.18
Week 56 (Day 393)	1	16	26.7	4	25.0	0.00	0.00	NE	NE
Week 60 (Day 421)	1	14	23.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	13	21.7	4	30.8	0.00	0.00	NE	NE
Week 68 (Day 477)	1	12	20.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	12	20.0	1	8.3	0.00	NE	NE	NE
Week 76 (Day 533)	1	11	18.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	11	18.3	2	18.2	0.00	0.00	NE	NE
Week 84 (Day 589)	1	9	15.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	1	8	13.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	1	3	5.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	1	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	60	100.0	58	96.7	15.52	23.54	9.33	21.71
End of Study (LOCF)	1	60	100.0	58	96.7	13.22	20.65	7.79	18.65
Baseline	>= 2	53	100.0	51	96.2	20.92	29.03	12.75	29.08
Week 4 (Day 29)	>= 2	53	100.0	45	84.9	12.59	22.80	5.74	19.44
Week 8 (Day 57)	>= 2	47	88.7	43	91.5	9.30	23.37	2.11	16.50
Week 12 (Day 85)	>= 2	45	84.9	42	93.3	6.35	15.16	1.63	11.07
Week 16 (Day 113)	>= 2	44	83.0	39	88.6	8.55	16.61	3.16	13.93

Week 20 (Day 141)	>= 2	41	77.4	40	97.6	9.17	21.33	2.34	15.99
Week 24 (Day 169)	>= 2	38	71.7	34	89.5	9.80	22.52	1.95	17.66
Week 28 (Day 197)	>= 2	36	67.9	35	97.2	5.71	15.09	0.53	10.90
Week 32 (Day 225)	>= 2	36	67.9	34	94.4	8.82	22.19	1.08	16.56
Week 36 (Day 253)	>= 2	36	67.9	34	94.4	8.82	18.91	2.23	15.42
Week 40 (Day 281)	>= 2	35	66.0	32	91.4	9.38	19.37	2.39	16.36
Week 44 (Day 309)	>= 2	32	60.4	31	96.9	5.38	15.15	-0.18	10.93
Week 48 (Day 337)	>= 2	31	58.5	17	54.8	3.92	16.17	-4.39	12.23
Week 52 (Day 365)	>= 2	22	41.5	2	9.1	0.00	0.00	NE	NE
Week 56 (Day 393)	>= 2	21	39.6	8	38.1	4.17	11.79	-5.69	14.02
Week 60 (Day 421)	>= 2	18	34.0	1	5.6	0.00	NE	NE	NE
Week 64 (Day 449)	>= 2	18	34.0	5	27.8	0.00	0.00	NE	NE
Week 68 (Day 477)	>= 2	16	30.2	1	6.3	0.00	NE	NE	NE
Week 72 (Day 505)	>= 2	16	30.2	3	18.8	0.00	0.00	NE	NE
Week 76 (Day 533)	>= 2	14	26.4	2	14.3	0.00	0.00	NE	NE
Week 80 (Day 561)	>= 2	14	26.4	4	28.6	25.00	50.00	-54.56	104.56
Week 84 (Day 589)	>= 2	9	17.0	1	11.1	0.00	NE	NE	NE
Week 88 (Day 617)	>= 2	6	11.3	2	33.3	0.00	0.00	NE	NE
Week 92 (Day 645)	>= 2	2	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 2	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 2	53	100.0	53	100.0	13.84	28.82	5.89	21.78
End of Study (LOCF)	>= 2	53	100.0	53	100.0	15.09	31.05	6.53	23.65

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
¹ in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
² mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TP_QSC30AP_SG.xls
27OCT2021 7:22

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Appetite Loss
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	38	35.2	26.8	44.6
	Cycle 12 (LOCF)	n/a	108	95.6	15	13.9	8.6	21.7
	End of Study (LOCF)	n/a	108	95.6	13	12.0	7.2	19.5
Sex	All visits	Female	67	59.3	24	35.8	25.4	47.8
		Male	41	36.3	14	34.1	21.6	49.5
	Cycle 12 (LOCF)	Female	67	59.3	9	13.4	7.2	23.6
		Male	41	36.3	6	14.6	6.9	28.4
	End of Study (LOCF)	Female	67	59.3	7	10.4	5.2	20.0
		Male	41	36.3	6	14.6	6.9	28.4
Age	All visits	< 65	73	64.6	25	34.2	24.4	45.7
		>= 65	35	31.0	13	37.1	23.2	53.7
	Cycle 12 (LOCF)	< 65	73	64.6	10	13.7	7.6	23.4
		>= 65	35	31.0	5	14.3	6.3	29.4
	End of Study (LOCF)	< 65	73	64.6	8	11.0	5.7	20.2
		>= 65	35	31.0	5	14.3	6.3	29.4
ECOG performance status	All visits	0	31	27.4	13	41.9	26.4	59.2
		1	76	67.3	25	32.9	23.4	44.1
		Missing	1	0.9	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	31	27.4	6	19.4	9.2	36.3
		1	76	67.3	9	11.8	6.4	21.0
		Missing	1	0.9	0	0.0	0.0	79.3
	End of Study (LOCF)	0	31	27.4	5	16.1	7.1	32.6
		1	76	67.3	8	10.5	5.4	19.4
		Missing	1	0.9	0	0.0	0.0	79.3
Geographic region	All visits	USA	22	19.5	5	22.7	10.1	43.4
		Europe (EU)	29	25.7	11	37.9	22.7	56.0
		Asia (AS)	57	50.4	22	38.6	27.1	51.6
	Cycle 12 (LOCF)	USA	22	19.5	1	4.5	0.8	21.8
		Europe (EU)	29	25.7	4	13.8	5.5	30.6
		Asia (AS)	57	50.4	10	17.5	9.8	29.4
	End of Study (LOCF)	USA	22	19.5	0	0.0	0.0	14.9
		Europe (EU)	29	25.7	3	10.3	3.6	26.4
		Asia (AS)	57	50.4	10	17.5	9.8	29.4
Race/ethnicity	All visits	Asian	58	51.3	22	37.9	26.6	50.8
		Non-Asian	44	38.9	15	34.1	21.9	48.9
		Unknown	6	5.3	1	16.7	3.0	56.4
	Cycle 12 (LOCF)	Asian	58	51.3	10	17.2	9.6	28.9

		Non-Asian	44	38.9	5	11.4	5.0	24.0
		Unknown	6	5.3	0	0.0	0.0	39.0
	End of Study (LOCF)	Asian	58	51.3	10	17.2	9.6	28.9
		Non-Asian	44	38.9	3	6.8	2.3	18.2
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	21	36.8	25.5	49.8
		>= 2	51	45.1	17	33.3	22.0	47.0
	Cycle 12 (LOCF)	1	57	50.4	9	15.8	8.5	27.4
		>= 2	51	45.1	6	11.8	5.5	23.4
	End of Study (LOCF)	1	57	50.4	7	12.3	6.1	23.2
		>= 2	51	45.1	6	11.8	5.5	23.4

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30AP_W10_SG.xls
15OCT2021 13:29

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Appetite Loss
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

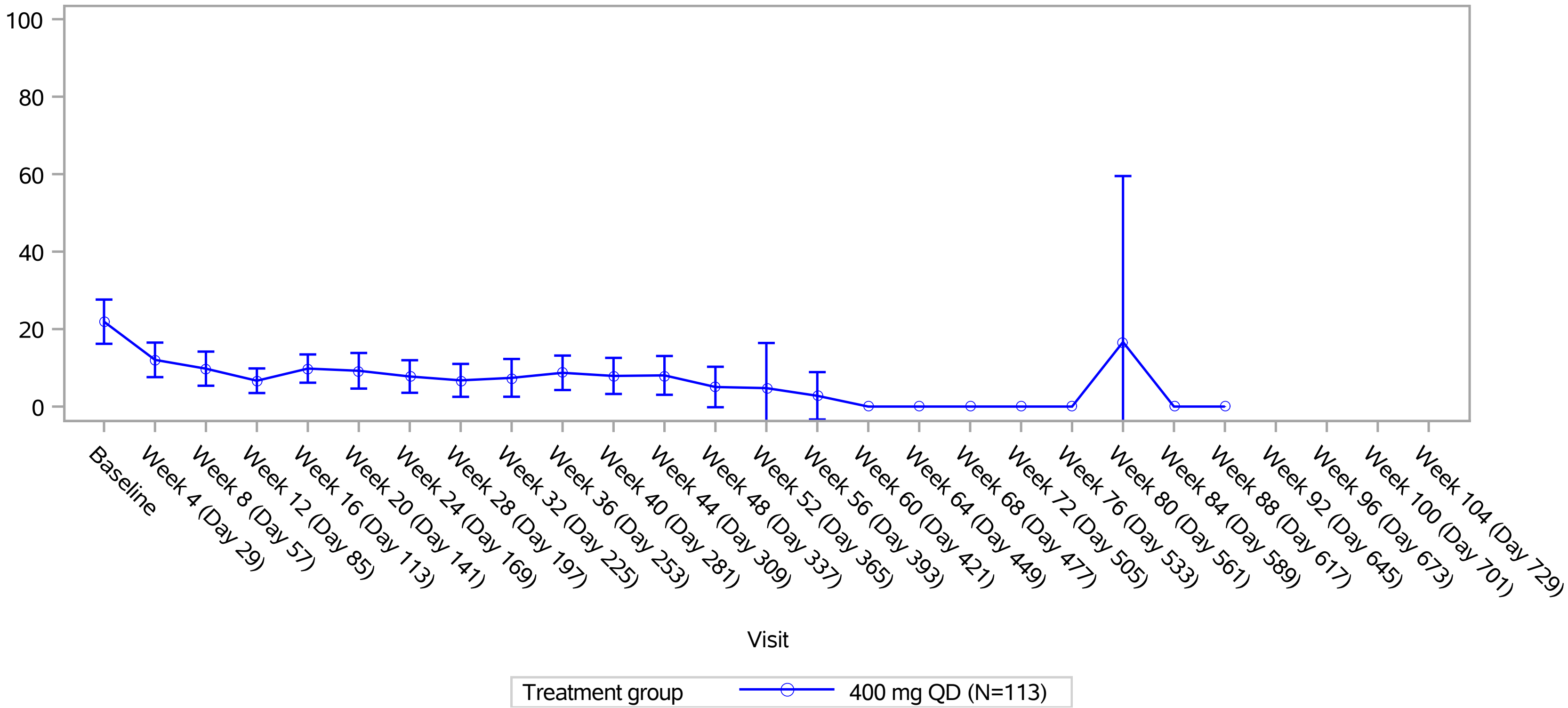
			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	38	35.2	26.8	44.6
	Cycle 12 (LOCF)	n/a	108	95.6	15	13.9	8.6	21.7
	End of Study (LOCF)	n/a	108	95.6	13	12.0	7.2	19.5
Sex	All visits	Female	67	59.3	24	35.8	25.4	47.8
		Male	41	36.3	14	34.1	21.6	49.5
	Cycle 12 (LOCF)	Female	67	59.3	9	13.4	7.2	23.6
		Male	41	36.3	6	14.6	6.9	28.4
	End of Study (LOCF)	Female	67	59.3	7	10.4	5.2	20.0
		Male	41	36.3	6	14.6	6.9	28.4
Age	All visits	< 65	73	64.6	25	34.2	24.4	45.7
		>= 65	35	31.0	13	37.1	23.2	53.7
	Cycle 12 (LOCF)	< 65	73	64.6	10	13.7	7.6	23.4
		>= 65	35	31.0	5	14.3	6.3	29.4
	End of Study (LOCF)	< 65	73	64.6	8	11.0	5.7	20.2
		>= 65	35	31.0	5	14.3	6.3	29.4
ECOG performance status	All visits	0	31	27.4	13	41.9	26.4	59.2
		1	76	67.3	25	32.9	23.4	44.1
		Missing	1	0.9	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	31	27.4	6	19.4	9.2	36.3
		1	76	67.3	9	11.8	6.4	21.0
		Missing	1	0.9	0	0.0	0.0	79.3
	End of Study (LOCF)	0	31	27.4	5	16.1	7.1	32.6
		1	76	67.3	8	10.5	5.4	19.4
		Missing	1	0.9	0	0.0	0.0	79.3
Geographic region	All visits	USA	22	19.5	5	22.7	10.1	43.4
		Europe (EU)	29	25.7	11	37.9	22.7	56.0
		Asia (AS)	57	50.4	22	38.6	27.1	51.6
	Cycle 12 (LOCF)	USA	22	19.5	1	4.5	0.8	21.8
		Europe (EU)	29	25.7	4	13.8	5.5	30.6
		Asia (AS)	57	50.4	10	17.5	9.8	29.4
	End of Study (LOCF)	USA	22	19.5	0	0.0	0.0	14.9
		Europe (EU)	29	25.7	3	10.3	3.6	26.4
		Asia (AS)	57	50.4	10	17.5	9.8	29.4
Race/ethnicity	All visits	Asian	58	51.3	22	37.9	26.6	50.8
		Non-Asian	44	38.9	15	34.1	21.9	48.9
		Unknown	6	5.3	1	16.7	3.0	56.4
	Cycle 12 (LOCF)	Asian	58	51.3	10	17.2	9.6	28.9

		Non-Asian	44	38.9	5	11.4	5.0	24.0
		Unknown	6	5.3	0	0.0	0.0	39.0
	End of Study (LOCF)	Asian	58	51.3	10	17.2	9.6	28.9
		Non-Asian	44	38.9	3	6.8	2.3	18.2
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	21	36.8	25.5	49.8
		>= 2	51	45.1	17	33.3	22.0	47.0
	Cycle 12 (LOCF)	1	57	50.4	9	15.8	8.5	27.4
		>= 2	51	45.1	6	11.8	5.5	23.4
	End of Study (LOCF)	1	57	50.4	7	12.3	6.1	23.2
		>= 2	51	45.1	6	11.8	5.5	23.4

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30AP_W15_SG.xls
15OCT2021 13:19

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Appetite Loss
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
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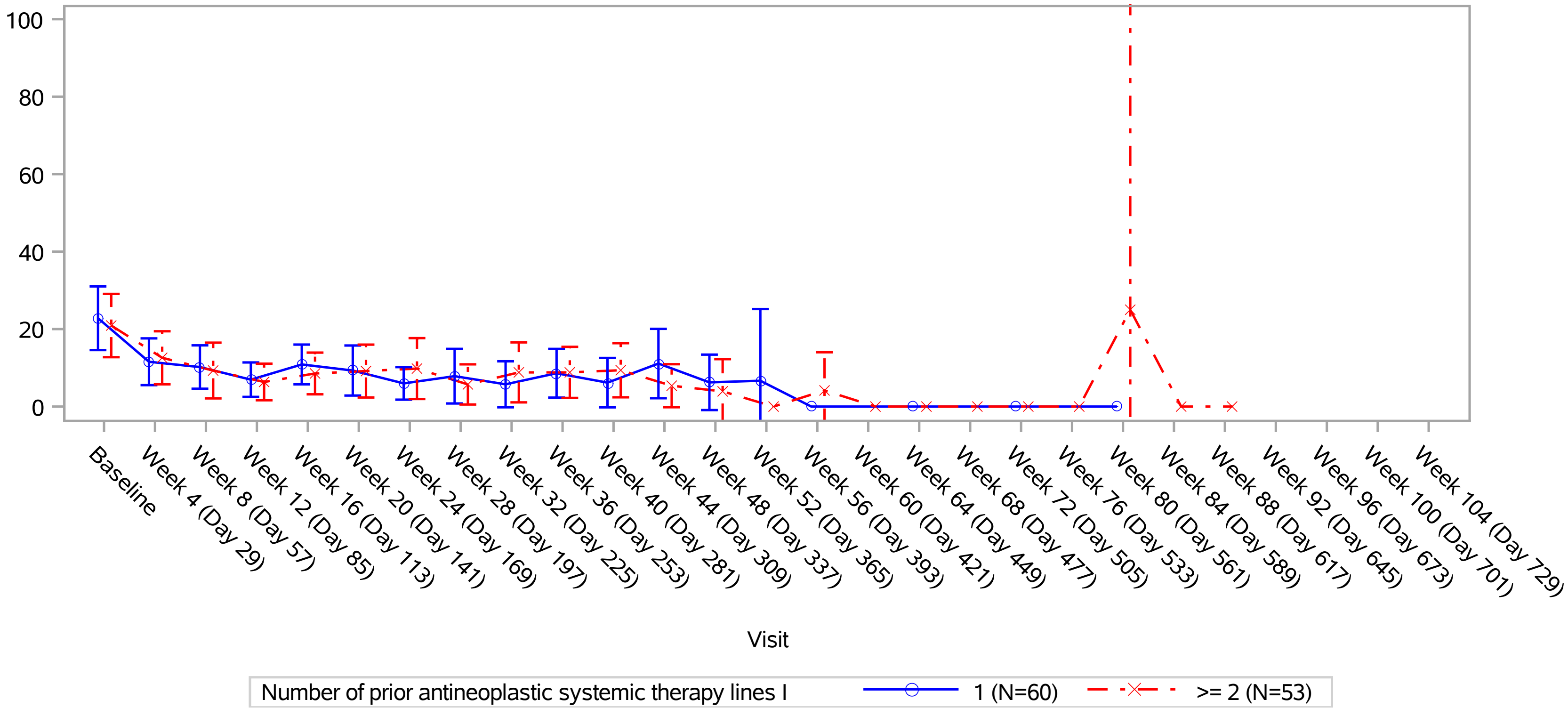
15OCT2021 17:12

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Appetite Loss
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
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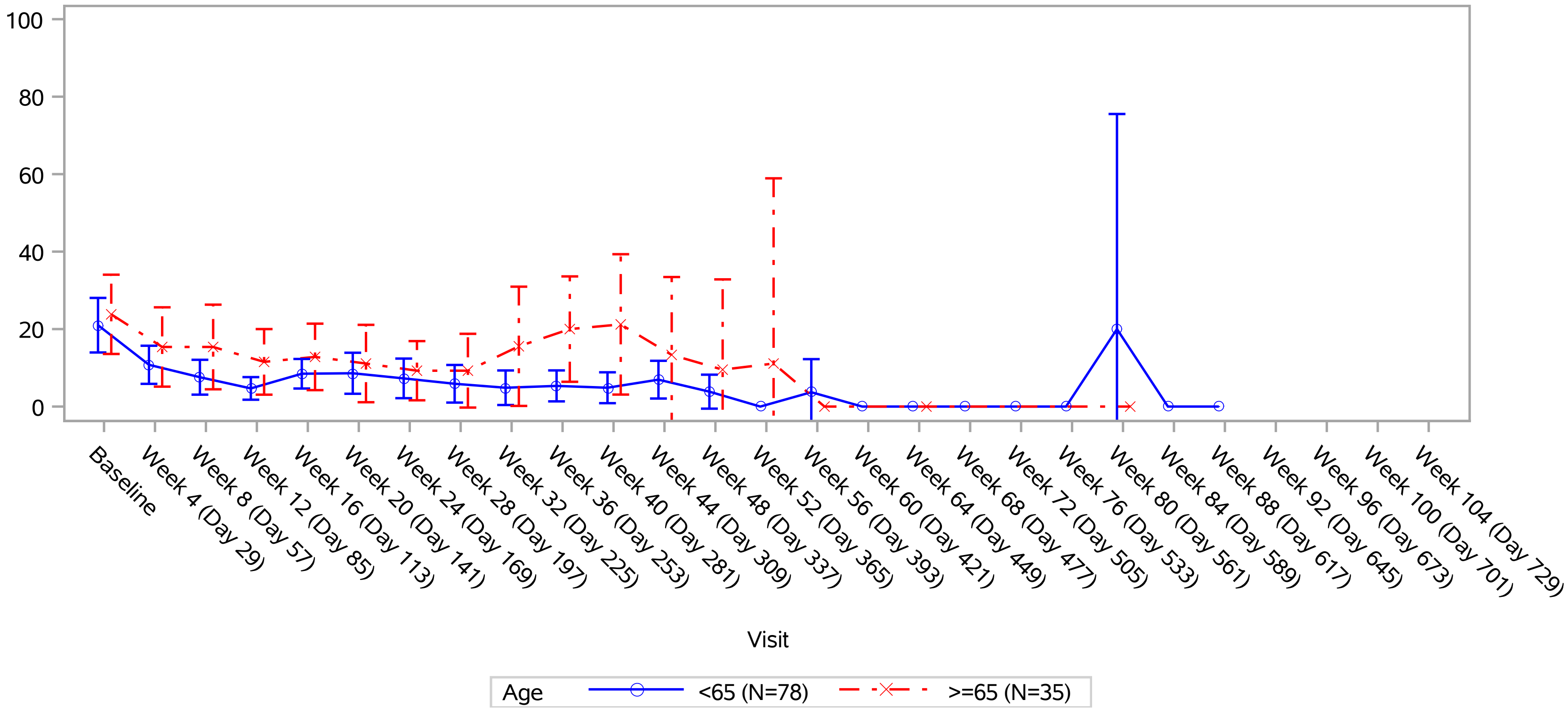
15OCT2021 20:03

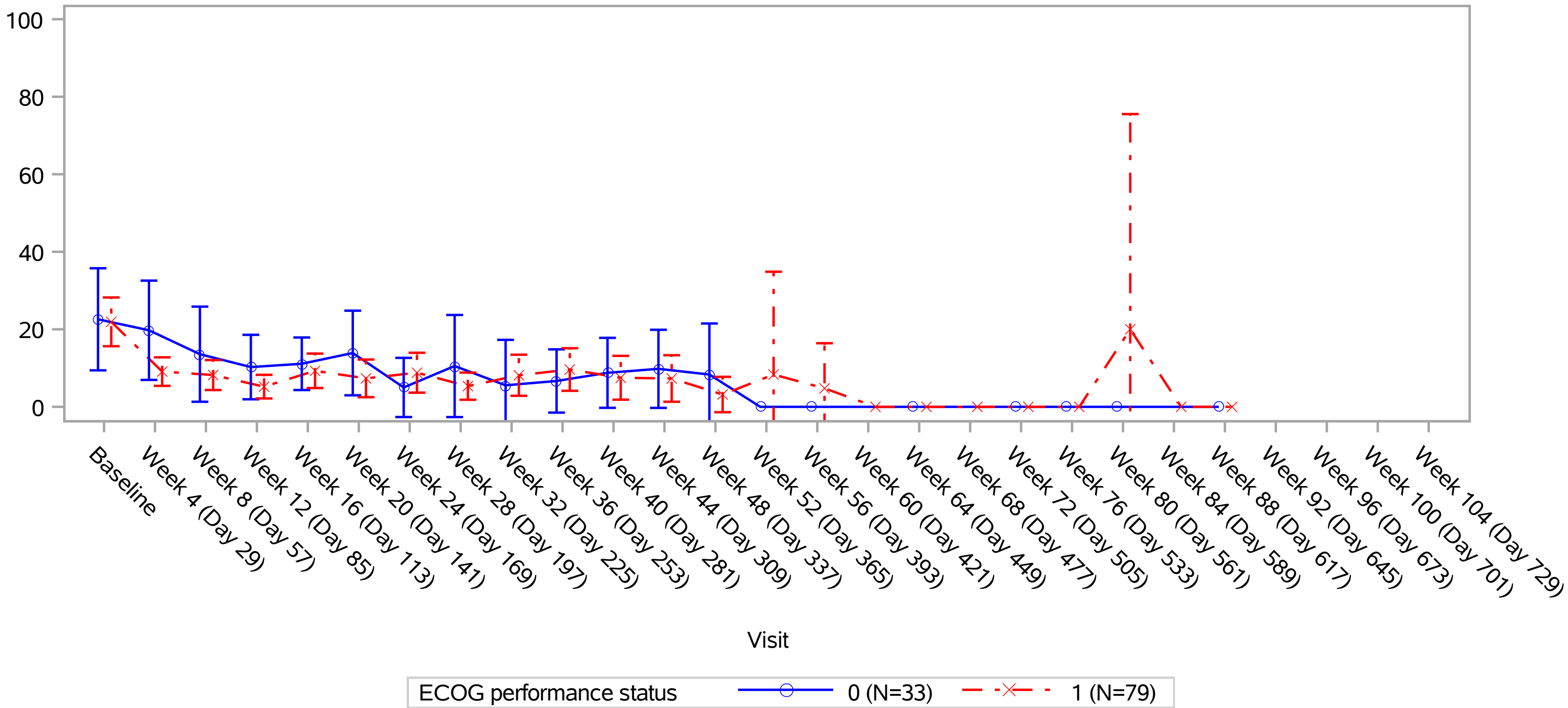
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Appetite Loss
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30AP_SGAGE65.pdf
15OCT2021 17:41

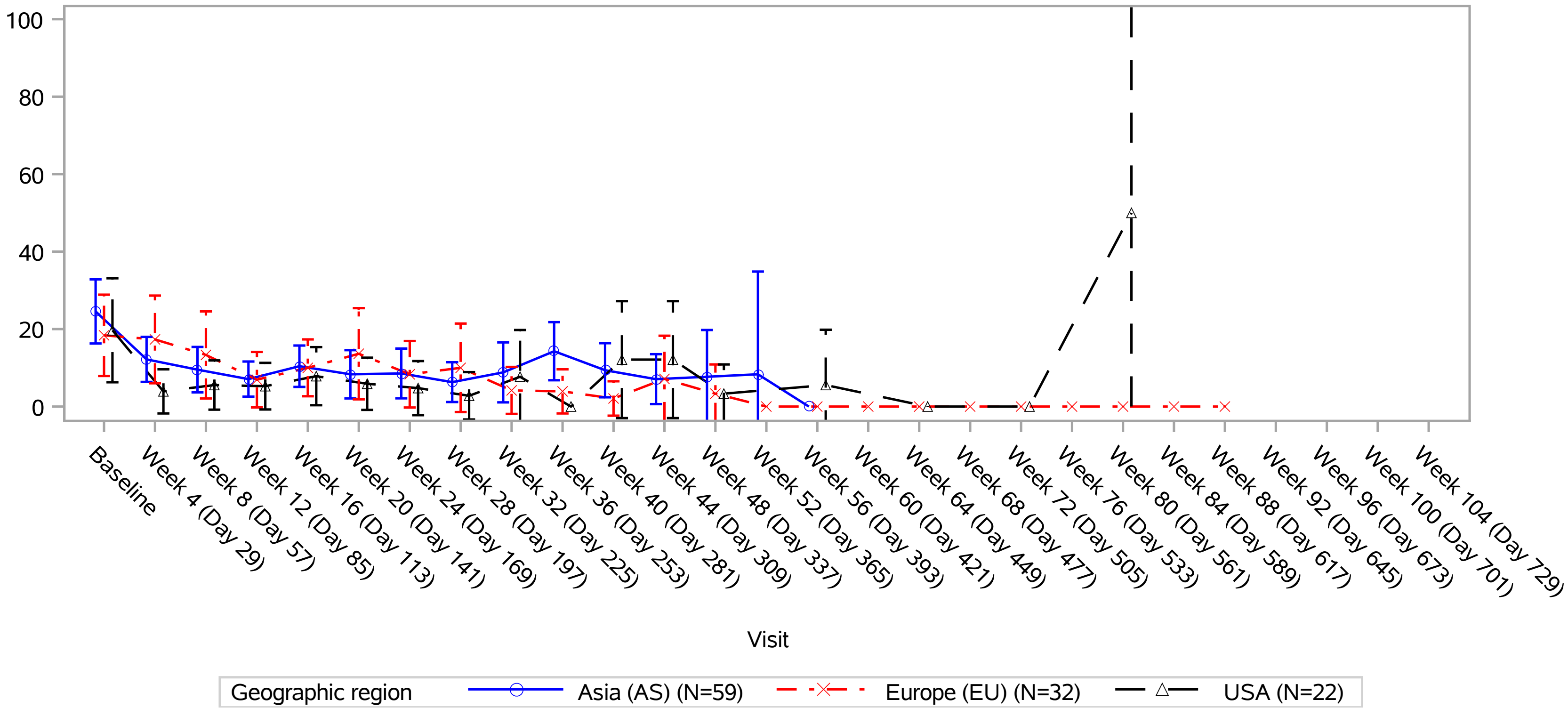
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Appetite Loss
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30AP_SGECOG.pdf
15OCT2021 18:11

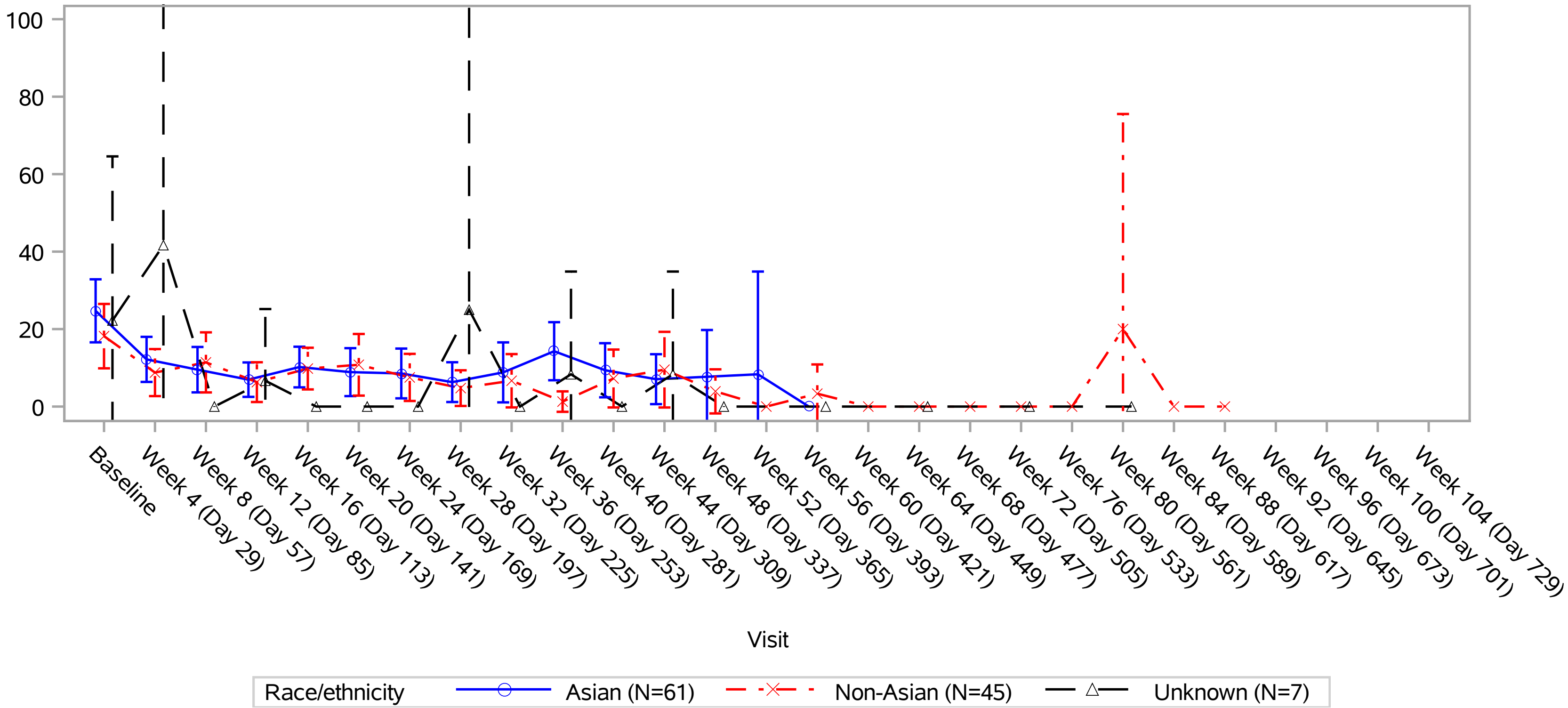
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Appetite Loss
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30AP_SGGEO.pdf
15OCT2021 18:42

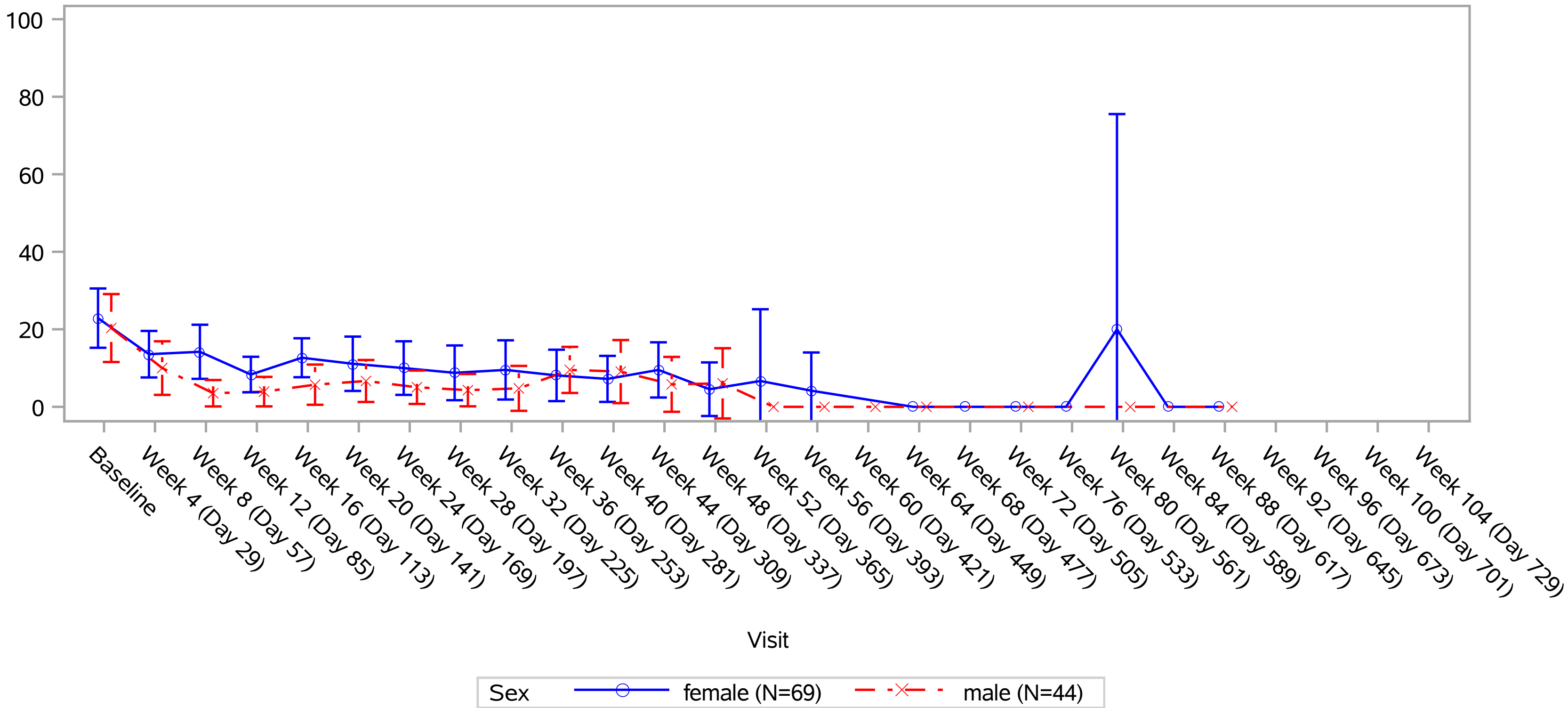
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Appetite Loss
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30AP_SGRE.pdf
15OCT2021 19:13

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Appetite Loss
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30AP_SGSEX.pdf
15OCT2021 19:43

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Cognitive functioning
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=113)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	113	100.0	108	95.6	86.88	18.66	83.32	90.44
Week 4 (Day 29)	n/a	113	100.0	95	84.1	88.77	18.90	84.92	92.62
Week 8 (Day 57)	n/a	101	89.4	92	91.1	91.12	15.52	87.91	94.34
Week 12 (Day 85)	n/a	97	85.8	90	92.8	89.07	15.43	85.84	92.31
Week 16 (Day 113)	n/a	95	84.1	85	89.5	87.84	16.34	84.32	91.37
Week 20 (Day 141)	n/a	89	78.8	83	93.3	87.75	18.96	83.61	91.89
Week 24 (Day 169)	n/a	81	71.7	73	90.1	88.81	15.97	85.09	92.54
Week 28 (Day 197)	n/a	74	65.5	69	93.2	89.61	16.69	85.60	93.62
Week 32 (Day 225)	n/a	71	62.8	63	88.7	87.30	20.68	82.09	92.51
Week 36 (Day 253)	n/a	71	62.8	65	91.5	86.92	21.35	81.63	92.21
Week 40 (Day 281)	n/a	67	59.3	59	88.1	87.85	19.78	82.70	93.01
Week 44 (Day 309)	n/a	64	56.6	58	90.6	87.36	22.58	81.42	93.29
Week 48 (Day 337)	n/a	58	51.3	33	56.9	85.86	22.87	77.75	93.97
Week 52 (Day 365)	n/a	45	39.8	7	15.6	97.62	6.30	91.79	103.45
Week 56 (Day 393)	n/a	37	32.7	12	32.4	86.11	21.12	72.69	99.53
Week 60 (Day 421)	n/a	32	28.3	1	3.1	100.00	NE	NE	NE
Week 64 (Day 449)	n/a	31	27.4	9	29.0	92.59	12.11	83.29	101.90
Week 68 (Day 477)	n/a	28	24.8	1	3.6	83.33	NE	NE	NE
Week 72 (Day 505)	n/a	28	24.8	4	14.3	100.00	0.00	NE	NE
Week 76 (Day 533)	n/a	25	22.1	2	8.0	100.00	0.00	NE	NE
Week 80 (Day 561)	n/a	25	22.1	6	24.0	75.00	31.18	42.28	107.72
Week 84 (Day 589)	n/a	18	15.9	1	5.6	100.00	NE	NE	NE
Week 88 (Day 617)	n/a	14	12.4	2	14.3	100.00	0.00	NE	NE
Week 92 (Day 645)	n/a	7	6.2	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	5.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	2.7	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	113	100.0	111	98.2	85.29	20.81	81.37	89.20
End of Study (LOCF)	n/a	113	100.0	111	98.2	84.53	20.68	80.64	88.43
Sex									
Baseline	Female	69	100.0	67	97.1	87.56	18.88	82.96	92.17
Week 4 (Day 29)	Female	69	100.0	55	79.7	91.52	15.34	87.37	95.66
Week 8 (Day 57)	Female	63	91.3	54	85.7	90.43	16.70	85.87	94.99
Week 12 (Day 85)	Female	60	87.0	56	93.3	88.39	16.49	83.98	92.81
Week 16 (Day 113)	Female	58	84.1	50	86.2	87.33	15.99	82.79	91.88
Week 20 (Day 141)	Female	53	76.8	48	90.6	88.19	20.90	82.13	94.26
Week 24 (Day 169)	Female	47	68.1	40	85.1	88.33	16.54	83.04	93.62
Week 28 (Day 197)	Female	42	60.9	38	90.5	88.16	18.55	82.06	94.25
Week 32 (Day 225)	Female	42	60.9	35	83.3	86.19	20.80	79.04	93.34
Week 36 (Day 253)	Female	42	60.9	37	88.1	85.59	23.62	77.71	93.46
Week 40 (Day 281)	Female	41	59.4	37	90.2	86.94	19.69	80.37	93.50
Week 44 (Day 309)	Female	41	59.4	35	85.4	86.67	23.15	78.71	94.62
Week 48 (Day 337)	Female	37	53.6	22	59.5	86.36	23.92	75.76	96.97
Week 52 (Day 365)	Female	29	42.0	5	17.2	96.67	7.45	87.41	105.92
Week 56 (Day 393)	Female	24	34.8	8	33.3	87.50	24.80	66.77	108.23
Week 60 (Day 421)	Female	22	31.9	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Female	22	31.9	6	27.3	94.44	8.61	85.41	103.48
Week 68 (Day 477)	Female	20	29.0	1	5.0	83.33	NE	NE	NE
Week 72 (Day 505)	Female	20	29.0	2	10.0	100.00	0.00	NE	NE
Week 76 (Day 533)	Female	18	26.1	2	11.1	100.00	0.00	NE	NE
Week 80 (Day 561)	Female	18	26.1	5	27.8	70.00	32.06	30.19	109.81
Week 84 (Day 589)	Female	12	17.4	1	8.3	100.00	NE	NE	NE
Week 88 (Day 617)	Female	9	13.0	1	11.1	100.00	NE	NE	NE
Week 92 (Day 645)	Female	6	8.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	7.2	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	2.9	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	1.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	69	100.0	68	98.6	85.54	20.34	80.62	90.46
End of Study (LOCF)	Female	69	100.0	68	98.6	84.31	21.53	79.10	89.52
Baseline	Male	44	100.0	41	93.2	85.77	18.47	79.94	91.60
Week 4 (Day 29)	Male	44	100.0	40	90.9	85.00	22.58	77.78	92.22
Week 8 (Day 57)	Male	38	86.4	38	100.0	92.11	13.83	87.56	96.65
Week 12 (Day 85)	Male	37	84.1	34	91.9	90.20	13.68	85.42	94.97
Week 16 (Day 113)	Male	37	84.1	35	94.6	88.57	17.04	82.72	94.43
Week 20 (Day 141)	Male	36	81.8	35	97.2	87.14	16.21	81.57	92.71
Week 24 (Day 169)	Male	34	77.3	33	97.1	89.39	15.49	83.90	94.89
Week 28 (Day 197)	Male	32	72.7	31	96.9	91.40	14.19	86.19	96.60
Week 32 (Day 225)	Male	29	65.9	28	96.6	88.69	20.81	80.62	96.76
Week 36 (Day 253)	Male	29	65.9	28	96.6	88.69	18.17	81.64	95.74
Week 40 (Day 281)	Male	26	59.1	22	84.6	89.39	20.28	80.40	98.39
Week 44 (Day 309)	Male	23	52.3	23	100.0	88.41	22.15	78.83	97.99
Week 48 (Day 337)	Male	21	47.7	11	52.4	84.85	21.67	70.29	99.41
Week 52 (Day 365)	Male	16	36.4	2	12.5	100.00	0.00	NE	NE
Week 56 (Day 393)	Male	13	29.5	4	30.8	83.33	13.61	61.68	104.99
Week 60 (Day 421)	Male	10	22.7	1	10.0	100.00	NE	NE	NE
Week 64 (Day 449)	Male	9	20.5	3	33.3	88.89	19.25	41.08	136.70
Week 68 (Day 477)	Male	8	18.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	8	18.2	2	25.0	100.00	0.00	NE	NE
Week 76 (Day 533)	Male	7	15.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	7	15.9	1	14.3	100.00	NE	NE	NE
Week 84 (Day 589)	Male	6	13.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	5	11.4	1	20.0	100.00	NE	NE	NE
Week 92 (Day 645)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	44	100.0	43	97.7	84.88	21.77	78.19	91.58
End of Study (LOCF)	Male	44	100.0	43	97.7	84.88	19.52	78.88	90.89
Age									

Baseline	< 65	78	100.0	73	93.6	89.04	18.26	84.78	93.30
Week 4 (Day 29)	< 65	78	100.0	68	87.2	91.18	16.66	87.14	95.21
Week 8 (Day 57)	< 65	73	93.6	66	90.4	93.18	12.74	90.05	96.31
Week 12 (Day 85)	< 65	71	91.0	64	90.1	92.19	12.93	88.96	95.42
Week 16 (Day 113)	< 65	69	88.5	59	85.5	90.68	14.27	86.96	94.40
Week 20 (Day 141)	< 65	65	83.3	62	95.4	89.25	17.10	84.91	93.59
Week 24 (Day 169)	< 65	59	75.6	55	93.2	89.70	15.55	85.49	93.90
Week 28 (Day 197)	< 65	55	70.5	51	92.7	91.50	14.29	87.48	95.52
Week 32 (Day 225)	< 65	53	67.9	48	90.6	89.93	19.67	84.22	95.64
Week 36 (Day 253)	< 65	53	67.9	50	94.3	89.33	19.85	83.69	94.98
Week 40 (Day 281)	< 65	52	66.7	48	92.3	89.93	18.11	84.67	95.19
Week 44 (Day 309)	< 65	52	66.7	48	92.3	89.93	20.84	83.88	95.98
Week 48 (Day 337)	< 65	47	60.3	26	55.3	90.38	17.75	83.22	97.55
Week 52 (Day 365)	< 65	36	46.2	4	11.1	100.00	0.00	NE	NE
Week 56 (Day 393)	< 65	30	38.5	9	30.0	85.19	22.74	67.71	102.66
Week 60 (Day 421)	< 65	25	32.1	1	4.0	100.00	NE	NE	NE
Week 64 (Day 449)	< 65	24	30.8	7	29.2	92.86	13.11	80.73	104.98
Week 68 (Day 477)	< 65	22	28.2	1	4.5	83.33	NE	NE	NE
Week 72 (Day 505)	< 65	22	28.2	4	18.2	100.00	0.00	NE	NE
Week 76 (Day 533)	< 65	21	26.9	2	9.5	100.00	0.00	NE	NE
Week 80 (Day 561)	< 65	21	26.9	5	23.8	73.33	34.56	30.42	116.25
Week 84 (Day 589)	< 65	15	19.2	1	6.7	100.00	NE	NE	NE
Week 88 (Day 617)	< 65	12	15.4	2	16.7	100.00	0.00	NE	NE
Week 92 (Day 645)	< 65	6	7.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	6.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	78	100.0	76	97.4	89.25	18.80	84.96	93.55
End of Study (LOCF)	< 65	78	100.0	76	97.4	87.94	18.78	83.65	92.23
Baseline	>= 65	35	100.0	35	100.0	82.38	18.94	75.88	88.89
Week 4 (Day 29)	>= 65	35	100.0	27	77.1	82.72	22.87	73.67	91.76
Week 8 (Day 57)	>= 65	28	80.0	26	92.9	85.90	20.38	77.67	94.13
Week 12 (Day 85)	>= 65	26	74.3	26	100.0	81.41	18.46	73.96	88.86

Week 16 (Day 113)	>= 65	26	74.3	26	100.0	81.41	19.05	73.72	89.10
Week 20 (Day 141)	>= 65	24	68.6	21	87.5	83.33	23.57	72.60	94.06
Week 24 (Day 169)	>= 65	22	62.9	18	81.8	86.11	17.39	77.47	94.76
Week 28 (Day 197)	>= 65	19	54.3	18	94.7	84.26	21.75	73.44	95.07
Week 32 (Day 225)	>= 65	18	51.4	15	83.3	78.89	22.24	66.57	91.21
Week 36 (Day 253)	>= 65	18	51.4	15	83.3	78.89	24.77	65.17	92.61
Week 40 (Day 281)	>= 65	15	42.9	11	73.3	78.79	24.82	62.11	95.46
Week 44 (Day 309)	>= 65	12	34.3	10	83.3	75.00	27.50	55.33	94.67
Week 48 (Day 337)	>= 65	11	31.4	7	63.6	69.05	32.53	38.96	99.13
Week 52 (Day 365)	>= 65	9	25.7	3	33.3	94.44	9.62	70.54	118.35
Week 56 (Day 393)	>= 65	7	20.0	3	42.9	88.89	19.25	41.08	136.70
Week 60 (Day 421)	>= 65	7	20.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	7	20.0	2	28.6	91.67	11.79	-14.22	197.55
Week 68 (Day 477)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	4	11.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	4	11.4	1	25.0	83.33	NE	NE	NE
Week 84 (Day 589)	>= 65	3	8.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	5.7	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	35	100.0	35	100.0	76.67	22.58	68.91	84.42
End of Study (LOCF)	>= 65	35	100.0	35	100.0	77.14	22.90	69.28	85.01
ECOG performance status									
Baseline	0	33	100.0	31	93.9	87.10	21.39	79.25	94.94
Week 4 (Day 29)	0	33	100.0	27	81.8	85.80	26.03	75.51	96.10
Week 8 (Day 57)	0	30	90.9	27	90.0	88.89	20.15	80.92	96.86
Week 12 (Day 85)	0	29	87.9	26	89.7	89.10	19.40	81.27	96.94
Week 16 (Day 113)	0	28	84.8	24	85.7	86.11	17.49	78.73	93.50
Week 20 (Day 141)	0	26	78.8	24	92.3	87.50	23.70	77.49	97.51
Week 24 (Day 169)	0	24	72.7	20	83.3	89.17	18.16	80.67	97.66
Week 28 (Day 197)	0	21	63.6	19	90.5	89.47	20.19	79.74	99.21

Week 32 (Day 225)	0	21	63.6	18	85.7	87.96	21.24	77.40	98.53
Week 36 (Day 253)	0	21	63.6	20	95.2	86.67	25.13	74.90	98.43
Week 40 (Day 281)	0	21	63.6	19	90.5	85.96	21.70	75.50	96.43
Week 44 (Day 309)	0	21	63.6	17	81.0	88.24	25.53	75.11	101.36
Week 48 (Day 337)	0	19	57.6	12	63.2	84.72	29.69	65.86	103.59
Week 52 (Day 365)	0	18	54.5	3	16.7	100.00	0.00	NE	NE
Week 56 (Day 393)	0	16	48.5	5	31.3	90.00	14.91	71.49	108.51
Week 60 (Day 421)	0	16	48.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	0	16	48.5	5	31.3	93.33	14.91	74.82	111.84
Week 68 (Day 477)	0	14	42.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	0	14	42.4	1	7.1	100.00	NE	NE	NE
Week 76 (Day 533)	0	12	36.4	1	8.3	100.00	NE	NE	NE
Week 80 (Day 561)	0	12	36.4	1	8.3	83.33	NE	NE	NE
Week 84 (Day 589)	0	10	30.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	9	27.3	1	11.1	100.00	NE	NE	NE
Week 92 (Day 645)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	9.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	3.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	33	100.0	33	100.0	85.35	25.26	76.40	94.31
End of Study (LOCF)	0	33	100.0	33	100.0	83.84	25.51	74.79	92.88
Baseline	1	79	100.0	76	96.2	86.62	17.64	82.59	90.65
Week 4 (Day 29)	1	79	100.0	67	84.8	89.80	15.34	86.06	93.54
Week 8 (Day 57)	1	70	88.6	65	92.9	92.05	13.21	88.78	95.32
Week 12 (Day 85)	1	68	86.1	64	94.1	89.06	13.68	85.65	92.48
Week 16 (Day 113)	1	67	84.8	61	91.0	88.52	15.97	84.43	92.61
Week 20 (Day 141)	1	63	79.7	59	93.7	87.85	16.90	83.45	92.26
Week 24 (Day 169)	1	57	72.2	53	93.0	88.68	15.25	84.48	92.88
Week 28 (Day 197)	1	53	67.1	50	94.3	89.67	15.39	85.29	94.04
Week 32 (Day 225)	1	50	63.3	45	90.0	87.04	20.69	80.82	93.25
Week 36 (Day 253)	1	50	63.3	45	90.0	87.04	19.75	81.10	92.97
Week 40 (Day 281)	1	46	58.2	40	87.0	88.75	19.02	82.67	94.83

Week 44 (Day 309)	1	43	54.4	41	95.3	86.99	21.57	80.18	93.80
Week 48 (Day 337)	1	39	49.4	21	53.8	86.51	18.72	77.99	95.03
Week 52 (Day 365)	1	27	34.2	4	14.8	95.83	8.33	82.57	109.09
Week 56 (Day 393)	1	21	26.6	7	33.3	83.33	25.46	59.79	106.88
Week 60 (Day 421)	1	16	20.3	1	6.3	100.00	NE	NE	NE
Week 64 (Day 449)	1	15	19.0	4	26.7	91.67	9.62	76.36	106.98
Week 68 (Day 477)	1	14	17.7	1	7.1	83.33	NE	NE	NE
Week 72 (Day 505)	1	14	17.7	3	21.4	100.00	0.00	NE	NE
Week 76 (Day 533)	1	13	16.5	1	7.7	100.00	NE	NE	NE
Week 80 (Day 561)	1	13	16.5	5	38.5	73.33	34.56	30.42	116.25
Week 84 (Day 589)	1	8	10.1	1	12.5	100.00	NE	NE	NE
Week 88 (Day 617)	1	5	6.3	1	20.0	100.00	NE	NE	NE
Week 92 (Day 645)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	2.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	79	100.0	77	97.5	85.06	18.85	80.79	89.34
End of Study (LOCF)	1	79	100.0	77	97.5	84.63	18.49	80.44	88.83
Baseline	Missing	1	100.0	1	100.0	100.00	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	100.00	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	100.00	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	100.00	NE	NE	NE
Geographic region									
Baseline	USA	22	100.0	22	100.0	90.91	13.34	84.99	96.82
Week 4 (Day 29)	USA	22	100.0	18	81.8	83.33	22.87	71.96	94.70
Week 8 (Day 57)	USA	20	90.9	18	90.0	89.81	15.27	82.22	97.41
Week 12 (Day 85)	USA	20	90.9	19	95.0	89.47	14.92	82.28	96.66
Week 16 (Day 113)	USA	19	86.4	17	89.5	87.25	17.21	78.41	96.10
Week 20 (Day 141)	USA	19	86.4	17	89.5	87.25	20.01	76.97	97.54
Week 24 (Day 169)	USA	16	72.7	14	87.5	86.90	16.25	77.52	96.29
Week 28 (Day 197)	USA	15	68.2	12	80.0	88.89	17.88	77.53	100.25
Week 32 (Day 225)	USA	15	68.2	13	86.7	82.05	31.52	63.00	101.10
Week 36 (Day 253)	USA	15	68.2	13	86.7	82.05	27.61	65.37	98.73
Week 40 (Day 281)	USA	14	63.6	11	78.6	81.82	27.34	63.45	100.19

Week 44 (Day 309)	USA	13	59.1	11	84.6	81.82	32.02	60.31	103.33
Week 48 (Day 337)	USA	13	59.1	10	76.9	81.67	25.40	63.50	99.84
Week 52 (Day 365)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	USA	12	54.5	6	50.0	83.33	27.89	54.07	112.60
Week 60 (Day 421)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	11	50.0	4	36.4	95.83	8.33	82.57	109.09
Week 68 (Day 477)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	10	45.5	1	10.0	100.00	NE	NE	NE
Week 76 (Day 533)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	10	45.5	2	20.0	50.00	47.14	-373.54	473.54
Week 84 (Day 589)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	13.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	4.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	22	100.0	22	100.0	84.09	24.92	73.04	95.14
End of Study (LOCF)	USA	22	100.0	22	100.0	84.09	23.84	73.52	94.66
Baseline	Europe (EU)	32	100.0	29	90.6	85.63	18.22	78.70	92.56
Week 4 (Day 29)	Europe (EU)	32	100.0	25	78.1	91.33	16.75	84.42	98.25
Week 8 (Day 57)	Europe (EU)	29	90.6	25	86.2	90.00	15.21	83.72	96.28
Week 12 (Day 85)	Europe (EU)	26	81.3	24	92.3	88.89	14.47	82.78	95.00
Week 16 (Day 113)	Europe (EU)	25	78.1	20	80.0	87.50	16.11	79.96	95.04
Week 20 (Day 141)	Europe (EU)	23	71.9	22	95.7	88.64	18.82	80.29	96.98
Week 24 (Day 169)	Europe (EU)	21	65.6	20	95.2	86.67	19.94	77.33	96.00
Week 28 (Day 197)	Europe (EU)	20	62.5	20	100.0	90.00	13.68	83.60	96.40
Week 32 (Day 225)	Europe (EU)	18	56.3	16	88.9	93.75	10.32	88.25	99.25
Week 36 (Day 253)	Europe (EU)	18	56.3	17	94.4	90.20	15.66	82.15	98.25
Week 40 (Day 281)	Europe (EU)	17	53.1	16	94.1	92.71	13.57	85.48	99.94
Week 44 (Day 309)	Europe (EU)	17	53.1	14	82.4	94.05	15.48	85.11	102.99

Week 48 (Day 337)	Europe (EU)	14	43.8	10	71.4	93.33	11.65	85.00	101.67
Week 52 (Day 365)	Europe (EU)	13	40.6	3	23.1	100.00	0.00	NE	NE
Week 56 (Day 393)	Europe (EU)	11	34.4	5	45.5	90.00	14.91	71.49	108.51
Week 60 (Day 421)	Europe (EU)	11	34.4	1	9.1	100.00	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	11	34.4	5	45.5	90.00	14.91	71.49	108.51
Week 68 (Day 477)	Europe (EU)	10	31.3	1	10.0	83.33	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	10	31.3	3	30.0	100.00	0.00	NE	NE
Week 76 (Day 533)	Europe (EU)	8	25.0	2	25.0	100.00	0.00	NE	NE
Week 80 (Day 561)	Europe (EU)	8	25.0	4	50.0	87.50	15.96	62.11	112.89
Week 84 (Day 589)	Europe (EU)	6	18.8	1	16.7	100.00	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	9.4	2	66.7	100.00	0.00	NE	NE
Cycle 12 (LOCF)	Europe (EU)	32	100.0	31	96.9	86.56	18.47	79.78	93.33
End of Study (LOCF)	Europe (EU)	32	100.0	31	96.9	84.41	18.73	77.54	91.28
Baseline	Asia (AS)	59	100.0	57	96.6	85.96	20.60	80.50	91.43
Week 4 (Day 29)	Asia (AS)	59	100.0	52	88.1	89.42	18.38	84.30	94.54
Week 8 (Day 57)	Asia (AS)	52	88.1	49	94.2	92.18	15.99	87.58	96.77
Week 12 (Day 85)	Asia (AS)	51	86.4	47	92.2	89.01	16.40	84.19	93.82
Week 16 (Day 113)	Asia (AS)	51	86.4	48	94.1	88.19	16.47	83.41	92.98
Week 20 (Day 141)	Asia (AS)	47	79.7	44	93.6	87.50	19.06	81.70	93.30
Week 24 (Day 169)	Asia (AS)	44	74.6	39	88.6	90.60	13.68	86.16	95.03
Week 28 (Day 197)	Asia (AS)	39	66.1	37	94.9	89.64	18.15	83.59	95.69
Week 32 (Day 225)	Asia (AS)	38	64.4	34	89.5	86.27	19.01	79.64	92.91
Week 36 (Day 253)	Asia (AS)	38	64.4	35	92.1	87.14	21.42	79.78	94.50
Week 40 (Day 281)	Asia (AS)	36	61.0	32	88.9	87.50	19.40	80.51	94.49
Week 44 (Day 309)	Asia (AS)	34	57.6	33	97.1	86.36	21.43	78.76	93.96
Week 48 (Day 337)	Asia (AS)	31	52.5	13	41.9	83.33	27.22	66.89	99.78
Week 52 (Day 365)	Asia (AS)	20	33.9	4	20.0	95.83	8.33	82.57	109.09
Week 56 (Day 393)	Asia (AS)	14	23.7	1	7.1	83.33	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	10.2	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	8.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	3.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	59	100.0	58	98.3	85.06	20.64	79.63	90.48
End of Study (LOCF)	Asia (AS)	59	100.0	58	98.3	84.77	20.78	79.31	90.23
Race/ethnicity									
Baseline	Asian	61	100.0	58	95.1	85.92	20.42	80.55	91.29
Week 4 (Day 29)	Asian	61	100.0	52	85.2	89.42	18.38	84.30	94.54
Week 8 (Day 57)	Asian	53	86.9	49	92.5	92.18	15.99	87.58	96.77
Week 12 (Day 85)	Asian	52	85.2	48	92.3	88.89	16.25	84.17	93.61
Week 16 (Day 113)	Asian	52	85.2	49	94.2	88.10	16.32	83.41	92.78
Week 20 (Day 141)	Asian	48	78.7	45	93.8	86.67	19.66	80.76	92.57
Week 24 (Day 169)	Asian	44	72.1	39	88.6	90.60	13.68	86.16	95.03
Week 28 (Day 197)	Asian	39	63.9	37	94.9	89.64	18.15	83.59	95.69
Week 32 (Day 225)	Asian	38	62.3	34	89.5	86.27	19.01	79.64	92.91
Week 36 (Day 253)	Asian	38	62.3	35	92.1	87.14	21.42	79.78	94.50
Week 40 (Day 281)	Asian	36	59.0	32	88.9	87.50	19.40	80.51	94.49
Week 44 (Day 309)	Asian	34	55.7	33	97.1	86.36	21.43	78.76	93.96
Week 48 (Day 337)	Asian	31	50.8	13	41.9	83.33	27.22	66.89	99.78
Week 52 (Day 365)	Asian	20	32.8	4	20.0	95.83	8.33	82.57	109.09
Week 56 (Day 393)	Asian	14	23.0	1	7.1	83.33	NE	NE	NE
Week 60 (Day 421)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	9.8	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	8.2	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	3.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	61	100.0	59	96.7	84.46	20.96	79.00	89.93
End of Study (LOCF)	Asian	61	100.0	59	96.7	84.18	21.09	78.69	89.68
Baseline	Non-Asian	45	100.0	44	97.8	89.02	15.23	84.39	93.64
Week 4 (Day 29)	Non-Asian	45	100.0	39	86.7	89.74	18.58	83.72	95.77
Week 8 (Day 57)	Non-Asian	42	93.3	38	90.5	89.91	15.27	84.89	94.93
Week 12 (Day 85)	Non-Asian	39	86.7	37	94.9	90.54	14.46	85.72	95.36
Week 16 (Day 113)	Non-Asian	37	82.2	34	91.9	87.25	16.95	81.34	93.17
Week 20 (Day 141)	Non-Asian	36	80.0	34	94.4	88.24	19.04	81.59	94.88
Week 24 (Day 169)	Non-Asian	32	71.1	31	96.9	86.56	18.47	79.78	93.33
Week 28 (Day 197)	Non-Asian	30	66.7	28	93.3	89.88	15.27	83.96	95.80
Week 32 (Day 225)	Non-Asian	28	62.2	25	89.3	87.33	24.19	77.35	97.32
Week 36 (Day 253)	Non-Asian	28	62.2	26	92.9	87.82	21.37	79.19	96.45
Week 40 (Day 281)	Non-Asian	26	57.8	23	88.5	88.41	21.58	79.08	97.74
Week 44 (Day 309)	Non-Asian	25	55.6	21	84.0	88.10	25.90	76.31	99.88
Week 48 (Day 337)	Non-Asian	23	51.1	17	73.9	86.27	21.44	75.25	97.30
Week 52 (Day 365)	Non-Asian	21	46.7	3	14.3	100.00	0.00	NE	NE
Week 56 (Day 393)	Non-Asian	19	42.2	10	52.6	88.33	22.29	72.39	104.28
Week 60 (Day 421)	Non-Asian	19	42.2	1	5.3	100.00	NE	NE	NE
Week 64 (Day 449)	Non-Asian	18	40.0	7	38.9	92.86	13.11	80.73	104.98
Week 68 (Day 477)	Non-Asian	17	37.8	1	5.9	83.33	NE	NE	NE
Week 72 (Day 505)	Non-Asian	17	37.8	3	17.6	100.00	0.00	NE	NE
Week 76 (Day 533)	Non-Asian	15	33.3	2	13.3	100.00	0.00	NE	NE
Week 80 (Day 561)	Non-Asian	15	33.3	5	33.3	76.67	34.56	33.75	119.58
Week 84 (Day 589)	Non-Asian	10	22.2	1	10.0	100.00	NE	NE	NE
Week 88 (Day 617)	Non-Asian	7	15.6	2	28.6	100.00	0.00	NE	NE
Week 92 (Day 645)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	45	100.0	45	100.0	85.56	21.50	79.10	92.01

End of Study (LOCF)	Non-Asian	45	100.0	45	100.0	84.07	21.01	77.76	90.39
Baseline	Unknown	7	100.0	6	85.7	80.56	24.53	54.81	106.30
Week 4 (Day 29)	Unknown	7	100.0	4	57.1	70.83	25.00	31.05	110.61
Week 8 (Day 57)	Unknown	6	85.7	5	83.3	90.00	14.91	71.49	108.51
Week 12 (Day 85)	Unknown	6	85.7	5	83.3	80.00	13.94	62.69	97.31
Week 16 (Day 113)	Unknown	6	85.7	2	33.3	91.67	11.79	-14.22	197.55
Week 20 (Day 141)	Unknown	5	71.4	4	80.0	95.83	8.33	82.57	109.09
Week 24 (Day 169)	Unknown	5	71.4	3	60.0	88.89	19.25	41.08	136.70
Week 28 (Day 197)	Unknown	5	71.4	4	80.0	87.50	15.96	62.11	112.89
Week 32 (Day 225)	Unknown	5	71.4	4	80.0	95.83	8.33	82.57	109.09
Week 36 (Day 253)	Unknown	5	71.4	4	80.0	79.17	25.00	39.39	118.95
Week 40 (Day 281)	Unknown	5	71.4	4	80.0	87.50	15.96	62.11	112.89
Week 44 (Day 309)	Unknown	5	71.4	4	80.0	91.67	16.67	65.15	118.19
Week 48 (Day 337)	Unknown	4	57.1	3	75.0	94.44	9.62	70.54	118.35
Week 52 (Day 365)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	4	57.1	1	25.0	66.67	NE	NE	NE
Week 60 (Day 421)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	4	57.1	2	50.0	91.67	11.79	-14.22	197.55
Week 68 (Day 477)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	3	42.9	1	33.3	100.00	NE	NE	NE
Week 76 (Day 533)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	3	42.9	1	33.3	66.67	NE	NE	NE
Week 84 (Day 589)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	14.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	7	100.0	7	100.0	90.48	16.27	75.43	105.52
End of Study (LOCF)	Unknown	7	100.0	7	100.0	90.48	16.27	75.43	105.52
Number of prior antineoplastic systemic therapy lines I									
Baseline	1	60	100.0	57	95.0	86.26	17.85	81.52	90.99

Week 4 (Day 29)	1	60	100.0	50	83.3	90.00	17.82	84.94	95.06
Week 8 (Day 57)	1	54	90.0	49	90.7	92.52	13.63	88.60	96.43
Week 12 (Day 85)	1	52	86.7	48	92.3	88.54	14.24	84.41	92.68
Week 16 (Day 113)	1	51	85.0	46	90.2	87.32	15.39	82.75	91.89
Week 20 (Day 141)	1	48	80.0	43	89.6	87.98	17.94	82.46	93.50
Week 24 (Day 169)	1	43	71.7	39	90.7	88.03	17.08	82.50	93.57
Week 28 (Day 197)	1	38	63.3	34	89.5	89.22	14.73	84.08	94.35
Week 32 (Day 225)	1	35	58.3	29	82.9	87.93	20.84	80.00	95.86
Week 36 (Day 253)	1	35	58.3	31	88.6	89.25	19.03	82.27	96.23
Week 40 (Day 281)	1	32	53.3	27	84.4	89.51	19.14	81.93	97.08
Week 44 (Day 309)	1	32	53.3	27	84.4	90.12	21.81	81.50	98.75
Week 48 (Day 337)	1	27	45.0	16	59.3	86.46	19.45	76.09	96.82
Week 52 (Day 365)	1	23	38.3	5	21.7	96.67	7.45	87.41	105.92
Week 56 (Day 393)	1	16	26.7	4	25.0	95.83	8.33	82.57	109.09
Week 60 (Day 421)	1	14	23.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	13	21.7	4	30.8	87.50	15.96	62.11	112.89
Week 68 (Day 477)	1	12	20.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	12	20.0	1	8.3	100.00	NE	NE	NE
Week 76 (Day 533)	1	11	18.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	11	18.3	2	18.2	83.33	0.00	NE	NE
Week 84 (Day 589)	1	9	15.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	1	8	13.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	1	3	5.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	1	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	60	100.0	58	96.7	86.49	19.86	81.27	91.72
End of Study (LOCF)	1	60	100.0	58	96.7	85.34	17.96	80.62	90.07
Baseline	>= 2	53	100.0	51	96.2	87.58	19.68	82.05	93.12
Week 4 (Day 29)	>= 2	53	100.0	45	84.9	87.41	20.15	81.35	93.46
Week 8 (Day 57)	>= 2	47	88.7	43	91.5	89.53	17.45	84.16	94.91
Week 12 (Day 85)	>= 2	45	84.9	42	93.3	89.68	16.85	84.43	94.93
Week 16 (Day 113)	>= 2	44	83.0	39	88.6	88.46	17.59	82.76	94.16

Week 20 (Day 141)	>= 2	41	77.4	40	97.6	87.50	20.24	81.03	93.97
Week 24 (Day 169)	>= 2	38	71.7	34	89.5	89.71	14.80	84.54	94.87
Week 28 (Day 197)	>= 2	36	67.9	35	97.2	90.00	18.61	83.61	96.39
Week 32 (Day 225)	>= 2	36	67.9	34	94.4	86.76	20.83	79.50	94.03
Week 36 (Day 253)	>= 2	36	67.9	34	94.4	84.80	23.34	76.66	92.95
Week 40 (Day 281)	>= 2	35	66.0	32	91.4	86.46	20.49	79.07	93.85
Week 44 (Day 309)	>= 2	32	60.4	31	96.9	84.95	23.32	76.39	93.50
Week 48 (Day 337)	>= 2	31	58.5	17	54.8	85.29	26.27	71.78	98.80
Week 52 (Day 365)	>= 2	22	41.5	2	9.1	100.00	0.00	NE	NE
Week 56 (Day 393)	>= 2	21	39.6	8	38.1	81.25	24.30	60.94	101.56
Week 60 (Day 421)	>= 2	18	34.0	1	5.6	100.00	NE	NE	NE
Week 64 (Day 449)	>= 2	18	34.0	5	27.8	96.67	7.45	87.41	105.92
Week 68 (Day 477)	>= 2	16	30.2	1	6.3	83.33	NE	NE	NE
Week 72 (Day 505)	>= 2	16	30.2	3	18.8	100.00	0.00	NE	NE
Week 76 (Day 533)	>= 2	14	26.4	2	14.3	100.00	0.00	NE	NE
Week 80 (Day 561)	>= 2	14	26.4	4	28.6	70.83	39.38	8.17	133.50
Week 84 (Day 589)	>= 2	9	17.0	1	11.1	100.00	NE	NE	NE
Week 88 (Day 617)	>= 2	6	11.3	2	33.3	100.00	0.00	NE	NE
Week 92 (Day 645)	>= 2	2	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 2	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 2	53	100.0	53	100.0	83.96	21.92	77.92	90.00
End of Study (LOCF)	>= 2	53	100.0	53	100.0	83.65	23.45	77.18	90.11

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TP_QSC30CF_SG.xls
27OCT2021 7:23

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Cognitive functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	47	43.5	34.6	52.9
	Cycle 12 (LOCF)	n/a	108	95.6	22	20.4	13.9	28.9
	End of Study (LOCF)	n/a	108	95.6	25	23.1	16.2	31.9
Sex	All visits	Female	67	59.3	26	38.8	28.0	50.8
		Male	41	36.3	21	51.2	36.5	65.7
	Cycle 12 (LOCF)	Female	67	59.3	12	17.9	10.6	28.7
		Male	41	36.3	10	24.4	13.8	39.3
	End of Study (LOCF)	Female	67	59.3	14	20.9	12.9	32.1
		Male	41	36.3	11	26.8	15.7	41.9
Age	All visits	< 65	73	64.6	28	38.4	28.1	49.8
		>= 65	35	31.0	19	54.3	38.2	69.5
	Cycle 12 (LOCF)	< 65	73	64.6	12	16.4	9.7	26.6
		>= 65	35	31.0	10	28.6	16.3	45.1
	End of Study (LOCF)	< 65	73	64.6	15	20.5	12.9	31.2
		>= 65	35	31.0	10	28.6	16.3	45.1
ECOG performance status	All visits	0	31	27.4	14	45.2	29.2	62.2
		1	76	67.3	33	43.4	32.9	54.6
		Missing	1	0.9	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	31	27.4	6	19.4	9.2	36.3
		1	76	67.3	16	21.1	13.4	31.5
		Missing	1	0.9	0	0.0	0.0	79.3
	End of Study (LOCF)	0	31	27.4	8	25.8	13.7	43.2
		1	76	67.3	17	22.4	14.5	32.9
		Missing	1	0.9	0	0.0	0.0	79.3
Geographic region	All visits	USA	22	19.5	10	45.5	26.9	65.3
		Europe (EU)	29	25.7	12	41.4	25.5	59.3
		Asia (AS)	57	50.4	25	43.9	31.8	56.7
	Cycle 12 (LOCF)	USA	22	19.5	7	31.8	16.4	52.7
		Europe (EU)	29	25.7	3	10.3	3.6	26.4
		Asia (AS)	57	50.4	12	21.1	12.5	33.3
	End of Study (LOCF)	USA	22	19.5	6	27.3	13.2	48.2
		Europe (EU)	29	25.7	6	20.7	9.8	38.4
		Asia (AS)	57	50.4	13	22.8	13.8	35.2
Race/ethnicity	All visits	Asian	58	51.3	26	44.8	32.7	57.5
		Non-Asian	44	38.9	20	45.5	31.7	59.9
		Unknown	6	5.3	1	16.7	3.0	56.4
	Cycle 12 (LOCF)	Asian	58	51.3	13	22.4	13.6	34.7

		Non-Asian	44	38.9	9	20.5	11.2	34.5
		Unknown	6	5.3	0	0.0	0.0	39.0
	End of Study (LOCF)	Asian	58	51.3	14	24.1	15.0	36.5
		Non-Asian	44	38.9	11	25.0	14.6	39.4
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	26	45.6	33.4	58.4
		>= 2	51	45.1	21	41.2	28.8	54.8
	Cycle 12 (LOCF)	1	57	50.4	9	15.8	8.5	27.4
		>= 2	51	45.1	13	25.5	15.5	38.9
	End of Study (LOCF)	1	57	50.4	12	21.1	12.5	33.3
		>= 2	51	45.1	13	25.5	15.5	38.9

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30CF_W10_SG.xls
15OCT2021 13:30

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Cognitive functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

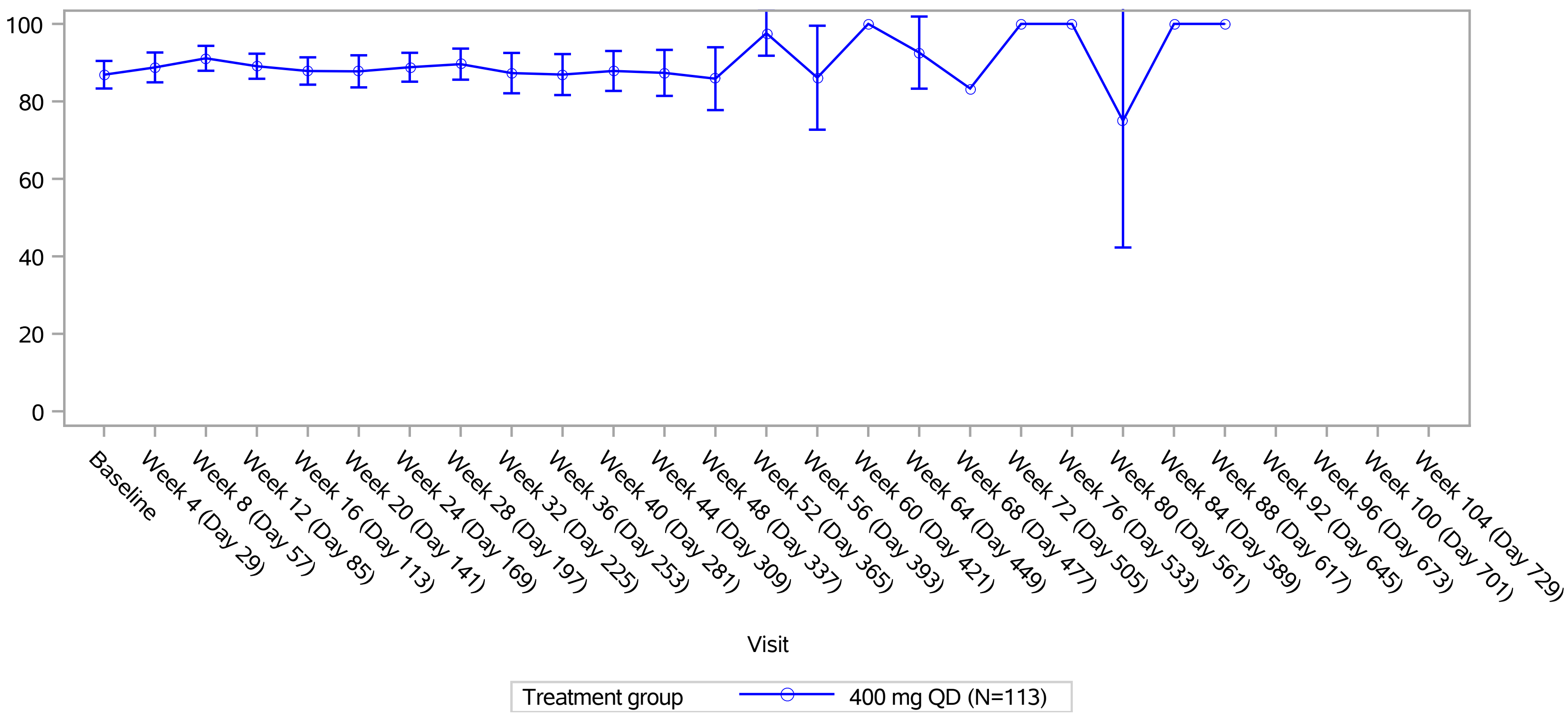
			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	47	43.5	34.6	52.9
	Cycle 12 (LOCF)	n/a	108	95.6	22	20.4	13.9	28.9
	End of Study (LOCF)	n/a	108	95.6	25	23.1	16.2	31.9
Sex	All visits	Female	67	59.3	26	38.8	28.0	50.8
		Male	41	36.3	21	51.2	36.5	65.7
	Cycle 12 (LOCF)	Female	67	59.3	12	17.9	10.6	28.7
		Male	41	36.3	10	24.4	13.8	39.3
	End of Study (LOCF)	Female	67	59.3	14	20.9	12.9	32.1
		Male	41	36.3	11	26.8	15.7	41.9
Age	All visits	< 65	73	64.6	28	38.4	28.1	49.8
		>= 65	35	31.0	19	54.3	38.2	69.5
	Cycle 12 (LOCF)	< 65	73	64.6	12	16.4	9.7	26.6
		>= 65	35	31.0	10	28.6	16.3	45.1
	End of Study (LOCF)	< 65	73	64.6	15	20.5	12.9	31.2
		>= 65	35	31.0	10	28.6	16.3	45.1
ECOG performance status	All visits	0	31	27.4	14	45.2	29.2	62.2
		1	76	67.3	33	43.4	32.9	54.6
		Missing	1	0.9	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	31	27.4	6	19.4	9.2	36.3
		1	76	67.3	16	21.1	13.4	31.5
		Missing	1	0.9	0	0.0	0.0	79.3
	End of Study (LOCF)	0	31	27.4	8	25.8	13.7	43.2
		1	76	67.3	17	22.4	14.5	32.9
		Missing	1	0.9	0	0.0	0.0	79.3
Geographic region	All visits	USA	22	19.5	10	45.5	26.9	65.3
		Europe (EU)	29	25.7	12	41.4	25.5	59.3
		Asia (AS)	57	50.4	25	43.9	31.8	56.7
	Cycle 12 (LOCF)	USA	22	19.5	7	31.8	16.4	52.7
		Europe (EU)	29	25.7	3	10.3	3.6	26.4
		Asia (AS)	57	50.4	12	21.1	12.5	33.3
	End of Study (LOCF)	USA	22	19.5	6	27.3	13.2	48.2
		Europe (EU)	29	25.7	6	20.7	9.8	38.4
		Asia (AS)	57	50.4	13	22.8	13.8	35.2
Race/ethnicity	All visits	Asian	58	51.3	26	44.8	32.7	57.5
		Non-Asian	44	38.9	20	45.5	31.7	59.9
		Unknown	6	5.3	1	16.7	3.0	56.4
	Cycle 12 (LOCF)	Asian	58	51.3	13	22.4	13.6	34.7

		Non-Asian	44	38.9	9	20.5	11.2	34.5
		Unknown	6	5.3	0	0.0	0.0	39.0
	End of Study (LOCF)	Asian	58	51.3	14	24.1	15.0	36.5
		Non-Asian	44	38.9	11	25.0	14.6	39.4
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	26	45.6	33.4	58.4
		>= 2	51	45.1	21	41.2	28.8	54.8
	Cycle 12 (LOCF)	1	57	50.4	9	15.8	8.5	27.4
		>= 2	51	45.1	13	25.5	15.5	38.9
	End of Study (LOCF)	1	57	50.4	12	21.1	12.5	33.3
		>= 2	51	45.1	13	25.5	15.5	38.9

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30CF_W15_SG.xls
15OCT2021 13:20

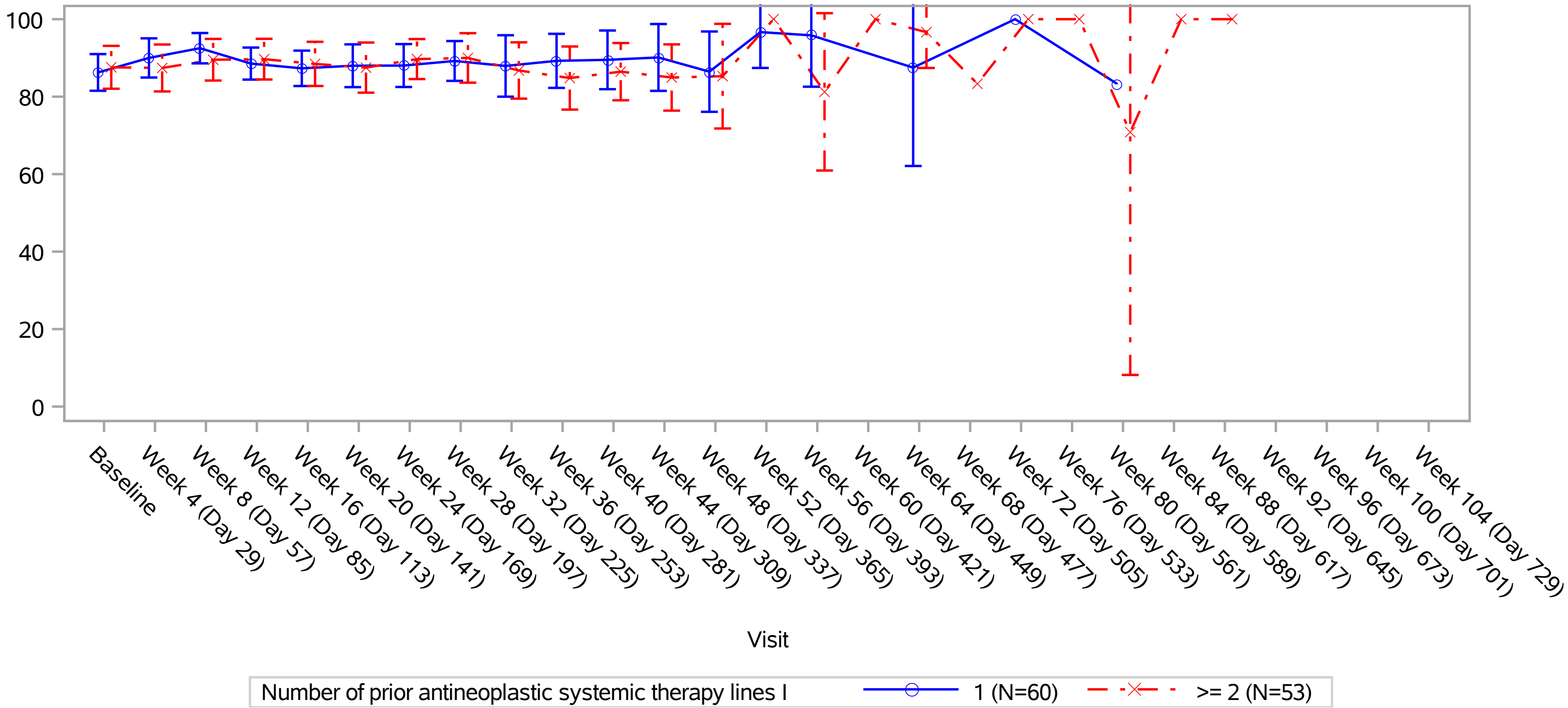
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Cognitive functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30CF.pdf
15OCT2021 17:13

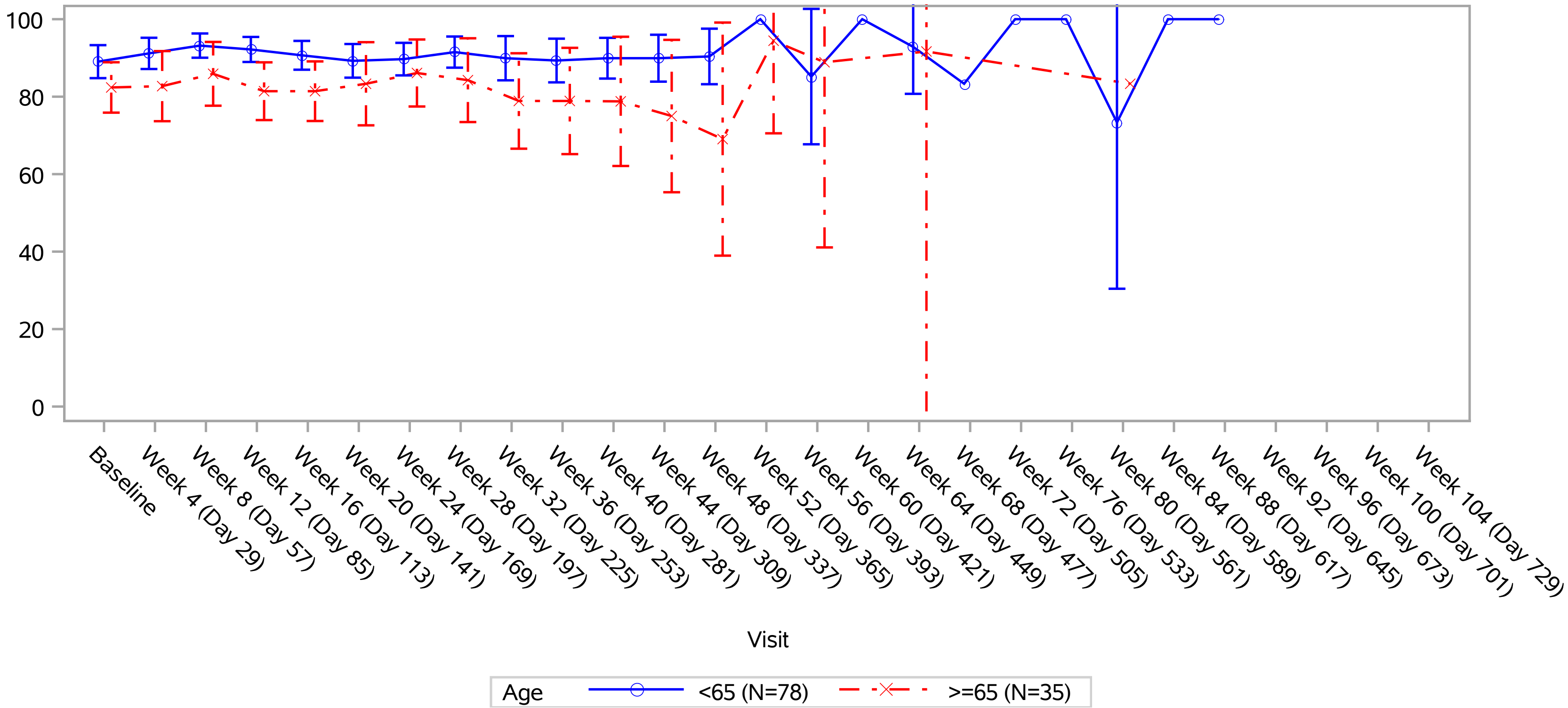
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Cognitive functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30CF_PRTHL1.pdf
15OCT2021 20:04

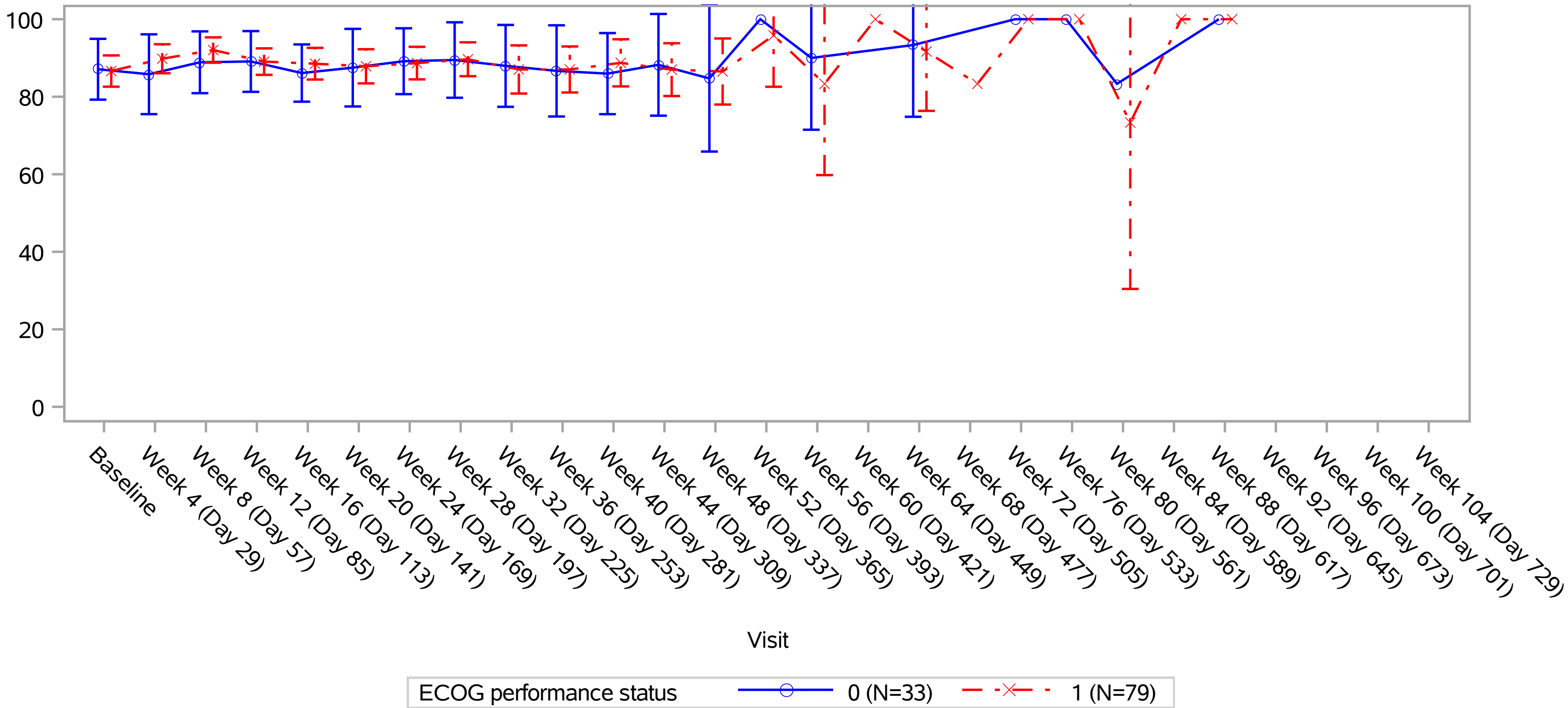
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Cognitive functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30CF_SGAGE65.pdf
15OCT2021 17:42

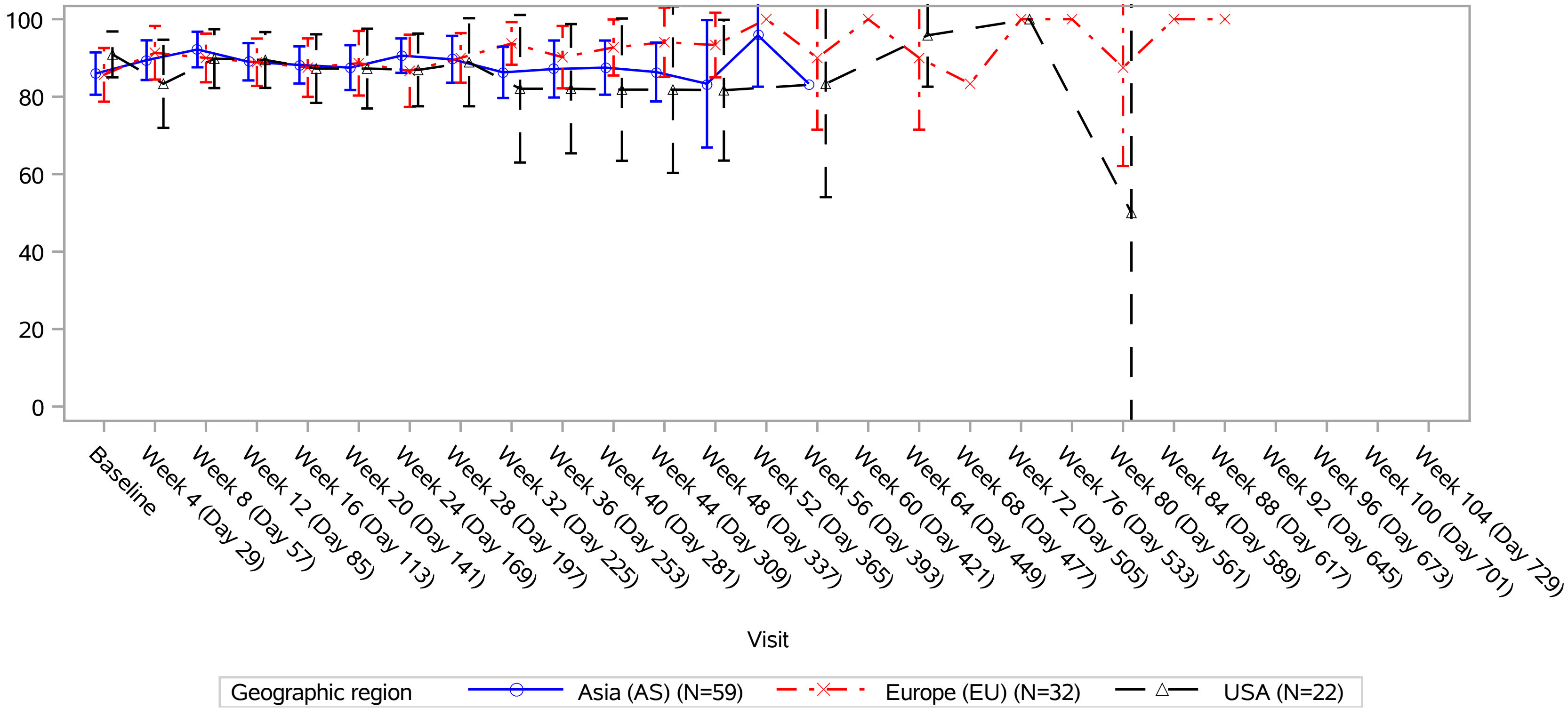
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Cognitive functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30CF_SGECOG.pdf
15OCT2021 18:12

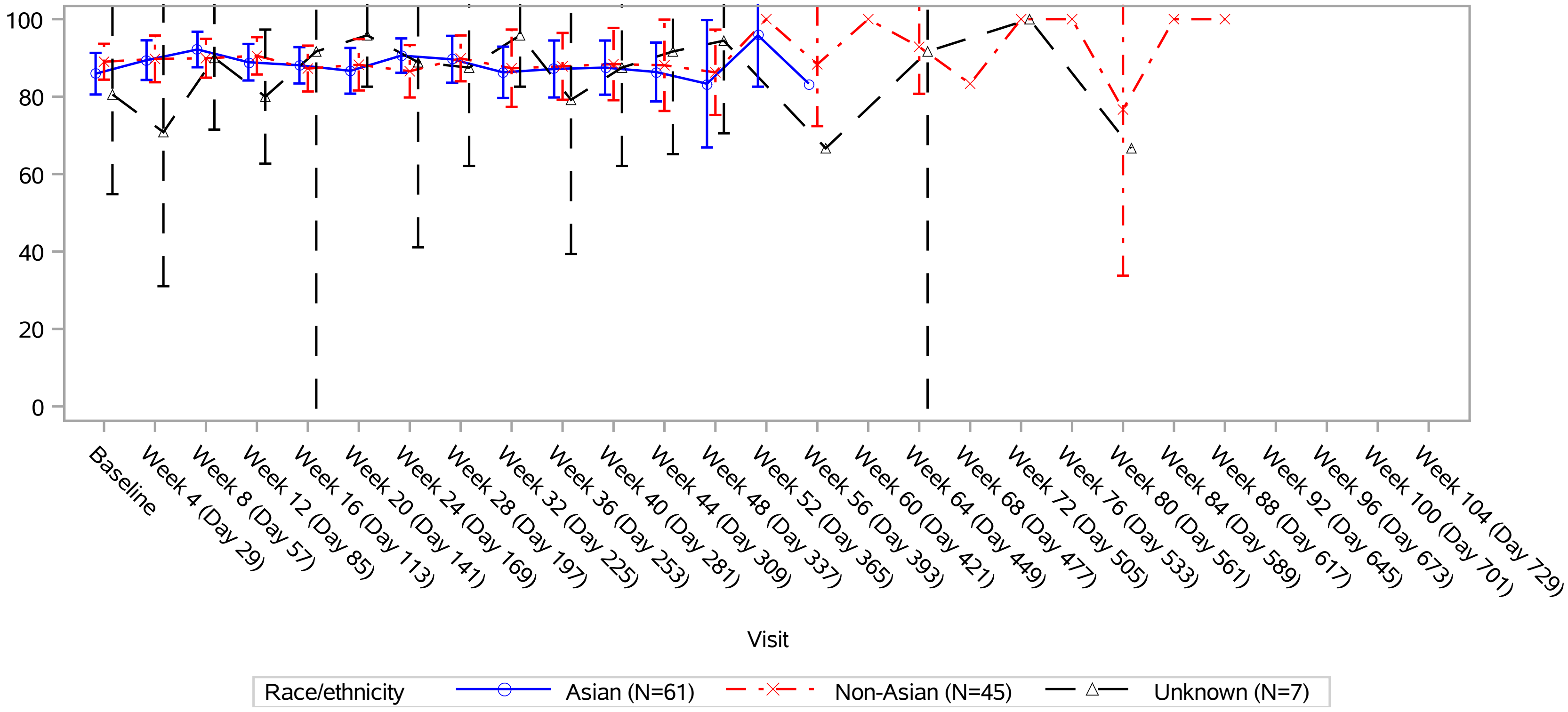
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Cognitive functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30CF_SGGEO.pdf
15OCT2021 18:43

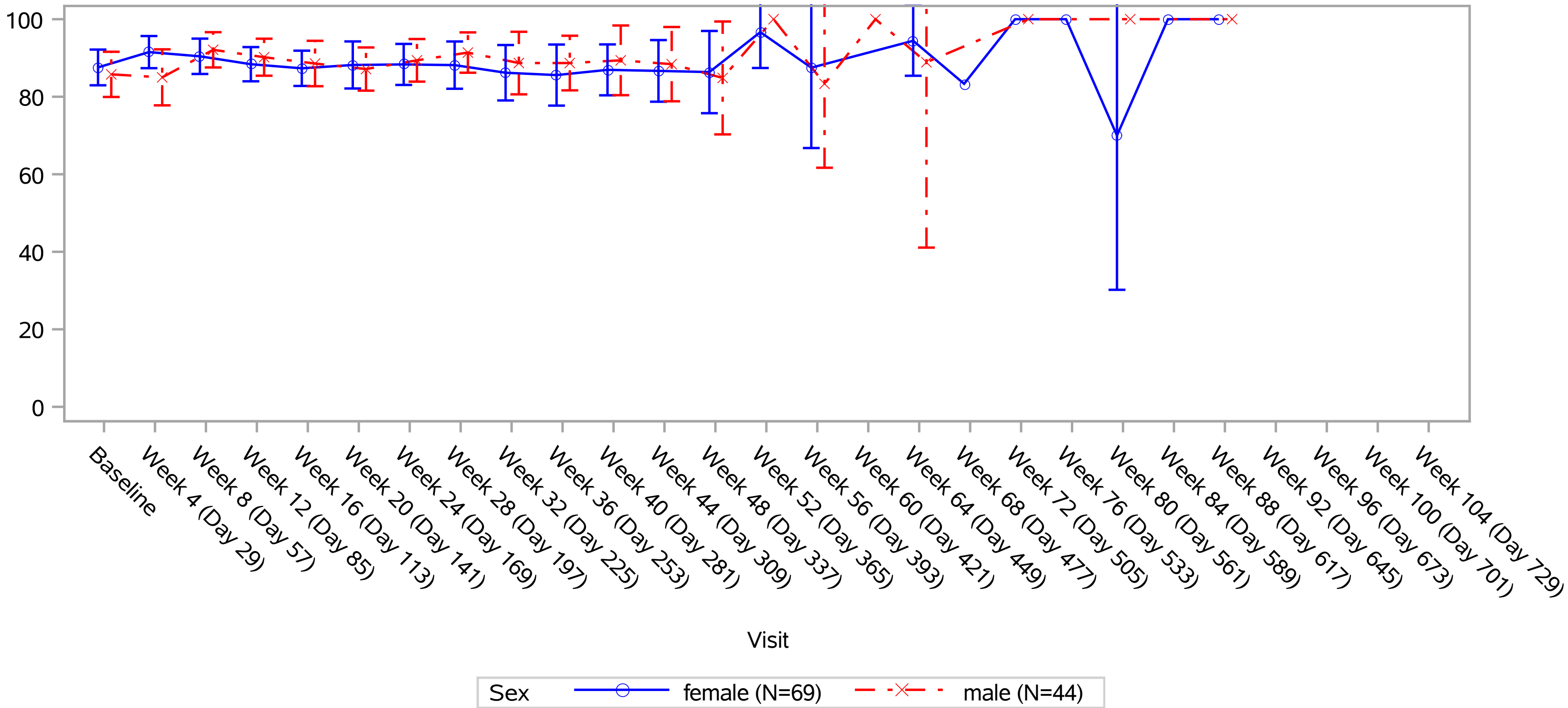
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Cognitive functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30CF_SGRE.pdf
15OCT2021 19:13

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Cognitive functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30CF_SGSEX.pdf
15OCT2021 19:44

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Constipation
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=113)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	113	100.0	108	95.6	15.74	24.73	11.02	20.46
Week 4 (Day 29)	n/a	113	100.0	95	84.1	27.37	31.13	21.03	33.71
Week 8 (Day 57)	n/a	101	89.4	92	91.1	20.29	27.94	14.50	26.08
Week 12 (Day 85)	n/a	97	85.8	90	92.8	18.89	22.93	14.09	23.69
Week 16 (Day 113)	n/a	95	84.1	85	89.5	18.04	23.32	13.01	23.07
Week 20 (Day 141)	n/a	89	78.8	83	93.3	17.67	25.15	12.18	23.16
Week 24 (Day 169)	n/a	81	71.7	73	90.1	14.61	22.90	9.27	19.95
Week 28 (Day 197)	n/a	74	65.5	69	93.2	20.77	28.06	14.03	27.51
Week 32 (Day 225)	n/a	71	62.8	63	88.7	15.34	23.05	9.54	21.15
Week 36 (Day 253)	n/a	71	62.8	65	91.5	18.46	26.37	11.93	25.00
Week 40 (Day 281)	n/a	67	59.3	59	88.1	15.82	27.23	8.72	22.92
Week 44 (Day 309)	n/a	64	56.6	58	90.6	16.67	30.11	8.75	24.58
Week 48 (Day 337)	n/a	58	51.3	33	56.9	11.11	24.53	2.41	19.81
Week 52 (Day 365)	n/a	45	39.8	7	15.6	14.29	17.82	-2.19	30.76
Week 56 (Day 393)	n/a	37	32.7	12	32.4	19.44	26.43	2.65	36.24
Week 60 (Day 421)	n/a	32	28.3	1	3.1	0.00	NE	NE	NE
Week 64 (Day 449)	n/a	31	27.4	9	29.0	14.81	24.22	-3.80	33.43
Week 68 (Day 477)	n/a	28	24.8	1	3.6	33.33	NE	NE	NE
Week 72 (Day 505)	n/a	28	24.8	4	14.3	16.67	33.33	-36.37	69.71
Week 76 (Day 533)	n/a	25	22.1	2	8.0	0.00	0.00	NE	NE
Week 80 (Day 561)	n/a	25	22.1	6	24.0	5.56	13.61	-8.73	19.84
Week 84 (Day 589)	n/a	18	15.9	1	5.6	0.00	NE	NE	NE
Week 88 (Day 617)	n/a	14	12.4	2	14.3	0.00	0.00	NE	NE
Week 92 (Day 645)	n/a	7	6.2	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	5.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	2.7	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	113	100.0	111	98.2	18.62	29.02	13.16	24.08
End of Study (LOCF)	n/a	113	100.0	111	98.2	17.12	26.92	12.05	22.18
Sex									
Baseline	Female	69	100.0	67	97.1	15.42	26.16	9.04	21.80
Week 4 (Day 29)	Female	69	100.0	55	79.7	34.55	33.31	25.54	43.55
Week 8 (Day 57)	Female	63	91.3	54	85.7	21.60	31.16	13.10	30.11
Week 12 (Day 85)	Female	60	87.0	56	93.3	21.43	24.97	14.74	28.11
Week 16 (Day 113)	Female	58	84.1	50	86.2	20.67	25.99	13.28	28.05
Week 20 (Day 141)	Female	53	76.8	48	90.6	21.53	29.57	12.94	30.11
Week 24 (Day 169)	Female	47	68.1	40	85.1	14.17	24.91	6.20	22.13
Week 28 (Day 197)	Female	42	60.9	38	90.5	21.05	28.39	11.72	30.38
Week 32 (Day 225)	Female	42	60.9	35	83.3	17.14	24.75	8.64	25.64
Week 36 (Day 253)	Female	42	60.9	37	88.1	20.72	28.71	11.15	30.29
Week 40 (Day 281)	Female	41	59.4	37	90.2	16.22	30.04	6.20	26.23
Week 44 (Day 309)	Female	41	59.4	35	85.4	16.19	30.65	5.66	26.72
Week 48 (Day 337)	Female	37	53.6	22	59.5	15.15	28.60	2.47	27.83
Week 52 (Day 365)	Female	29	42.0	5	17.2	20.00	18.26	-2.67	42.67
Week 56 (Day 393)	Female	24	34.8	8	33.3	16.67	25.20	-4.40	37.73
Week 60 (Day 421)	Female	22	31.9	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Female	22	31.9	6	27.3	22.22	27.22	-6.34	50.78
Week 68 (Day 477)	Female	20	29.0	1	5.0	33.33	NE	NE	NE
Week 72 (Day 505)	Female	20	29.0	2	10.0	33.33	47.14	-390.21	456.87
Week 76 (Day 533)	Female	18	26.1	2	11.1	0.00	0.00	NE	NE
Week 80 (Day 561)	Female	18	26.1	5	27.8	6.67	14.91	-11.84	25.18
Week 84 (Day 589)	Female	12	17.4	1	8.3	0.00	NE	NE	NE
Week 88 (Day 617)	Female	9	13.0	1	11.1	0.00	NE	NE	NE
Week 92 (Day 645)	Female	6	8.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	7.2	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	2.9	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	1.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	69	100.0	68	98.6	18.63	30.68	11.20	26.05
End of Study (LOCF)	Female	69	100.0	68	98.6	17.65	27.90	10.89	24.40
Baseline	Male	44	100.0	41	93.2	16.26	22.51	9.15	23.37
Week 4 (Day 29)	Male	44	100.0	40	90.9	17.50	25.02	9.50	25.50
Week 8 (Day 57)	Male	38	86.4	38	100.0	18.42	22.86	10.91	25.93
Week 12 (Day 85)	Male	37	84.1	34	91.9	14.71	18.70	8.18	21.23
Week 16 (Day 113)	Male	37	84.1	35	94.6	14.29	18.59	7.90	20.67
Week 20 (Day 141)	Male	36	81.8	35	97.2	12.38	16.34	6.77	17.99
Week 24 (Day 169)	Male	34	77.3	33	97.1	15.15	20.57	7.86	22.44
Week 28 (Day 197)	Male	32	72.7	31	96.9	20.43	28.12	10.11	30.75
Week 32 (Day 225)	Male	29	65.9	28	96.6	13.10	20.96	4.97	21.22
Week 36 (Day 253)	Male	29	65.9	28	96.6	15.48	23.10	6.52	24.43
Week 40 (Day 281)	Male	26	59.1	22	84.6	15.15	22.37	5.23	25.07
Week 44 (Day 309)	Male	23	52.3	23	100.0	17.39	29.93	4.45	30.33
Week 48 (Day 337)	Male	21	47.7	11	52.4	3.03	10.05	-3.72	9.78
Week 52 (Day 365)	Male	16	36.4	2	12.5	0.00	0.00	NE	NE
Week 56 (Day 393)	Male	13	29.5	4	30.8	25.00	31.91	-25.78	75.78
Week 60 (Day 421)	Male	10	22.7	1	10.0	0.00	NE	NE	NE
Week 64 (Day 449)	Male	9	20.5	3	33.3	0.00	0.00	NE	NE
Week 68 (Day 477)	Male	8	18.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	8	18.2	2	25.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Male	7	15.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	7	15.9	1	14.3	0.00	NE	NE	NE
Week 84 (Day 589)	Male	6	13.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	5	11.4	1	20.0	0.00	NE	NE	NE
Week 92 (Day 645)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	44	100.0	43	97.7	18.60	26.53	10.44	26.77
End of Study (LOCF)	Male	44	100.0	43	97.7	16.28	25.59	8.41	24.15
Age									

Baseline	< 65	78	100.0	73	93.6	14.16	25.41	8.23	20.08
Week 4 (Day 29)	< 65	78	100.0	68	87.2	26.96	31.15	19.42	34.50
Week 8 (Day 57)	< 65	73	93.6	66	90.4	20.20	29.16	13.03	27.37
Week 12 (Day 85)	< 65	71	91.0	64	90.1	17.19	21.41	11.84	22.53
Week 16 (Day 113)	< 65	69	88.5	59	85.5	15.25	19.89	10.07	20.44
Week 20 (Day 141)	< 65	65	83.3	62	95.4	16.13	23.17	10.24	22.01
Week 24 (Day 169)	< 65	59	75.6	55	93.2	14.55	23.80	8.11	20.98
Week 28 (Day 197)	< 65	55	70.5	51	92.7	19.61	25.97	12.30	26.91
Week 32 (Day 225)	< 65	53	67.9	48	90.6	11.81	18.82	6.34	17.27
Week 36 (Day 253)	< 65	53	67.9	50	94.3	17.33	24.50	10.37	24.30
Week 40 (Day 281)	< 65	52	66.7	48	92.3	14.58	25.64	7.14	22.03
Week 44 (Day 309)	< 65	52	66.7	48	92.3	14.58	26.55	6.87	22.29
Week 48 (Day 337)	< 65	47	60.3	26	55.3	8.97	20.13	0.84	17.10
Week 52 (Day 365)	< 65	36	46.2	4	11.1	8.33	16.67	-18.19	34.85
Week 56 (Day 393)	< 65	30	38.5	9	30.0	18.52	24.22	-0.10	37.13
Week 60 (Day 421)	< 65	25	32.1	1	4.0	0.00	NE	NE	NE
Week 64 (Day 449)	< 65	24	30.8	7	29.2	14.29	26.23	-9.97	38.54
Week 68 (Day 477)	< 65	22	28.2	1	4.5	33.33	NE	NE	NE
Week 72 (Day 505)	< 65	22	28.2	4	18.2	16.67	33.33	-36.37	69.71
Week 76 (Day 533)	< 65	21	26.9	2	9.5	0.00	0.00	NE	NE
Week 80 (Day 561)	< 65	21	26.9	5	23.8	6.67	14.91	-11.84	25.18
Week 84 (Day 589)	< 65	15	19.2	1	6.7	0.00	NE	NE	NE
Week 88 (Day 617)	< 65	12	15.4	2	16.7	0.00	0.00	NE	NE
Week 92 (Day 645)	< 65	6	7.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	6.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	78	100.0	76	97.4	17.11	28.02	10.70	23.51
End of Study (LOCF)	< 65	78	100.0	76	97.4	14.04	24.50	8.44	19.63
Baseline	>= 65	35	100.0	35	100.0	19.05	23.27	11.05	27.04
Week 4 (Day 29)	>= 65	35	100.0	27	77.1	28.40	31.63	15.88	40.91
Week 8 (Day 57)	>= 65	28	80.0	26	92.9	20.51	25.08	10.38	30.64
Week 12 (Day 85)	>= 65	26	74.3	26	100.0	23.08	26.28	12.46	33.69

Week 16 (Day 113)	>= 65	26	74.3	26	100.0	24.36	29.15	12.59	36.13
Week 20 (Day 141)	>= 65	24	68.6	21	87.5	22.22	30.43	8.37	36.07
Week 24 (Day 169)	>= 65	22	62.9	18	81.8	14.81	20.52	4.61	25.02
Week 28 (Day 197)	>= 65	19	54.3	18	94.7	24.07	33.93	7.20	40.95
Week 32 (Day 225)	>= 65	18	51.4	15	83.3	26.67	31.37	9.29	44.04
Week 36 (Day 253)	>= 65	18	51.4	15	83.3	22.22	32.53	4.21	40.24
Week 40 (Day 281)	>= 65	15	42.9	11	73.3	21.21	34.23	-1.78	44.21
Week 44 (Day 309)	>= 65	12	34.3	10	83.3	26.67	43.89	-4.73	58.06
Week 48 (Day 337)	>= 65	11	31.4	7	63.6	19.05	37.80	-15.91	54.00
Week 52 (Day 365)	>= 65	9	25.7	3	33.3	22.22	19.25	-25.59	70.03
Week 56 (Day 393)	>= 65	7	20.0	3	42.9	22.22	38.49	-73.39	117.84
Week 60 (Day 421)	>= 65	7	20.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	7	20.0	2	28.6	16.67	23.57	-195.10	228.44
Week 68 (Day 477)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	4	11.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	4	11.4	1	25.0	0.00	NE	NE	NE
Week 84 (Day 589)	>= 65	3	8.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	5.7	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	35	100.0	35	100.0	21.90	31.25	11.17	32.64
End of Study (LOCF)	>= 65	35	100.0	35	100.0	23.81	30.86	13.21	34.41
ECOG performance status									
Baseline	0	33	100.0	31	93.9	15.05	29.61	4.19	25.92
Week 4 (Day 29)	0	33	100.0	27	81.8	33.33	36.98	18.70	47.96
Week 8 (Day 57)	0	30	90.9	27	90.0	24.69	31.48	12.24	37.14
Week 12 (Day 85)	0	29	87.9	26	89.7	24.36	29.15	12.59	36.13
Week 16 (Day 113)	0	28	84.8	24	85.7	22.22	32.10	8.67	35.78
Week 20 (Day 141)	0	26	78.8	24	92.3	20.83	30.79	7.83	33.84
Week 24 (Day 169)	0	24	72.7	20	83.3	11.67	19.57	2.51	20.83
Week 28 (Day 197)	0	21	63.6	19	90.5	21.05	29.84	6.67	35.43

Week 32 (Day 225)	0	21	63.6	18	85.7	16.67	28.58	2.45	30.88
Week 36 (Day 253)	0	21	63.6	20	95.2	16.67	25.36	4.80	28.54
Week 40 (Day 281)	0	21	63.6	19	90.5	19.30	32.04	3.85	34.74
Week 44 (Day 309)	0	21	63.6	17	81.0	13.73	29.01	-1.19	28.64
Week 48 (Day 337)	0	19	57.6	12	63.2	11.11	29.59	-7.69	29.91
Week 52 (Day 365)	0	18	54.5	3	16.7	22.22	19.25	-25.59	70.03
Week 56 (Day 393)	0	16	48.5	5	31.3	26.67	27.89	-7.96	61.30
Week 60 (Day 421)	0	16	48.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	0	16	48.5	5	31.3	13.33	18.26	-9.34	36.00
Week 68 (Day 477)	0	14	42.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	0	14	42.4	1	7.1	0.00	NE	NE	NE
Week 76 (Day 533)	0	12	36.4	1	8.3	0.00	NE	NE	NE
Week 80 (Day 561)	0	12	36.4	1	8.3	0.00	NE	NE	NE
Week 84 (Day 589)	0	10	30.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	9	27.3	1	11.1	0.00	NE	NE	NE
Week 92 (Day 645)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	9.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	3.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	33	100.0	33	100.0	17.17	30.19	6.47	27.88
End of Study (LOCF)	0	33	100.0	33	100.0	16.16	26.51	6.76	25.56
Baseline	1	79	100.0	76	96.2	16.23	22.77	11.03	21.43
Week 4 (Day 29)	1	79	100.0	67	84.8	24.88	28.63	17.89	31.86
Week 8 (Day 57)	1	70	88.6	65	92.9	18.46	26.37	11.93	25.00
Week 12 (Day 85)	1	68	86.1	64	94.1	16.67	19.70	11.75	21.59
Week 16 (Day 113)	1	67	84.8	61	91.0	16.39	18.88	11.56	21.23
Week 20 (Day 141)	1	63	79.7	59	93.7	16.38	22.64	10.49	22.28
Week 24 (Day 169)	1	57	72.2	53	93.0	15.72	24.11	9.08	22.37
Week 28 (Day 197)	1	53	67.1	50	94.3	20.67	27.68	12.80	28.53
Week 32 (Day 225)	1	50	63.3	45	90.0	14.81	20.79	8.57	21.06
Week 36 (Day 253)	1	50	63.3	45	90.0	19.26	27.05	11.13	27.39
Week 40 (Day 281)	1	46	58.2	40	87.0	14.17	24.91	6.20	22.13

Week 44 (Day 309)	1	43	54.4	41	95.3	17.89	30.82	8.16	27.61
Week 48 (Day 337)	1	39	49.4	21	53.8	11.11	21.94	1.12	21.10
Week 52 (Day 365)	1	27	34.2	4	14.8	8.33	16.67	-18.19	34.85
Week 56 (Day 393)	1	21	26.6	7	33.3	14.29	26.23	-9.97	38.54
Week 60 (Day 421)	1	16	20.3	1	6.3	0.00	NE	NE	NE
Week 64 (Day 449)	1	15	19.0	4	26.7	16.67	33.33	-36.37	69.71
Week 68 (Day 477)	1	14	17.7	1	7.1	33.33	NE	NE	NE
Week 72 (Day 505)	1	14	17.7	3	21.4	22.22	38.49	-73.39	117.84
Week 76 (Day 533)	1	13	16.5	1	7.7	0.00	NE	NE	NE
Week 80 (Day 561)	1	13	16.5	5	38.5	6.67	14.91	-11.84	25.18
Week 84 (Day 589)	1	8	10.1	1	12.5	0.00	NE	NE	NE
Week 88 (Day 617)	1	5	6.3	1	20.0	0.00	NE	NE	NE
Week 92 (Day 645)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	2.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	79	100.0	77	97.5	19.05	28.83	12.50	25.59
End of Study (LOCF)	1	79	100.0	77	97.5	17.32	27.36	11.10	23.53
Baseline	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	33.33	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	33.33	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	33.33	NE	NE	NE
Geographic region									
Baseline	USA	22	100.0	22	100.0	16.67	17.06	9.10	24.23
Week 4 (Day 29)	USA	22	100.0	18	81.8	31.48	33.28	14.93	48.03
Week 8 (Day 57)	USA	20	90.9	18	90.0	27.78	30.78	12.47	43.09
Week 12 (Day 85)	USA	20	90.9	19	95.0	22.81	24.98	10.77	34.84
Week 16 (Day 113)	USA	19	86.4	17	89.5	17.65	17.15	8.83	26.46
Week 20 (Day 141)	USA	19	86.4	17	89.5	9.80	15.66	1.75	17.85
Week 24 (Day 169)	USA	16	72.7	14	87.5	16.67	17.30	6.68	26.65
Week 28 (Day 197)	USA	15	68.2	12	80.0	27.78	23.92	12.58	42.98
Week 32 (Day 225)	USA	15	68.2	13	86.7	20.51	25.60	5.04	35.98
Week 36 (Day 253)	USA	15	68.2	13	86.7	23.08	25.04	7.95	38.21
Week 40 (Day 281)	USA	14	63.6	11	78.6	15.15	22.92	-0.25	30.55

Week 44 (Day 309)	USA	13	59.1	11	84.6	15.15	27.34	-3.22	33.52
Week 48 (Day 337)	USA	13	59.1	10	76.9	0.00	0.00	NE	NE
Week 52 (Day 365)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	USA	12	54.5	6	50.0	22.22	27.22	-6.34	50.78
Week 60 (Day 421)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	11	50.0	4	36.4	8.33	16.67	-18.19	34.85
Week 68 (Day 477)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	10	45.5	1	10.0	0.00	NE	NE	NE
Week 76 (Day 533)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	10	45.5	2	20.0	0.00	0.00	NE	NE
Week 84 (Day 589)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	13.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	4.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	22	100.0	22	100.0	19.70	30.27	6.28	33.12
End of Study (LOCF)	USA	22	100.0	22	100.0	19.70	30.27	6.28	33.12
Baseline	Europe (EU)	32	100.0	29	90.6	14.94	24.54	5.61	24.28
Week 4 (Day 29)	Europe (EU)	32	100.0	25	78.1	37.33	35.12	22.84	51.83
Week 8 (Day 57)	Europe (EU)	29	90.6	25	86.2	25.33	30.85	12.60	38.07
Week 12 (Day 85)	Europe (EU)	26	81.3	24	92.3	18.06	24.04	7.91	28.20
Week 16 (Day 113)	Europe (EU)	25	78.1	20	80.0	21.67	29.17	8.01	35.32
Week 20 (Day 141)	Europe (EU)	23	71.9	22	95.7	27.27	31.93	13.11	41.43
Week 24 (Day 169)	Europe (EU)	21	65.6	20	95.2	18.33	29.57	4.50	32.17
Week 28 (Day 197)	Europe (EU)	20	62.5	20	100.0	21.67	29.17	8.01	35.32
Week 32 (Day 225)	Europe (EU)	18	56.3	16	88.9	16.67	21.08	5.43	27.90
Week 36 (Day 253)	Europe (EU)	18	56.3	17	94.4	23.53	30.65	7.77	39.29
Week 40 (Day 281)	Europe (EU)	17	53.1	16	94.1	25.00	35.49	6.09	43.91
Week 44 (Day 309)	Europe (EU)	17	53.1	14	82.4	16.67	33.97	-2.95	36.28

Week 48 (Day 337)	Europe (EU)	14	43.8	10	71.4	20.00	28.11	-0.11	40.11
Week 52 (Day 365)	Europe (EU)	13	40.6	3	23.1	22.22	19.25	-25.59	70.03
Week 56 (Day 393)	Europe (EU)	11	34.4	5	45.5	20.00	29.81	-17.02	57.02
Week 60 (Day 421)	Europe (EU)	11	34.4	1	9.1	0.00	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	11	34.4	5	45.5	20.00	29.81	-17.02	57.02
Week 68 (Day 477)	Europe (EU)	10	31.3	1	10.0	33.33	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	10	31.3	3	30.0	22.22	38.49	-73.39	117.84
Week 76 (Day 533)	Europe (EU)	8	25.0	2	25.0	0.00	0.00	NE	NE
Week 80 (Day 561)	Europe (EU)	8	25.0	4	50.0	8.33	16.67	-18.19	34.85
Week 84 (Day 589)	Europe (EU)	6	18.8	1	16.7	0.00	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	9.4	2	66.7	0.00	0.00	NE	NE
Cycle 12 (LOCF)	Europe (EU)	32	100.0	31	96.9	22.58	32.65	10.61	34.56
End of Study (LOCF)	Europe (EU)	32	100.0	31	96.9	21.51	27.95	11.25	31.76
Baseline	Asia (AS)	59	100.0	57	96.6	15.79	27.53	8.48	23.10
Week 4 (Day 29)	Asia (AS)	59	100.0	52	88.1	21.15	27.24	13.57	28.74
Week 8 (Day 57)	Asia (AS)	52	88.1	49	94.2	14.97	24.59	7.90	22.03
Week 12 (Day 85)	Asia (AS)	51	86.4	47	92.2	17.73	21.82	11.33	24.14
Week 16 (Day 113)	Asia (AS)	51	86.4	48	94.1	16.67	22.81	10.04	23.29
Week 20 (Day 141)	Asia (AS)	47	79.7	44	93.6	15.91	23.28	8.83	22.99
Week 24 (Day 169)	Asia (AS)	44	74.6	39	88.6	11.97	20.92	5.18	18.75
Week 28 (Day 197)	Asia (AS)	39	66.1	37	94.9	18.02	28.97	8.36	27.68
Week 32 (Day 225)	Asia (AS)	38	64.4	34	89.5	12.75	23.23	4.64	20.85
Week 36 (Day 253)	Asia (AS)	38	64.4	35	92.1	14.29	24.64	5.82	22.75
Week 40 (Day 281)	Asia (AS)	36	61.0	32	88.9	11.46	23.36	3.04	19.88
Week 44 (Day 309)	Asia (AS)	34	57.6	33	97.1	17.17	30.19	6.47	27.88
Week 48 (Day 337)	Asia (AS)	31	52.5	13	41.9	12.82	28.99	-4.70	30.34
Week 52 (Day 365)	Asia (AS)	20	33.9	4	20.0	8.33	16.67	-18.19	34.85
Week 56 (Day 393)	Asia (AS)	14	23.7	1	7.1	0.00	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	10.2	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	8.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	3.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	59	100.0	58	98.3	16.09	26.67	9.08	23.10
End of Study (LOCF)	Asia (AS)	59	100.0	58	98.3	13.79	25.00	7.22	20.37
Race/ethnicity									
Baseline	Asian	61	100.0	58	95.1	16.09	27.39	8.89	23.29
Week 4 (Day 29)	Asian	61	100.0	52	85.2	21.15	27.24	13.57	28.74
Week 8 (Day 57)	Asian	53	86.9	49	92.5	14.97	24.59	7.90	22.03
Week 12 (Day 85)	Asian	52	85.2	48	92.3	17.36	21.73	11.05	23.67
Week 16 (Day 113)	Asian	52	85.2	49	94.2	16.33	22.69	9.81	22.84
Week 20 (Day 141)	Asian	48	78.7	45	93.8	15.56	23.14	8.60	22.51
Week 24 (Day 169)	Asian	44	72.1	39	88.6	11.97	20.92	5.18	18.75
Week 28 (Day 197)	Asian	39	63.9	37	94.9	18.02	28.97	8.36	27.68
Week 32 (Day 225)	Asian	38	62.3	34	89.5	12.75	23.23	4.64	20.85
Week 36 (Day 253)	Asian	38	62.3	35	92.1	14.29	24.64	5.82	22.75
Week 40 (Day 281)	Asian	36	59.0	32	88.9	11.46	23.36	3.04	19.88
Week 44 (Day 309)	Asian	34	55.7	33	97.1	17.17	30.19	6.47	27.88
Week 48 (Day 337)	Asian	31	50.8	13	41.9	12.82	28.99	-4.70	30.34
Week 52 (Day 365)	Asian	20	32.8	4	20.0	8.33	16.67	-18.19	34.85
Week 56 (Day 393)	Asian	14	23.0	1	7.1	0.00	NE	NE	NE
Week 60 (Day 421)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	9.8	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	8.2	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	3.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	61	100.0	59	96.7	15.82	26.52	8.91	22.73
End of Study (LOCF)	Asian	61	100.0	59	96.7	13.56	24.85	7.08	20.04
Baseline	Non-Asian	45	100.0	44	97.8	15.15	22.10	8.43	21.87
Week 4 (Day 29)	Non-Asian	45	100.0	39	86.7	32.48	32.88	21.82	43.14
Week 8 (Day 57)	Non-Asian	42	93.3	38	90.5	26.32	30.17	16.40	36.23
Week 12 (Day 85)	Non-Asian	39	86.7	37	94.9	21.62	25.11	13.25	29.99
Week 16 (Day 113)	Non-Asian	37	82.2	34	91.9	20.59	24.64	11.99	29.18
Week 20 (Day 141)	Non-Asian	36	80.0	34	94.4	20.59	27.23	11.09	30.09
Week 24 (Day 169)	Non-Asian	32	71.1	31	96.9	17.20	25.63	7.80	26.61
Week 28 (Day 197)	Non-Asian	30	66.7	28	93.3	26.19	27.75	15.43	36.95
Week 32 (Day 225)	Non-Asian	28	62.2	25	89.3	18.67	23.73	8.87	28.46
Week 36 (Day 253)	Non-Asian	28	62.2	26	92.9	24.36	29.15	12.59	36.13
Week 40 (Day 281)	Non-Asian	26	57.8	23	88.5	23.19	32.47	9.15	37.23
Week 44 (Day 309)	Non-Asian	25	55.6	21	84.0	17.46	32.69	2.58	32.34
Week 48 (Day 337)	Non-Asian	23	51.1	17	73.9	11.76	23.40	-0.26	23.79
Week 52 (Day 365)	Non-Asian	21	46.7	3	14.3	22.22	19.25	-25.59	70.03
Week 56 (Day 393)	Non-Asian	19	42.2	10	52.6	23.33	27.44	3.70	42.96
Week 60 (Day 421)	Non-Asian	19	42.2	1	5.3	0.00	NE	NE	NE
Week 64 (Day 449)	Non-Asian	18	40.0	7	38.9	19.05	26.23	-5.21	43.30
Week 68 (Day 477)	Non-Asian	17	37.8	1	5.9	33.33	NE	NE	NE
Week 72 (Day 505)	Non-Asian	17	37.8	3	17.6	22.22	38.49	-73.39	117.84
Week 76 (Day 533)	Non-Asian	15	33.3	2	13.3	0.00	0.00	NE	NE
Week 80 (Day 561)	Non-Asian	15	33.3	5	33.3	6.67	14.91	-11.84	25.18
Week 84 (Day 589)	Non-Asian	10	22.2	1	10.0	0.00	NE	NE	NE
Week 88 (Day 617)	Non-Asian	7	15.6	2	28.6	0.00	0.00	NE	NE
Week 92 (Day 645)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	45	100.0	45	100.0	22.96	33.20	12.99	32.94

End of Study (LOCF)	Non-Asian	45	100.0	45	100.0	22.96	30.00	13.95	31.98
Baseline	Unknown	7	100.0	6	85.7	16.67	18.26	-2.49	35.83
Week 4 (Day 29)	Unknown	7	100.0	4	57.1	58.33	41.94	-8.41	125.07
Week 8 (Day 57)	Unknown	6	85.7	5	83.3	26.67	36.51	-18.67	72.01
Week 12 (Day 85)	Unknown	6	85.7	5	83.3	13.33	18.26	-9.34	36.00
Week 16 (Day 113)	Unknown	6	85.7	2	33.3	16.67	23.57	-195.10	228.44
Week 20 (Day 141)	Unknown	5	71.4	4	80.0	16.67	33.33	-36.37	69.71
Week 24 (Day 169)	Unknown	5	71.4	3	60.0	22.22	19.25	-25.59	70.03
Week 28 (Day 197)	Unknown	5	71.4	4	80.0	8.33	16.67	-18.19	34.85
Week 32 (Day 225)	Unknown	5	71.4	4	80.0	16.67	19.25	-13.96	47.29
Week 36 (Day 253)	Unknown	5	71.4	4	80.0	16.67	19.25	-13.96	47.29
Week 40 (Day 281)	Unknown	5	71.4	4	80.0	8.33	16.67	-18.19	34.85
Week 44 (Day 309)	Unknown	5	71.4	4	80.0	8.33	16.67	-18.19	34.85
Week 48 (Day 337)	Unknown	4	57.1	3	75.0	0.00	0.00	NE	NE
Week 52 (Day 365)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	4	57.1	1	25.0	0.00	NE	NE	NE
Week 60 (Day 421)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	4	57.1	2	50.0	0.00	0.00	NE	NE
Week 68 (Day 477)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	3	42.9	1	33.3	0.00	NE	NE	NE
Week 76 (Day 533)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	3	42.9	1	33.3	0.00	NE	NE	NE
Week 84 (Day 589)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	14.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	7	100.0	7	100.0	14.29	17.82	-2.19	30.76
End of Study (LOCF)	Unknown	7	100.0	7	100.0	9.52	16.27	-5.52	24.57
Number of prior antineoplastic systemic therapy lines I									
Baseline	1	60	100.0	57	95.0	18.13	26.03	11.22	25.03

Week 4 (Day 29)	1	60	100.0	50	83.3	28.67	34.35	18.91	38.43
Week 8 (Day 57)	1	54	90.0	49	90.7	19.73	26.28	12.18	27.28
Week 12 (Day 85)	1	52	86.7	48	92.3	15.28	20.58	9.30	21.25
Week 16 (Day 113)	1	51	85.0	46	90.2	18.12	22.99	11.29	24.94
Week 20 (Day 141)	1	48	80.0	43	89.6	17.83	25.56	9.96	25.70
Week 24 (Day 169)	1	43	71.7	39	90.7	15.38	24.00	7.61	23.16
Week 28 (Day 197)	1	38	63.3	34	89.5	21.57	27.07	12.12	31.01
Week 32 (Day 225)	1	35	58.3	29	82.9	14.94	21.06	6.93	22.95
Week 36 (Day 253)	1	35	58.3	31	88.6	18.28	25.59	8.89	27.67
Week 40 (Day 281)	1	32	53.3	27	84.4	18.52	29.72	6.76	30.27
Week 44 (Day 309)	1	32	53.3	27	84.4	22.22	32.03	9.55	34.89
Week 48 (Day 337)	1	27	45.0	16	59.3	10.42	20.07	-0.28	21.11
Week 52 (Day 365)	1	23	38.3	5	21.7	20.00	18.26	-2.67	42.67
Week 56 (Day 393)	1	16	26.7	4	25.0	8.33	16.67	-18.19	34.85
Week 60 (Day 421)	1	14	23.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	13	21.7	4	30.8	8.33	16.67	-18.19	34.85
Week 68 (Day 477)	1	12	20.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	12	20.0	1	8.3	0.00	NE	NE	NE
Week 76 (Day 533)	1	11	18.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	11	18.3	2	18.2	0.00	0.00	NE	NE
Week 84 (Day 589)	1	9	15.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	1	8	13.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	1	3	5.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	1	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	60	100.0	58	96.7	21.84	30.30	13.87	29.81
End of Study (LOCF)	1	60	100.0	58	96.7	18.39	26.62	11.39	25.39
Baseline	>= 2	53	100.0	51	96.2	13.07	23.17	6.56	19.59
Week 4 (Day 29)	>= 2	53	100.0	45	84.9	25.93	27.42	17.69	34.16
Week 8 (Day 57)	>= 2	47	88.7	43	91.5	20.93	30.01	11.69	30.17
Week 12 (Day 85)	>= 2	45	84.9	42	93.3	23.02	24.95	15.24	30.79
Week 16 (Day 113)	>= 2	44	83.0	39	88.6	17.95	24.00	10.17	25.73

Week 20 (Day 141)	>= 2	41	77.4	40	97.6	17.50	25.02	9.50	25.50
Week 24 (Day 169)	>= 2	38	71.7	34	89.5	13.73	21.89	6.09	21.36
Week 28 (Day 197)	>= 2	36	67.9	35	97.2	20.00	29.37	9.91	30.09
Week 32 (Day 225)	>= 2	36	67.9	34	94.4	15.69	24.94	6.98	24.39
Week 36 (Day 253)	>= 2	36	67.9	34	94.4	18.63	27.45	9.05	28.21
Week 40 (Day 281)	>= 2	35	66.0	32	91.4	13.54	25.20	4.46	22.63
Week 44 (Day 309)	>= 2	32	60.4	31	96.9	11.83	27.95	1.57	22.08
Week 48 (Day 337)	>= 2	31	58.5	17	54.8	11.76	28.73	-3.00	26.53
Week 52 (Day 365)	>= 2	22	41.5	2	9.1	0.00	0.00	NE	NE
Week 56 (Day 393)	>= 2	21	39.6	8	38.1	25.00	29.55	0.30	49.70
Week 60 (Day 421)	>= 2	18	34.0	1	5.6	0.00	NE	NE	NE
Week 64 (Day 449)	>= 2	18	34.0	5	27.8	20.00	29.81	-17.02	57.02
Week 68 (Day 477)	>= 2	16	30.2	1	6.3	33.33	NE	NE	NE
Week 72 (Day 505)	>= 2	16	30.2	3	18.8	22.22	38.49	-73.39	117.84
Week 76 (Day 533)	>= 2	14	26.4	2	14.3	0.00	0.00	NE	NE
Week 80 (Day 561)	>= 2	14	26.4	4	28.6	8.33	16.67	-18.19	34.85
Week 84 (Day 589)	>= 2	9	17.0	1	11.1	0.00	NE	NE	NE
Week 88 (Day 617)	>= 2	6	11.3	2	33.3	0.00	0.00	NE	NE
Week 92 (Day 645)	>= 2	2	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 2	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 2	53	100.0	53	100.0	15.09	27.40	7.54	22.65
End of Study (LOCF)	>= 2	53	100.0	53	100.0	15.72	27.43	8.16	23.28

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TP_QSC30CO_SG.xls
27OCT2021 7:24

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Constipation
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	56	51.9	42.5	61.0
	Cycle 12 (LOCF)	n/a	108	95.6	23	21.3	14.6	29.9
	End of Study (LOCF)	n/a	108	95.6	21	19.4	13.1	27.9
Sex	All visits	Female	67	59.3	40	59.7	47.7	70.6
		Male	41	36.3	16	39.0	25.7	54.3
	Cycle 12 (LOCF)	Female	67	59.3	15	22.4	14.1	33.7
		Male	41	36.3	8	19.5	10.2	34.0
	End of Study (LOCF)	Female	67	59.3	14	20.9	12.9	32.1
		Male	41	36.3	7	17.1	8.5	31.3
Age	All visits	< 65	73	64.6	39	53.4	42.1	64.4
		>= 65	35	31.0	17	48.6	33.0	64.4
	Cycle 12 (LOCF)	< 65	73	64.6	16	21.9	14.0	32.7
		>= 65	35	31.0	7	20.0	10.0	35.9
	End of Study (LOCF)	< 65	73	64.6	14	19.2	11.8	29.7
		>= 65	35	31.0	7	20.0	10.0	35.9
ECOG performance status	All visits	0	31	27.4	17	54.8	37.8	70.8
		1	76	67.3	38	50.0	39.0	61.0
		Missing	1	0.9	1	100.0	20.7	100.0
	Cycle 12 (LOCF)	0	31	27.4	6	19.4	9.2	36.3
		1	76	67.3	16	21.1	13.4	31.5
		Missing	1	0.9	1	100.0	20.7	100.0
	End of Study (LOCF)	0	31	27.4	6	19.4	9.2	36.3
		1	76	67.3	14	18.4	11.3	28.6
		Missing	1	0.9	1	100.0	20.7	100.0
Geographic region	All visits	USA	22	19.5	13	59.1	38.7	76.7
		Europe (EU)	29	25.7	18	62.1	44.0	77.3
		Asia (AS)	57	50.4	25	43.9	31.8	56.7
	Cycle 12 (LOCF)	USA	22	19.5	5	22.7	10.1	43.4
		Europe (EU)	29	25.7	9	31.0	17.3	49.2
		Asia (AS)	57	50.4	9	15.8	8.5	27.4
	End of Study (LOCF)	USA	22	19.5	5	22.7	10.1	43.4
		Europe (EU)	29	25.7	9	31.0	17.3	49.2
		Asia (AS)	57	50.4	7	12.3	6.1	23.2
Race/ethnicity	All visits	Asian	58	51.3	25	43.1	31.2	55.9
		Non-Asian	44	38.9	29	65.9	51.1	78.1
		Unknown	6	5.3	2	33.3	9.7	70.0
	Cycle 12 (LOCF)	Asian	58	51.3	9	15.5	8.4	26.9

		Non-Asian	44	38.9	13	29.5	18.2	44.2
		Unknown	6	5.3	1	16.7	3.0	56.4
	End of Study (LOCF)	Asian	58	51.3	7	12.1	6.0	22.9
		Non-Asian	44	38.9	14	31.8	20.0	46.6
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	29	50.9	38.3	63.4
		>= 2	51	45.1	27	52.9	39.5	65.9
	Cycle 12 (LOCF)	1	57	50.4	15	26.3	16.6	39.0
		>= 2	51	45.1	8	15.7	8.2	28.0
	End of Study (LOCF)	1	57	50.4	12	21.1	12.5	33.3
		>= 2	51	45.1	9	17.6	9.6	30.3

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30CO_W10_SG.xls
15OCT2021 13:31

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Constipation
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

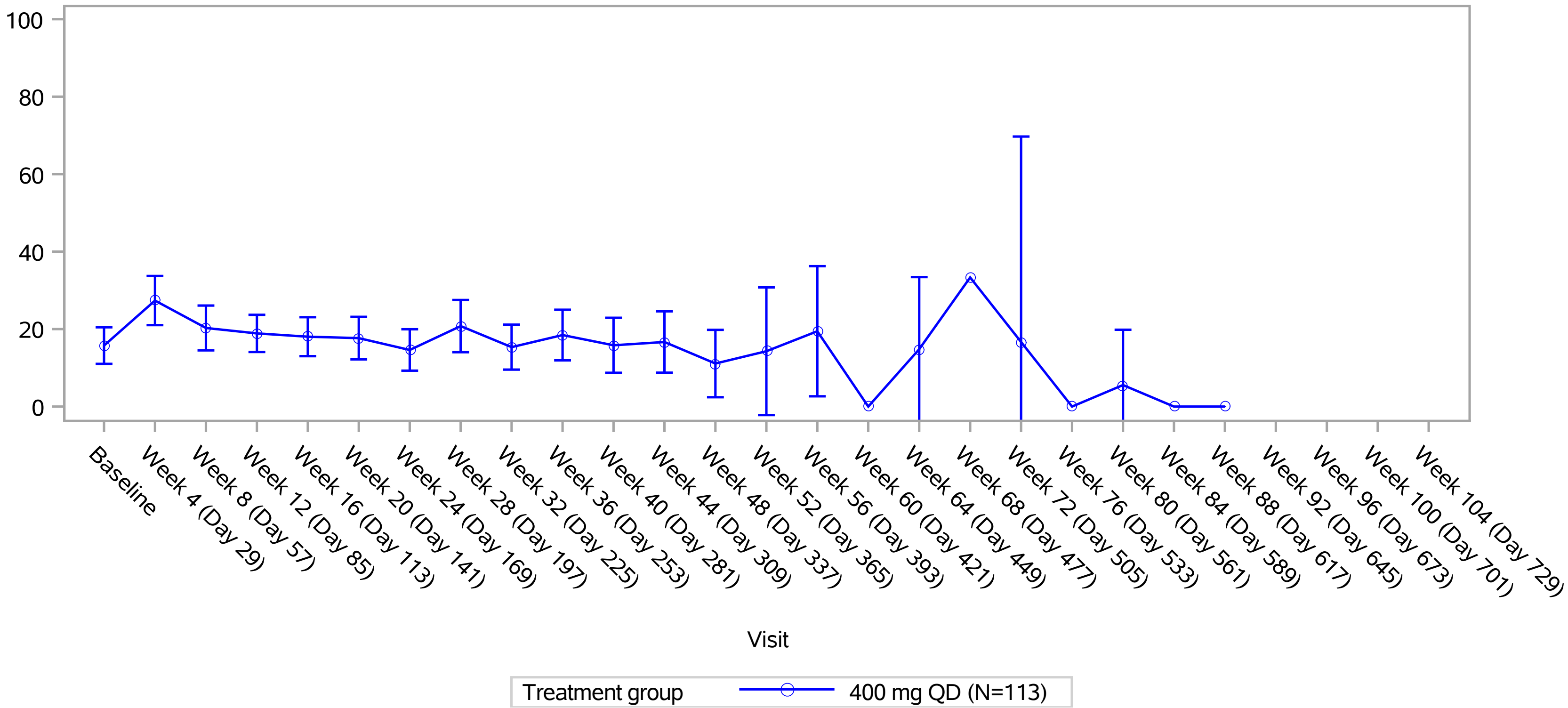
			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	56	51.9	42.5	61.0
	Cycle 12 (LOCF)	n/a	108	95.6	23	21.3	14.6	29.9
	End of Study (LOCF)	n/a	108	95.6	21	19.4	13.1	27.9
Sex	All visits	Female	67	59.3	40	59.7	47.7	70.6
		Male	41	36.3	16	39.0	25.7	54.3
	Cycle 12 (LOCF)	Female	67	59.3	15	22.4	14.1	33.7
		Male	41	36.3	8	19.5	10.2	34.0
	End of Study (LOCF)	Female	67	59.3	14	20.9	12.9	32.1
		Male	41	36.3	7	17.1	8.5	31.3
Age	All visits	< 65	73	64.6	39	53.4	42.1	64.4
		>= 65	35	31.0	17	48.6	33.0	64.4
	Cycle 12 (LOCF)	< 65	73	64.6	16	21.9	14.0	32.7
		>= 65	35	31.0	7	20.0	10.0	35.9
	End of Study (LOCF)	< 65	73	64.6	14	19.2	11.8	29.7
		>= 65	35	31.0	7	20.0	10.0	35.9
ECOG performance status	All visits	0	31	27.4	17	54.8	37.8	70.8
		1	76	67.3	38	50.0	39.0	61.0
		Missing	1	0.9	1	100.0	20.7	100.0
	Cycle 12 (LOCF)	0	31	27.4	6	19.4	9.2	36.3
		1	76	67.3	16	21.1	13.4	31.5
		Missing	1	0.9	1	100.0	20.7	100.0
	End of Study (LOCF)	0	31	27.4	6	19.4	9.2	36.3
		1	76	67.3	14	18.4	11.3	28.6
		Missing	1	0.9	1	100.0	20.7	100.0
Geographic region	All visits	USA	22	19.5	13	59.1	38.7	76.7
		Europe (EU)	29	25.7	18	62.1	44.0	77.3
		Asia (AS)	57	50.4	25	43.9	31.8	56.7
	Cycle 12 (LOCF)	USA	22	19.5	5	22.7	10.1	43.4
		Europe (EU)	29	25.7	9	31.0	17.3	49.2
		Asia (AS)	57	50.4	9	15.8	8.5	27.4
	End of Study (LOCF)	USA	22	19.5	5	22.7	10.1	43.4
		Europe (EU)	29	25.7	9	31.0	17.3	49.2
		Asia (AS)	57	50.4	7	12.3	6.1	23.2
Race/ethnicity	All visits	Asian	58	51.3	25	43.1	31.2	55.9
		Non-Asian	44	38.9	29	65.9	51.1	78.1
		Unknown	6	5.3	2	33.3	9.7	70.0
	Cycle 12 (LOCF)	Asian	58	51.3	9	15.5	8.4	26.9

		Non-Asian	44	38.9	13	29.5	18.2	44.2
		Unknown	6	5.3	1	16.7	3.0	56.4
	End of Study (LOCF)	Asian	58	51.3	7	12.1	6.0	22.9
		Non-Asian	44	38.9	14	31.8	20.0	46.6
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	29	50.9	38.3	63.4
		>= 2	51	45.1	27	52.9	39.5	65.9
	Cycle 12 (LOCF)	1	57	50.4	15	26.3	16.6	39.0
		>= 2	51	45.1	8	15.7	8.2	28.0
	End of Study (LOCF)	1	57	50.4	12	21.1	12.5	33.3
		>= 2	51	45.1	9	17.6	9.6	30.3

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30CO_W15_SG.xls
15OCT2021 13:21

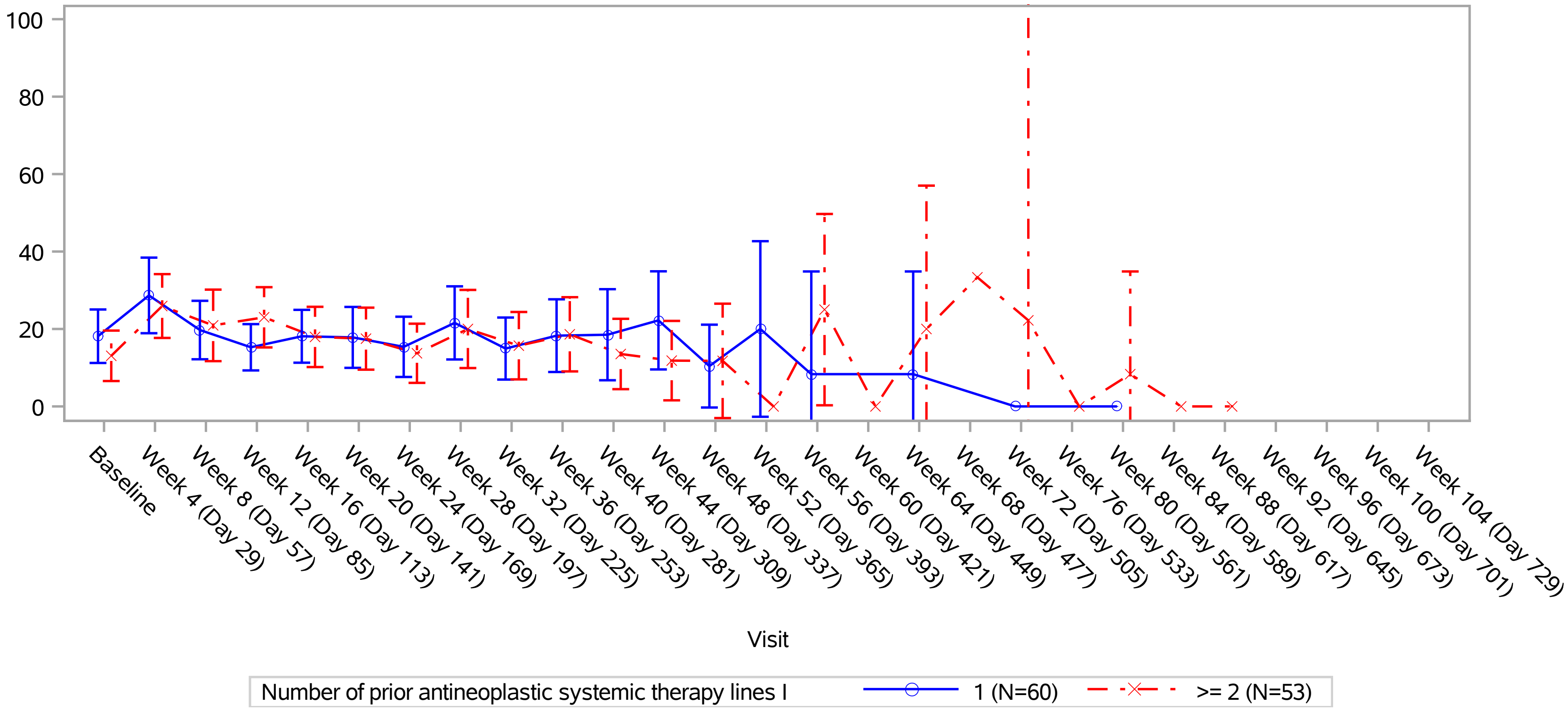
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Constipation
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30CO.pdf
15OCT2021 17:13

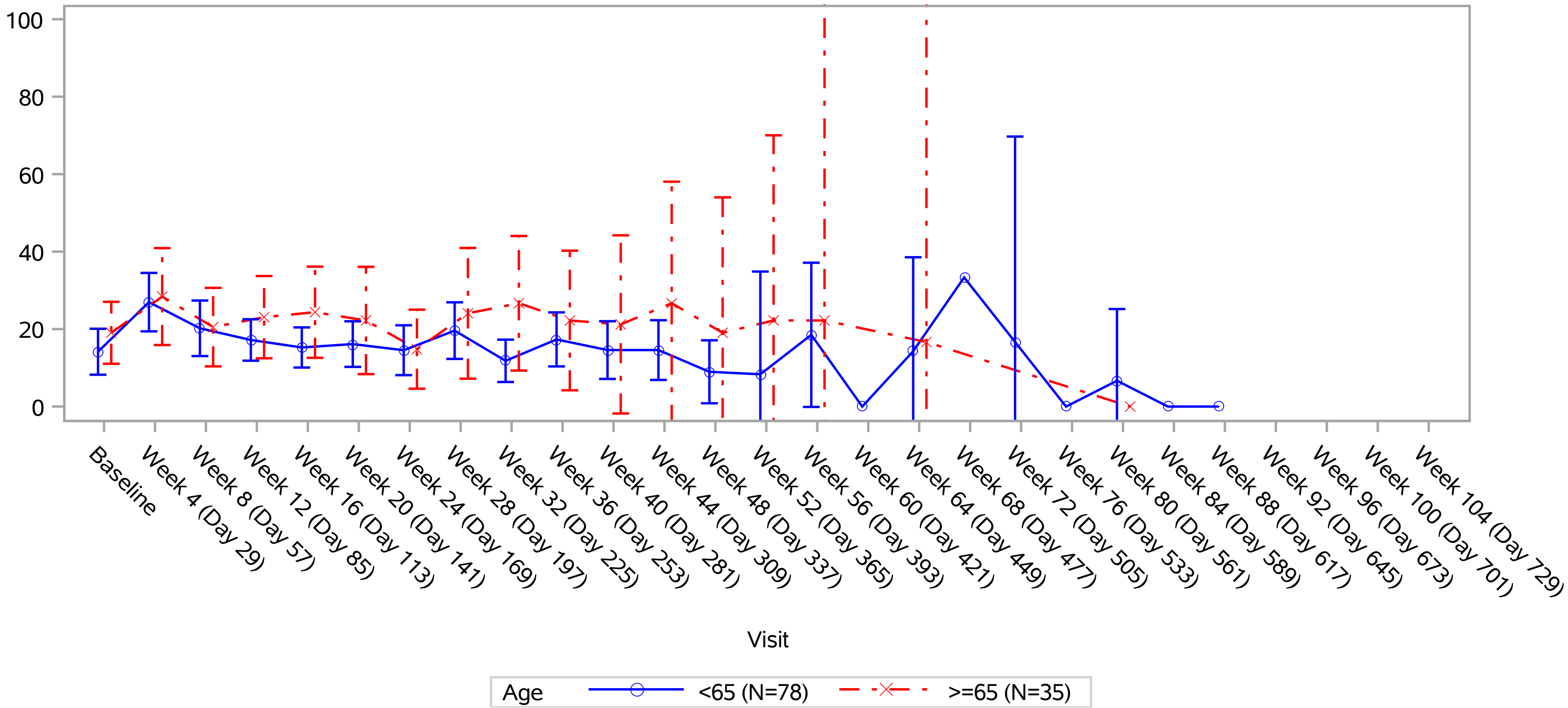
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Constipation
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30CO_PRTHL1.pdf
15OCT2021 20:05

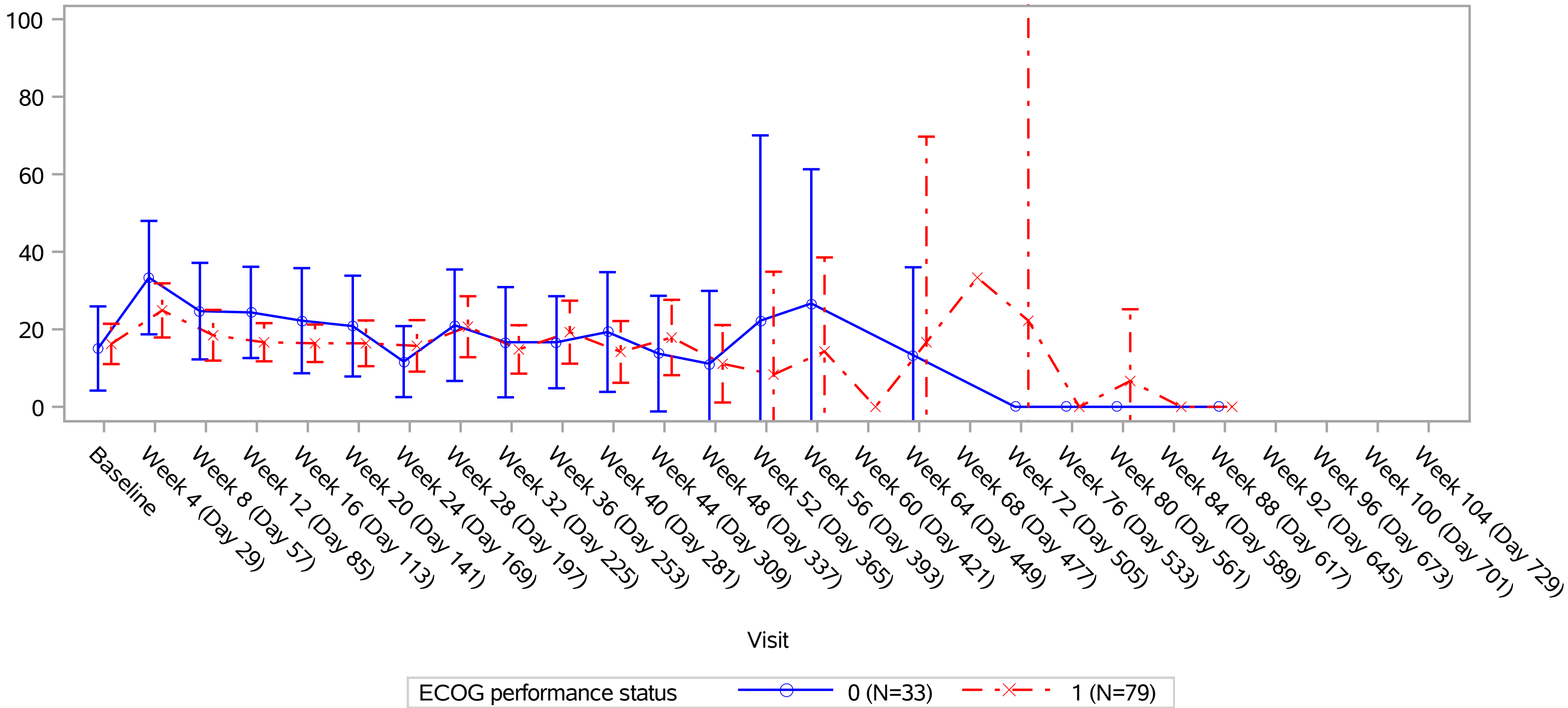
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Constipation
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30CO_SGAGE65.pdf
15OCT2021 17:42

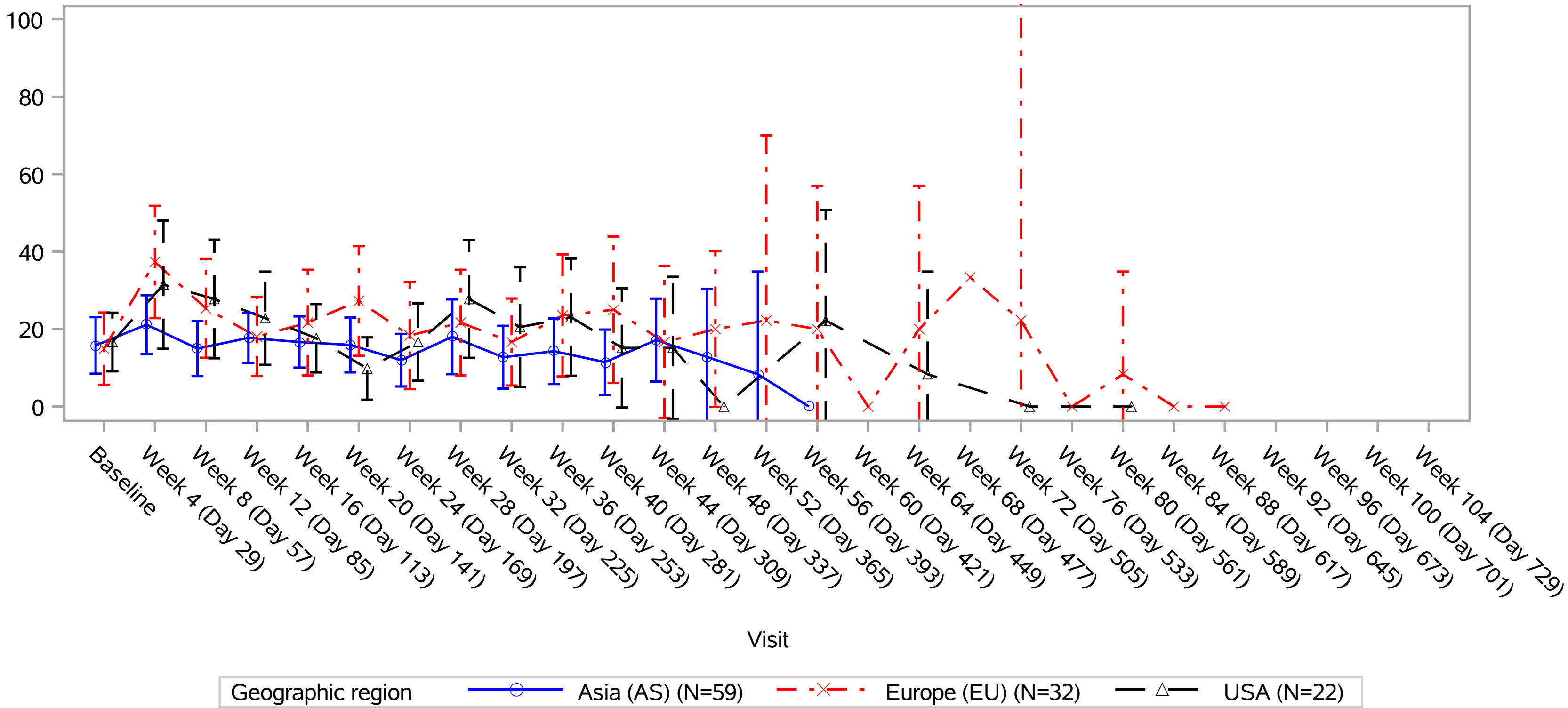
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Constipation
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30CO_SGECOG.pdf
15OCT2021 18:12

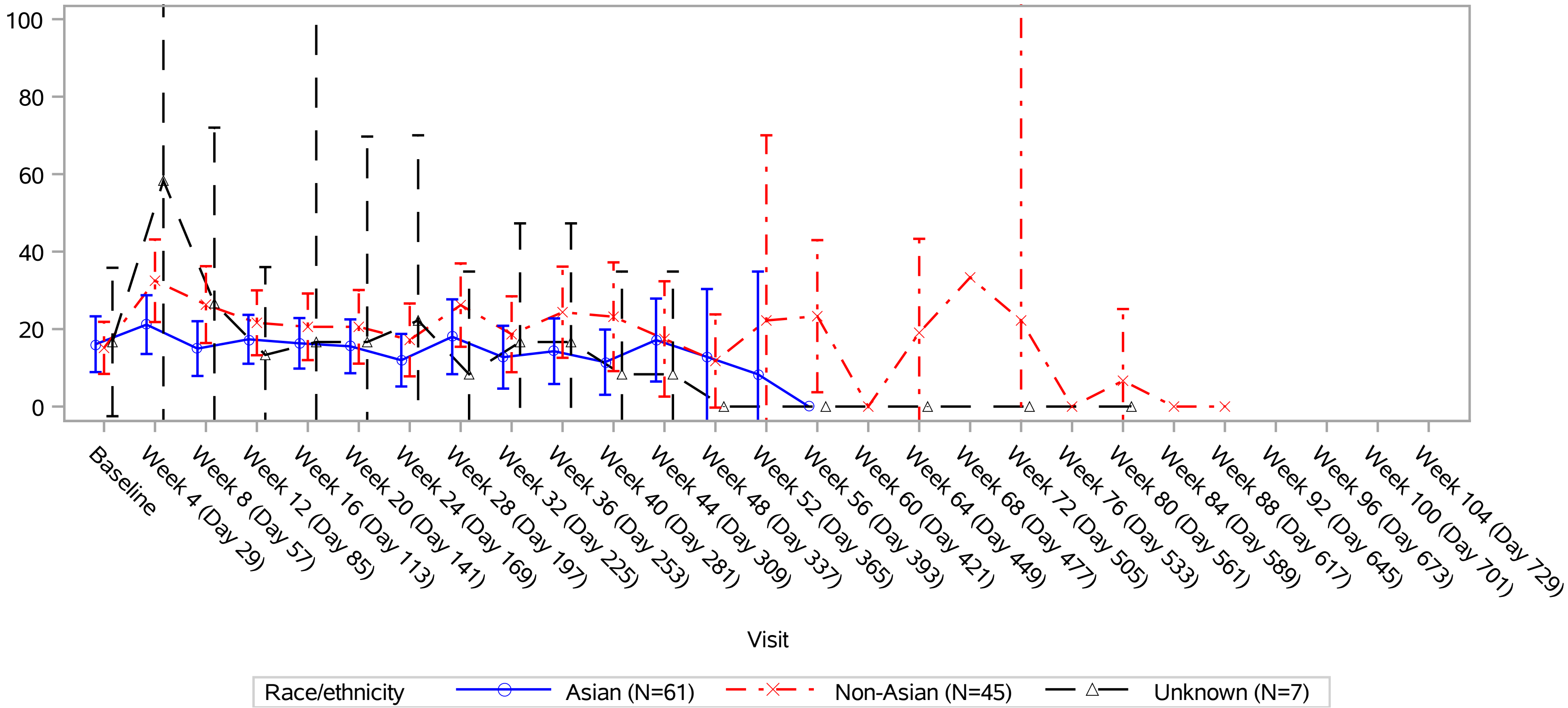
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Constipation
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30CO_SGGEO.pdf
15OCT2021 18:44

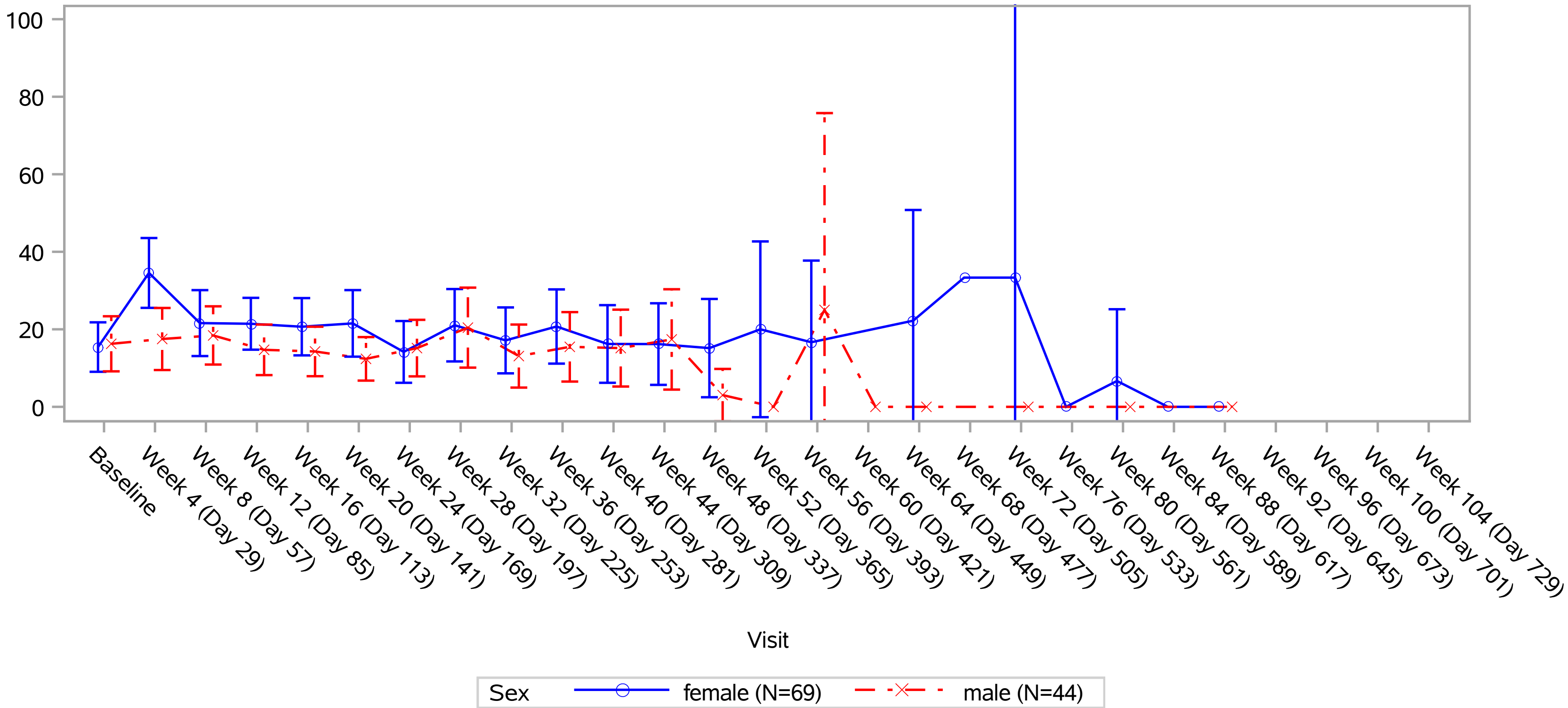
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Constipation
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30CO_SGRE.pdf
15OCT2021 19:14

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Constipation
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30CO_SGSEX.pdf
15OCT2021 19:45

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Diarrhoea
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=113)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	113	100.0	108	95.6	4.94	14.28	2.21	7.66
Week 4 (Day 29)	n/a	113	100.0	95	84.1	5.61	15.87	2.38	8.85
Week 8 (Day 57)	n/a	101	89.4	92	91.1	7.25	17.70	3.58	10.91
Week 12 (Day 85)	n/a	97	85.8	90	92.8	5.56	12.49	2.94	8.17
Week 16 (Day 113)	n/a	95	84.1	85	89.5	4.31	11.25	1.89	6.74
Week 20 (Day 141)	n/a	89	78.8	83	93.3	6.43	16.01	2.93	9.92
Week 24 (Day 169)	n/a	81	71.7	73	90.1	5.94	13.99	2.67	9.20
Week 28 (Day 197)	n/a	74	65.5	69	93.2	8.70	20.33	3.81	13.58
Week 32 (Day 225)	n/a	71	62.8	63	88.7	6.35	18.80	1.62	11.08
Week 36 (Day 253)	n/a	71	62.8	65	91.5	5.64	16.21	1.62	9.66
Week 40 (Day 281)	n/a	67	59.3	58	86.6	5.75	16.68	1.36	10.13
Week 44 (Day 309)	n/a	64	56.6	58	90.6	8.05	18.00	3.31	12.78
Week 48 (Day 337)	n/a	58	51.3	33	56.9	4.04	11.05	0.12	7.96
Week 52 (Day 365)	n/a	45	39.8	7	15.6	9.52	16.27	-5.52	24.57
Week 56 (Day 393)	n/a	37	32.7	12	32.4	0.00	0.00	NE	NE
Week 60 (Day 421)	n/a	32	28.3	1	3.1	0.00	NE	NE	NE
Week 64 (Day 449)	n/a	31	27.4	9	29.0	3.70	11.11	-4.84	12.24
Week 68 (Day 477)	n/a	28	24.8	1	3.6	0.00	NE	NE	NE
Week 72 (Day 505)	n/a	28	24.8	4	14.3	0.00	0.00	NE	NE
Week 76 (Day 533)	n/a	25	22.1	2	8.0	0.00	0.00	NE	NE
Week 80 (Day 561)	n/a	25	22.1	6	24.0	0.00	0.00	NE	NE
Week 84 (Day 589)	n/a	18	15.9	1	5.6	0.00	NE	NE	NE
Week 88 (Day 617)	n/a	14	12.4	2	14.3	0.00	0.00	NE	NE
Week 92 (Day 645)	n/a	7	6.2	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	5.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	2.7	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	113	100.0	111	98.2	9.91	20.40	6.07	13.75
End of Study (LOCF)	n/a	113	100.0	111	98.2	9.01	20.07	5.23	12.78
Sex									
Baseline	Female	69	100.0	67	97.1	3.98	12.34	0.97	6.99
Week 4 (Day 29)	Female	69	100.0	55	79.7	4.85	13.48	1.20	8.49
Week 8 (Day 57)	Female	63	91.3	54	85.7	9.88	21.11	4.11	15.64
Week 12 (Day 85)	Female	60	87.0	56	93.3	5.95	12.88	2.50	9.40
Week 16 (Day 113)	Female	58	84.1	50	86.2	6.67	13.47	2.84	10.49
Week 20 (Day 141)	Female	53	76.8	48	90.6	6.94	16.78	2.07	11.82
Week 24 (Day 169)	Female	47	68.1	40	85.1	8.33	16.45	3.07	13.59
Week 28 (Day 197)	Female	42	60.9	38	90.5	7.02	17.60	1.23	12.80
Week 32 (Day 225)	Female	42	60.9	35	83.3	3.81	10.76	0.11	7.51
Week 36 (Day 253)	Female	42	60.9	37	88.1	3.60	10.49	0.10	7.10
Week 40 (Day 281)	Female	41	59.4	36	87.8	3.70	10.62	0.11	7.30
Week 44 (Day 309)	Female	41	59.4	35	85.4	8.57	20.36	1.58	15.57
Week 48 (Day 337)	Female	37	53.6	22	59.5	4.55	11.71	-0.65	9.74
Week 52 (Day 365)	Female	29	42.0	5	17.2	6.67	14.91	-11.84	25.18
Week 56 (Day 393)	Female	24	34.8	8	33.3	0.00	0.00	NE	NE
Week 60 (Day 421)	Female	22	31.9	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Female	22	31.9	6	27.3	5.56	13.61	-8.73	19.84
Week 68 (Day 477)	Female	20	29.0	1	5.0	0.00	NE	NE	NE
Week 72 (Day 505)	Female	20	29.0	2	10.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Female	18	26.1	2	11.1	0.00	0.00	NE	NE
Week 80 (Day 561)	Female	18	26.1	5	27.8	0.00	0.00	NE	NE
Week 84 (Day 589)	Female	12	17.4	1	8.3	0.00	NE	NE	NE
Week 88 (Day 617)	Female	9	13.0	1	11.1	0.00	NE	NE	NE
Week 92 (Day 645)	Female	6	8.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	7.2	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	2.9	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	1.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	69	100.0	68	98.6	11.27	20.45	6.32	16.22
End of Study (LOCF)	Female	69	100.0	68	98.6	10.29	20.16	5.41	15.17
Baseline	Male	44	100.0	41	93.2	6.50	17.03	1.13	11.88
Week 4 (Day 29)	Male	44	100.0	40	90.9	6.67	18.80	0.66	12.68
Week 8 (Day 57)	Male	38	86.4	38	100.0	3.51	10.37	0.10	6.92
Week 12 (Day 85)	Male	37	84.1	34	91.9	4.90	11.98	0.72	9.08
Week 16 (Day 113)	Male	37	84.1	35	94.6	0.95	5.63	-0.98	2.89
Week 20 (Day 141)	Male	36	81.8	35	97.2	5.71	15.09	0.53	10.90
Week 24 (Day 169)	Male	34	77.3	33	97.1	3.03	9.73	-0.42	6.48
Week 28 (Day 197)	Male	32	72.7	31	96.9	10.75	23.39	2.17	19.33
Week 32 (Day 225)	Male	29	65.9	28	96.6	9.52	25.43	-0.34	19.38
Week 36 (Day 253)	Male	29	65.9	28	96.6	8.33	21.52	-0.01	16.68
Week 40 (Day 281)	Male	26	59.1	22	84.6	9.09	23.42	-1.29	19.47
Week 44 (Day 309)	Male	23	52.3	23	100.0	7.25	14.06	1.17	13.33
Week 48 (Day 337)	Male	21	47.7	11	52.4	3.03	10.05	-3.72	9.78
Week 52 (Day 365)	Male	16	36.4	2	12.5	16.67	23.57	-195.10	228.44
Week 56 (Day 393)	Male	13	29.5	4	30.8	0.00	0.00	NE	NE
Week 60 (Day 421)	Male	10	22.7	1	10.0	0.00	NE	NE	NE
Week 64 (Day 449)	Male	9	20.5	3	33.3	0.00	0.00	NE	NE
Week 68 (Day 477)	Male	8	18.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	8	18.2	2	25.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Male	7	15.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	7	15.9	1	14.3	0.00	NE	NE	NE
Week 84 (Day 589)	Male	6	13.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	5	11.4	1	20.0	0.00	NE	NE	NE
Week 92 (Day 645)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	44	100.0	43	97.7	7.75	20.36	1.49	14.02
End of Study (LOCF)	Male	44	100.0	43	97.7	6.98	20.00	0.82	13.13
Age									

Baseline	< 65	78	100.0	73	93.6	2.74	10.76	0.23	5.25
Week 4 (Day 29)	< 65	78	100.0	68	87.2	3.43	10.20	0.96	5.90
Week 8 (Day 57)	< 65	73	93.6	66	90.4	7.58	18.30	3.08	12.07
Week 12 (Day 85)	< 65	71	91.0	64	90.1	3.65	10.49	1.03	6.27
Week 16 (Day 113)	< 65	69	88.5	59	85.5	5.08	12.09	1.93	8.23
Week 20 (Day 141)	< 65	65	83.3	62	95.4	4.84	13.29	1.46	8.21
Week 24 (Day 169)	< 65	59	75.6	55	93.2	4.85	11.86	1.64	8.05
Week 28 (Day 197)	< 65	55	70.5	51	92.7	6.54	16.36	1.94	11.14
Week 32 (Day 225)	< 65	53	67.9	48	90.6	3.47	15.74	-1.10	8.04
Week 36 (Day 253)	< 65	53	67.9	50	94.3	4.00	14.51	-0.12	8.12
Week 40 (Day 281)	< 65	52	66.7	48	92.3	4.86	16.83	-0.03	9.75
Week 44 (Day 309)	< 65	52	66.7	48	92.3	8.33	18.83	2.87	13.80
Week 48 (Day 337)	< 65	47	60.3	26	55.3	3.85	10.86	-0.54	8.23
Week 52 (Day 365)	< 65	36	46.2	4	11.1	0.00	0.00	NE	NE
Week 56 (Day 393)	< 65	30	38.5	9	30.0	0.00	0.00	NE	NE
Week 60 (Day 421)	< 65	25	32.1	1	4.0	0.00	NE	NE	NE
Week 64 (Day 449)	< 65	24	30.8	7	29.2	4.76	12.60	-6.89	16.41
Week 68 (Day 477)	< 65	22	28.2	1	4.5	0.00	NE	NE	NE
Week 72 (Day 505)	< 65	22	28.2	4	18.2	0.00	0.00	NE	NE
Week 76 (Day 533)	< 65	21	26.9	2	9.5	0.00	0.00	NE	NE
Week 80 (Day 561)	< 65	21	26.9	5	23.8	0.00	0.00	NE	NE
Week 84 (Day 589)	< 65	15	19.2	1	6.7	0.00	NE	NE	NE
Week 88 (Day 617)	< 65	12	15.4	2	16.7	0.00	0.00	NE	NE
Week 92 (Day 645)	< 65	6	7.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	6.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	78	100.0	76	97.4	10.53	20.52	5.84	15.22
End of Study (LOCF)	< 65	78	100.0	76	97.4	9.65	20.23	5.03	14.27
Baseline	>= 65	35	100.0	35	100.0	9.52	19.08	2.97	16.08
Week 4 (Day 29)	>= 65	35	100.0	27	77.1	11.11	24.46	1.44	20.79
Week 8 (Day 57)	>= 65	28	80.0	26	92.9	6.41	16.38	-0.21	13.03
Week 12 (Day 85)	>= 65	26	74.3	26	100.0	10.26	15.69	3.92	16.59

Week 16 (Day 113)	>= 65	26	74.3	26	100.0	2.56	9.06	-1.09	6.22
Week 20 (Day 141)	>= 65	24	68.6	21	87.5	11.11	21.94	1.12	21.10
Week 24 (Day 169)	>= 65	22	62.9	18	81.8	9.26	19.15	-0.26	18.78
Week 28 (Day 197)	>= 65	19	54.3	18	94.7	14.81	28.52	0.63	29.00
Week 32 (Day 225)	>= 65	18	51.4	15	83.3	15.56	24.77	1.84	29.28
Week 36 (Day 253)	>= 65	18	51.4	15	83.3	11.11	20.57	-0.28	22.50
Week 40 (Day 281)	>= 65	15	42.9	10	66.7	10.00	16.10	-1.52	21.52
Week 44 (Day 309)	>= 65	12	34.3	10	83.3	6.67	14.05	-3.39	16.72
Week 48 (Day 337)	>= 65	11	31.4	7	63.6	4.76	12.60	-6.89	16.41
Week 52 (Day 365)	>= 65	9	25.7	3	33.3	22.22	19.25	-25.59	70.03
Week 56 (Day 393)	>= 65	7	20.0	3	42.9	0.00	0.00	NE	NE
Week 60 (Day 421)	>= 65	7	20.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	7	20.0	2	28.6	0.00	0.00	NE	NE
Week 68 (Day 477)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	4	11.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	4	11.4	1	25.0	0.00	NE	NE	NE
Week 84 (Day 589)	>= 65	3	8.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	5.7	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	35	100.0	35	100.0	8.57	20.36	1.58	15.57
End of Study (LOCF)	>= 65	35	100.0	35	100.0	7.62	19.94	0.77	14.47
ECOG performance status									
Baseline	0	33	100.0	31	93.9	6.45	15.91	0.61	12.29
Week 4 (Day 29)	0	33	100.0	27	81.8	6.17	20.75	-2.04	14.38
Week 8 (Day 57)	0	30	90.9	27	90.0	8.64	19.81	0.80	16.48
Week 12 (Day 85)	0	29	87.9	26	89.7	7.69	14.32	1.91	13.48
Week 16 (Day 113)	0	28	84.8	24	85.7	4.17	11.26	-0.59	8.92
Week 20 (Day 141)	0	26	78.8	24	92.3	6.94	16.97	-0.22	14.11
Week 24 (Day 169)	0	24	72.7	20	83.3	10.00	19.04	1.09	18.91
Week 28 (Day 197)	0	21	63.6	19	90.5	12.28	27.69	-1.07	25.63

Week 32 (Day 225)	0	21	63.6	18	85.7	5.56	17.15	-2.97	14.08
Week 36 (Day 253)	0	21	63.6	20	95.2	5.00	12.21	-0.72	10.72
Week 40 (Day 281)	0	21	63.6	19	90.5	8.77	15.08	1.50	16.04
Week 44 (Day 309)	0	21	63.6	17	81.0	15.69	26.66	1.98	29.39
Week 48 (Day 337)	0	19	57.6	12	63.2	5.56	12.97	-2.69	13.80
Week 52 (Day 365)	0	18	54.5	3	16.7	11.11	19.25	-36.70	58.92
Week 56 (Day 393)	0	16	48.5	5	31.3	0.00	0.00	NE	NE
Week 60 (Day 421)	0	16	48.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	0	16	48.5	5	31.3	6.67	14.91	-11.84	25.18
Week 68 (Day 477)	0	14	42.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	0	14	42.4	1	7.1	0.00	NE	NE	NE
Week 76 (Day 533)	0	12	36.4	1	8.3	0.00	NE	NE	NE
Week 80 (Day 561)	0	12	36.4	1	8.3	0.00	NE	NE	NE
Week 84 (Day 589)	0	10	30.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	9	27.3	1	11.1	0.00	NE	NE	NE
Week 92 (Day 645)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	9.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	3.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	33	100.0	33	100.0	18.18	27.75	8.34	28.02
End of Study (LOCF)	0	33	100.0	33	100.0	15.15	27.75	5.31	24.99
Baseline	1	79	100.0	76	96.2	4.39	13.71	1.25	7.52
Week 4 (Day 29)	1	79	100.0	67	84.8	5.47	13.73	2.12	8.82
Week 8 (Day 57)	1	70	88.6	65	92.9	6.67	16.87	2.49	10.85
Week 12 (Day 85)	1	68	86.1	64	94.1	4.69	11.68	1.77	7.60
Week 16 (Day 113)	1	67	84.8	61	91.0	4.37	11.35	1.47	7.28
Week 20 (Day 141)	1	63	79.7	59	93.7	6.21	15.75	2.11	10.32
Week 24 (Day 169)	1	57	72.2	53	93.0	4.40	11.39	1.26	7.54
Week 28 (Day 197)	1	53	67.1	50	94.3	7.33	16.89	2.53	12.13
Week 32 (Day 225)	1	50	63.3	45	90.0	6.67	19.59	0.78	12.55
Week 36 (Day 253)	1	50	63.3	45	90.0	5.93	17.82	0.57	11.28
Week 40 (Day 281)	1	46	58.2	39	84.8	4.27	17.40	-1.37	9.92

Week 44 (Day 309)	1	43	54.4	41	95.3	4.88	11.93	1.11	8.64
Week 48 (Day 337)	1	39	49.4	21	53.8	3.17	10.03	-1.39	7.74
Week 52 (Day 365)	1	27	34.2	4	14.8	8.33	16.67	-18.19	34.85
Week 56 (Day 393)	1	21	26.6	7	33.3	0.00	0.00	NE	NE
Week 60 (Day 421)	1	16	20.3	1	6.3	0.00	NE	NE	NE
Week 64 (Day 449)	1	15	19.0	4	26.7	0.00	0.00	NE	NE
Week 68 (Day 477)	1	14	17.7	1	7.1	0.00	NE	NE	NE
Week 72 (Day 505)	1	14	17.7	3	21.4	0.00	0.00	NE	NE
Week 76 (Day 533)	1	13	16.5	1	7.7	0.00	NE	NE	NE
Week 80 (Day 561)	1	13	16.5	5	38.5	0.00	0.00	NE	NE
Week 84 (Day 589)	1	8	10.1	1	12.5	0.00	NE	NE	NE
Week 88 (Day 617)	1	5	6.3	1	20.0	0.00	NE	NE	NE
Week 92 (Day 645)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	2.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	79	100.0	77	97.5	6.49	15.33	3.01	9.97
End of Study (LOCF)	1	79	100.0	77	97.5	6.49	15.33	3.01	9.97
Baseline	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Geographic region									
Baseline	USA	22	100.0	22	100.0	9.09	18.35	0.96	17.23
Week 4 (Day 29)	USA	22	100.0	18	81.8	11.11	19.80	1.26	20.96
Week 8 (Day 57)	USA	20	90.9	18	90.0	14.81	23.49	3.13	26.50
Week 12 (Day 85)	USA	20	90.9	19	95.0	10.53	15.92	2.85	18.20
Week 16 (Day 113)	USA	19	86.4	17	89.5	7.84	14.57	0.35	15.34
Week 20 (Day 141)	USA	19	86.4	17	89.5	9.80	19.60	-0.27	19.88
Week 24 (Day 169)	USA	16	72.7	14	87.5	9.52	15.63	0.50	18.55
Week 28 (Day 197)	USA	15	68.2	12	80.0	13.89	30.01	-5.18	32.96
Week 32 (Day 225)	USA	15	68.2	13	86.7	17.95	32.25	-1.54	37.44
Week 36 (Day 253)	USA	15	68.2	13	86.7	10.26	21.01	-2.44	22.96
Week 40 (Day 281)	USA	14	63.6	10	71.4	16.67	32.39	-6.51	39.84

Week 44 (Day 309)	USA	13	59.1	11	84.6	12.12	16.82	0.82	23.42
Week 48 (Day 337)	USA	13	59.1	10	76.9	6.67	14.05	-3.39	16.72
Week 52 (Day 365)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	USA	12	54.5	6	50.0	0.00	0.00	NE	NE
Week 60 (Day 421)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	11	50.0	4	36.4	8.33	16.67	-18.19	34.85
Week 68 (Day 477)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	10	45.5	1	10.0	0.00	NE	NE	NE
Week 76 (Day 533)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	10	45.5	2	20.0	0.00	0.00	NE	NE
Week 84 (Day 589)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	13.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	4.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	22	100.0	22	100.0	13.64	19.68	4.91	22.36
End of Study (LOCF)	USA	22	100.0	22	100.0	9.09	18.35	0.96	17.23
Baseline	Europe (EU)	32	100.0	29	90.6	3.45	10.33	-0.48	7.38
Week 4 (Day 29)	Europe (EU)	32	100.0	25	78.1	1.33	6.67	-1.42	4.09
Week 8 (Day 57)	Europe (EU)	29	90.6	25	86.2	13.33	23.57	3.60	23.06
Week 12 (Day 85)	Europe (EU)	26	81.3	24	92.3	2.78	9.41	-1.20	6.75
Week 16 (Day 113)	Europe (EU)	25	78.1	20	80.0	6.67	13.68	0.26	13.07
Week 20 (Day 141)	Europe (EU)	23	71.9	22	95.7	7.58	17.61	-0.23	15.39
Week 24 (Day 169)	Europe (EU)	21	65.6	20	95.2	8.33	18.34	-0.25	16.92
Week 28 (Day 197)	Europe (EU)	20	62.5	20	100.0	6.67	17.44	-1.49	14.83
Week 32 (Day 225)	Europe (EU)	18	56.3	16	88.9	2.08	8.33	-2.36	6.52
Week 36 (Day 253)	Europe (EU)	18	56.3	17	94.4	1.96	8.08	-2.20	6.12
Week 40 (Day 281)	Europe (EU)	17	53.1	16	94.1	4.17	11.39	-1.90	10.23
Week 44 (Day 309)	Europe (EU)	17	53.1	14	82.4	9.52	27.51	-6.36	25.41

Week 48 (Day 337)	Europe (EU)	14	43.8	10	71.4	3.33	10.54	-4.21	10.87
Week 52 (Day 365)	Europe (EU)	13	40.6	3	23.1	11.11	19.25	-36.70	58.92
Week 56 (Day 393)	Europe (EU)	11	34.4	5	45.5	0.00	0.00	NE	NE
Week 60 (Day 421)	Europe (EU)	11	34.4	1	9.1	0.00	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	11	34.4	5	45.5	0.00	0.00	NE	NE
Week 68 (Day 477)	Europe (EU)	10	31.3	1	10.0	0.00	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	10	31.3	3	30.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Europe (EU)	8	25.0	2	25.0	0.00	0.00	NE	NE
Week 80 (Day 561)	Europe (EU)	8	25.0	4	50.0	0.00	0.00	NE	NE
Week 84 (Day 589)	Europe (EU)	6	18.8	1	16.7	0.00	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	9.4	2	66.7	0.00	0.00	NE	NE
Cycle 12 (LOCF)	Europe (EU)	32	100.0	31	96.9	10.75	23.39	2.17	19.33
End of Study (LOCF)	Europe (EU)	32	100.0	31	96.9	10.75	23.39	2.17	19.33
Baseline	Asia (AS)	59	100.0	57	96.6	4.09	14.18	0.33	7.86
Week 4 (Day 29)	Asia (AS)	59	100.0	52	88.1	5.77	17.11	1.00	10.53
Week 8 (Day 57)	Asia (AS)	52	88.1	49	94.2	1.36	6.66	-0.55	3.27
Week 12 (Day 85)	Asia (AS)	51	86.4	47	92.2	4.96	12.00	1.44	8.49
Week 16 (Day 113)	Asia (AS)	51	86.4	48	94.1	2.08	8.15	-0.28	4.45
Week 20 (Day 141)	Asia (AS)	47	79.7	44	93.6	4.55	13.62	0.40	8.69
Week 24 (Day 169)	Asia (AS)	44	74.6	39	88.6	3.42	10.25	0.10	6.74
Week 28 (Day 197)	Asia (AS)	39	66.1	37	94.9	8.11	18.27	2.02	14.20
Week 32 (Day 225)	Asia (AS)	38	64.4	34	89.5	3.92	13.64	-0.84	8.68
Week 36 (Day 253)	Asia (AS)	38	64.4	35	92.1	5.71	17.12	-0.17	11.60
Week 40 (Day 281)	Asia (AS)	36	61.0	32	88.9	3.13	9.87	-0.43	6.68
Week 44 (Day 309)	Asia (AS)	34	57.6	33	97.1	6.06	13.06	1.43	10.69
Week 48 (Day 337)	Asia (AS)	31	52.5	13	41.9	2.56	9.25	-3.02	8.15
Week 52 (Day 365)	Asia (AS)	20	33.9	4	20.0	8.33	16.67	-18.19	34.85
Week 56 (Day 393)	Asia (AS)	14	23.7	1	7.1	0.00	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	10.2	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	8.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	3.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	59	100.0	58	98.3	8.05	19.05	3.04	13.06
End of Study (LOCF)	Asia (AS)	59	100.0	58	98.3	8.05	19.05	3.04	13.06
Race/ethnicity									
Baseline	Asian	61	100.0	58	95.1	4.02	14.07	0.32	7.72
Week 4 (Day 29)	Asian	61	100.0	52	85.2	5.77	17.11	1.00	10.53
Week 8 (Day 57)	Asian	53	86.9	49	92.5	1.36	6.66	-0.55	3.27
Week 12 (Day 85)	Asian	52	85.2	48	92.3	4.86	11.89	1.41	8.31
Week 16 (Day 113)	Asian	52	85.2	49	94.2	2.04	8.07	-0.28	4.36
Week 20 (Day 141)	Asian	48	78.7	45	93.8	5.93	16.34	1.02	10.84
Week 24 (Day 169)	Asian	44	72.1	39	88.6	3.42	10.25	0.10	6.74
Week 28 (Day 197)	Asian	39	63.9	37	94.9	8.11	18.27	2.02	14.20
Week 32 (Day 225)	Asian	38	62.3	34	89.5	3.92	13.64	-0.84	8.68
Week 36 (Day 253)	Asian	38	62.3	35	92.1	5.71	17.12	-0.17	11.60
Week 40 (Day 281)	Asian	36	59.0	32	88.9	3.13	9.87	-0.43	6.68
Week 44 (Day 309)	Asian	34	55.7	33	97.1	6.06	13.06	1.43	10.69
Week 48 (Day 337)	Asian	31	50.8	13	41.9	2.56	9.25	-3.02	8.15
Week 52 (Day 365)	Asian	20	32.8	4	20.0	8.33	16.67	-18.19	34.85
Week 56 (Day 393)	Asian	14	23.0	1	7.1	0.00	NE	NE	NE
Week 60 (Day 421)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	9.8	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	8.2	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	3.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	61	100.0	59	96.7	9.04	20.37	3.73	14.35
End of Study (LOCF)	Asian	61	100.0	59	96.7	9.04	20.37	3.73	14.35
Baseline	Non-Asian	45	100.0	44	97.8	6.82	15.38	2.14	11.50
Week 4 (Day 29)	Non-Asian	45	100.0	39	86.7	5.98	15.05	1.11	10.86
Week 8 (Day 57)	Non-Asian	42	93.3	38	90.5	14.04	22.77	6.55	21.52
Week 12 (Day 85)	Non-Asian	39	86.7	37	94.9	7.21	13.91	2.57	11.85
Week 16 (Day 113)	Non-Asian	37	82.2	34	91.9	7.84	14.35	2.84	12.85
Week 20 (Day 141)	Non-Asian	36	80.0	34	94.4	7.84	16.53	2.07	13.61
Week 24 (Day 169)	Non-Asian	32	71.1	31	96.9	9.68	17.62	3.21	16.14
Week 28 (Day 197)	Non-Asian	30	66.7	28	93.3	8.33	21.52	-0.01	16.68
Week 32 (Day 225)	Non-Asian	28	62.2	25	89.3	10.67	24.94	0.37	20.96
Week 36 (Day 253)	Non-Asian	28	62.2	26	92.9	6.41	16.38	-0.21	13.03
Week 40 (Day 281)	Non-Asian	26	57.8	22	84.6	9.09	23.42	-1.29	19.47
Week 44 (Day 309)	Non-Asian	25	55.6	21	84.0	6.35	13.41	0.24	12.45
Week 48 (Day 337)	Non-Asian	23	51.1	17	73.9	5.88	13.10	-0.85	12.62
Week 52 (Day 365)	Non-Asian	21	46.7	3	14.3	11.11	19.25	-36.70	58.92
Week 56 (Day 393)	Non-Asian	19	42.2	10	52.6	0.00	0.00	NE	NE
Week 60 (Day 421)	Non-Asian	19	42.2	1	5.3	0.00	NE	NE	NE
Week 64 (Day 449)	Non-Asian	18	40.0	7	38.9	0.00	0.00	NE	NE
Week 68 (Day 477)	Non-Asian	17	37.8	1	5.9	0.00	NE	NE	NE
Week 72 (Day 505)	Non-Asian	17	37.8	3	17.6	0.00	0.00	NE	NE
Week 76 (Day 533)	Non-Asian	15	33.3	2	13.3	0.00	0.00	NE	NE
Week 80 (Day 561)	Non-Asian	15	33.3	5	33.3	0.00	0.00	NE	NE
Week 84 (Day 589)	Non-Asian	10	22.2	1	10.0	0.00	NE	NE	NE
Week 88 (Day 617)	Non-Asian	7	15.6	2	28.6	0.00	0.00	NE	NE
Week 92 (Day 645)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	45	100.0	45	100.0	8.89	16.51	3.93	13.85

End of Study (LOCF)	Non-Asian	45	100.0	45	100.0	7.41	15.71	2.69	12.13
Baseline	Unknown	7	100.0	6	85.7	0.00	0.00	NE	NE
Week 4 (Day 29)	Unknown	7	100.0	4	57.1	0.00	0.00	NE	NE
Week 8 (Day 57)	Unknown	6	85.7	5	83.3	13.33	29.81	-23.69	50.35
Week 12 (Day 85)	Unknown	6	85.7	5	83.3	0.00	0.00	NE	NE
Week 16 (Day 113)	Unknown	6	85.7	2	33.3	0.00	0.00	NE	NE
Week 20 (Day 141)	Unknown	5	71.4	4	80.0	0.00	0.00	NE	NE
Week 24 (Day 169)	Unknown	5	71.4	3	60.0	0.00	0.00	NE	NE
Week 28 (Day 197)	Unknown	5	71.4	4	80.0	16.67	33.33	-36.37	69.71
Week 32 (Day 225)	Unknown	5	71.4	4	80.0	0.00	0.00	NE	NE
Week 36 (Day 253)	Unknown	5	71.4	4	80.0	0.00	0.00	NE	NE
Week 40 (Day 281)	Unknown	5	71.4	4	80.0	8.33	16.67	-18.19	34.85
Week 44 (Day 309)	Unknown	5	71.4	4	80.0	33.33	47.14	-41.68	108.34
Week 48 (Day 337)	Unknown	4	57.1	3	75.0	0.00	0.00	NE	NE
Week 52 (Day 365)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	4	57.1	1	25.0	0.00	NE	NE	NE
Week 60 (Day 421)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	4	57.1	2	50.0	16.67	23.57	-195.10	228.44
Week 68 (Day 477)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	3	42.9	1	33.3	0.00	NE	NE	NE
Week 76 (Day 533)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	3	42.9	1	33.3	0.00	NE	NE	NE
Week 84 (Day 589)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	14.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	7	100.0	7	100.0	23.81	37.09	-10.49	58.11
End of Study (LOCF)	Unknown	7	100.0	7	100.0	19.05	37.80	-15.91	54.00
Number of prior antineoplastic systemic therapy lines I									
Baseline	1	60	100.0	57	95.0	3.51	10.32	0.77	6.25

Week 4 (Day 29)	1	60	100.0	50	83.3	5.33	14.06	1.34	9.33
Week 8 (Day 57)	1	54	90.0	49	90.7	6.12	14.71	1.90	10.35
Week 12 (Day 85)	1	52	86.7	48	92.3	4.86	11.89	1.41	8.31
Week 16 (Day 113)	1	51	85.0	46	90.2	4.35	11.35	0.98	7.72
Week 20 (Day 141)	1	48	80.0	43	89.6	9.30	19.69	3.24	15.36
Week 24 (Day 169)	1	43	71.7	39	90.7	5.98	15.05	1.11	10.86
Week 28 (Day 197)	1	38	63.3	34	89.5	7.84	18.46	1.40	14.28
Week 32 (Day 225)	1	35	58.3	29	82.9	8.05	21.19	-0.01	16.10
Week 36 (Day 253)	1	35	58.3	31	88.6	7.53	18.68	0.68	14.38
Week 40 (Day 281)	1	32	53.3	26	81.3	6.41	21.12	-2.12	14.94
Week 44 (Day 309)	1	32	53.3	27	84.4	9.88	22.29	1.06	18.70
Week 48 (Day 337)	1	27	45.0	16	59.3	4.17	11.39	-1.90	10.23
Week 52 (Day 365)	1	23	38.3	5	21.7	6.67	14.91	-11.84	25.18
Week 56 (Day 393)	1	16	26.7	4	25.0	0.00	0.00	NE	NE
Week 60 (Day 421)	1	14	23.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	13	21.7	4	30.8	0.00	0.00	NE	NE
Week 68 (Day 477)	1	12	20.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	12	20.0	1	8.3	0.00	NE	NE	NE
Week 76 (Day 533)	1	11	18.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	11	18.3	2	18.2	0.00	0.00	NE	NE
Week 84 (Day 589)	1	9	15.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	1	8	13.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	1	3	5.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	1	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	60	100.0	58	96.7	10.34	20.90	4.85	15.84
End of Study (LOCF)	1	60	100.0	58	96.7	9.20	20.51	3.80	14.59
Baseline	>= 2	53	100.0	51	96.2	6.54	17.66	1.57	11.50
Week 4 (Day 29)	>= 2	53	100.0	45	84.9	5.93	17.82	0.57	11.28
Week 8 (Day 57)	>= 2	47	88.7	43	91.5	8.53	20.69	2.16	14.90
Week 12 (Day 85)	>= 2	45	84.9	42	93.3	6.35	13.25	2.22	10.48
Week 16 (Day 113)	>= 2	44	83.0	39	88.6	4.27	11.29	0.61	7.93

Week 20 (Day 141)	>= 2	41	77.4	40	97.6	3.33	10.13	0.09	6.57
Week 24 (Day 169)	>= 2	38	71.7	34	89.5	5.88	12.90	1.38	10.38
Week 28 (Day 197)	>= 2	36	67.9	35	97.2	9.52	22.25	1.88	17.17
Week 32 (Day 225)	>= 2	36	67.9	34	94.4	4.90	16.68	-0.92	10.72
Week 36 (Day 253)	>= 2	36	67.9	34	94.4	3.92	13.64	-0.84	8.68
Week 40 (Day 281)	>= 2	35	66.0	32	91.4	5.21	12.30	0.77	9.64
Week 44 (Day 309)	>= 2	32	60.4	31	96.9	6.45	13.39	1.54	11.36
Week 48 (Day 337)	>= 2	31	58.5	17	54.8	3.92	11.07	-1.77	9.61
Week 52 (Day 365)	>= 2	22	41.5	2	9.1	16.67	23.57	-195.10	228.44
Week 56 (Day 393)	>= 2	21	39.6	8	38.1	0.00	0.00	NE	NE
Week 60 (Day 421)	>= 2	18	34.0	1	5.6	0.00	NE	NE	NE
Week 64 (Day 449)	>= 2	18	34.0	5	27.8	6.67	14.91	-11.84	25.18
Week 68 (Day 477)	>= 2	16	30.2	1	6.3	0.00	NE	NE	NE
Week 72 (Day 505)	>= 2	16	30.2	3	18.8	0.00	0.00	NE	NE
Week 76 (Day 533)	>= 2	14	26.4	2	14.3	0.00	0.00	NE	NE
Week 80 (Day 561)	>= 2	14	26.4	4	28.6	0.00	0.00	NE	NE
Week 84 (Day 589)	>= 2	9	17.0	1	11.1	0.00	NE	NE	NE
Week 88 (Day 617)	>= 2	6	11.3	2	33.3	0.00	0.00	NE	NE
Week 92 (Day 645)	>= 2	2	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 2	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 2	53	100.0	53	100.0	9.43	20.02	3.92	14.95
End of Study (LOCF)	>= 2	53	100.0	53	100.0	8.81	19.78	3.35	14.26

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TP_QSC30DI_SG.xls
27OCT2021 7:24

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Diarrhoea
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	45	41.7	32.8	51.1
	Cycle 12 (LOCF)	n/a	108	95.6	18	16.7	10.8	24.8
	End of Study (LOCF)	n/a	108	95.6	17	15.7	10.1	23.8
Sex	All visits	Female	67	59.3	29	43.3	32.1	55.2
		Male	41	36.3	16	39.0	25.7	54.3
	Cycle 12 (LOCF)	Female	67	59.3	13	19.4	11.7	30.4
		Male	41	36.3	5	12.2	5.3	25.5
	End of Study (LOCF)	Female	67	59.3	12	17.9	10.6	28.7
		Male	41	36.3	5	12.2	5.3	25.5
Age	All visits	< 65	73	64.6	31	42.5	31.8	53.9
		>= 65	35	31.0	14	40.0	25.6	56.4
	Cycle 12 (LOCF)	< 65	73	64.6	15	20.5	12.9	31.2
		>= 65	35	31.0	3	8.6	3.0	22.4
	End of Study (LOCF)	< 65	73	64.6	14	19.2	11.8	29.7
		>= 65	35	31.0	3	8.6	3.0	22.4
ECOG performance status	All visits	0	31	27.4	17	54.8	37.8	70.8
		1	76	67.3	28	36.8	26.9	48.1
		Missing	1	0.9	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	31	27.4	10	32.3	18.6	49.9
		1	76	67.3	8	10.5	5.4	19.4
		Missing	1	0.9	0	0.0	0.0	79.3
	End of Study (LOCF)	0	31	27.4	8	25.8	13.7	43.2
		1	76	67.3	9	11.8	6.4	21.0
		Missing	1	0.9	0	0.0	0.0	79.3
Geographic region	All visits	USA	22	19.5	14	63.6	43.0	80.3
		Europe (EU)	29	25.7	13	44.8	28.4	62.5
		Asia (AS)	57	50.4	18	31.6	21.0	44.5
	Cycle 12 (LOCF)	USA	22	19.5	6	27.3	13.2	48.2
		Europe (EU)	29	25.7	5	17.2	7.6	34.5
		Asia (AS)	57	50.4	7	12.3	6.1	23.2
	End of Study (LOCF)	USA	22	19.5	4	18.2	7.3	38.5
		Europe (EU)	29	25.7	6	20.7	9.8	38.4
		Asia (AS)	57	50.4	7	12.3	6.1	23.2
Race/ethnicity	All visits	Asian	58	51.3	19	32.8	22.1	45.6
		Non-Asian	44	38.9	22	50.0	35.8	64.2
		Unknown	6	5.3	4	66.7	30.0	90.3
	Cycle 12 (LOCF)	Asian	58	51.3	8	13.8	7.2	24.9

		Non-Asian	44	38.9	7	15.9	7.9	29.4
		Unknown	6	5.3	3	50.0	18.8	81.2
	End of Study (LOCF)	Asian	58	51.3	8	13.8	7.2	24.9
		Non-Asian	44	38.9	7	15.9	7.9	29.4
		Unknown	6	5.3	2	33.3	9.7	70.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	25	43.9	31.8	56.7
		>= 2	51	45.1	20	39.2	27.0	52.9
	Cycle 12 (LOCF)	1	57	50.4	9	15.8	8.5	27.4
		>= 2	51	45.1	9	17.6	9.6	30.3
	End of Study (LOCF)	1	57	50.4	9	15.8	8.5	27.4
		>= 2	51	45.1	8	15.7	8.2	28.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30DI_W10_SG.xls
15OCT2021 13:31

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Diarrhoea
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

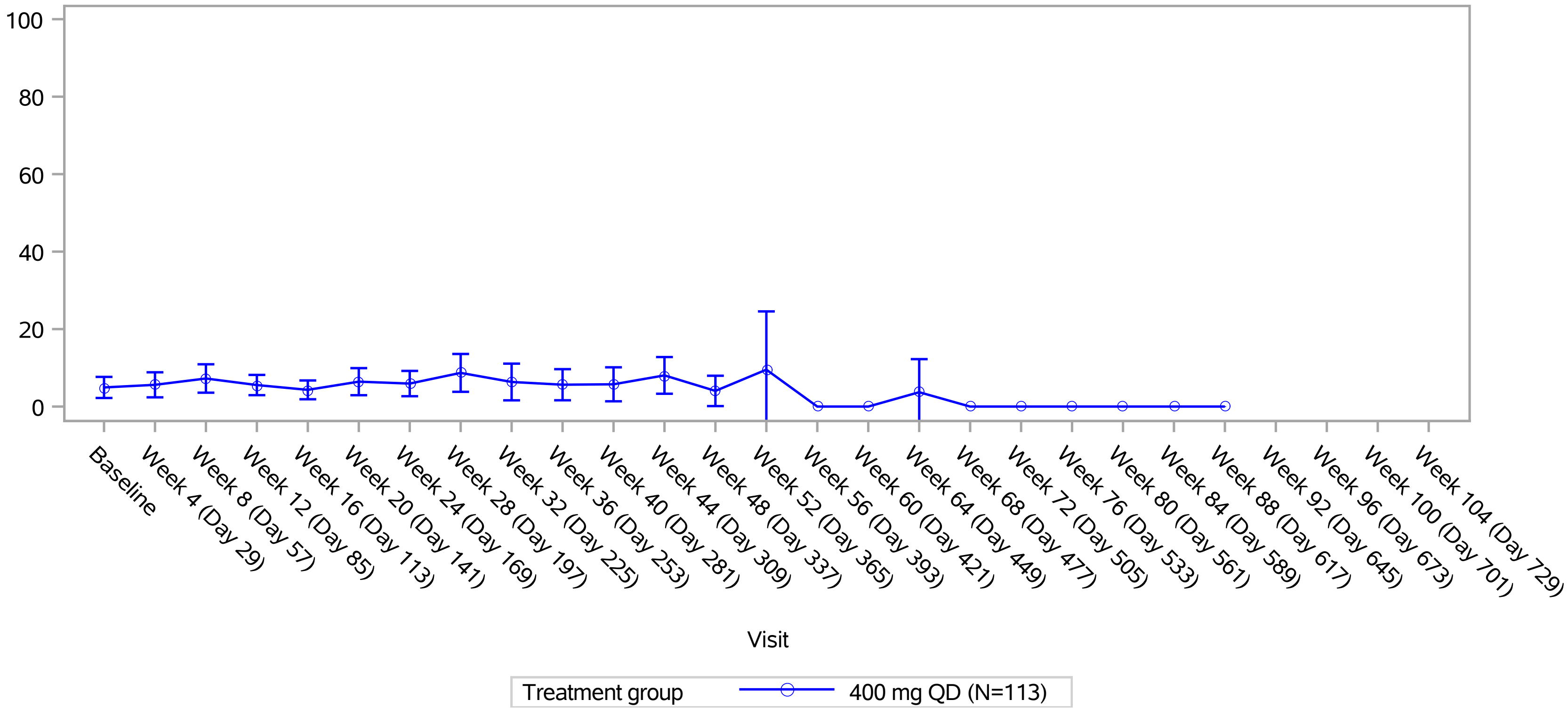
			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	45	41.7	32.8	51.1
	Cycle 12 (LOCF)	n/a	108	95.6	18	16.7	10.8	24.8
	End of Study (LOCF)	n/a	108	95.6	17	15.7	10.1	23.8
Sex	All visits	Female	67	59.3	29	43.3	32.1	55.2
		Male	41	36.3	16	39.0	25.7	54.3
	Cycle 12 (LOCF)	Female	67	59.3	13	19.4	11.7	30.4
		Male	41	36.3	5	12.2	5.3	25.5
	End of Study (LOCF)	Female	67	59.3	12	17.9	10.6	28.7
		Male	41	36.3	5	12.2	5.3	25.5
Age	All visits	< 65	73	64.6	31	42.5	31.8	53.9
		>= 65	35	31.0	14	40.0	25.6	56.4
	Cycle 12 (LOCF)	< 65	73	64.6	15	20.5	12.9	31.2
		>= 65	35	31.0	3	8.6	3.0	22.4
	End of Study (LOCF)	< 65	73	64.6	14	19.2	11.8	29.7
		>= 65	35	31.0	3	8.6	3.0	22.4
ECOG performance status	All visits	0	31	27.4	17	54.8	37.8	70.8
		1	76	67.3	28	36.8	26.9	48.1
		Missing	1	0.9	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	31	27.4	10	32.3	18.6	49.9
		1	76	67.3	8	10.5	5.4	19.4
		Missing	1	0.9	0	0.0	0.0	79.3
	End of Study (LOCF)	0	31	27.4	8	25.8	13.7	43.2
		1	76	67.3	9	11.8	6.4	21.0
		Missing	1	0.9	0	0.0	0.0	79.3
Geographic region	All visits	USA	22	19.5	14	63.6	43.0	80.3
		Europe (EU)	29	25.7	13	44.8	28.4	62.5
		Asia (AS)	57	50.4	18	31.6	21.0	44.5
	Cycle 12 (LOCF)	USA	22	19.5	6	27.3	13.2	48.2
		Europe (EU)	29	25.7	5	17.2	7.6	34.5
		Asia (AS)	57	50.4	7	12.3	6.1	23.2
	End of Study (LOCF)	USA	22	19.5	4	18.2	7.3	38.5
		Europe (EU)	29	25.7	6	20.7	9.8	38.4
		Asia (AS)	57	50.4	7	12.3	6.1	23.2
Race/ethnicity	All visits	Asian	58	51.3	19	32.8	22.1	45.6
		Non-Asian	44	38.9	22	50.0	35.8	64.2
		Unknown	6	5.3	4	66.7	30.0	90.3
	Cycle 12 (LOCF)	Asian	58	51.3	8	13.8	7.2	24.9

		Non-Asian	44	38.9	7	15.9	7.9	29.4
		Unknown	6	5.3	3	50.0	18.8	81.2
	End of Study (LOCF)	Asian	58	51.3	8	13.8	7.2	24.9
		Non-Asian	44	38.9	7	15.9	7.9	29.4
		Unknown	6	5.3	2	33.3	9.7	70.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	25	43.9	31.8	56.7
		>= 2	51	45.1	20	39.2	27.0	52.9
	Cycle 12 (LOCF)	1	57	50.4	9	15.8	8.5	27.4
		>= 2	51	45.1	9	17.6	9.6	30.3
	End of Study (LOCF)	1	57	50.4	9	15.8	8.5	27.4
		>= 2	51	45.1	8	15.7	8.2	28.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30DI_W15_SG.xls
15OCT2021 13:21

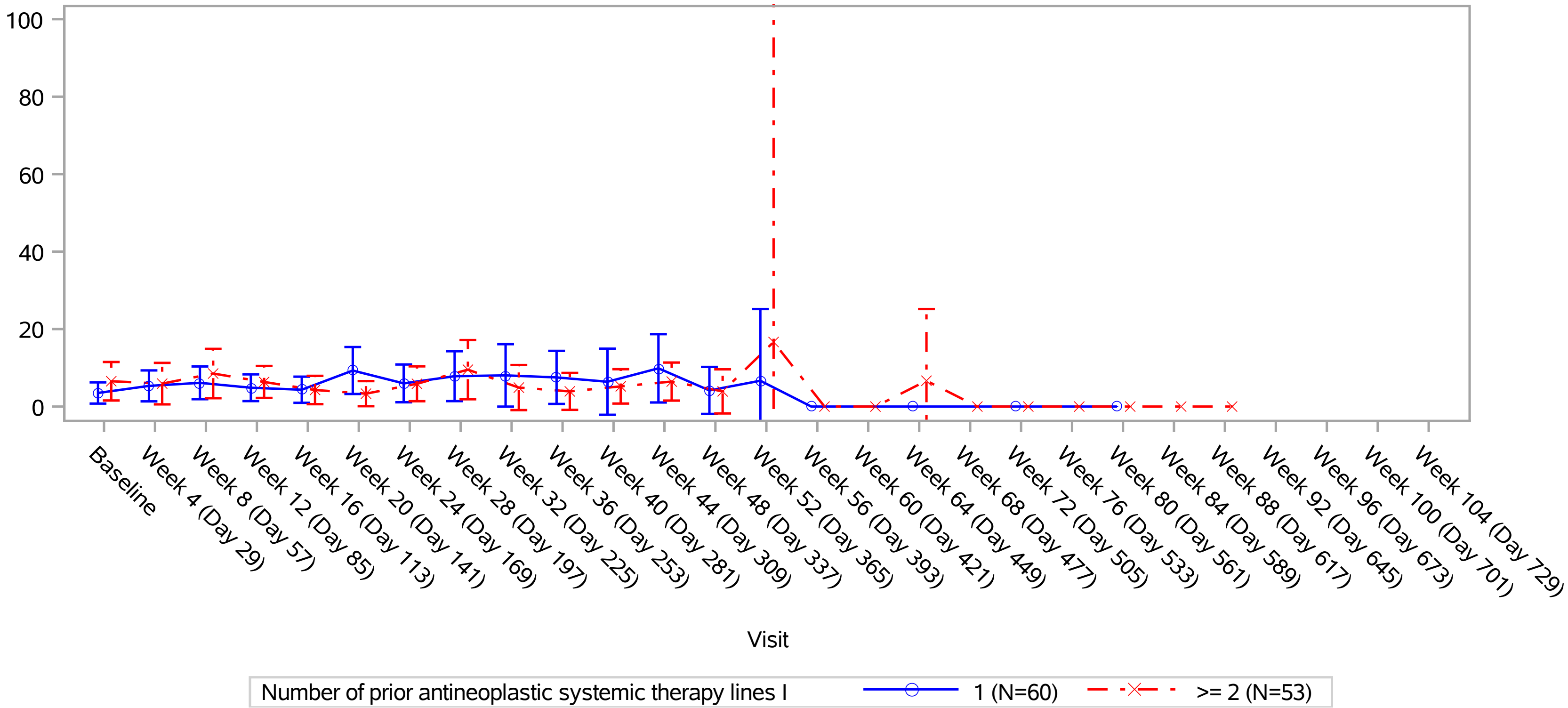
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Diarrhoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30DI.pdf
15OCT2021 17:14

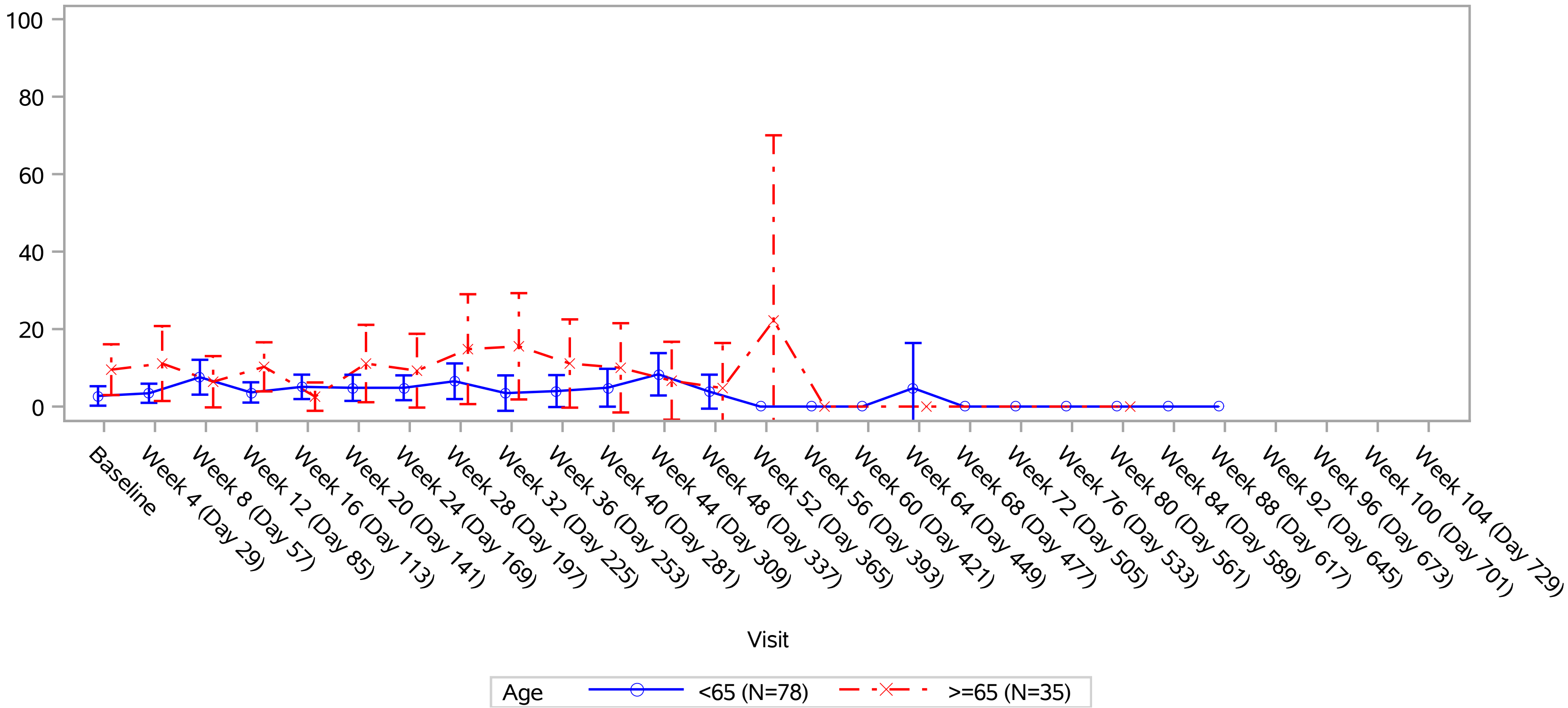
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Diarrhoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30DI_PRTHL1.pdf
15OCT2021 20:05

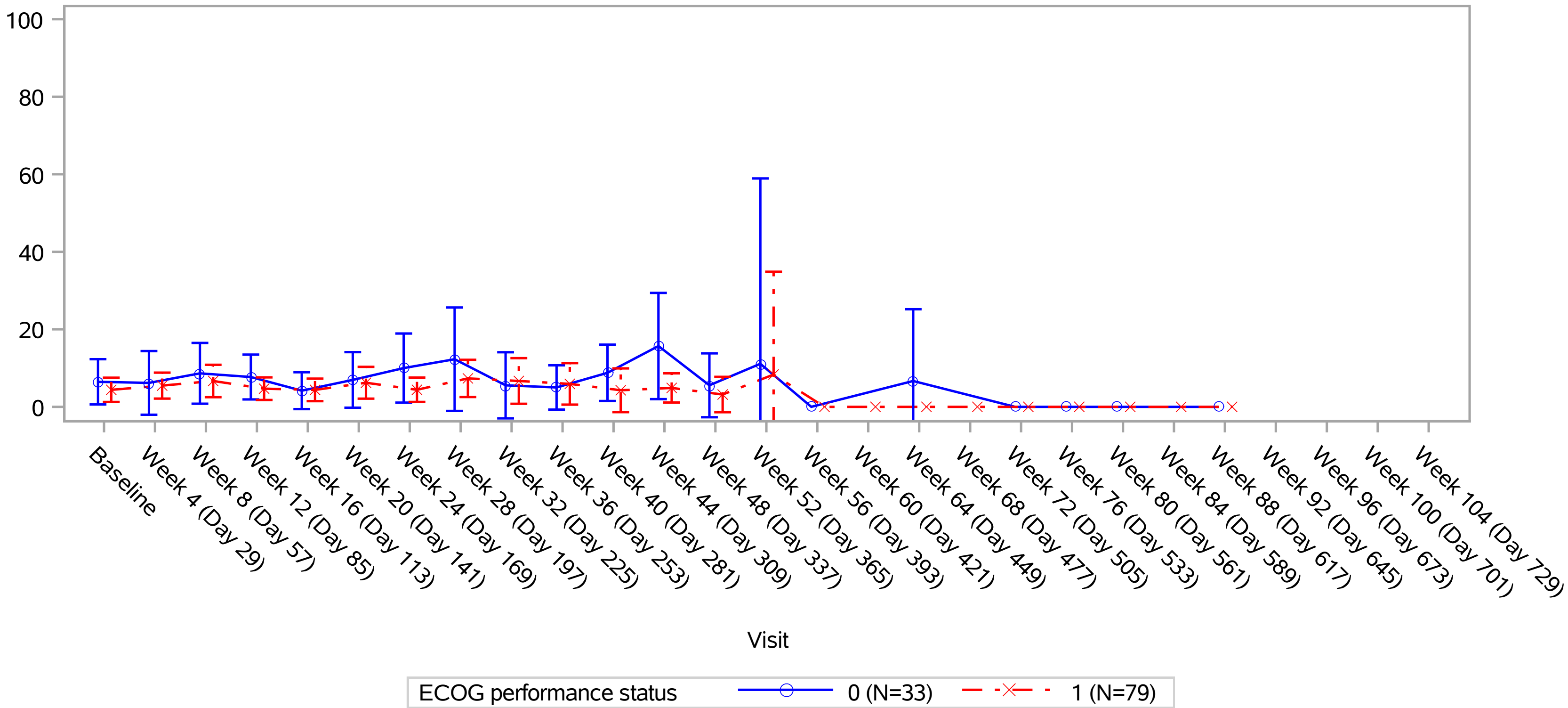
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Diarrhoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30DI_SGAGE65.pdf
15OCT2021 17:43

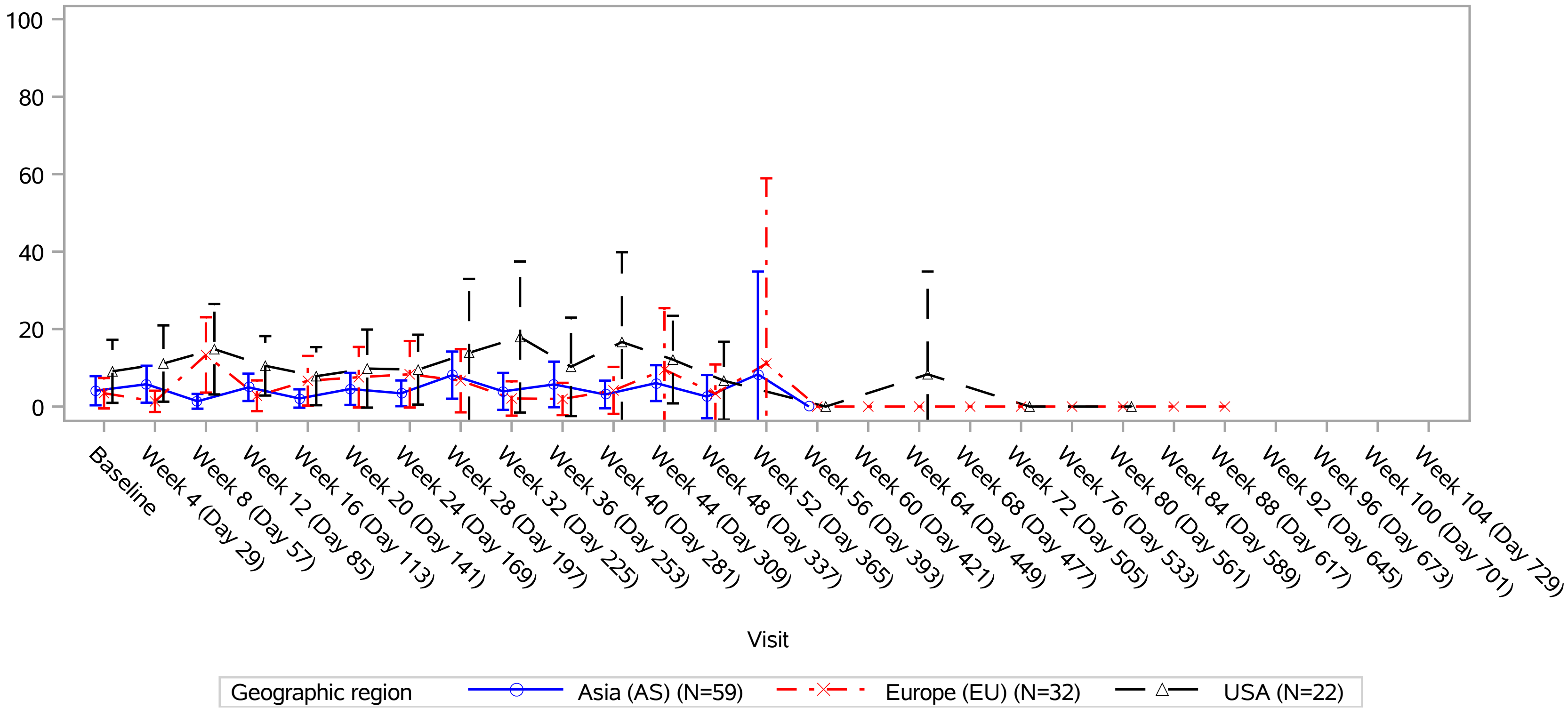
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Diarrhoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30DI_SGECOG.pdf
15OCT2021 18:13

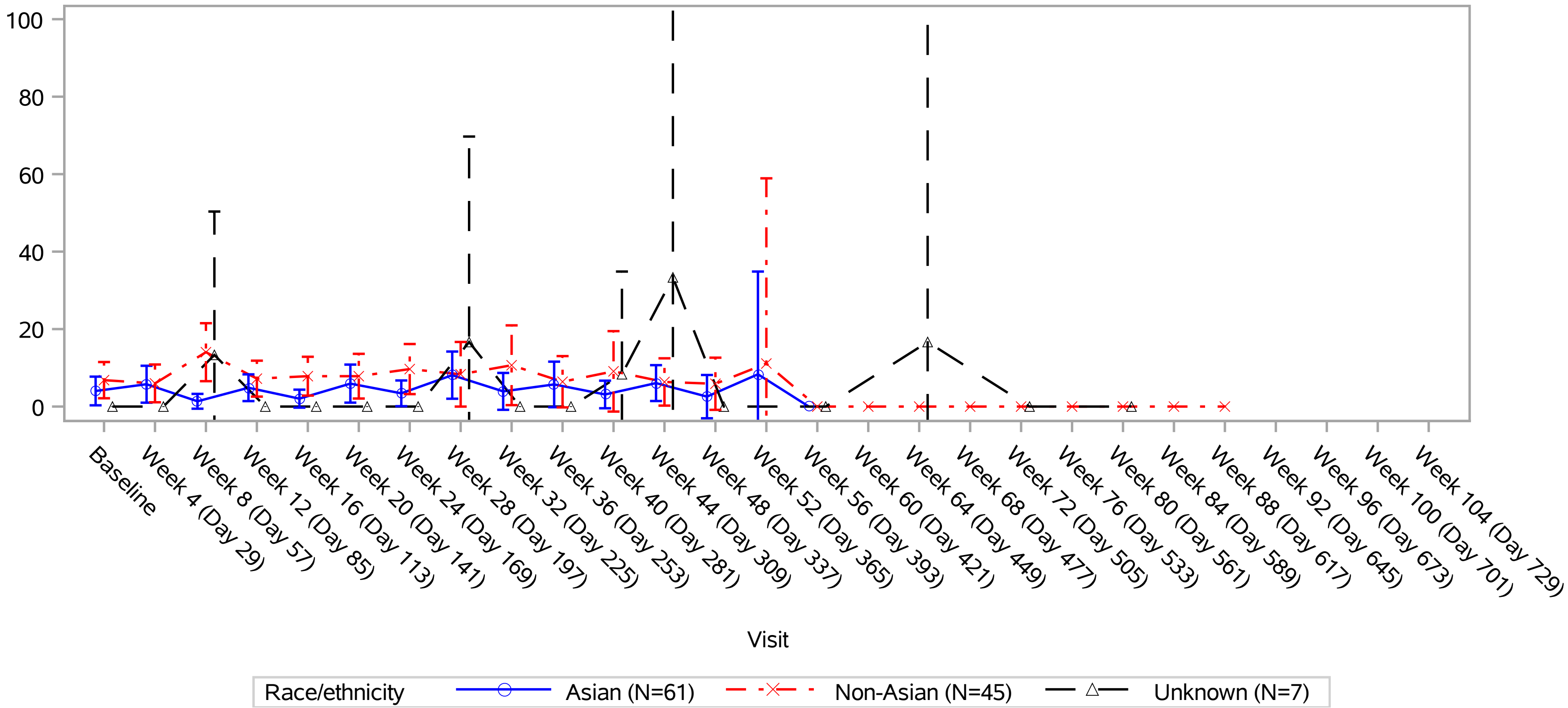
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Diarrhoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30DI_SGGEO.pdf
15OCT2021 18:44

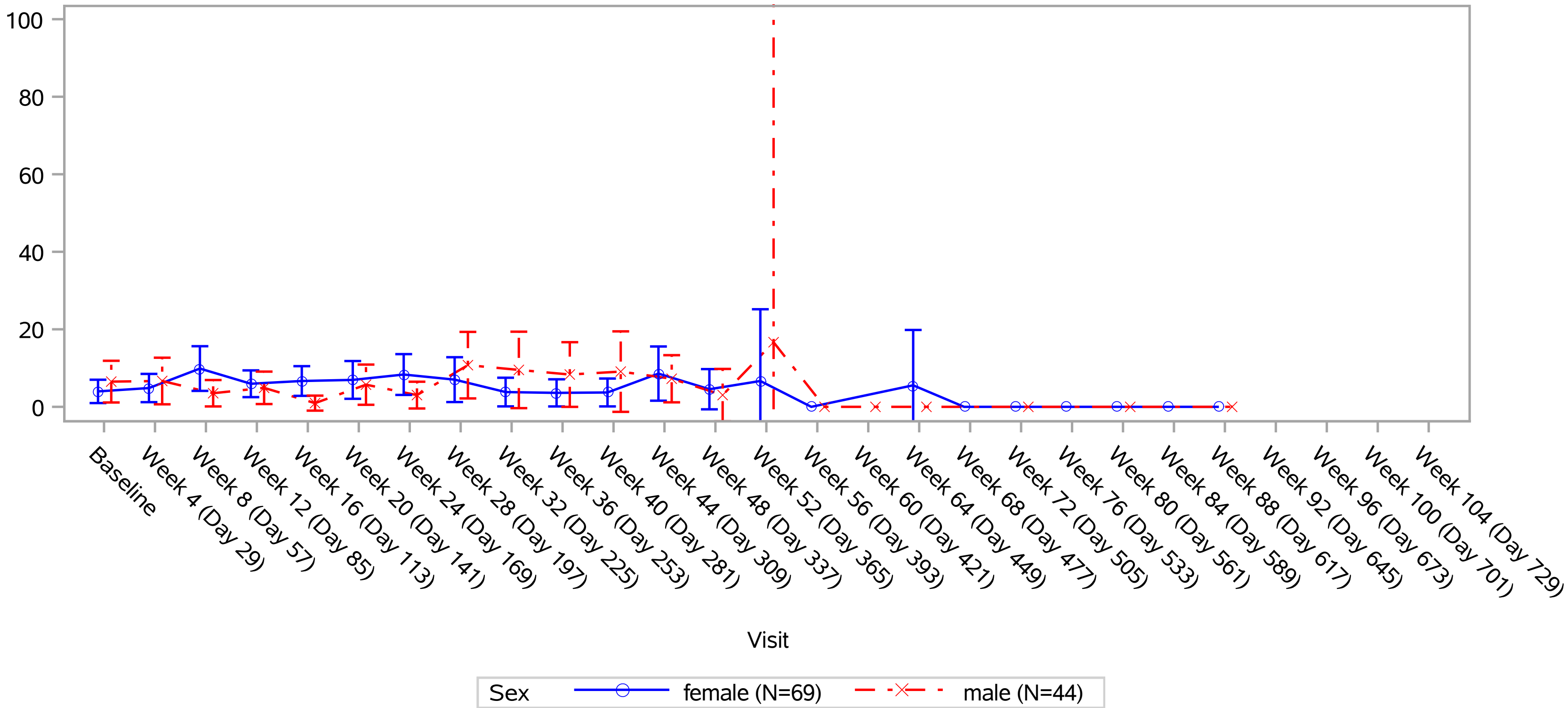
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Diarrhoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30DI_SGRE.pdf
15OCT2021 19:15

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Diarrhoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30DI_SGSEX.pdf
15OCT2021 19:45

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Dyspnoea
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=113)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	113	100.0	107	94.7	31.15	30.46	25.31	36.99
Week 4 (Day 29)	n/a	113	100.0	95	84.1	20.00	22.49	15.42	24.58
Week 8 (Day 57)	n/a	101	89.4	92	91.1	20.29	23.16	15.49	25.09
Week 12 (Day 85)	n/a	97	85.8	90	92.8	18.52	22.41	13.83	23.21
Week 16 (Day 113)	n/a	95	84.1	85	89.5	18.82	21.48	14.19	23.46
Week 20 (Day 141)	n/a	89	78.8	83	93.3	20.88	25.35	15.35	26.42
Week 24 (Day 169)	n/a	81	71.7	73	90.1	16.89	22.99	11.53	22.26
Week 28 (Day 197)	n/a	74	65.5	69	93.2	14.49	20.99	9.45	19.53
Week 32 (Day 225)	n/a	71	62.8	63	88.7	14.29	20.49	9.13	19.45
Week 36 (Day 253)	n/a	71	62.8	65	91.5	16.92	23.66	11.06	22.79
Week 40 (Day 281)	n/a	67	59.3	59	88.1	14.69	18.85	9.78	19.60
Week 44 (Day 309)	n/a	64	56.6	58	90.6	17.24	23.56	11.05	23.44
Week 48 (Day 337)	n/a	58	51.3	33	56.9	18.18	22.19	10.31	26.05
Week 52 (Day 365)	n/a	45	39.8	7	15.6	9.52	16.27	-5.52	24.57
Week 56 (Day 393)	n/a	37	32.7	12	32.4	16.67	22.47	2.39	30.95
Week 60 (Day 421)	n/a	32	28.3	1	3.1	0.00	NE	NE	NE
Week 64 (Day 449)	n/a	31	27.4	9	29.0	14.81	17.57	1.31	28.32
Week 68 (Day 477)	n/a	28	24.8	1	3.6	0.00	NE	NE	NE
Week 72 (Day 505)	n/a	28	24.8	4	14.3	8.33	16.67	-18.19	34.85
Week 76 (Day 533)	n/a	25	22.1	2	8.0	0.00	0.00	NE	NE
Week 80 (Day 561)	n/a	25	22.1	6	24.0	22.22	17.21	4.16	40.29
Week 84 (Day 589)	n/a	18	15.9	1	5.6	33.33	NE	NE	NE
Week 88 (Day 617)	n/a	14	12.4	2	14.3	16.67	23.57	-195.10	228.44
Week 92 (Day 645)	n/a	7	6.2	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	5.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	2.7	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	113	100.0	111	98.2	24.32	26.95	19.26	29.39
End of Study (LOCF)	n/a	113	100.0	111	98.2	23.12	25.74	18.28	27.96
Sex									
Baseline	Female	69	100.0	67	97.1	33.33	31.25	25.71	40.96
Week 4 (Day 29)	Female	69	100.0	55	79.7	19.39	19.97	14.00	24.79
Week 8 (Day 57)	Female	63	91.3	54	85.7	22.84	25.76	15.81	29.87
Week 12 (Day 85)	Female	60	87.0	56	93.3	20.24	24.35	13.72	26.76
Week 16 (Day 113)	Female	58	84.1	50	86.2	18.00	20.44	12.19	23.81
Week 20 (Day 141)	Female	53	76.8	48	90.6	22.22	27.79	14.15	30.29
Week 24 (Day 169)	Female	47	68.1	40	85.1	15.83	25.02	7.83	23.84
Week 28 (Day 197)	Female	42	60.9	38	90.5	10.53	17.51	4.77	16.28
Week 32 (Day 225)	Female	42	60.9	35	83.3	13.33	20.13	6.42	20.25
Week 36 (Day 253)	Female	42	60.9	37	88.1	17.12	27.91	7.81	26.42
Week 40 (Day 281)	Female	41	59.4	37	90.2	15.32	18.58	9.12	21.51
Week 44 (Day 309)	Female	41	59.4	35	85.4	18.10	23.35	10.07	26.12
Week 48 (Day 337)	Female	37	53.6	22	59.5	15.15	22.37	5.23	25.07
Week 52 (Day 365)	Female	29	42.0	5	17.2	6.67	14.91	-11.84	25.18
Week 56 (Day 393)	Female	24	34.8	8	33.3	16.67	25.20	-4.40	37.73
Week 60 (Day 421)	Female	22	31.9	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Female	22	31.9	6	27.3	11.11	17.21	-6.95	29.18
Week 68 (Day 477)	Female	20	29.0	1	5.0	0.00	NE	NE	NE
Week 72 (Day 505)	Female	20	29.0	2	10.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Female	18	26.1	2	11.1	0.00	0.00	NE	NE
Week 80 (Day 561)	Female	18	26.1	5	27.8	20.00	18.26	-2.67	42.67
Week 84 (Day 589)	Female	12	17.4	1	8.3	33.33	NE	NE	NE
Week 88 (Day 617)	Female	9	13.0	1	11.1	0.00	NE	NE	NE
Week 92 (Day 645)	Female	6	8.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	7.2	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	2.9	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	1.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	69	100.0	68	98.6	25.98	28.71	19.03	32.93
End of Study (LOCF)	Female	69	100.0	68	98.6	24.02	28.12	17.21	30.83
Baseline	Male	44	100.0	40	90.9	27.50	29.13	18.19	36.81
Week 4 (Day 29)	Male	44	100.0	40	90.9	20.83	25.81	12.58	29.09
Week 8 (Day 57)	Male	38	86.4	38	100.0	16.67	18.58	10.56	22.77
Week 12 (Day 85)	Male	37	84.1	34	91.9	15.69	18.78	9.13	22.24
Week 16 (Day 113)	Male	37	84.1	35	94.6	20.00	23.15	12.05	27.95
Week 20 (Day 141)	Male	36	81.8	35	97.2	19.05	21.82	11.55	26.54
Week 24 (Day 169)	Male	34	77.3	33	97.1	18.18	20.57	10.89	25.47
Week 28 (Day 197)	Male	32	72.7	31	96.9	19.35	24.00	10.55	28.16
Week 32 (Day 225)	Male	29	65.9	28	96.6	15.48	21.24	7.24	23.71
Week 36 (Day 253)	Male	29	65.9	28	96.6	16.67	16.97	10.09	23.25
Week 40 (Day 281)	Male	26	59.1	22	84.6	13.64	19.68	4.91	22.36
Week 44 (Day 309)	Male	23	52.3	23	100.0	15.94	24.35	5.41	26.47
Week 48 (Day 337)	Male	21	47.7	11	52.4	24.24	21.56	9.76	38.72
Week 52 (Day 365)	Male	16	36.4	2	12.5	16.67	23.57	-195.10	228.44
Week 56 (Day 393)	Male	13	29.5	4	30.8	16.67	19.25	-13.96	47.29
Week 60 (Day 421)	Male	10	22.7	1	10.0	0.00	NE	NE	NE
Week 64 (Day 449)	Male	9	20.5	3	33.3	22.22	19.25	-25.59	70.03
Week 68 (Day 477)	Male	8	18.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	8	18.2	2	25.0	16.67	23.57	-195.10	228.44
Week 76 (Day 533)	Male	7	15.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	7	15.9	1	14.3	33.33	NE	NE	NE
Week 84 (Day 589)	Male	6	13.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	5	11.4	1	20.0	33.33	NE	NE	NE
Week 92 (Day 645)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	44	100.0	43	97.7	21.71	24.00	14.32	29.09
End of Study (LOCF)	Male	44	100.0	43	97.7	21.71	21.68	15.03	28.38
Age									

Baseline	< 65	78	100.0	73	93.6	29.68	30.21	22.63	36.73
Week 4 (Day 29)	< 65	78	100.0	68	87.2	18.14	21.88	12.84	23.43
Week 8 (Day 57)	< 65	73	93.6	66	90.4	16.67	21.28	11.43	21.90
Week 12 (Day 85)	< 65	71	91.0	64	90.1	14.06	20.41	8.97	19.16
Week 16 (Day 113)	< 65	69	88.5	59	85.5	14.69	17.80	10.05	19.33
Week 20 (Day 141)	< 65	65	83.3	62	95.4	16.67	23.18	10.78	22.55
Week 24 (Day 169)	< 65	59	75.6	55	93.2	12.73	20.78	7.11	18.34
Week 28 (Day 197)	< 65	55	70.5	51	92.7	11.11	18.46	5.92	16.30
Week 32 (Day 225)	< 65	53	67.9	48	90.6	11.11	18.62	5.70	16.52
Week 36 (Day 253)	< 65	53	67.9	50	94.3	13.33	21.30	7.28	19.39
Week 40 (Day 281)	< 65	52	66.7	48	92.3	11.81	17.52	6.72	16.89
Week 44 (Day 309)	< 65	52	66.7	48	92.3	15.97	23.81	9.06	22.89
Week 48 (Day 337)	< 65	47	60.3	26	55.3	16.67	21.60	7.94	25.39
Week 52 (Day 365)	< 65	36	46.2	4	11.1	0.00	0.00	NE	NE
Week 56 (Day 393)	< 65	30	38.5	9	30.0	18.52	24.22	-0.10	37.13
Week 60 (Day 421)	< 65	25	32.1	1	4.0	0.00	NE	NE	NE
Week 64 (Day 449)	< 65	24	30.8	7	29.2	14.29	17.82	-2.19	30.76
Week 68 (Day 477)	< 65	22	28.2	1	4.5	0.00	NE	NE	NE
Week 72 (Day 505)	< 65	22	28.2	4	18.2	8.33	16.67	-18.19	34.85
Week 76 (Day 533)	< 65	21	26.9	2	9.5	0.00	0.00	NE	NE
Week 80 (Day 561)	< 65	21	26.9	5	23.8	20.00	18.26	-2.67	42.67
Week 84 (Day 589)	< 65	15	19.2	1	6.7	33.33	NE	NE	NE
Week 88 (Day 617)	< 65	12	15.4	2	16.7	16.67	23.57	-195.10	228.44
Week 92 (Day 645)	< 65	6	7.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	6.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	78	100.0	76	97.4	21.93	28.05	15.52	28.34
End of Study (LOCF)	< 65	78	100.0	76	97.4	20.61	26.09	14.65	26.58
Baseline	>= 65	35	100.0	34	97.1	34.31	31.23	23.42	45.21
Week 4 (Day 29)	>= 65	35	100.0	27	77.1	24.69	23.74	15.30	34.08
Week 8 (Day 57)	>= 65	28	80.0	26	92.9	29.49	25.52	19.18	39.80
Week 12 (Day 85)	>= 65	26	74.3	26	100.0	29.49	23.71	19.91	39.07

Week 16 (Day 113)	>= 65	26	74.3	26	100.0	28.21	26.15	17.64	38.77
Week 20 (Day 141)	>= 65	24	68.6	21	87.5	33.33	27.89	20.64	46.03
Week 24 (Day 169)	>= 65	22	62.9	18	81.8	29.63	25.28	17.06	42.20
Week 28 (Day 197)	>= 65	19	54.3	18	94.7	24.07	25.06	11.61	36.54
Week 32 (Day 225)	>= 65	18	51.4	15	83.3	24.44	23.46	11.45	37.43
Week 36 (Day 253)	>= 65	18	51.4	15	83.3	28.89	27.79	13.50	44.28
Week 40 (Day 281)	>= 65	15	42.9	11	73.3	27.27	20.10	13.77	40.78
Week 44 (Day 309)	>= 65	12	34.3	10	83.3	23.33	22.50	7.24	39.43
Week 48 (Day 337)	>= 65	11	31.4	7	63.6	23.81	25.20	0.51	47.11
Week 52 (Day 365)	>= 65	9	25.7	3	33.3	22.22	19.25	-25.59	70.03
Week 56 (Day 393)	>= 65	7	20.0	3	42.9	11.11	19.25	-36.70	58.92
Week 60 (Day 421)	>= 65	7	20.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	7	20.0	2	28.6	16.67	23.57	-195.10	228.44
Week 68 (Day 477)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	4	11.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	4	11.4	1	25.0	33.33	NE	NE	NE
Week 84 (Day 589)	>= 65	3	8.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	5.7	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	35	100.0	35	100.0	29.52	23.94	21.30	37.75
End of Study (LOCF)	>= 65	35	100.0	35	100.0	28.57	24.45	20.17	36.97
ECOG performance status									
Baseline	0	33	100.0	31	93.9	22.58	24.93	13.44	31.72
Week 4 (Day 29)	0	33	100.0	27	81.8	16.05	25.10	6.12	25.98
Week 8 (Day 57)	0	30	90.9	27	90.0	24.69	28.63	13.36	36.02
Week 12 (Day 85)	0	29	87.9	26	89.7	19.23	26.95	8.34	30.12
Week 16 (Day 113)	0	28	84.8	24	85.7	12.50	19.19	4.40	20.60
Week 20 (Day 141)	0	26	78.8	24	92.3	19.44	27.66	7.77	31.12
Week 24 (Day 169)	0	24	72.7	20	83.3	11.67	24.84	0.04	23.29
Week 28 (Day 197)	0	21	63.6	19	90.5	12.28	22.80	1.29	23.27

Week 32 (Day 225)	0	21	63.6	18	85.7	7.41	18.28	-1.68	16.50
Week 36 (Day 253)	0	21	63.6	20	95.2	15.00	27.52	2.12	27.88
Week 40 (Day 281)	0	21	63.6	19	90.5	19.30	23.08	8.17	30.42
Week 44 (Day 309)	0	21	63.6	17	81.0	17.65	29.15	2.66	32.63
Week 48 (Day 337)	0	19	57.6	12	63.2	19.44	26.43	2.65	36.24
Week 52 (Day 365)	0	18	54.5	3	16.7	0.00	0.00	NE	NE
Week 56 (Day 393)	0	16	48.5	5	31.3	6.67	14.91	-11.84	25.18
Week 60 (Day 421)	0	16	48.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	0	16	48.5	5	31.3	13.33	18.26	-9.34	36.00
Week 68 (Day 477)	0	14	42.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	0	14	42.4	1	7.1	0.00	NE	NE	NE
Week 76 (Day 533)	0	12	36.4	1	8.3	0.00	NE	NE	NE
Week 80 (Day 561)	0	12	36.4	1	8.3	0.00	NE	NE	NE
Week 84 (Day 589)	0	10	30.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	9	27.3	1	11.1	0.00	NE	NE	NE
Week 92 (Day 645)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	9.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	3.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	33	100.0	33	100.0	26.26	32.01	14.91	37.61
End of Study (LOCF)	0	33	100.0	33	100.0	23.23	30.60	12.38	34.08
Baseline	1	79	100.0	75	94.9	35.11	31.90	27.77	42.45
Week 4 (Day 29)	1	79	100.0	67	84.8	21.39	21.48	16.15	26.63
Week 8 (Day 57)	1	70	88.6	65	92.9	18.46	20.44	13.40	23.53
Week 12 (Day 85)	1	68	86.1	64	94.1	18.23	20.51	13.11	23.35
Week 16 (Day 113)	1	67	84.8	61	91.0	21.31	21.97	15.68	26.94
Week 20 (Day 141)	1	63	79.7	59	93.7	21.47	24.58	15.06	27.87
Week 24 (Day 169)	1	57	72.2	53	93.0	18.87	22.18	12.75	24.98
Week 28 (Day 197)	1	53	67.1	50	94.3	15.33	20.44	9.53	21.14
Week 32 (Day 225)	1	50	63.3	45	90.0	17.04	20.87	10.77	23.31
Week 36 (Day 253)	1	50	63.3	45	90.0	17.78	22.02	11.16	24.39
Week 40 (Day 281)	1	46	58.2	40	87.0	12.50	16.34	7.27	17.73

Week 44 (Day 309)	1	43	54.4	41	95.3	17.07	21.24	10.37	23.78
Week 48 (Day 337)	1	39	49.4	21	53.8	17.46	20.05	8.33	26.59
Week 52 (Day 365)	1	27	34.2	4	14.8	16.67	19.25	-13.96	47.29
Week 56 (Day 393)	1	21	26.6	7	33.3	23.81	25.20	0.51	47.11
Week 60 (Day 421)	1	16	20.3	1	6.3	0.00	NE	NE	NE
Week 64 (Day 449)	1	15	19.0	4	26.7	16.67	19.25	-13.96	47.29
Week 68 (Day 477)	1	14	17.7	1	7.1	0.00	NE	NE	NE
Week 72 (Day 505)	1	14	17.7	3	21.4	11.11	19.25	-36.70	58.92
Week 76 (Day 533)	1	13	16.5	1	7.7	0.00	NE	NE	NE
Week 80 (Day 561)	1	13	16.5	5	38.5	26.67	14.91	8.16	45.18
Week 84 (Day 589)	1	8	10.1	1	12.5	33.33	NE	NE	NE
Week 88 (Day 617)	1	5	6.3	1	20.0	33.33	NE	NE	NE
Week 92 (Day 645)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	2.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	79	100.0	77	97.5	23.38	24.82	17.74	29.01
End of Study (LOCF)	1	79	100.0	77	97.5	22.94	23.73	17.56	28.33
Baseline	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	33.33	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	33.33	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	33.33	NE	NE	NE
Geographic region									
Baseline	USA	22	100.0	21	95.5	33.33	34.96	17.42	49.25
Week 4 (Day 29)	USA	22	100.0	18	81.8	20.37	23.26	8.80	31.94
Week 8 (Day 57)	USA	20	90.9	18	90.0	16.67	26.20	3.64	29.69
Week 12 (Day 85)	USA	20	90.9	19	95.0	17.54	25.74	5.14	29.95
Week 16 (Day 113)	USA	19	86.4	17	89.5	19.61	23.74	7.40	31.82
Week 20 (Day 141)	USA	19	86.4	17	89.5	23.53	25.72	10.30	36.76
Week 24 (Day 169)	USA	16	72.7	14	87.5	9.52	15.63	0.50	18.55
Week 28 (Day 197)	USA	15	68.2	12	80.0	11.11	16.41	0.68	21.54
Week 32 (Day 225)	USA	15	68.2	13	86.7	17.95	22.01	4.65	31.25
Week 36 (Day 253)	USA	15	68.2	13	86.7	20.51	21.68	7.41	33.61
Week 40 (Day 281)	USA	14	63.6	11	78.6	12.12	16.82	0.82	23.42

Week 44 (Day 309)	USA	13	59.1	11	84.6	21.21	22.47	6.11	36.31
Week 48 (Day 337)	USA	13	59.1	10	76.9	16.67	23.57	-0.19	33.53
Week 52 (Day 365)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	USA	12	54.5	6	50.0	16.67	27.89	-12.60	45.93
Week 60 (Day 421)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	11	50.0	4	36.4	16.67	19.25	-13.96	47.29
Week 68 (Day 477)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	10	45.5	1	10.0	0.00	NE	NE	NE
Week 76 (Day 533)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	10	45.5	2	20.0	33.33	0.00	NE	NE
Week 84 (Day 589)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	13.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	4.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	22	100.0	22	100.0	22.73	23.87	12.14	33.31
End of Study (LOCF)	USA	22	100.0	22	100.0	18.18	22.37	8.27	28.10
Baseline	Europe (EU)	32	100.0	29	90.6	32.18	33.90	19.29	45.08
Week 4 (Day 29)	Europe (EU)	32	100.0	25	78.1	21.33	27.01	10.18	32.48
Week 8 (Day 57)	Europe (EU)	29	90.6	25	86.2	25.33	27.69	13.90	36.76
Week 12 (Day 85)	Europe (EU)	26	81.3	24	92.3	25.00	26.47	13.82	36.18
Week 16 (Day 113)	Europe (EU)	25	78.1	20	80.0	20.00	22.69	9.38	30.62
Week 20 (Day 141)	Europe (EU)	23	71.9	22	95.7	24.24	27.57	12.02	36.47
Week 24 (Day 169)	Europe (EU)	21	65.6	20	95.2	21.67	27.09	8.99	34.35
Week 28 (Day 197)	Europe (EU)	20	62.5	20	100.0	15.00	20.16	5.56	24.44
Week 32 (Day 225)	Europe (EU)	18	56.3	16	88.9	12.50	16.67	3.62	21.38
Week 36 (Day 253)	Europe (EU)	18	56.3	17	94.4	13.73	26.51	0.10	27.35
Week 40 (Day 281)	Europe (EU)	17	53.1	16	94.1	14.58	17.08	5.48	23.68
Week 44 (Day 309)	Europe (EU)	17	53.1	14	82.4	16.67	25.32	2.05	31.29

Week 48 (Day 337)	Europe (EU)	14	43.8	10	71.4	16.67	17.57	4.10	29.23
Week 52 (Day 365)	Europe (EU)	13	40.6	3	23.1	0.00	0.00	NE	NE
Week 56 (Day 393)	Europe (EU)	11	34.4	5	45.5	13.33	18.26	-9.34	36.00
Week 60 (Day 421)	Europe (EU)	11	34.4	1	9.1	0.00	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	11	34.4	5	45.5	13.33	18.26	-9.34	36.00
Week 68 (Day 477)	Europe (EU)	10	31.3	1	10.0	0.00	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	10	31.3	3	30.0	11.11	19.25	-36.70	58.92
Week 76 (Day 533)	Europe (EU)	8	25.0	2	25.0	0.00	0.00	NE	NE
Week 80 (Day 561)	Europe (EU)	8	25.0	4	50.0	16.67	19.25	-13.96	47.29
Week 84 (Day 589)	Europe (EU)	6	18.8	1	16.7	33.33	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	9.4	2	66.7	16.67	23.57	-195.10	228.44
Cycle 12 (LOCF)	Europe (EU)	32	100.0	31	96.9	30.11	30.25	19.01	41.20
End of Study (LOCF)	Europe (EU)	32	100.0	31	96.9	30.11	29.00	19.47	40.75
Baseline	Asia (AS)	59	100.0	57	96.6	29.82	27.23	22.60	37.05
Week 4 (Day 29)	Asia (AS)	59	100.0	52	88.1	19.23	20.18	13.61	24.85
Week 8 (Day 57)	Asia (AS)	52	88.1	49	94.2	19.05	19.25	13.52	24.58
Week 12 (Day 85)	Asia (AS)	51	86.4	47	92.2	15.60	18.19	10.26	20.94
Week 16 (Day 113)	Asia (AS)	51	86.4	48	94.1	18.06	20.58	12.08	24.03
Week 20 (Day 141)	Asia (AS)	47	79.7	44	93.6	18.18	24.33	10.78	25.58
Week 24 (Day 169)	Asia (AS)	44	74.6	39	88.6	17.09	22.78	9.71	24.48
Week 28 (Day 197)	Asia (AS)	39	66.1	37	94.9	15.32	23.03	7.64	22.99
Week 32 (Day 225)	Asia (AS)	38	64.4	34	89.5	13.73	21.89	6.09	21.36
Week 36 (Day 253)	Asia (AS)	38	64.4	35	92.1	17.14	23.39	9.11	25.18
Week 40 (Day 281)	Asia (AS)	36	61.0	32	88.9	15.62	20.71	8.16	23.09
Week 44 (Day 309)	Asia (AS)	34	57.6	33	97.1	16.16	23.75	7.74	24.58
Week 48 (Day 337)	Asia (AS)	31	52.5	13	41.9	20.51	25.60	5.04	35.98
Week 52 (Day 365)	Asia (AS)	20	33.9	4	20.0	16.67	19.25	-13.96	47.29
Week 56 (Day 393)	Asia (AS)	14	23.7	1	7.1	33.33	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	10.2	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	8.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	3.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	59	100.0	58	98.3	21.84	26.16	14.96	28.72
End of Study (LOCF)	Asia (AS)	59	100.0	58	98.3	21.26	24.74	14.76	27.77
Race/ethnicity									
Baseline	Asian	61	100.0	58	95.1	29.31	27.27	22.14	36.48
Week 4 (Day 29)	Asian	61	100.0	52	85.2	19.23	20.18	13.61	24.85
Week 8 (Day 57)	Asian	53	86.9	49	92.5	19.05	19.25	13.52	24.58
Week 12 (Day 85)	Asian	52	85.2	48	92.3	15.28	18.14	10.01	20.54
Week 16 (Day 113)	Asian	52	85.2	49	94.2	17.69	20.53	11.79	23.58
Week 20 (Day 141)	Asian	48	78.7	45	93.8	17.78	24.20	10.51	25.05
Week 24 (Day 169)	Asian	44	72.1	39	88.6	17.09	22.78	9.71	24.48
Week 28 (Day 197)	Asian	39	63.9	37	94.9	15.32	23.03	7.64	22.99
Week 32 (Day 225)	Asian	38	62.3	34	89.5	13.73	21.89	6.09	21.36
Week 36 (Day 253)	Asian	38	62.3	35	92.1	17.14	23.39	9.11	25.18
Week 40 (Day 281)	Asian	36	59.0	32	88.9	15.62	20.71	8.16	23.09
Week 44 (Day 309)	Asian	34	55.7	33	97.1	16.16	23.75	7.74	24.58
Week 48 (Day 337)	Asian	31	50.8	13	41.9	20.51	25.60	5.04	35.98
Week 52 (Day 365)	Asian	20	32.8	4	20.0	16.67	19.25	-13.96	47.29
Week 56 (Day 393)	Asian	14	23.0	1	7.1	33.33	NE	NE	NE
Week 60 (Day 421)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	9.8	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	8.2	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	3.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	61	100.0	59	96.7	21.47	26.09	14.67	28.27
End of Study (LOCF)	Asian	61	100.0	59	96.7	20.90	24.68	14.47	27.34
Baseline	Non-Asian	45	100.0	43	95.6	33.33	34.88	22.60	44.07
Week 4 (Day 29)	Non-Asian	45	100.0	39	86.7	19.66	22.58	12.34	26.98
Week 8 (Day 57)	Non-Asian	42	93.3	38	90.5	21.93	27.15	13.00	30.85
Week 12 (Day 85)	Non-Asian	39	86.7	37	94.9	22.52	26.12	13.81	31.23
Week 16 (Day 113)	Non-Asian	37	82.2	34	91.9	21.57	23.04	13.53	29.61
Week 20 (Day 141)	Non-Asian	36	80.0	34	94.4	26.47	26.94	17.07	35.87
Week 24 (Day 169)	Non-Asian	32	71.1	31	96.9	18.28	24.10	9.44	27.12
Week 28 (Day 197)	Non-Asian	30	66.7	28	93.3	15.48	19.21	8.03	22.92
Week 32 (Day 225)	Non-Asian	28	62.2	25	89.3	17.33	19.53	9.27	25.40
Week 36 (Day 253)	Non-Asian	28	62.2	26	92.9	14.10	19.26	6.32	21.88
Week 40 (Day 281)	Non-Asian	26	57.8	23	88.5	13.04	16.63	5.85	20.24
Week 44 (Day 309)	Non-Asian	25	55.6	21	84.0	19.05	24.88	7.72	30.37
Week 48 (Day 337)	Non-Asian	23	51.1	17	73.9	19.61	20.61	9.01	30.21
Week 52 (Day 365)	Non-Asian	21	46.7	3	14.3	0.00	0.00	NE	NE
Week 56 (Day 393)	Non-Asian	19	42.2	10	52.6	16.67	23.57	-0.19	33.53
Week 60 (Day 421)	Non-Asian	19	42.2	1	5.3	0.00	NE	NE	NE
Week 64 (Day 449)	Non-Asian	18	40.0	7	38.9	14.29	17.82	-2.19	30.76
Week 68 (Day 477)	Non-Asian	17	37.8	1	5.9	0.00	NE	NE	NE
Week 72 (Day 505)	Non-Asian	17	37.8	3	17.6	11.11	19.25	-36.70	58.92
Week 76 (Day 533)	Non-Asian	15	33.3	2	13.3	0.00	0.00	NE	NE
Week 80 (Day 561)	Non-Asian	15	33.3	5	33.3	20.00	18.26	-2.67	42.67
Week 84 (Day 589)	Non-Asian	10	22.2	1	10.0	33.33	NE	NE	NE
Week 88 (Day 617)	Non-Asian	7	15.6	2	28.6	16.67	23.57	-195.10	228.44
Week 92 (Day 645)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	45	100.0	45	100.0	28.15	28.39	19.62	36.68

End of Study (LOCF)	Non-Asian	45	100.0	45	100.0	25.19	27.67	16.87	33.50
Baseline	Unknown	7	100.0	6	85.7	33.33	29.81	2.05	64.62
Week 4 (Day 29)	Unknown	7	100.0	4	57.1	33.33	47.14	-41.68	108.34
Week 8 (Day 57)	Unknown	6	85.7	5	83.3	20.00	29.81	-17.02	57.02
Week 12 (Day 85)	Unknown	6	85.7	5	83.3	20.00	29.81	-17.02	57.02
Week 16 (Day 113)	Unknown	6	85.7	2	33.3	0.00	0.00	NE	NE
Week 20 (Day 141)	Unknown	5	71.4	4	80.0	8.33	16.67	-18.19	34.85
Week 24 (Day 169)	Unknown	5	71.4	3	60.0	0.00	0.00	NE	NE
Week 28 (Day 197)	Unknown	5	71.4	4	80.0	0.00	0.00	NE	NE
Week 32 (Day 225)	Unknown	5	71.4	4	80.0	0.00	0.00	NE	NE
Week 36 (Day 253)	Unknown	5	71.4	4	80.0	33.33	47.14	-41.68	108.34
Week 40 (Day 281)	Unknown	5	71.4	4	80.0	16.67	19.25	-13.96	47.29
Week 44 (Day 309)	Unknown	5	71.4	4	80.0	16.67	19.25	-13.96	47.29
Week 48 (Day 337)	Unknown	4	57.1	3	75.0	0.00	0.00	NE	NE
Week 52 (Day 365)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	4	57.1	1	25.0	0.00	NE	NE	NE
Week 60 (Day 421)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	4	57.1	2	50.0	16.67	23.57	-195.10	228.44
Week 68 (Day 477)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	3	42.9	1	33.3	0.00	NE	NE	NE
Week 76 (Day 533)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	3	42.9	1	33.3	33.33	NE	NE	NE
Week 84 (Day 589)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	14.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	7	100.0	7	100.0	23.81	25.20	0.51	47.11
End of Study (LOCF)	Unknown	7	100.0	7	100.0	28.57	23.00	7.30	49.84
Number of prior antineoplastic systemic therapy lines I									
Baseline	1	60	100.0	57	95.0	31.58	32.38	22.99	40.17

Week 4 (Day 29)	1	60	100.0	50	83.3	20.67	22.22	14.35	26.98
Week 8 (Day 57)	1	54	90.0	49	90.7	21.77	23.13	15.13	28.41
Week 12 (Day 85)	1	52	86.7	48	92.3	22.92	23.97	15.96	29.88
Week 16 (Day 113)	1	51	85.0	46	90.2	21.01	21.50	14.63	27.40
Week 20 (Day 141)	1	48	80.0	43	89.6	21.71	26.11	13.67	29.74
Week 24 (Day 169)	1	43	71.7	39	90.7	19.66	23.84	11.93	27.39
Week 28 (Day 197)	1	38	63.3	34	89.5	14.71	22.01	7.03	22.38
Week 32 (Day 225)	1	35	58.3	29	82.9	14.94	21.06	6.93	22.95
Week 36 (Day 253)	1	35	58.3	31	88.6	18.28	27.00	8.38	28.18
Week 40 (Day 281)	1	32	53.3	27	84.4	18.52	19.25	10.91	26.13
Week 44 (Day 309)	1	32	53.3	27	84.4	19.75	26.57	9.24	30.26
Week 48 (Day 337)	1	27	45.0	16	59.3	18.75	20.97	7.57	29.93
Week 52 (Day 365)	1	23	38.3	5	21.7	6.67	14.91	-11.84	25.18
Week 56 (Day 393)	1	16	26.7	4	25.0	16.67	19.25	-13.96	47.29
Week 60 (Day 421)	1	14	23.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	13	21.7	4	30.8	16.67	19.25	-13.96	47.29
Week 68 (Day 477)	1	12	20.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	12	20.0	1	8.3	0.00	NE	NE	NE
Week 76 (Day 533)	1	11	18.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	11	18.3	2	18.2	16.67	23.57	-195.10	228.44
Week 84 (Day 589)	1	9	15.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	1	8	13.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	1	3	5.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	1	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	60	100.0	58	96.7	26.44	25.56	19.72	33.16
End of Study (LOCF)	1	60	100.0	58	96.7	22.99	24.35	16.59	29.39
Baseline	>= 2	53	100.0	50	94.3	30.67	28.44	22.58	38.75
Week 4 (Day 29)	>= 2	53	100.0	45	84.9	19.26	23.02	12.34	26.17
Week 8 (Day 57)	>= 2	47	88.7	43	91.5	18.60	23.35	11.42	25.79
Week 12 (Day 85)	>= 2	45	84.9	42	93.3	13.49	19.56	7.40	19.59
Week 16 (Day 113)	>= 2	44	83.0	39	88.6	16.24	21.46	9.28	23.19

Week 20 (Day 141)	>= 2	41	77.4	40	97.6	20.00	24.81	12.07	27.93
Week 24 (Day 169)	>= 2	38	71.7	34	89.5	13.73	21.89	6.09	21.36
Week 28 (Day 197)	>= 2	36	67.9	35	97.2	14.29	20.27	7.32	21.25
Week 32 (Day 225)	>= 2	36	67.9	34	94.4	13.73	20.30	6.64	20.81
Week 36 (Day 253)	>= 2	36	67.9	34	94.4	15.69	20.49	8.54	22.84
Week 40 (Day 281)	>= 2	35	66.0	32	91.4	11.46	18.18	4.90	18.01
Week 44 (Day 309)	>= 2	32	60.4	31	96.9	15.05	20.80	7.43	22.68
Week 48 (Day 337)	>= 2	31	58.5	17	54.8	17.65	23.91	5.35	29.94
Week 52 (Day 365)	>= 2	22	41.5	2	9.1	16.67	23.57	-195.10	228.44
Week 56 (Day 393)	>= 2	21	39.6	8	38.1	16.67	25.20	-4.40	37.73
Week 60 (Day 421)	>= 2	18	34.0	1	5.6	0.00	NE	NE	NE
Week 64 (Day 449)	>= 2	18	34.0	5	27.8	13.33	18.26	-9.34	36.00
Week 68 (Day 477)	>= 2	16	30.2	1	6.3	0.00	NE	NE	NE
Week 72 (Day 505)	>= 2	16	30.2	3	18.8	11.11	19.25	-36.70	58.92
Week 76 (Day 533)	>= 2	14	26.4	2	14.3	0.00	0.00	NE	NE
Week 80 (Day 561)	>= 2	14	26.4	4	28.6	25.00	16.67	-1.52	51.52
Week 84 (Day 589)	>= 2	9	17.0	1	11.1	33.33	NE	NE	NE
Week 88 (Day 617)	>= 2	6	11.3	2	33.3	16.67	23.57	-195.10	228.44
Week 92 (Day 645)	>= 2	2	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 2	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 2	53	100.0	53	100.0	22.01	28.45	14.17	29.86
End of Study (LOCF)	>= 2	53	100.0	53	100.0	23.27	27.41	15.71	30.83

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
¹ in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
² mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TP_QSC30DY_SG.xls
27OCT2021 7:25

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Dyspnoea
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	107	94.7	42	39.3	30.5	48.7
	Cycle 12 (LOCF)	n/a	107	94.7	20	18.7	12.4	27.1
	End of Study (LOCF)	n/a	107	94.7	19	17.8	11.7	26.1
Sex	All visits	Female	67	59.3	25	37.3	26.7	49.3
		Male	40	35.4	17	42.5	28.5	57.8
	Cycle 12 (LOCF)	Female	67	59.3	13	19.4	11.7	30.4
		Male	40	35.4	7	17.5	8.7	31.9
	End of Study (LOCF)	Female	67	59.3	11	16.4	9.4	27.1
		Male	40	35.4	8	20.0	10.5	34.8
Age	All visits	< 65	73	64.6	28	38.4	28.1	49.8
		>= 65	34	30.1	14	41.2	26.4	57.8
	Cycle 12 (LOCF)	< 65	73	64.6	14	19.2	11.8	29.7
		>= 65	34	30.1	6	17.6	8.3	33.5
	End of Study (LOCF)	< 65	73	64.6	14	19.2	11.8	29.7
		>= 65	34	30.1	5	14.7	6.4	30.1
ECOG performance status	All visits	0	31	27.4	15	48.4	32.0	65.2
		1	75	66.4	26	34.7	24.9	45.9
		Missing	1	0.9	1	100.0	20.7	100.0
	Cycle 12 (LOCF)	0	31	27.4	9	29.0	16.1	46.6
		1	75	66.4	10	13.3	7.4	22.8
		Missing	1	0.9	1	100.0	20.7	100.0
	End of Study (LOCF)	0	31	27.4	7	22.6	11.4	39.8
		1	75	66.4	11	14.7	8.4	24.4
		Missing	1	0.9	1	100.0	20.7	100.0
Geographic region	All visits	USA	21	18.6	6	28.6	13.8	50.0
		Europe (EU)	29	25.7	14	48.3	31.4	65.6
		Asia (AS)	57	50.4	22	38.6	27.1	51.6
	Cycle 12 (LOCF)	USA	21	18.6	3	14.3	5.0	34.6
		Europe (EU)	29	25.7	8	27.6	14.7	45.7
		Asia (AS)	57	50.4	9	15.8	8.5	27.4
	End of Study (LOCF)	USA	21	18.6	2	9.5	2.7	28.9
		Europe (EU)	29	25.7	8	27.6	14.7	45.7
		Asia (AS)	57	50.4	9	15.8	8.5	27.4
Race/ethnicity	All visits	Asian	58	51.3	22	37.9	26.6	50.8
		Non-Asian	43	38.1	18	41.9	28.4	56.7
		Unknown	6	5.3	2	33.3	9.7	70.0
	Cycle 12 (LOCF)	Asian	58	51.3	9	15.5	8.4	26.9

		Non-Asian	43	38.1	11	25.6	14.9	40.2
		Unknown	6	5.3	0	0.0	0.0	39.0
	End of Study (LOCF)	Asian	58	51.3	9	15.5	8.4	26.9
		Non-Asian	43	38.1	10	23.3	13.2	37.7
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	24	42.1	30.2	55.0
		>= 2	50	44.2	18	36.0	24.1	49.9
	Cycle 12 (LOCF)	1	57	50.4	12	21.1	12.5	33.3
		>= 2	50	44.2	8	16.0	8.3	28.5
	End of Study (LOCF)	1	57	50.4	9	15.8	8.5	27.4
		>= 2	50	44.2	10	20.0	11.2	33.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30DY_W10_SG.xls
15OCT2021 13:32

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Dyspnoea
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

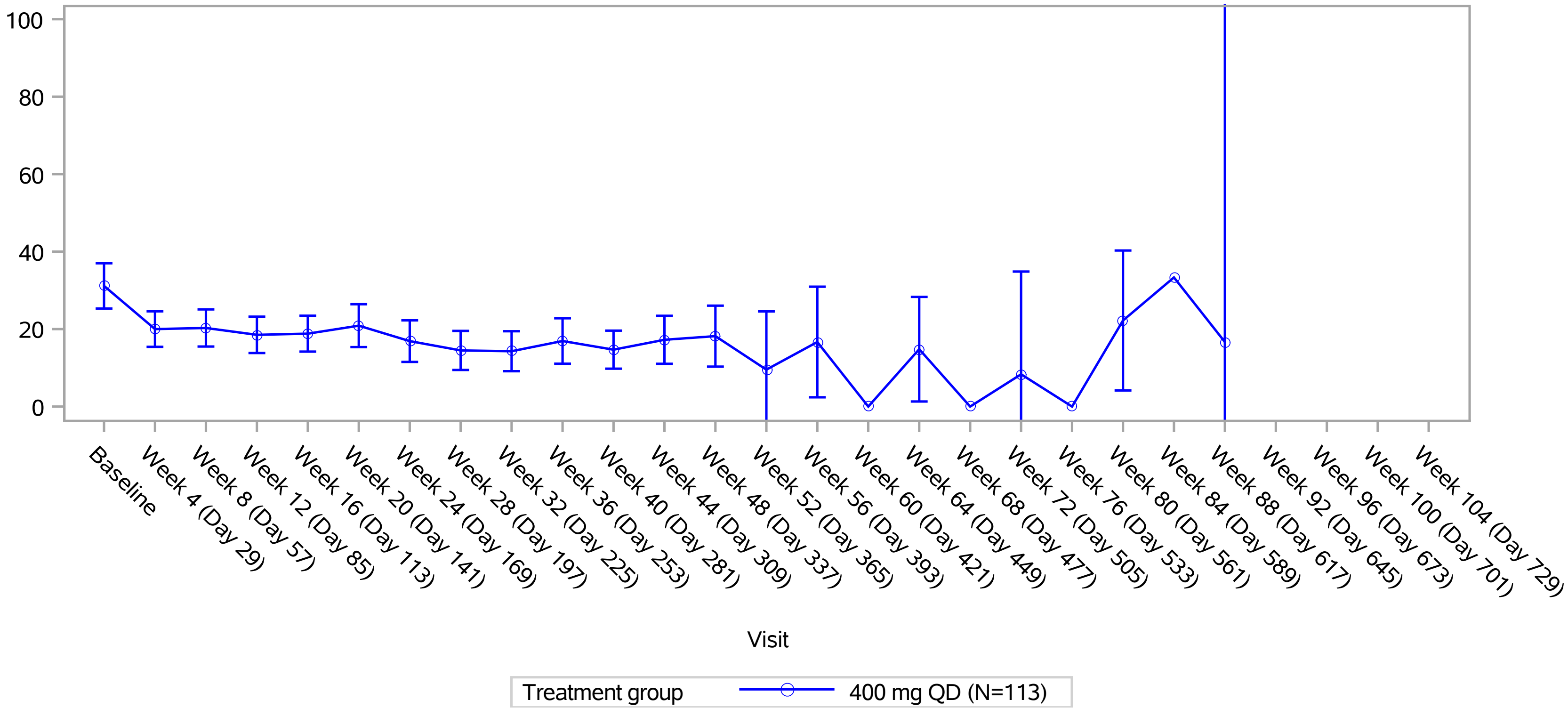
			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	107	94.7	42	39.3	30.5	48.7
	Cycle 12 (LOCF)	n/a	107	94.7	20	18.7	12.4	27.1
	End of Study (LOCF)	n/a	107	94.7	19	17.8	11.7	26.1
Sex	All visits	Female	67	59.3	25	37.3	26.7	49.3
		Male	40	35.4	17	42.5	28.5	57.8
	Cycle 12 (LOCF)	Female	67	59.3	13	19.4	11.7	30.4
		Male	40	35.4	7	17.5	8.7	31.9
	End of Study (LOCF)	Female	67	59.3	11	16.4	9.4	27.1
		Male	40	35.4	8	20.0	10.5	34.8
Age	All visits	< 65	73	64.6	28	38.4	28.1	49.8
		>= 65	34	30.1	14	41.2	26.4	57.8
	Cycle 12 (LOCF)	< 65	73	64.6	14	19.2	11.8	29.7
		>= 65	34	30.1	6	17.6	8.3	33.5
	End of Study (LOCF)	< 65	73	64.6	14	19.2	11.8	29.7
		>= 65	34	30.1	5	14.7	6.4	30.1
ECOG performance status	All visits	0	31	27.4	15	48.4	32.0	65.2
		1	75	66.4	26	34.7	24.9	45.9
		Missing	1	0.9	1	100.0	20.7	100.0
	Cycle 12 (LOCF)	0	31	27.4	9	29.0	16.1	46.6
		1	75	66.4	10	13.3	7.4	22.8
		Missing	1	0.9	1	100.0	20.7	100.0
	End of Study (LOCF)	0	31	27.4	7	22.6	11.4	39.8
		1	75	66.4	11	14.7	8.4	24.4
		Missing	1	0.9	1	100.0	20.7	100.0
Geographic region	All visits	USA	21	18.6	6	28.6	13.8	50.0
		Europe (EU)	29	25.7	14	48.3	31.4	65.6
		Asia (AS)	57	50.4	22	38.6	27.1	51.6
	Cycle 12 (LOCF)	USA	21	18.6	3	14.3	5.0	34.6
		Europe (EU)	29	25.7	8	27.6	14.7	45.7
		Asia (AS)	57	50.4	9	15.8	8.5	27.4
	End of Study (LOCF)	USA	21	18.6	2	9.5	2.7	28.9
		Europe (EU)	29	25.7	8	27.6	14.7	45.7
		Asia (AS)	57	50.4	9	15.8	8.5	27.4
Race/ethnicity	All visits	Asian	58	51.3	22	37.9	26.6	50.8
		Non-Asian	43	38.1	18	41.9	28.4	56.7
		Unknown	6	5.3	2	33.3	9.7	70.0
	Cycle 12 (LOCF)	Asian	58	51.3	9	15.5	8.4	26.9

		Non-Asian	43	38.1	11	25.6	14.9	40.2
		Unknown	6	5.3	0	0.0	0.0	39.0
	End of Study (LOCF)	Asian	58	51.3	9	15.5	8.4	26.9
		Non-Asian	43	38.1	10	23.3	13.2	37.7
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	24	42.1	30.2	55.0
		>= 2	50	44.2	18	36.0	24.1	49.9
	Cycle 12 (LOCF)	1	57	50.4	12	21.1	12.5	33.3
		>= 2	50	44.2	8	16.0	8.3	28.5
	End of Study (LOCF)	1	57	50.4	9	15.8	8.5	27.4
		>= 2	50	44.2	10	20.0	11.2	33.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30DY_W15_SG.xls
15OCT2021 13:22

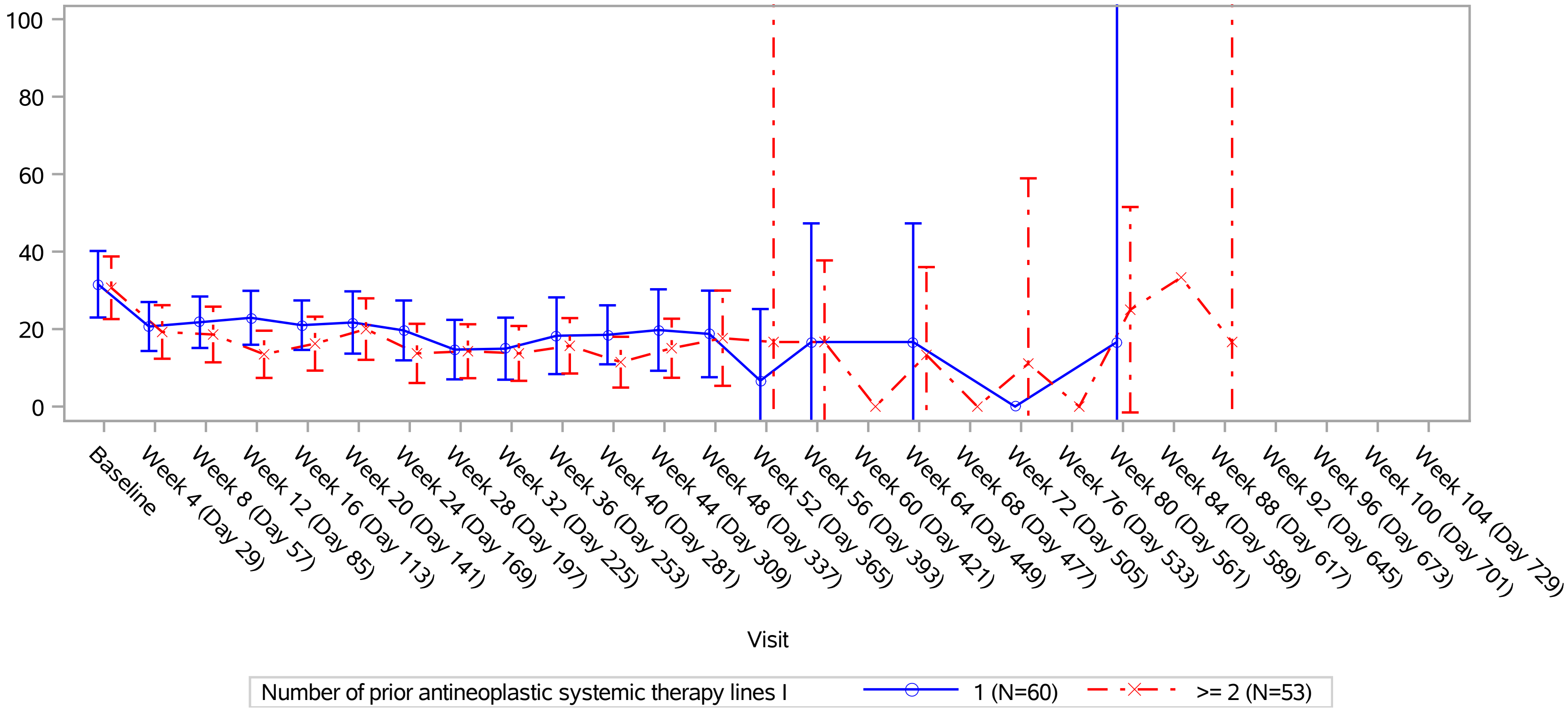
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Dyspnoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30DY.pdf
15OCT2021 17:15

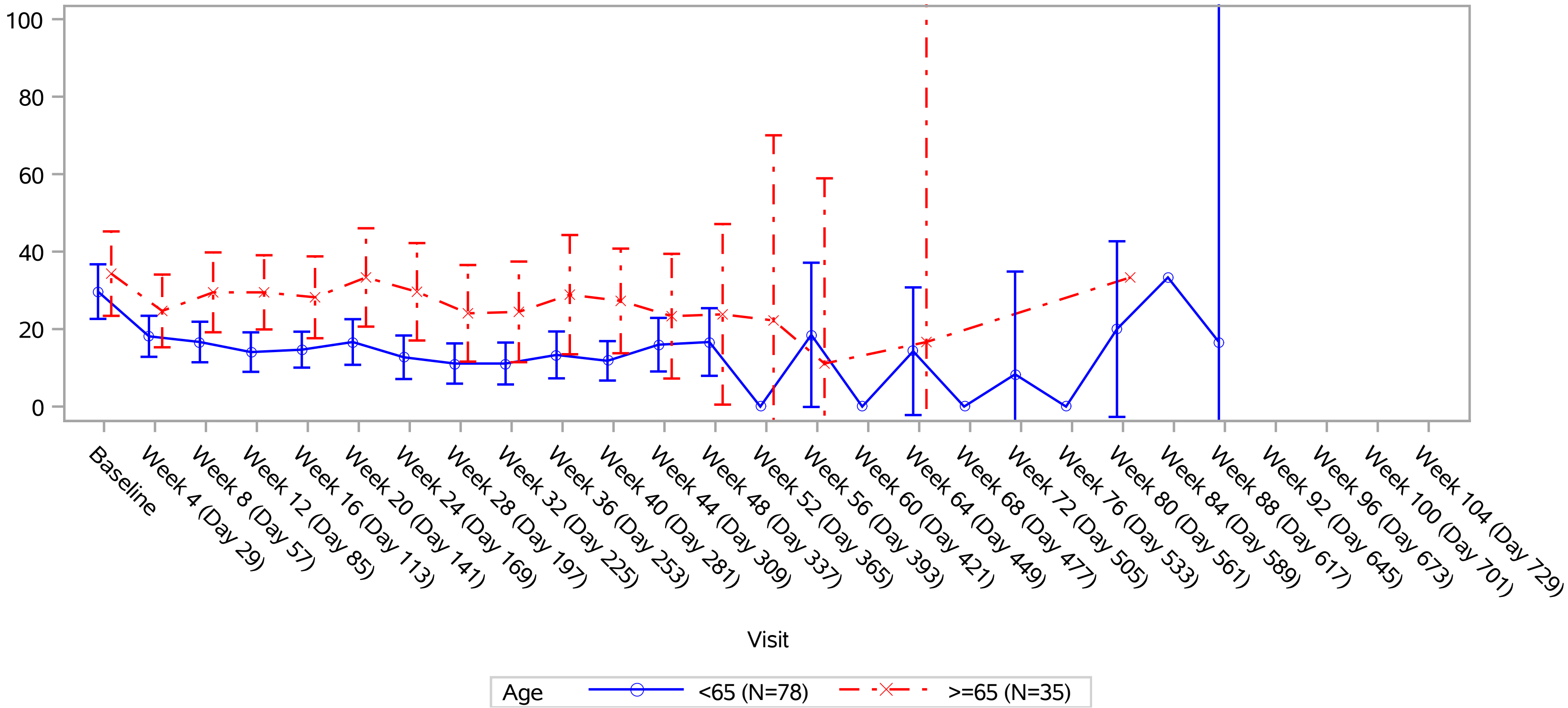
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Dyspnoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30DY_PRTHL1.pdf
15OCT2021 20:06

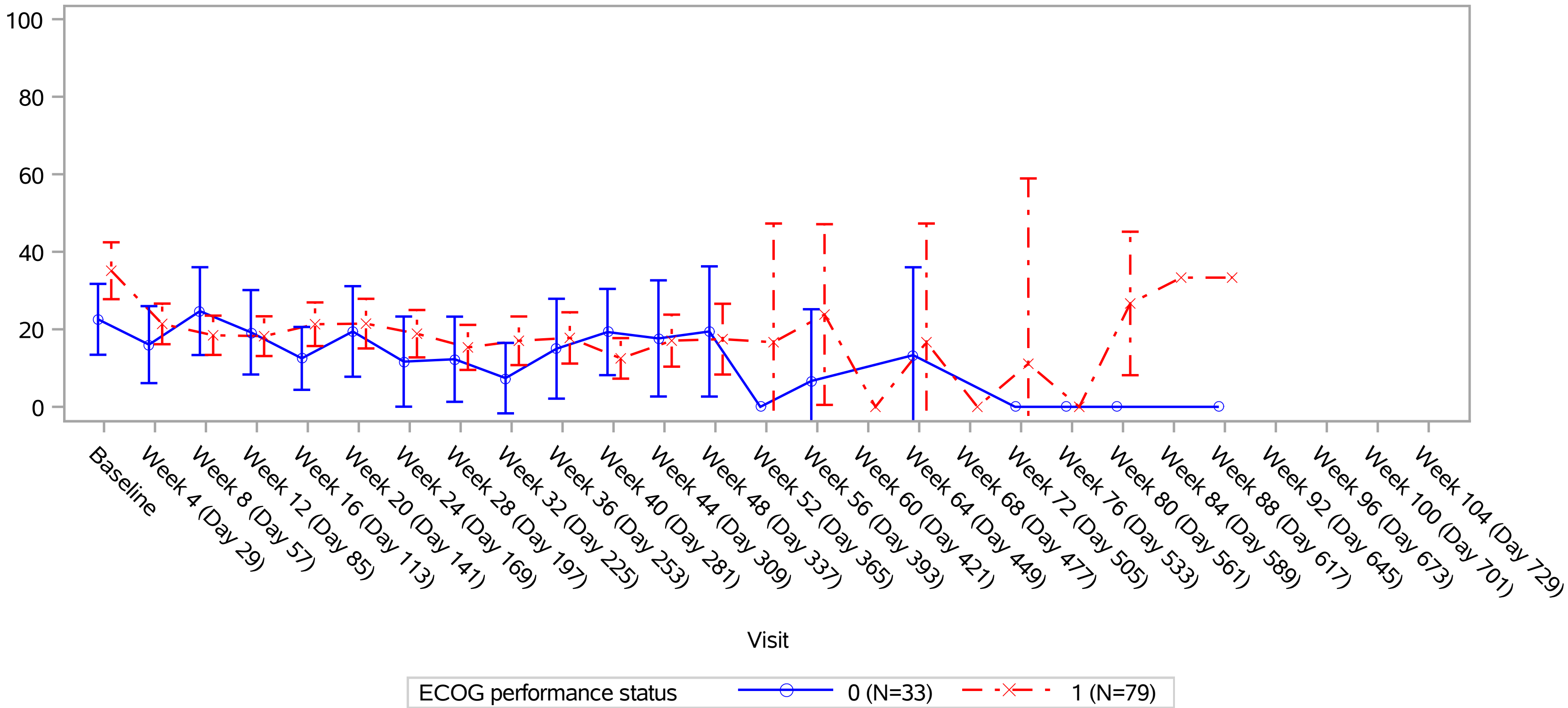
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Dyspnoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30DY_SGAGE65.pdf
15OCT2021 17:44

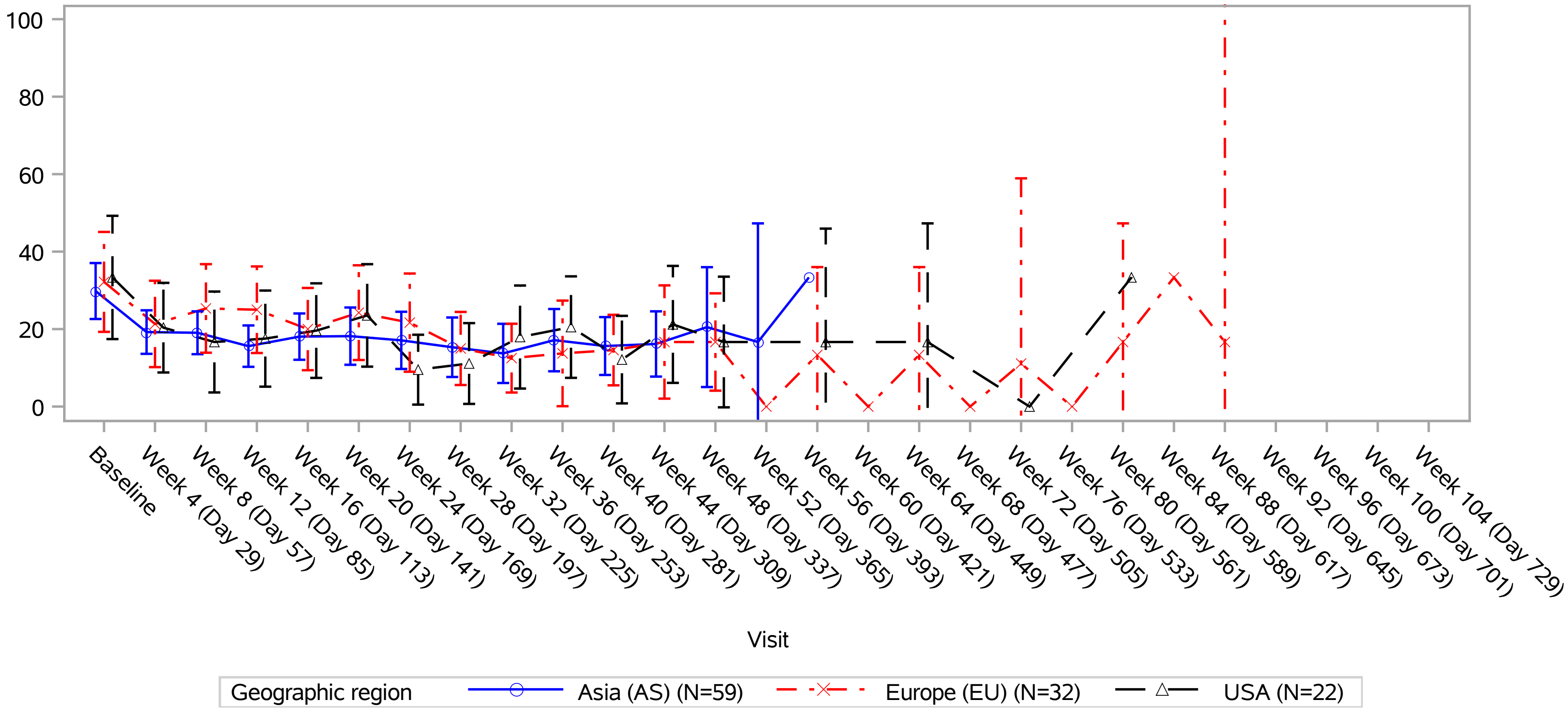
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Dyspnoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30DY_SGECOG.pdf
15OCT2021 18:14

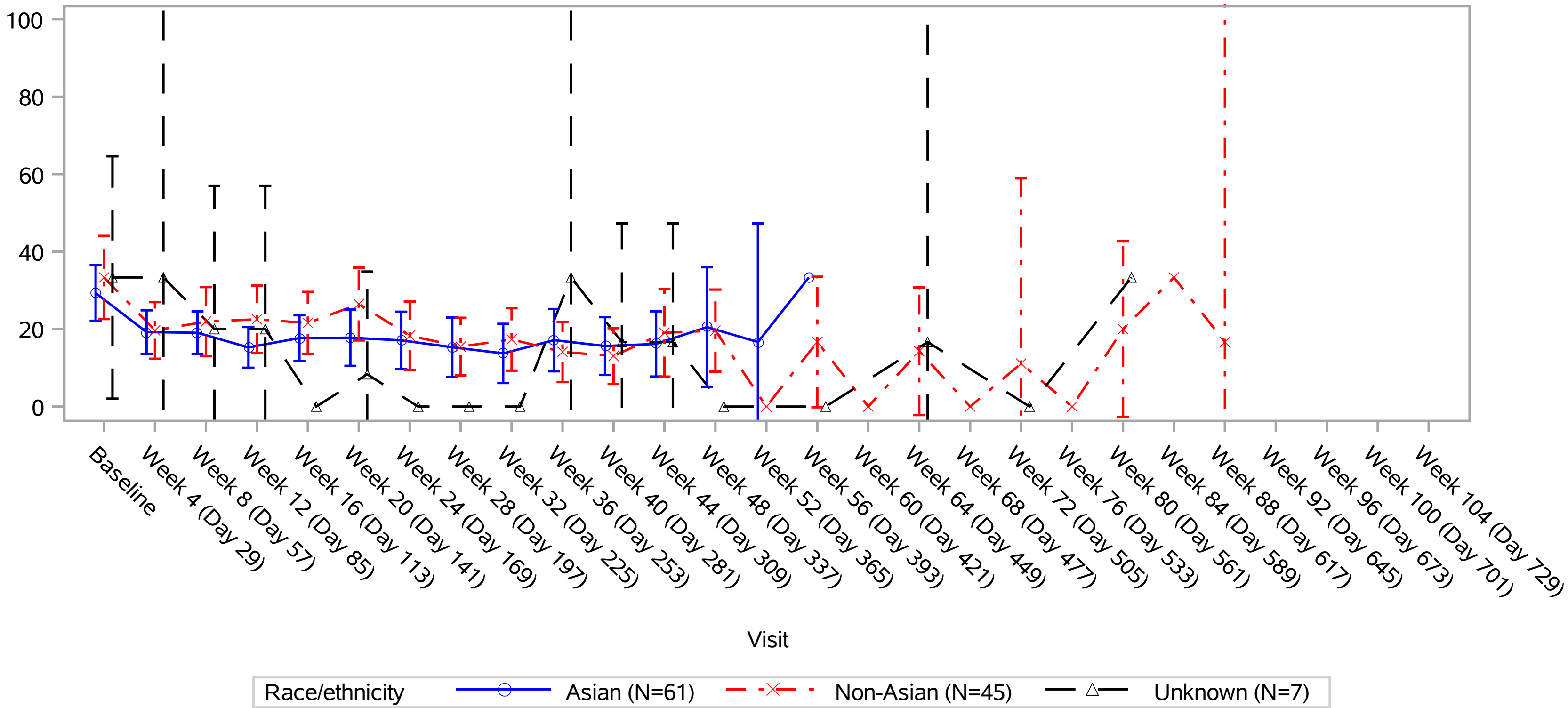
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Dyspnoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30DY_SGGEO.pdf
15OCT2021 18:45

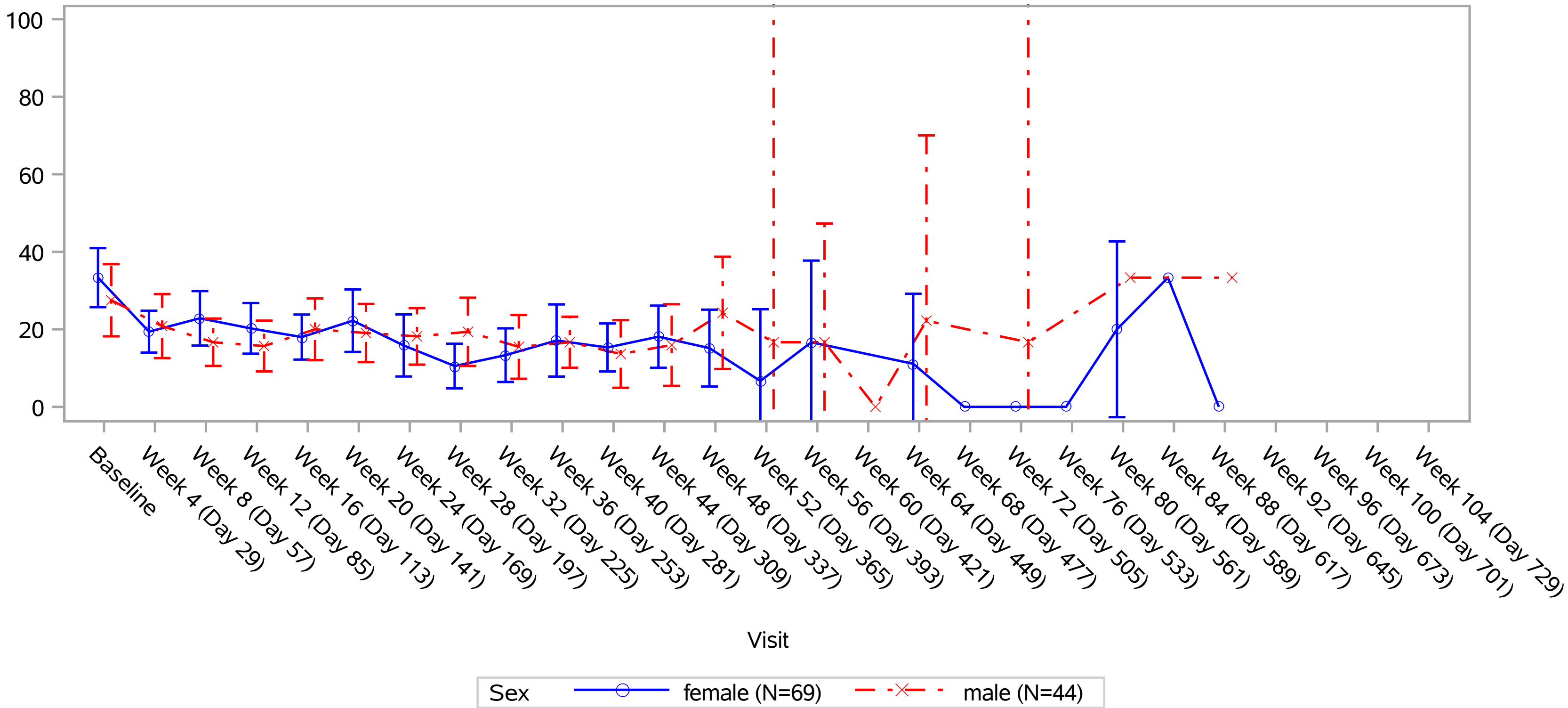
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Dyspnoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30DY_SGRE.pdf
15OCT2021 19:15

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Dyspnoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30DY_SGSEX.pdf
15OCT2021 19:46

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Emotional functioning
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=113)							
		Patients				Statistics			
Name Visit	Level	in study¹	%	with value¹	%	mean²	SD	CI LL	CI UL
All									
Baseline	n/a	113	100.0	108	95.6	80.61	20.53	76.69	84.52
Week 4 (Day 29)	n/a	113	100.0	95	84.1	85.53	18.24	81.81	89.24
Week 8 (Day 57)	n/a	101	89.4	92	91.1	86.50	17.11	82.96	90.05
Week 12 (Day 85)	n/a	97	85.8	90	92.8	86.67	17.70	82.96	90.37
Week 16 (Day 113)	n/a	95	84.1	85	89.5	87.09	17.76	83.26	90.92
Week 20 (Day 141)	n/a	89	78.8	83	93.3	86.24	17.34	82.46	90.03
Week 24 (Day 169)	n/a	81	71.7	73	90.1	86.87	18.05	82.66	91.08
Week 28 (Day 197)	n/a	74	65.5	69	93.2	85.39	21.60	80.20	90.58
Week 32 (Day 225)	n/a	71	62.8	63	88.7	86.90	18.13	82.34	91.47
Week 36 (Day 253)	n/a	71	62.8	65	91.5	86.92	18.92	82.23	91.61
Week 40 (Day 281)	n/a	67	59.3	59	88.1	85.88	18.33	81.10	90.65
Week 44 (Day 309)	n/a	64	56.6	58	90.6	85.54	21.51	79.88	91.19
Week 48 (Day 337)	n/a	58	51.3	33	56.9	85.61	18.90	78.91	92.31
Week 52 (Day 365)	n/a	45	39.8	7	15.6	78.57	21.44	58.74	98.40
Week 56 (Day 393)	n/a	37	32.7	12	32.4	80.56	16.41	70.13	90.98
Week 60 (Day 421)	n/a	32	28.3	1	3.1	83.33	NE	NE	NE
Week 64 (Day 449)	n/a	31	27.4	9	29.0	87.04	16.20	74.59	99.49
Week 68 (Day 477)	n/a	28	24.8	1	3.6	75.00	NE	NE	NE
Week 72 (Day 505)	n/a	28	24.8	4	14.3	91.67	16.67	65.15	118.19
Week 76 (Day 533)	n/a	25	22.1	2	8.0	83.33	0.00	NE	NE
Week 80 (Day 561)	n/a	25	22.1	6	24.0	79.17	26.74	51.10	107.23
Week 84 (Day 589)	n/a	18	15.9	1	5.6	83.33	NE	NE	NE
Week 88 (Day 617)	n/a	14	12.4	2	14.3	91.67	11.79	-14.22	197.55
Week 92 (Day 645)	n/a	7	6.2	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	5.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	2.7	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	113	100.0	111	98.2	82.61	21.64	78.54	86.68
End of Study (LOCF)	n/a	113	100.0	111	98.2	82.36	21.98	78.22	86.49
Sex									
Baseline	Female	69	100.0	67	97.1	78.19	22.28	72.76	83.63
Week 4 (Day 29)	Female	69	100.0	55	79.7	83.94	17.48	79.21	88.67
Week 8 (Day 57)	Female	63	91.3	54	85.7	83.49	18.56	78.42	88.55
Week 12 (Day 85)	Female	60	87.0	56	93.3	83.48	19.62	78.23	88.74
Week 16 (Day 113)	Female	58	84.1	50	86.2	84.72	19.47	79.19	90.25
Week 20 (Day 141)	Female	53	76.8	48	90.6	82.64	18.66	77.22	88.06
Week 24 (Day 169)	Female	47	68.1	40	85.1	85.21	19.84	78.86	91.55
Week 28 (Day 197)	Female	42	60.9	38	90.5	80.70	23.26	73.06	88.35
Week 32 (Day 225)	Female	42	60.9	35	83.3	84.05	21.33	76.72	91.37
Week 36 (Day 253)	Female	42	60.9	37	88.1	83.78	22.39	76.32	91.25
Week 40 (Day 281)	Female	41	59.4	37	90.2	85.36	20.36	78.57	92.15
Week 44 (Day 309)	Female	41	59.4	35	85.4	82.14	24.93	73.58	90.71
Week 48 (Day 337)	Female	37	53.6	22	59.5	82.95	20.81	73.73	92.18
Week 52 (Day 365)	Female	29	42.0	5	17.2	73.33	23.12	44.62	102.05
Week 56 (Day 393)	Female	24	34.8	8	33.3	77.08	18.23	61.84	92.32
Week 60 (Day 421)	Female	22	31.9	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Female	22	31.9	6	27.3	80.56	16.39	63.36	97.75
Week 68 (Day 477)	Female	20	29.0	1	5.0	75.00	NE	NE	NE
Week 72 (Day 505)	Female	20	29.0	2	10.0	83.33	23.57	-128.44	295.10
Week 76 (Day 533)	Female	18	26.1	2	11.1	83.33	0.00	NE	NE
Week 80 (Day 561)	Female	18	26.1	5	27.8	75.00	27.64	40.68	109.32
Week 84 (Day 589)	Female	12	17.4	1	8.3	83.33	NE	NE	NE
Week 88 (Day 617)	Female	9	13.0	1	11.1	83.33	NE	NE	NE
Week 92 (Day 645)	Female	6	8.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	7.2	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	2.9	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	1.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	69	100.0	68	98.6	80.88	22.68	75.39	86.37
End of Study (LOCF)	Female	69	100.0	68	98.6	79.90	23.27	74.27	85.53
Baseline	Male	44	100.0	41	93.2	84.55	16.83	79.24	89.86
Week 4 (Day 29)	Male	44	100.0	40	90.9	87.71	19.24	81.55	93.86
Week 8 (Day 57)	Male	38	86.4	38	100.0	90.79	13.94	86.21	95.37
Week 12 (Day 85)	Male	37	84.1	34	91.9	91.91	12.56	87.53	96.29
Week 16 (Day 113)	Male	37	84.1	35	94.6	90.48	14.59	85.46	95.49
Week 20 (Day 141)	Male	36	81.8	35	97.2	91.19	14.14	86.33	96.05
Week 24 (Day 169)	Male	34	77.3	33	97.1	88.89	15.68	83.33	94.45
Week 28 (Day 197)	Male	32	72.7	31	96.9	91.13	18.12	84.48	97.78
Week 32 (Day 225)	Male	29	65.9	28	96.6	90.48	12.57	85.60	95.35
Week 36 (Day 253)	Male	29	65.9	28	96.6	91.07	12.20	86.34	95.80
Week 40 (Day 281)	Male	26	59.1	22	84.6	86.74	14.70	80.23	93.26
Week 44 (Day 309)	Male	23	52.3	23	100.0	90.70	13.85	84.71	96.69
Week 48 (Day 337)	Male	21	47.7	11	52.4	90.91	13.67	81.73	100.09
Week 52 (Day 365)	Male	16	36.4	2	12.5	91.67	11.79	-14.22	197.55
Week 56 (Day 393)	Male	13	29.5	4	30.8	87.50	10.76	70.38	104.62
Week 60 (Day 421)	Male	10	22.7	1	10.0	83.33	NE	NE	NE
Week 64 (Day 449)	Male	9	20.5	3	33.3	100.00	0.00	NE	NE
Week 68 (Day 477)	Male	8	18.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	8	18.2	2	25.0	100.00	0.00	NE	NE
Week 76 (Day 533)	Male	7	15.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	7	15.9	1	14.3	100.00	NE	NE	NE
Week 84 (Day 589)	Male	6	13.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	5	11.4	1	20.0	100.00	NE	NE	NE
Week 92 (Day 645)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	44	100.0	43	97.7	85.34	19.85	79.23	91.44
End of Study (LOCF)	Male	44	100.0	43	97.7	86.24	19.41	80.27	92.21
Age									

Baseline	< 65	78	100.0	73	93.6	81.28	20.31	76.54	86.02
Week 4 (Day 29)	< 65	78	100.0	68	87.2	86.15	17.61	81.89	90.41
Week 8 (Day 57)	< 65	73	93.6	66	90.4	87.63	14.27	84.12	91.13
Week 12 (Day 85)	< 65	71	91.0	64	90.1	88.28	15.76	84.34	92.22
Week 16 (Day 113)	< 65	69	88.5	59	85.5	88.18	15.58	84.12	92.24
Week 20 (Day 141)	< 65	65	83.3	62	95.4	86.29	17.21	81.92	90.66
Week 24 (Day 169)	< 65	59	75.6	55	93.2	87.42	16.81	82.88	91.97
Week 28 (Day 197)	< 65	55	70.5	51	92.7	84.97	21.80	78.84	91.10
Week 32 (Day 225)	< 65	53	67.9	48	90.6	87.33	15.85	82.72	91.93
Week 36 (Day 253)	< 65	53	67.9	50	94.3	87.83	17.59	82.83	92.83
Week 40 (Day 281)	< 65	52	66.7	48	92.3	86.63	16.19	81.93	91.33
Week 44 (Day 309)	< 65	52	66.7	48	92.3	86.00	21.01	79.89	92.10
Week 48 (Day 337)	< 65	47	60.3	26	55.3	88.78	14.33	83.00	94.57
Week 52 (Day 365)	< 65	36	46.2	4	11.1	85.42	19.69	54.08	116.75
Week 56 (Day 393)	< 65	30	38.5	9	30.0	84.26	16.37	71.67	96.85
Week 60 (Day 421)	< 65	25	32.1	1	4.0	83.33	NE	NE	NE
Week 64 (Day 449)	< 65	24	30.8	7	29.2	92.86	13.11	80.73	104.98
Week 68 (Day 477)	< 65	22	28.2	1	4.5	75.00	NE	NE	NE
Week 72 (Day 505)	< 65	22	28.2	4	18.2	91.67	16.67	65.15	118.19
Week 76 (Day 533)	< 65	21	26.9	2	9.5	83.33	0.00	NE	NE
Week 80 (Day 561)	< 65	21	26.9	5	23.8	81.67	29.11	45.53	117.81
Week 84 (Day 589)	< 65	15	19.2	1	6.7	83.33	NE	NE	NE
Week 88 (Day 617)	< 65	12	15.4	2	16.7	91.67	11.79	-14.22	197.55
Week 92 (Day 645)	< 65	6	7.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	6.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	78	100.0	76	97.4	84.80	20.80	80.04	89.55
End of Study (LOCF)	< 65	78	100.0	76	97.4	84.65	21.17	79.81	89.49
Baseline	>= 65	35	100.0	35	100.0	79.21	21.22	71.92	86.50
Week 4 (Day 29)	>= 65	35	100.0	27	77.1	83.95	20.01	76.04	91.86
Week 8 (Day 57)	>= 65	28	80.0	26	92.9	83.65	22.91	74.40	92.91
Week 12 (Day 85)	>= 65	26	74.3	26	100.0	82.69	21.59	73.97	91.41

Week 16 (Day 113)	>= 65	26	74.3	26	100.0	84.62	22.07	75.70	93.53
Week 20 (Day 141)	>= 65	24	68.6	21	87.5	86.11	18.13	77.86	94.36
Week 24 (Day 169)	>= 65	22	62.9	18	81.8	85.19	21.87	74.31	96.06
Week 28 (Day 197)	>= 65	19	54.3	18	94.7	86.57	21.61	75.83	97.32
Week 32 (Day 225)	>= 65	18	51.4	15	83.3	85.56	24.69	71.88	99.23
Week 36 (Day 253)	>= 65	18	51.4	15	83.3	83.89	23.25	71.02	96.76
Week 40 (Day 281)	>= 65	15	42.9	11	73.3	82.58	26.47	64.79	100.36
Week 44 (Day 309)	>= 65	12	34.3	10	83.3	83.33	24.85	65.56	101.11
Week 48 (Day 337)	>= 65	11	31.4	7	63.6	73.81	29.04	46.95	100.67
Week 52 (Day 365)	>= 65	9	25.7	3	33.3	69.44	24.06	9.69	129.20
Week 56 (Day 393)	>= 65	7	20.0	3	42.9	69.44	12.73	37.82	101.07
Week 60 (Day 421)	>= 65	7	20.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	7	20.0	2	28.6	66.67	0.00	NE	NE
Week 68 (Day 477)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	4	11.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	4	11.4	1	25.0	66.67	NE	NE	NE
Week 84 (Day 589)	>= 65	3	8.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	5.7	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	35	100.0	35	100.0	77.86	22.95	69.97	85.74
End of Study (LOCF)	>= 65	35	100.0	35	100.0	77.38	23.18	69.42	85.34
ECOG performance status									
Baseline	0	33	100.0	31	93.9	79.75	21.91	71.71	87.79
Week 4 (Day 29)	0	33	100.0	27	81.8	79.63	22.68	70.66	88.60
Week 8 (Day 57)	0	30	90.9	27	90.0	80.86	21.03	72.54	89.18
Week 12 (Day 85)	0	29	87.9	26	89.7	78.85	22.01	69.95	87.74
Week 16 (Day 113)	0	28	84.8	24	85.7	81.25	21.60	72.13	90.37
Week 20 (Day 141)	0	26	78.8	24	92.3	81.94	18.98	73.93	89.96
Week 24 (Day 169)	0	24	72.7	20	83.3	82.08	21.34	72.10	92.07
Week 28 (Day 197)	0	21	63.6	19	90.5	80.70	27.79	67.31	94.09

Week 32 (Day 225)	0	21	63.6	18	85.7	82.41	21.37	71.78	93.03
Week 36 (Day 253)	0	21	63.6	20	95.2	83.75	22.37	73.28	94.22
Week 40 (Day 281)	0	21	63.6	19	90.5	82.02	21.74	71.54	92.50
Week 44 (Day 309)	0	21	63.6	17	81.0	82.84	24.02	70.49	95.19
Week 48 (Day 337)	0	19	57.6	12	63.2	80.56	23.92	65.35	95.76
Week 52 (Day 365)	0	18	54.5	3	16.7	61.11	20.97	9.01	113.21
Week 56 (Day 393)	0	16	48.5	5	31.3	83.33	17.68	61.38	105.28
Week 60 (Day 421)	0	16	48.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	0	16	48.5	5	31.3	90.00	14.91	71.49	108.51
Week 68 (Day 477)	0	14	42.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	0	14	42.4	1	7.1	100.00	NE	NE	NE
Week 76 (Day 533)	0	12	36.4	1	8.3	83.33	NE	NE	NE
Week 80 (Day 561)	0	12	36.4	1	8.3	100.00	NE	NE	NE
Week 84 (Day 589)	0	10	30.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	9	27.3	1	11.1	83.33	NE	NE	NE
Week 92 (Day 645)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	9.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	3.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	33	100.0	33	100.0	78.79	25.61	69.71	87.87
End of Study (LOCF)	0	33	100.0	33	100.0	77.78	25.99	68.56	86.99
Baseline	1	79	100.0	76	96.2	81.36	19.90	76.81	85.91
Week 4 (Day 29)	1	79	100.0	67	84.8	88.18	15.63	84.37	92.00
Week 8 (Day 57)	1	70	88.6	65	92.9	88.85	14.75	85.19	92.50
Week 12 (Day 85)	1	68	86.1	64	94.1	89.84	14.66	86.18	93.51
Week 16 (Day 113)	1	67	84.8	61	91.0	89.39	15.61	85.39	93.39
Week 20 (Day 141)	1	63	79.7	59	93.7	87.99	16.47	83.70	92.29
Week 24 (Day 169)	1	57	72.2	53	93.0	88.68	16.51	84.13	93.23
Week 28 (Day 197)	1	53	67.1	50	94.3	87.17	18.76	81.83	92.50
Week 32 (Day 225)	1	50	63.3	45	90.0	88.70	16.59	83.72	93.69
Week 36 (Day 253)	1	50	63.3	45	90.0	88.33	17.26	83.15	93.52
Week 40 (Day 281)	1	46	58.2	40	87.0	87.71	16.45	82.45	92.97

Week 44 (Day 309)	1	43	54.4	41	95.3	86.65	20.59	80.15	93.15
Week 48 (Day 337)	1	39	49.4	21	53.8	88.49	15.25	81.55	95.43
Week 52 (Day 365)	1	27	34.2	4	14.8	91.67	9.62	76.36	106.98
Week 56 (Day 393)	1	21	26.6	7	33.3	78.57	16.57	63.25	93.89
Week 60 (Day 421)	1	16	20.3	1	6.3	83.33	NE	NE	NE
Week 64 (Day 449)	1	15	19.0	4	26.7	83.33	19.25	52.71	113.96
Week 68 (Day 477)	1	14	17.7	1	7.1	75.00	NE	NE	NE
Week 72 (Day 505)	1	14	17.7	3	21.4	88.89	19.25	41.08	136.70
Week 76 (Day 533)	1	13	16.5	1	7.7	83.33	NE	NE	NE
Week 80 (Day 561)	1	13	16.5	5	38.5	75.00	27.64	40.68	109.32
Week 84 (Day 589)	1	8	10.1	1	12.5	83.33	NE	NE	NE
Week 88 (Day 617)	1	5	6.3	1	20.0	100.00	NE	NE	NE
Week 92 (Day 645)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	2.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	79	100.0	77	97.5	84.45	19.72	79.98	88.93
End of Study (LOCF)	1	79	100.0	77	97.5	84.52	19.95	80.00	89.05
Baseline	Missing	1	100.0	1	100.0	50.00	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	66.67	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	66.67	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	66.67	NE	NE	NE
Geographic region									
Baseline	USA	22	100.0	22	100.0	77.65	17.70	69.80	85.50
Week 4 (Day 29)	USA	22	100.0	18	81.8	79.17	19.23	69.61	88.73
Week 8 (Day 57)	USA	20	90.9	18	90.0	85.65	14.80	78.29	93.01
Week 12 (Day 85)	USA	20	90.9	19	95.0	85.96	17.36	77.60	94.33
Week 16 (Day 113)	USA	19	86.4	17	89.5	86.76	15.88	78.60	94.93
Week 20 (Day 141)	USA	19	86.4	17	89.5	87.25	15.34	79.37	95.14
Week 24 (Day 169)	USA	16	72.7	14	87.5	84.52	18.74	73.71	95.34
Week 28 (Day 197)	USA	15	68.2	12	80.0	87.50	21.47	73.86	101.14
Week 32 (Day 225)	USA	15	68.2	13	86.7	86.54	21.39	73.61	99.47
Week 36 (Day 253)	USA	15	68.2	13	86.7	85.26	26.39	69.31	101.20
Week 40 (Day 281)	USA	14	63.6	11	78.6	81.06	23.89	65.01	97.11

Week 44 (Day 309)	USA	13	59.1	11	84.6	82.83	19.67	69.61	96.05
Week 48 (Day 337)	USA	13	59.1	10	76.9	86.67	15.81	75.36	97.98
Week 52 (Day 365)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	USA	12	54.5	6	50.0	80.56	19.48	60.11	101.00
Week 60 (Day 421)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	11	50.0	4	36.4	87.50	15.96	62.11	112.89
Week 68 (Day 477)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	10	45.5	1	10.0	100.00	NE	NE	NE
Week 76 (Day 533)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	10	45.5	2	20.0	50.00	23.57	-161.77	261.77
Week 84 (Day 589)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	13.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	4.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	22	100.0	22	100.0	84.22	16.92	76.72	91.72
End of Study (LOCF)	USA	22	100.0	22	100.0	82.20	17.50	74.44	89.96
Baseline	Europe (EU)	32	100.0	29	90.6	72.32	23.65	63.32	81.31
Week 4 (Day 29)	Europe (EU)	32	100.0	25	78.1	80.33	19.38	72.33	88.33
Week 8 (Day 57)	Europe (EU)	29	90.6	25	86.2	79.33	18.65	71.63	87.03
Week 12 (Day 85)	Europe (EU)	26	81.3	24	92.3	78.13	20.09	69.64	86.61
Week 16 (Day 113)	Europe (EU)	25	78.1	20	80.0	80.14	21.78	69.94	90.33
Week 20 (Day 141)	Europe (EU)	23	71.9	22	95.7	77.27	19.95	68.43	86.12
Week 24 (Day 169)	Europe (EU)	21	65.6	20	95.2	76.67	24.42	65.24	88.10
Week 28 (Day 197)	Europe (EU)	20	62.5	20	100.0	73.75	24.97	62.07	85.43
Week 32 (Day 225)	Europe (EU)	18	56.3	16	88.9	82.81	14.74	74.96	90.67
Week 36 (Day 253)	Europe (EU)	18	56.3	17	94.4	81.37	12.68	74.85	87.89
Week 40 (Day 281)	Europe (EU)	17	53.1	16	94.1	83.85	13.08	76.89	90.82
Week 44 (Day 309)	Europe (EU)	17	53.1	14	82.4	74.40	28.21	58.12	90.69

Week 48 (Day 337)	Europe (EU)	14	43.8	10	71.4	78.33	14.27	68.12	88.54
Week 52 (Day 365)	Europe (EU)	13	40.6	3	23.1	61.11	20.97	9.01	113.21
Week 56 (Day 393)	Europe (EU)	11	34.4	5	45.5	78.33	15.14	59.54	97.13
Week 60 (Day 421)	Europe (EU)	11	34.4	1	9.1	83.33	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	11	34.4	5	45.5	86.67	18.26	64.00	109.34
Week 68 (Day 477)	Europe (EU)	10	31.3	1	10.0	75.00	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	10	31.3	3	30.0	88.89	19.25	41.08	136.70
Week 76 (Day 533)	Europe (EU)	8	25.0	2	25.0	83.33	0.00	NE	NE
Week 80 (Day 561)	Europe (EU)	8	25.0	4	50.0	93.75	12.50	73.86	113.64
Week 84 (Day 589)	Europe (EU)	6	18.8	1	16.7	83.33	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	9.4	2	66.7	91.67	11.79	-14.22	197.55
Cycle 12 (LOCF)	Europe (EU)	32	100.0	31	96.9	72.31	27.92	62.07	82.55
End of Study (LOCF)	Europe (EU)	32	100.0	31	96.9	72.58	28.56	62.10	83.06
Baseline	Asia (AS)	59	100.0	57	96.6	85.96	18.44	81.07	90.86
Week 4 (Day 29)	Asia (AS)	59	100.0	52	88.1	90.22	16.23	85.71	94.74
Week 8 (Day 57)	Asia (AS)	52	88.1	49	94.2	90.48	16.14	85.84	95.11
Week 12 (Day 85)	Asia (AS)	51	86.4	47	92.2	91.31	15.04	86.89	95.73
Week 16 (Day 113)	Asia (AS)	51	86.4	48	94.1	90.10	16.00	85.46	94.75
Week 20 (Day 141)	Asia (AS)	47	79.7	44	93.6	90.34	15.24	85.71	94.98
Week 24 (Day 169)	Asia (AS)	44	74.6	39	88.6	92.95	10.21	89.64	96.26
Week 28 (Day 197)	Asia (AS)	39	66.1	37	94.9	90.99	17.39	85.19	96.79
Week 32 (Day 225)	Asia (AS)	38	64.4	34	89.5	88.97	18.43	82.54	95.40
Week 36 (Day 253)	Asia (AS)	38	64.4	35	92.1	90.24	18.02	84.05	96.43
Week 40 (Day 281)	Asia (AS)	36	61.0	32	88.9	88.54	18.54	81.86	95.23
Week 44 (Day 309)	Asia (AS)	34	57.6	33	97.1	91.16	17.05	85.12	97.21
Week 48 (Day 337)	Asia (AS)	31	52.5	13	41.9	90.38	23.29	76.31	104.46
Week 52 (Day 365)	Asia (AS)	20	33.9	4	20.0	91.67	9.62	76.36	106.98
Week 56 (Day 393)	Asia (AS)	14	23.7	1	7.1	91.67	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	10.2	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	8.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	3.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	59	100.0	58	98.3	87.50	17.47	82.91	92.09
End of Study (LOCF)	Asia (AS)	59	100.0	58	98.3	87.64	17.61	83.01	92.27
Race/ethnicity									
Baseline	Asian	61	100.0	58	95.1	85.92	18.28	81.11	90.73
Week 4 (Day 29)	Asian	61	100.0	52	85.2	90.22	16.23	85.71	94.74
Week 8 (Day 57)	Asian	53	86.9	49	92.5	90.48	16.14	85.84	95.11
Week 12 (Day 85)	Asian	52	85.2	48	92.3	91.15	14.93	86.81	95.48
Week 16 (Day 113)	Asian	52	85.2	49	94.2	89.46	16.47	84.72	94.19
Week 20 (Day 141)	Asian	48	78.7	45	93.8	89.81	15.48	85.16	94.46
Week 24 (Day 169)	Asian	44	72.1	39	88.6	92.95	10.21	89.64	96.26
Week 28 (Day 197)	Asian	39	63.9	37	94.9	90.99	17.39	85.19	96.79
Week 32 (Day 225)	Asian	38	62.3	34	89.5	88.97	18.43	82.54	95.40
Week 36 (Day 253)	Asian	38	62.3	35	92.1	90.24	18.02	84.05	96.43
Week 40 (Day 281)	Asian	36	59.0	32	88.9	88.54	18.54	81.86	95.23
Week 44 (Day 309)	Asian	34	55.7	33	97.1	91.16	17.05	85.12	97.21
Week 48 (Day 337)	Asian	31	50.8	13	41.9	90.38	23.29	76.31	104.46
Week 52 (Day 365)	Asian	20	32.8	4	20.0	91.67	9.62	76.36	106.98
Week 56 (Day 393)	Asian	14	23.0	1	7.1	91.67	NE	NE	NE
Week 60 (Day 421)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	9.8	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	8.2	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	3.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	61	100.0	59	96.7	87.15	17.53	82.58	91.72
End of Study (LOCF)	Asian	61	100.0	59	96.7	87.29	17.67	82.68	91.89
Baseline	Non-Asian	45	100.0	44	97.8	74.94	21.09	68.52	81.35
Week 4 (Day 29)	Non-Asian	45	100.0	39	86.7	80.77	17.85	74.98	86.55
Week 8 (Day 57)	Non-Asian	42	93.3	38	90.5	81.80	17.85	75.93	87.66
Week 12 (Day 85)	Non-Asian	39	86.7	37	94.9	80.41	19.76	73.82	86.99
Week 16 (Day 113)	Non-Asian	37	82.2	34	91.9	83.42	19.50	76.61	90.22
Week 20 (Day 141)	Non-Asian	36	80.0	34	94.4	81.86	17.82	75.64	88.08
Week 24 (Day 169)	Non-Asian	32	71.1	31	96.9	79.03	22.66	70.72	87.34
Week 28 (Day 197)	Non-Asian	30	66.7	28	93.3	80.65	20.17	72.84	88.47
Week 32 (Day 225)	Non-Asian	28	62.2	25	89.3	84.33	18.21	76.82	91.85
Week 36 (Day 253)	Non-Asian	28	62.2	26	92.9	83.65	19.07	75.95	91.36
Week 40 (Day 281)	Non-Asian	26	57.8	23	88.5	83.33	18.46	75.35	91.32
Week 44 (Day 309)	Non-Asian	25	55.6	21	84.0	79.10	24.32	68.03	90.17
Week 48 (Day 337)	Non-Asian	23	51.1	17	73.9	81.37	14.89	73.72	89.03
Week 52 (Day 365)	Non-Asian	21	46.7	3	14.3	61.11	20.97	9.01	113.21
Week 56 (Day 393)	Non-Asian	19	42.2	10	52.6	79.17	17.68	66.52	91.81
Week 60 (Day 421)	Non-Asian	19	42.2	1	5.3	83.33	NE	NE	NE
Week 64 (Day 449)	Non-Asian	18	40.0	7	38.9	90.48	16.27	75.43	105.52
Week 68 (Day 477)	Non-Asian	17	37.8	1	5.9	75.00	NE	NE	NE
Week 72 (Day 505)	Non-Asian	17	37.8	3	17.6	100.00	0.00	NE	NE
Week 76 (Day 533)	Non-Asian	15	33.3	2	13.3	83.33	0.00	NE	NE
Week 80 (Day 561)	Non-Asian	15	33.3	5	33.3	80.00	29.81	42.98	117.02
Week 84 (Day 589)	Non-Asian	10	22.2	1	10.0	83.33	NE	NE	NE
Week 88 (Day 617)	Non-Asian	7	15.6	2	28.6	91.67	11.79	-14.22	197.55
Week 92 (Day 645)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	45	100.0	45	100.0	76.91	25.03	69.39	84.43

End of Study (LOCF)	Non-Asian	45	100.0	45	100.0	76.11	25.54	68.44	83.78
Baseline	Unknown	7	100.0	6	85.7	70.83	25.69	43.88	97.79
Week 4 (Day 29)	Unknown	7	100.0	4	57.1	70.83	30.81	21.81	119.85
Week 8 (Day 57)	Unknown	6	85.7	5	83.3	83.33	13.18	66.97	99.69
Week 12 (Day 85)	Unknown	6	85.7	5	83.3	90.00	14.91	71.49	108.51
Week 16 (Day 113)	Unknown	6	85.7	2	33.3	91.67	11.79	-14.22	197.55
Week 20 (Day 141)	Unknown	5	71.4	4	80.0	83.33	28.05	38.69	127.97
Week 24 (Day 169)	Unknown	5	71.4	3	60.0	88.89	19.25	41.08	136.70
Week 28 (Day 197)	Unknown	5	71.4	4	80.0	66.67	47.14	-8.34	141.68
Week 32 (Day 225)	Unknown	5	71.4	4	80.0	85.42	17.18	58.08	112.75
Week 36 (Day 253)	Unknown	5	71.4	4	80.0	79.17	25.00	39.39	118.95
Week 40 (Day 281)	Unknown	5	71.4	4	80.0	79.17	15.96	53.78	104.56
Week 44 (Day 309)	Unknown	5	71.4	4	80.0	72.92	29.95	25.26	120.57
Week 48 (Day 337)	Unknown	4	57.1	3	75.0	88.89	19.25	41.08	136.70
Week 52 (Day 365)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	4	57.1	1	25.0	83.33	NE	NE	NE
Week 60 (Day 421)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	4	57.1	2	50.0	75.00	11.79	-30.89	180.89
Week 68 (Day 477)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	3	42.9	1	33.3	66.67	NE	NE	NE
Week 76 (Day 533)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	3	42.9	1	33.3	75.00	NE	NE	NE
Week 84 (Day 589)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	14.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	7	100.0	7	100.0	80.95	23.92	58.83	103.07
End of Study (LOCF)	Unknown	7	100.0	7	100.0	80.95	22.93	59.75	102.16
Number of prior antineoplastic systemic therapy lines I									
Baseline	1	60	100.0	57	95.0	78.46	21.35	72.79	84.13

Week 4 (Day 29)	1	60	100.0	50	83.3	84.17	19.36	78.66	89.67
Week 8 (Day 57)	1	54	90.0	49	90.7	85.88	16.86	81.04	90.73
Week 12 (Day 85)	1	52	86.7	48	92.3	84.03	18.34	78.70	89.35
Week 16 (Day 113)	1	51	85.0	46	90.2	85.75	17.91	80.43	91.07
Week 20 (Day 141)	1	48	80.0	43	89.6	85.85	16.22	80.86	90.84
Week 24 (Day 169)	1	43	71.7	39	90.7	84.62	20.55	77.95	91.28
Week 28 (Day 197)	1	38	63.3	34	89.5	83.09	23.16	75.01	91.17
Week 32 (Day 225)	1	35	58.3	29	82.9	87.36	14.71	81.76	92.95
Week 36 (Day 253)	1	35	58.3	31	88.6	88.44	13.21	83.60	93.29
Week 40 (Day 281)	1	32	53.3	27	84.4	86.42	13.70	81.00	91.84
Week 44 (Day 309)	1	32	53.3	27	84.4	84.67	24.25	75.08	94.26
Week 48 (Day 337)	1	27	45.0	16	59.3	83.33	15.81	74.91	91.76
Week 52 (Day 365)	1	23	38.3	5	21.7	76.67	25.95	44.44	108.89
Week 56 (Day 393)	1	16	26.7	4	25.0	75.00	18.00	46.35	103.65
Week 60 (Day 421)	1	14	23.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	13	21.7	4	30.8	83.33	19.25	52.71	113.96
Week 68 (Day 477)	1	12	20.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	12	20.0	1	8.3	100.00	NE	NE	NE
Week 76 (Day 533)	1	11	18.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	11	18.3	2	18.2	83.33	23.57	-128.44	295.10
Week 84 (Day 589)	1	9	15.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	1	8	13.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	1	3	5.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	1	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	60	100.0	58	96.7	80.80	24.22	74.43	87.16
End of Study (LOCF)	1	60	100.0	58	96.7	80.32	24.37	73.91	86.72
Baseline	>= 2	53	100.0	51	96.2	83.01	19.51	77.52	88.49
Week 4 (Day 29)	>= 2	53	100.0	45	84.9	87.04	17.00	81.93	92.14
Week 8 (Day 57)	>= 2	47	88.7	43	91.5	87.21	17.57	81.80	92.62
Week 12 (Day 85)	>= 2	45	84.9	42	93.3	89.68	16.65	84.49	94.87
Week 16 (Day 113)	>= 2	44	83.0	39	88.6	88.68	17.68	82.95	94.41

Week 20 (Day 141)	>= 2	41	77.4	40	97.6	86.67	18.66	80.70	92.64
Week 24 (Day 169)	>= 2	38	71.7	34	89.5	89.46	14.55	84.38	94.54
Week 28 (Day 197)	>= 2	36	67.9	35	97.2	87.62	20.05	80.73	94.51
Week 32 (Day 225)	>= 2	36	67.9	34	94.4	86.52	20.82	79.25	93.78
Week 36 (Day 253)	>= 2	36	67.9	34	94.4	85.54	23.06	77.49	93.58
Week 40 (Day 281)	>= 2	35	66.0	32	91.4	85.42	21.69	77.60	93.24
Week 44 (Day 309)	>= 2	32	60.4	31	96.9	86.29	19.19	79.25	93.33
Week 48 (Day 337)	>= 2	31	58.5	17	54.8	87.75	21.67	76.60	98.89
Week 52 (Day 365)	>= 2	22	41.5	2	9.1	83.33	0.00	NE	NE
Week 56 (Day 393)	>= 2	21	39.6	8	38.1	83.33	16.06	69.91	96.76
Week 60 (Day 421)	>= 2	18	34.0	1	5.6	83.33	NE	NE	NE
Week 64 (Day 449)	>= 2	18	34.0	5	27.8	90.00	14.91	71.49	108.51
Week 68 (Day 477)	>= 2	16	30.2	1	6.3	75.00	NE	NE	NE
Week 72 (Day 505)	>= 2	16	30.2	3	18.8	88.89	19.25	41.08	136.70
Week 76 (Day 533)	>= 2	14	26.4	2	14.3	83.33	0.00	NE	NE
Week 80 (Day 561)	>= 2	14	26.4	4	28.6	77.08	31.46	27.03	127.14
Week 84 (Day 589)	>= 2	9	17.0	1	11.1	83.33	NE	NE	NE
Week 88 (Day 617)	>= 2	6	11.3	2	33.3	91.67	11.79	-14.22	197.55
Week 92 (Day 645)	>= 2	2	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 2	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 2	53	100.0	53	100.0	84.59	18.45	79.51	89.68
End of Study (LOCF)	>= 2	53	100.0	53	100.0	84.59	19.02	79.35	89.83

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TP_QSC30EF_SG.xls
27OCT2021 7:26

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Emotional functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	35	32.4	24.3	41.7
	Cycle 12 (LOCF)	n/a	108	95.6	14	13.0	7.9	20.6
	End of Study (LOCF)	n/a	108	95.6	15	13.9	8.6	21.7
Sex	All visits	Female	67	59.3	22	32.8	22.8	44.7
		Male	41	36.3	13	31.7	19.6	47.0
	Cycle 12 (LOCF)	Female	67	59.3	8	11.9	6.2	21.8
		Male	41	36.3	6	14.6	6.9	28.4
	End of Study (LOCF)	Female	67	59.3	9	13.4	7.2	23.6
		Male	41	36.3	6	14.6	6.9	28.4
Age	All visits	< 65	73	64.6	23	31.5	22.0	42.9
		>= 65	35	31.0	12	34.3	20.8	50.8
	Cycle 12 (LOCF)	< 65	73	64.6	8	11.0	5.7	20.2
		>= 65	35	31.0	6	17.1	8.1	32.7
	End of Study (LOCF)	< 65	73	64.6	8	11.0	5.7	20.2
		>= 65	35	31.0	7	20.0	10.0	35.9
ECOG performance status	All visits	0	31	27.4	14	45.2	29.2	62.2
		1	76	67.3	21	27.6	18.8	38.6
		Missing	1	0.9	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	31	27.4	6	19.4	9.2	36.3
		1	76	67.3	8	10.5	5.4	19.4
		Missing	1	0.9	0	0.0	0.0	79.3
	End of Study (LOCF)	0	31	27.4	7	22.6	11.4	39.8
		1	76	67.3	8	10.5	5.4	19.4
		Missing	1	0.9	0	0.0	0.0	79.3
Geographic region	All visits	USA	22	19.5	5	22.7	10.1	43.4
		Europe (EU)	29	25.7	14	48.3	31.4	65.6
		Asia (AS)	57	50.4	16	28.1	18.1	40.8
	Cycle 12 (LOCF)	USA	22	19.5	1	4.5	0.8	21.8
		Europe (EU)	29	25.7	6	20.7	9.8	38.4
		Asia (AS)	57	50.4	7	12.3	6.1	23.2
	End of Study (LOCF)	USA	22	19.5	2	9.1	2.5	27.8
		Europe (EU)	29	25.7	6	20.7	9.8	38.4
		Asia (AS)	57	50.4	7	12.3	6.1	23.2
Race/ethnicity	All visits	Asian	58	51.3	17	29.3	19.2	42.0
		Non-Asian	44	38.9	15	34.1	21.9	48.9
		Unknown	6	5.3	3	50.0	18.8	81.2
	Cycle 12 (LOCF)	Asian	58	51.3	8	13.8	7.2	24.9

		Non-Asian	44	38.9	6	13.6	6.4	26.7
		Unknown	6	5.3	0	0.0	0.0	39.0
	End of Study (LOCF)	Asian	58	51.3	8	13.8	7.2	24.9
		Non-Asian	44	38.9	7	15.9	7.9	29.4
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	18	31.6	21.0	44.5
		>= 2	51	45.1	17	33.3	22.0	47.0
	Cycle 12 (LOCF)	1	57	50.4	7	12.3	6.1	23.2
		>= 2	51	45.1	7	13.7	6.8	25.7
	End of Study (LOCF)	1	57	50.4	9	15.8	8.5	27.4
		>= 2	51	45.1	6	11.8	5.5	23.4

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30EF_W10_SG.xls
15OCT2021 13:33

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Emotional functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

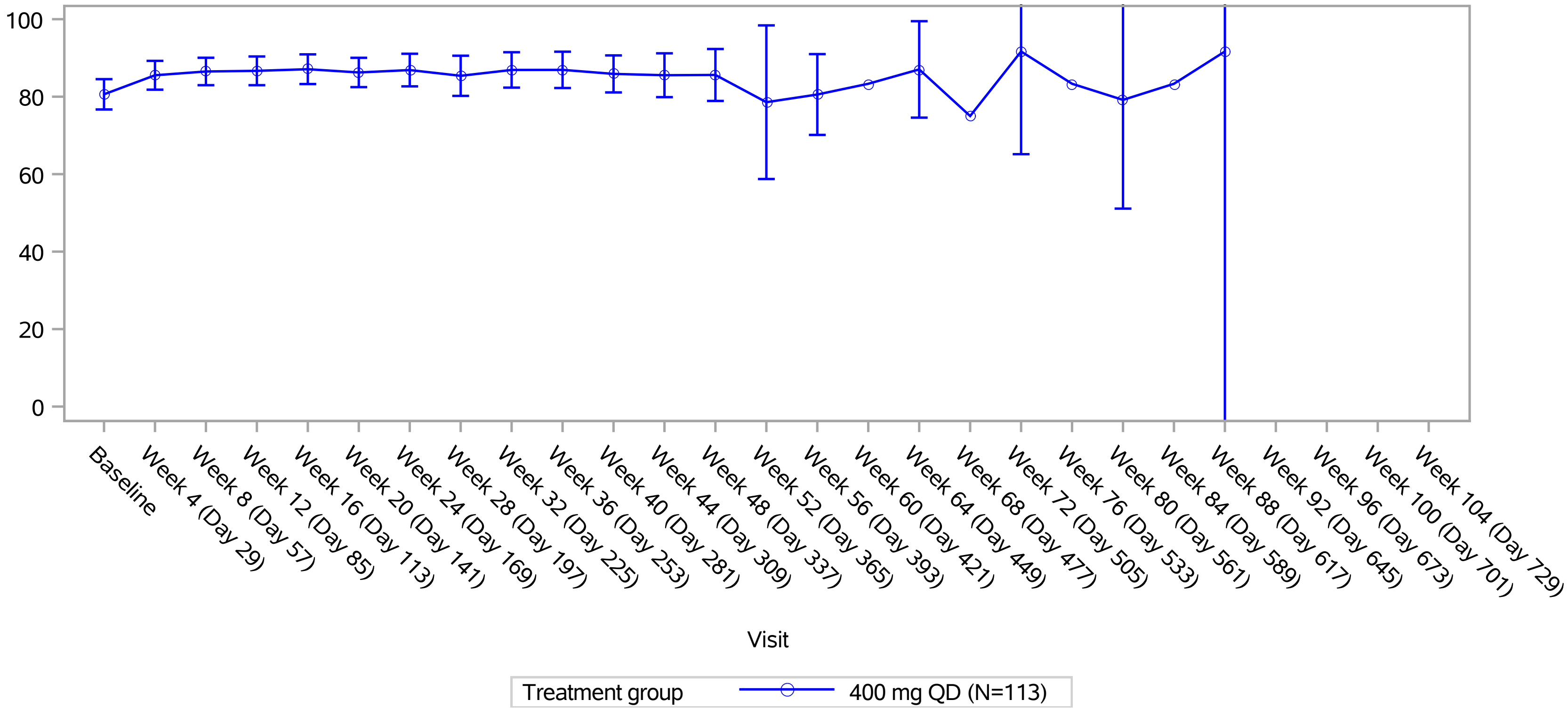
			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	34	31.5	23.5	40.7
	Cycle 12 (LOCF)	n/a	108	95.6	14	13.0	7.9	20.6
	End of Study (LOCF)	n/a	108	95.6	15	13.9	8.6	21.7
Sex	All visits	Female	67	59.3	21	31.3	21.5	43.2
		Male	41	36.3	13	31.7	19.6	47.0
	Cycle 12 (LOCF)	Female	67	59.3	8	11.9	6.2	21.8
		Male	41	36.3	6	14.6	6.9	28.4
	End of Study (LOCF)	Female	67	59.3	9	13.4	7.2	23.6
		Male	41	36.3	6	14.6	6.9	28.4
Age	All visits	< 65	73	64.6	23	31.5	22.0	42.9
		>= 65	35	31.0	11	31.4	18.6	48.0
	Cycle 12 (LOCF)	< 65	73	64.6	8	11.0	5.7	20.2
		>= 65	35	31.0	6	17.1	8.1	32.7
	End of Study (LOCF)	< 65	73	64.6	8	11.0	5.7	20.2
		>= 65	35	31.0	7	20.0	10.0	35.9
ECOG performance status	All visits	0	31	27.4	13	41.9	26.4	59.2
		1	76	67.3	21	27.6	18.8	38.6
		Missing	1	0.9	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	31	27.4	6	19.4	9.2	36.3
		1	76	67.3	8	10.5	5.4	19.4
		Missing	1	0.9	0	0.0	0.0	79.3
	End of Study (LOCF)	0	31	27.4	7	22.6	11.4	39.8
		1	76	67.3	8	10.5	5.4	19.4
		Missing	1	0.9	0	0.0	0.0	79.3
Geographic region	All visits	USA	22	19.5	5	22.7	10.1	43.4
		Europe (EU)	29	25.7	13	44.8	28.4	62.5
		Asia (AS)	57	50.4	16	28.1	18.1	40.8
	Cycle 12 (LOCF)	USA	22	19.5	1	4.5	0.8	21.8
		Europe (EU)	29	25.7	6	20.7	9.8	38.4
		Asia (AS)	57	50.4	7	12.3	6.1	23.2
	End of Study (LOCF)	USA	22	19.5	2	9.1	2.5	27.8
		Europe (EU)	29	25.7	6	20.7	9.8	38.4
		Asia (AS)	57	50.4	7	12.3	6.1	23.2
Race/ethnicity	All visits	Asian	58	51.3	17	29.3	19.2	42.0
		Non-Asian	44	38.9	14	31.8	20.0	46.6
		Unknown	6	5.3	3	50.0	18.8	81.2
	Cycle 12 (LOCF)	Asian	58	51.3	8	13.8	7.2	24.9

		Non-Asian	44	38.9	6	13.6	6.4	26.7
		Unknown	6	5.3	0	0.0	0.0	39.0
	End of Study (LOCF)	Asian	58	51.3	8	13.8	7.2	24.9
		Non-Asian	44	38.9	7	15.9	7.9	29.4
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	17	29.8	19.5	42.7
		>= 2	51	45.1	17	33.3	22.0	47.0
	Cycle 12 (LOCF)	1	57	50.4	7	12.3	6.1	23.2
		>= 2	51	45.1	7	13.7	6.8	25.7
	End of Study (LOCF)	1	57	50.4	9	15.8	8.5	27.4
		>= 2	51	45.1	6	11.8	5.5	23.4

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30EF_W15_SG.xls
15OCT2021 13:23

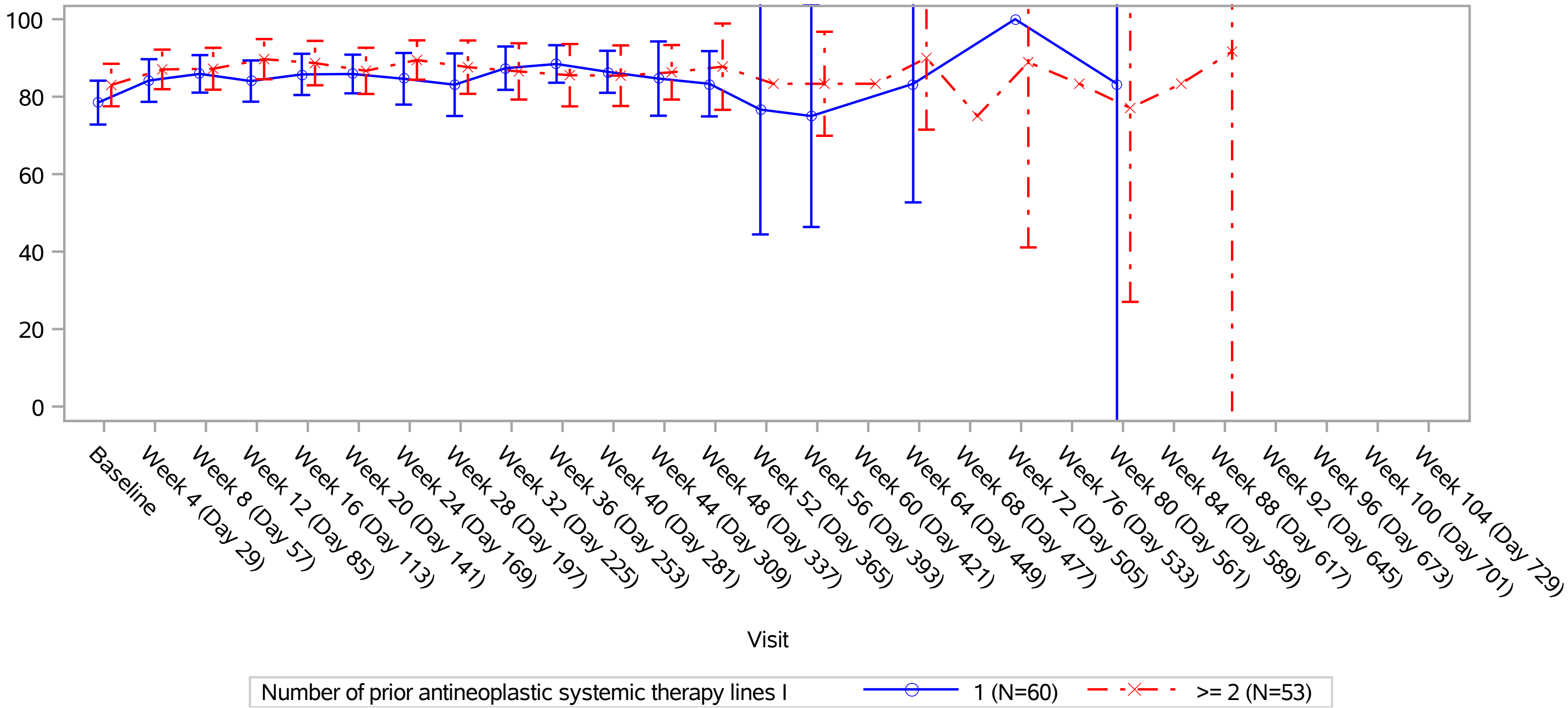
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Emotional functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30EF.pdf
15OCT2021 17:15

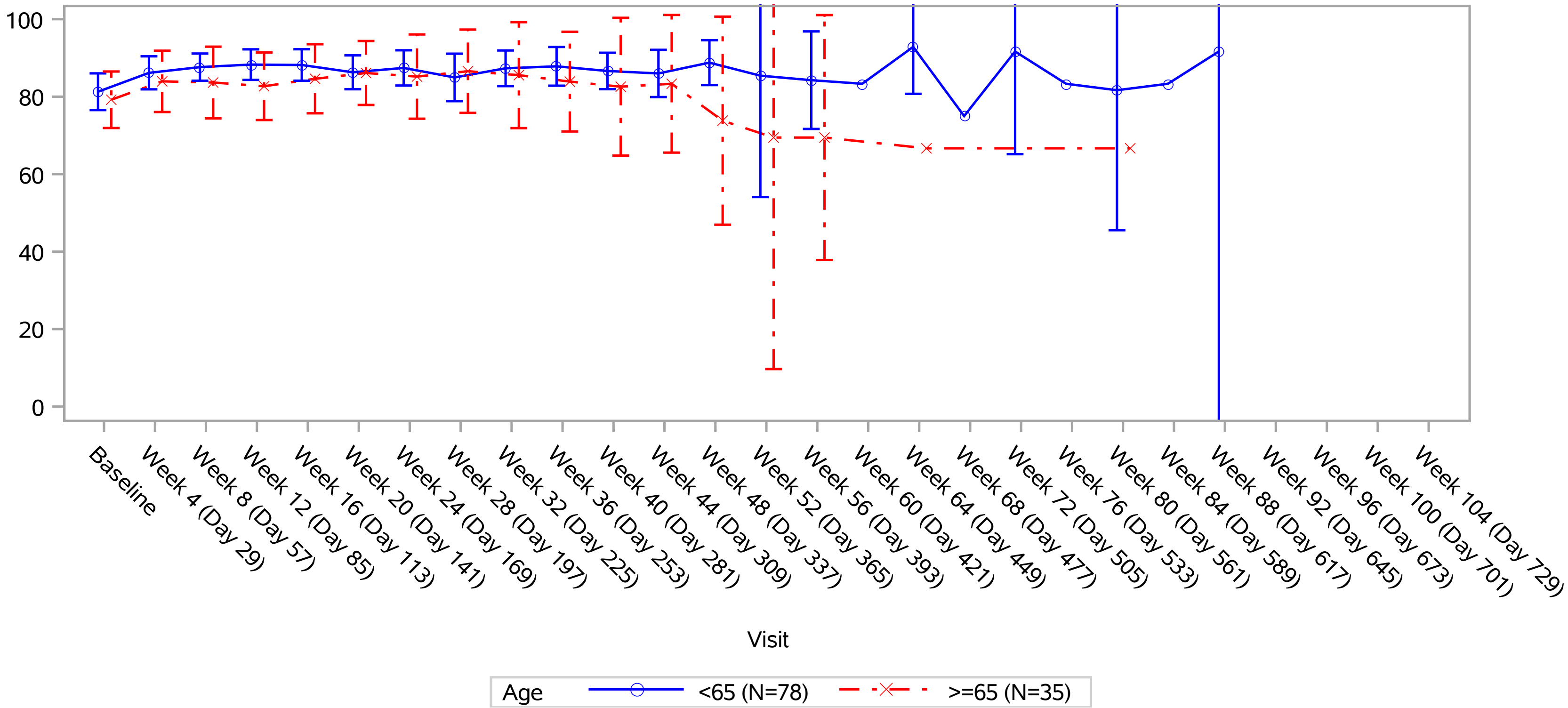
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Emotional functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30EF_PRTHL1.pdf
15OCT2021 20:07

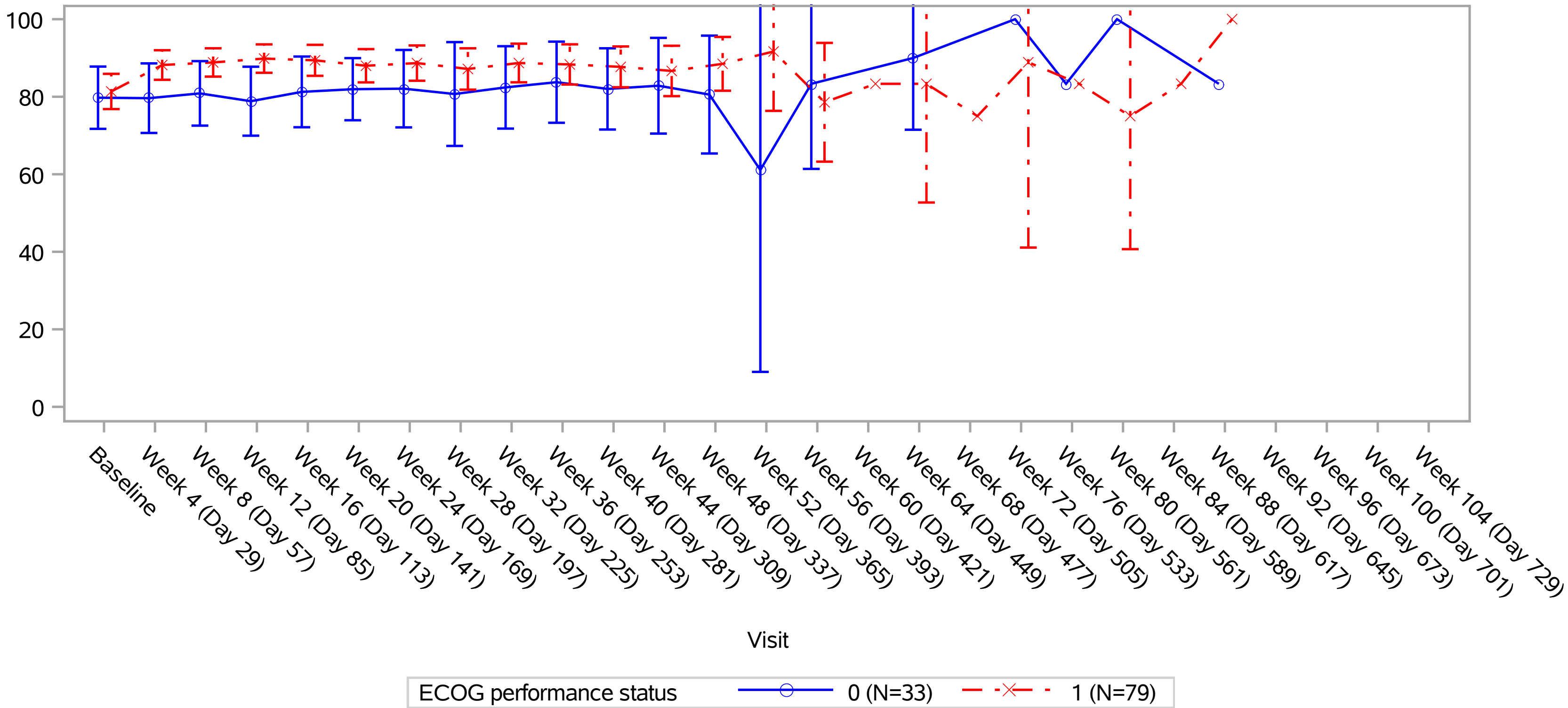
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Emotional functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30EF_SGAGE65.pdf
15OCT2021 17:44

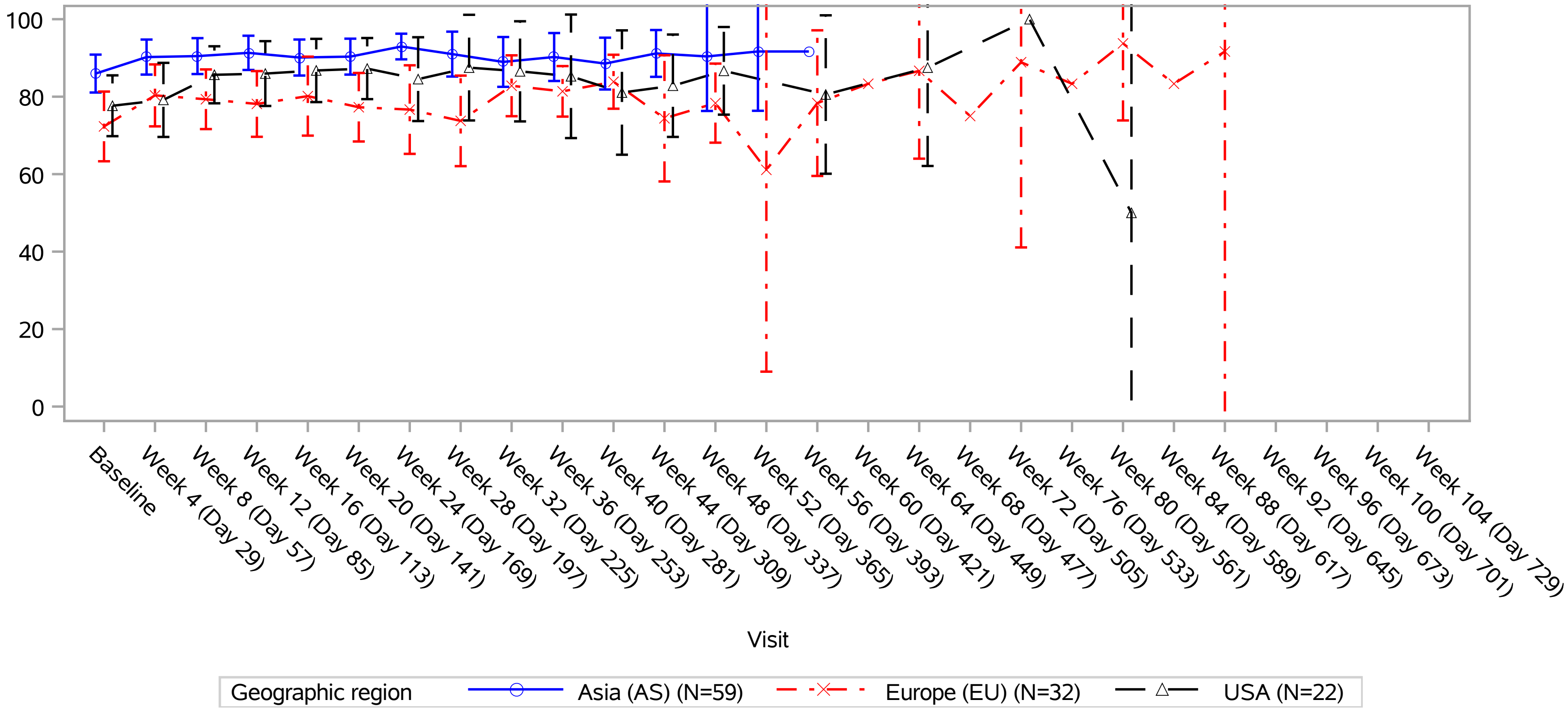
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Emotional functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30EF_SGECOG.pdf
15OCT2021 18:14

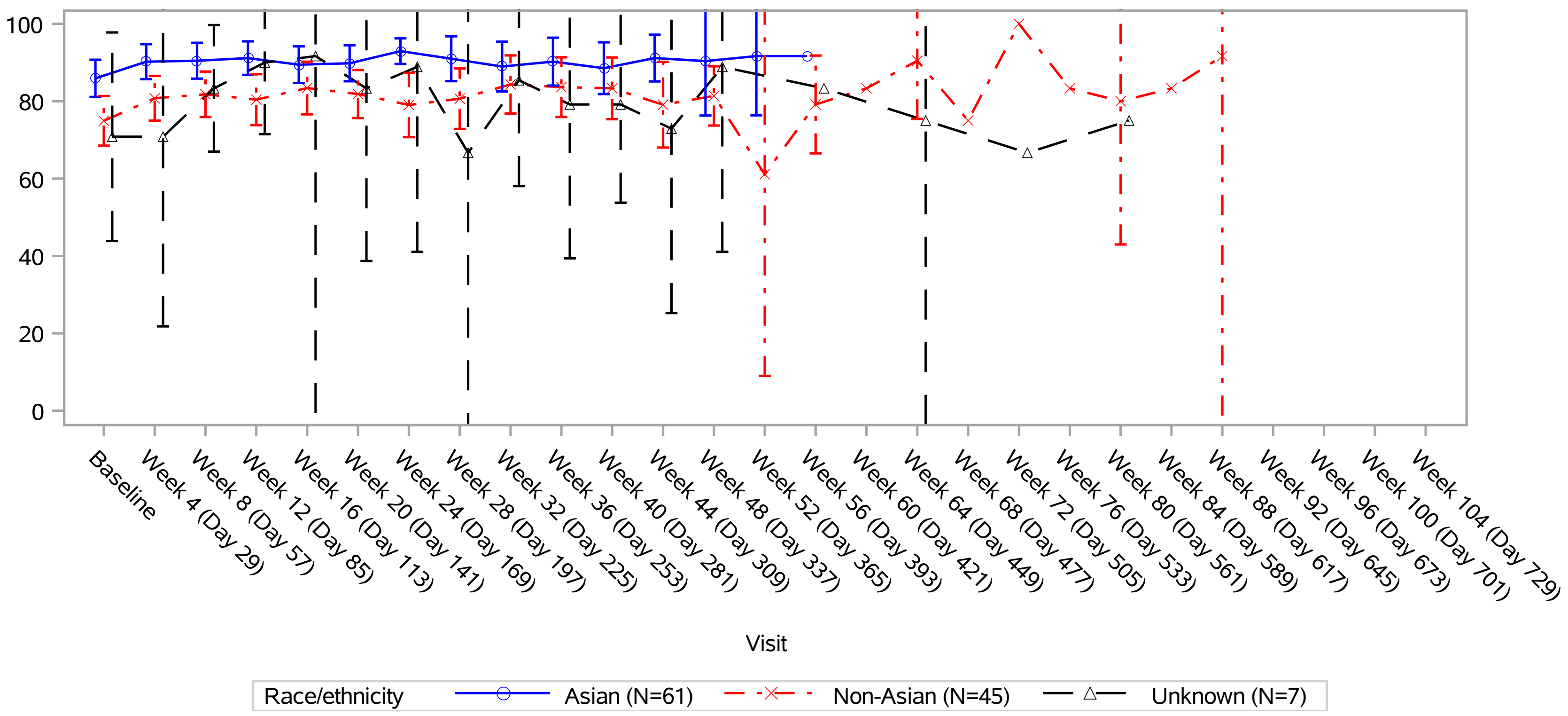
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Emotional functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30EF_SGGEO.pdf
15OCT2021 18:46

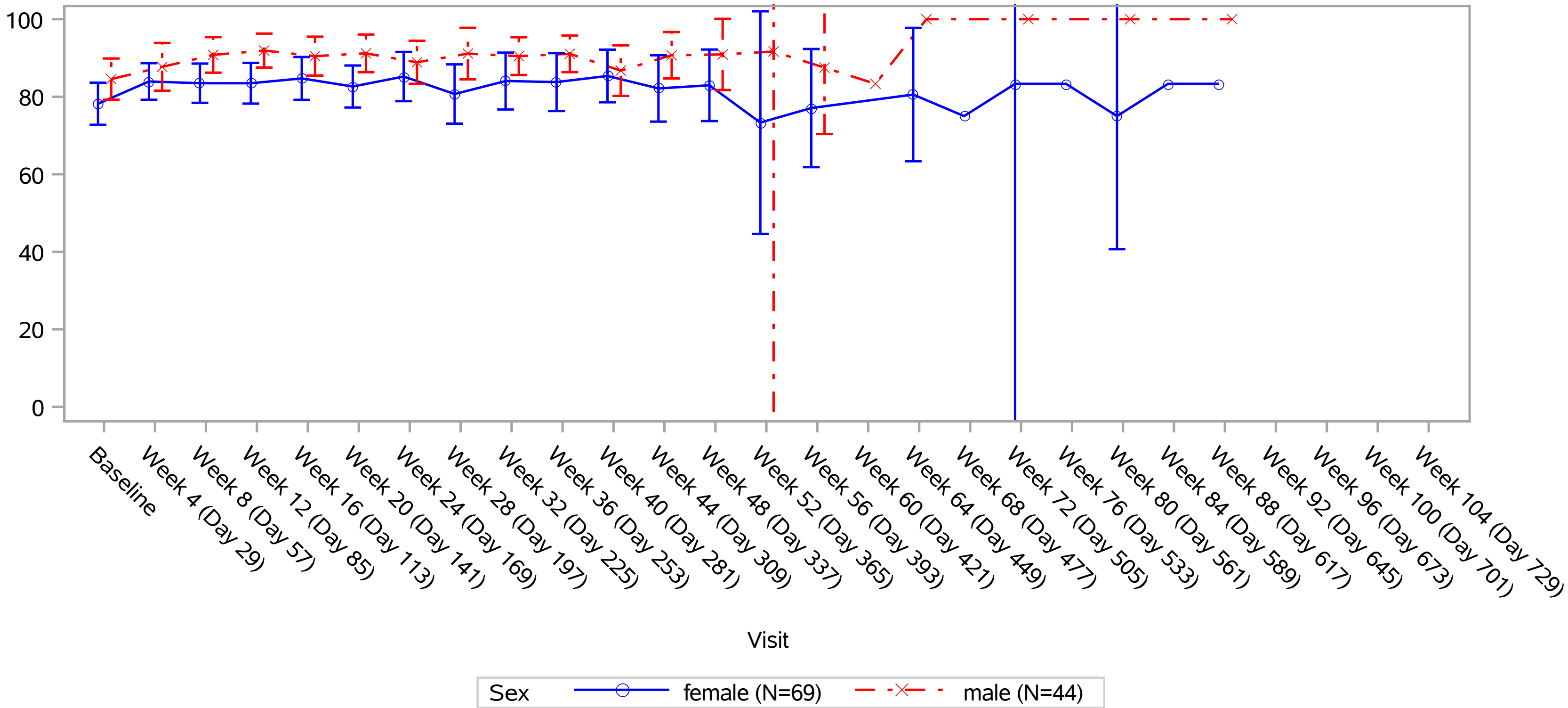
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Emotional functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30EF_SGRE.pdf
15OCT2021 19:16

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Emotional functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30EF_SGSEX.pdf
15OCT2021 19:47

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Fatigue
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=113)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	113	100.0	108	95.6	31.28	23.49	26.79	35.76
Week 4 (Day 29)	n/a	113	100.0	95	84.1	26.90	21.84	22.45	31.35
Week 8 (Day 57)	n/a	101	89.4	92	91.1	26.21	22.01	21.65	30.77
Week 12 (Day 85)	n/a	97	85.8	90	92.8	25.99	21.13	21.56	30.41
Week 16 (Day 113)	n/a	95	84.1	85	89.5	24.71	21.58	20.05	29.36
Week 20 (Day 141)	n/a	89	78.8	83	93.3	24.90	24.52	19.55	30.25
Week 24 (Day 169)	n/a	81	71.7	73	90.1	22.07	20.75	17.23	26.91
Week 28 (Day 197)	n/a	74	65.5	69	93.2	18.36	18.65	13.88	22.84
Week 32 (Day 225)	n/a	71	62.8	63	88.7	22.93	22.65	17.22	28.63
Week 36 (Day 253)	n/a	71	62.8	65	91.5	23.93	21.08	18.71	29.16
Week 40 (Day 281)	n/a	67	59.3	59	88.1	22.60	22.03	16.86	28.34
Week 44 (Day 309)	n/a	64	56.6	58	90.6	23.95	24.61	17.48	30.42
Week 48 (Day 337)	n/a	58	51.3	33	56.9	24.58	23.20	16.35	32.81
Week 52 (Day 365)	n/a	45	39.8	7	15.6	23.81	19.70	5.59	42.03
Week 56 (Day 393)	n/a	37	32.7	12	32.4	24.07	20.01	11.36	36.79
Week 60 (Day 421)	n/a	32	28.3	1	3.1	33.33	NE	NE	NE
Week 64 (Day 449)	n/a	31	27.4	9	29.0	18.52	22.91	0.91	36.13
Week 68 (Day 477)	n/a	28	24.8	1	3.6	33.33	NE	NE	NE
Week 72 (Day 505)	n/a	28	24.8	4	14.3	11.11	15.71	-13.89	36.11
Week 76 (Day 533)	n/a	25	22.1	2	8.0	33.33	15.71	-107.85	174.51
Week 80 (Day 561)	n/a	25	22.1	6	24.0	18.52	16.73	0.96	36.07
Week 84 (Day 589)	n/a	18	15.9	1	5.6	22.22	NE	NE	NE
Week 88 (Day 617)	n/a	14	12.4	2	14.3	16.67	7.86	-53.92	87.26
Week 92 (Day 645)	n/a	7	6.2	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	5.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	2.7	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	113	100.0	111	98.2	30.53	25.93	25.65	35.41
End of Study (LOCF)	n/a	113	100.0	111	98.2	29.13	25.47	24.34	33.92
Sex									
Baseline	Female	69	100.0	67	97.1	32.67	24.38	26.72	38.62
Week 4 (Day 29)	Female	69	100.0	55	79.7	28.89	19.67	23.57	34.21
Week 8 (Day 57)	Female	63	91.3	54	85.7	31.69	22.88	25.44	37.93
Week 12 (Day 85)	Female	60	87.0	56	93.3	29.27	21.96	23.39	35.15
Week 16 (Day 113)	Female	58	84.1	50	86.2	27.78	22.59	21.36	34.20
Week 20 (Day 141)	Female	53	76.8	48	90.6	28.70	27.68	20.67	36.74
Week 24 (Day 169)	Female	47	68.1	40	85.1	23.06	23.52	15.53	30.58
Week 28 (Day 197)	Female	42	60.9	38	90.5	18.42	19.89	11.88	24.96
Week 32 (Day 225)	Female	42	60.9	35	83.3	24.13	24.62	15.67	32.59
Week 36 (Day 253)	Female	42	60.9	37	88.1	25.53	25.10	17.16	33.89
Week 40 (Day 281)	Female	41	59.4	37	90.2	21.92	23.05	14.24	29.61
Week 44 (Day 309)	Female	41	59.4	35	85.4	21.90	24.92	13.35	30.46
Week 48 (Day 337)	Female	37	53.6	22	59.5	23.23	24.47	12.38	34.08
Week 52 (Day 365)	Female	29	42.0	5	17.2	28.89	20.18	3.83	53.95
Week 56 (Day 393)	Female	24	34.8	8	33.3	23.61	24.08	3.48	43.74
Week 60 (Day 421)	Female	22	31.9	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Female	22	31.9	6	27.3	18.52	26.91	-9.72	46.76
Week 68 (Day 477)	Female	20	29.0	1	5.0	33.33	NE	NE	NE
Week 72 (Day 505)	Female	20	29.0	2	10.0	5.56	7.86	-65.03	76.15
Week 76 (Day 533)	Female	18	26.1	2	11.1	33.33	15.71	-107.85	174.51
Week 80 (Day 561)	Female	18	26.1	5	27.8	20.00	18.26	-2.67	42.67
Week 84 (Day 589)	Female	12	17.4	1	8.3	22.22	NE	NE	NE
Week 88 (Day 617)	Female	9	13.0	1	11.1	22.22	NE	NE	NE
Week 92 (Day 645)	Female	6	8.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	7.2	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	2.9	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	1.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	69	100.0	68	98.6	30.72	27.36	24.10	37.34
End of Study (LOCF)	Female	69	100.0	68	98.6	30.07	27.76	23.35	36.78
Baseline	Male	44	100.0	41	93.2	29.00	22.07	22.03	35.96
Week 4 (Day 29)	Male	44	100.0	40	90.9	24.17	24.51	16.33	32.01
Week 8 (Day 57)	Male	38	86.4	38	100.0	18.42	18.32	12.40	24.44
Week 12 (Day 85)	Male	37	84.1	34	91.9	20.59	18.78	14.04	27.14
Week 16 (Day 113)	Male	37	84.1	35	94.6	20.32	19.52	13.61	27.02
Week 20 (Day 141)	Male	36	81.8	35	97.2	19.68	18.49	13.33	26.03
Week 24 (Day 169)	Male	34	77.3	33	97.1	20.88	17.07	14.82	26.93
Week 28 (Day 197)	Male	32	72.7	31	96.9	18.28	17.34	11.92	24.64
Week 32 (Day 225)	Male	29	65.9	28	96.6	21.43	20.27	13.57	29.29
Week 36 (Day 253)	Male	29	65.9	28	96.6	21.83	14.34	16.27	27.39
Week 40 (Day 281)	Male	26	59.1	22	84.6	23.74	20.66	14.58	32.90
Week 44 (Day 309)	Male	23	52.3	23	100.0	27.05	24.35	16.52	37.58
Week 48 (Day 337)	Male	21	47.7	11	52.4	27.27	21.29	12.97	41.58
Week 52 (Day 365)	Male	16	36.4	2	12.5	11.11	15.71	-130.07	152.29
Week 56 (Day 393)	Male	13	29.5	4	30.8	25.00	10.64	8.07	41.93
Week 60 (Day 421)	Male	10	22.7	1	10.0	33.33	NE	NE	NE
Week 64 (Day 449)	Male	9	20.5	3	33.3	18.52	16.97	-23.64	60.68
Week 68 (Day 477)	Male	8	18.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	8	18.2	2	25.0	16.67	23.57	-195.10	228.44
Week 76 (Day 533)	Male	7	15.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	7	15.9	1	14.3	11.11	NE	NE	NE
Week 84 (Day 589)	Male	6	13.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	5	11.4	1	20.0	11.11	NE	NE	NE
Week 92 (Day 645)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	44	100.0	43	97.7	30.23	23.80	22.91	37.56
End of Study (LOCF)	Male	44	100.0	43	97.7	27.65	21.60	21.00	34.30
Age									

Baseline	< 65	78	100.0	73	93.6	30.44	23.72	24.91	35.98
Week 4 (Day 29)	< 65	78	100.0	68	87.2	26.47	22.80	20.95	31.99
Week 8 (Day 57)	< 65	73	93.6	66	90.4	23.74	21.61	18.43	29.05
Week 12 (Day 85)	< 65	71	91.0	64	90.1	22.31	19.31	17.49	27.13
Week 16 (Day 113)	< 65	69	88.5	59	85.5	19.96	19.00	15.01	24.91
Week 20 (Day 141)	< 65	65	83.3	62	95.4	22.94	23.96	16.85	29.02
Week 24 (Day 169)	< 65	59	75.6	55	93.2	18.99	21.88	13.08	24.90
Week 28 (Day 197)	< 65	55	70.5	51	92.7	16.12	19.41	10.66	21.58
Week 32 (Day 225)	< 65	53	67.9	48	90.6	20.83	22.06	14.43	27.24
Week 36 (Day 253)	< 65	53	67.9	50	94.3	22.00	21.24	15.96	28.04
Week 40 (Day 281)	< 65	52	66.7	48	92.3	20.83	21.94	14.46	27.20
Week 44 (Day 309)	< 65	52	66.7	48	92.3	23.38	25.55	15.96	30.80
Week 48 (Day 337)	< 65	47	60.3	26	55.3	22.65	22.77	13.45	31.85
Week 52 (Day 365)	< 65	36	46.2	4	11.1	16.67	19.25	-13.96	47.29
Week 56 (Day 393)	< 65	30	38.5	9	30.0	19.75	19.86	4.49	35.02
Week 60 (Day 421)	< 65	25	32.1	1	4.0	33.33	NE	NE	NE
Week 64 (Day 449)	< 65	24	30.8	7	29.2	9.52	13.50	-2.96	22.01
Week 68 (Day 477)	< 65	22	28.2	1	4.5	33.33	NE	NE	NE
Week 72 (Day 505)	< 65	22	28.2	4	18.2	11.11	15.71	-13.89	36.11
Week 76 (Day 533)	< 65	21	26.9	2	9.5	33.33	15.71	-107.85	174.51
Week 80 (Day 561)	< 65	21	26.9	5	23.8	15.56	16.85	-5.37	36.48
Week 84 (Day 589)	< 65	15	19.2	1	6.7	22.22	NE	NE	NE
Week 88 (Day 617)	< 65	12	15.4	2	16.7	16.67	7.86	-53.92	87.26
Week 92 (Day 645)	< 65	6	7.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	6.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	78	100.0	76	97.4	29.82	28.35	23.35	36.30
End of Study (LOCF)	< 65	78	100.0	76	97.4	27.63	27.25	21.41	33.86
Baseline	>= 65	35	100.0	35	100.0	33.02	23.26	25.03	41.01
Week 4 (Day 29)	>= 65	35	100.0	27	77.1	27.98	19.58	20.24	35.73
Week 8 (Day 57)	>= 65	28	80.0	26	92.9	32.48	22.21	23.51	41.45
Week 12 (Day 85)	>= 65	26	74.3	26	100.0	35.04	23.03	25.74	44.34

Week 16 (Day 113)	>= 65	26	74.3	26	100.0	35.47	23.52	25.97	44.97
Week 20 (Day 141)	>= 65	24	68.6	21	87.5	30.69	25.80	18.95	42.43
Week 24 (Day 169)	>= 65	22	62.9	18	81.8	31.48	13.34	24.85	38.11
Week 28 (Day 197)	>= 65	19	54.3	18	94.7	24.69	15.03	17.22	32.17
Week 32 (Day 225)	>= 65	18	51.4	15	83.3	29.63	24.00	16.34	42.92
Week 36 (Day 253)	>= 65	18	51.4	15	83.3	30.37	19.91	19.35	41.39
Week 40 (Day 281)	>= 65	15	42.9	11	73.3	30.30	21.71	15.72	44.89
Week 44 (Day 309)	>= 65	12	34.3	10	83.3	26.67	20.42	12.06	41.27
Week 48 (Day 337)	>= 65	11	31.4	7	63.6	31.75	25.20	8.44	55.05
Week 52 (Day 365)	>= 65	9	25.7	3	33.3	33.33	19.25	-14.47	81.14
Week 56 (Day 393)	>= 65	7	20.0	3	42.9	37.04	16.97	-5.12	79.20
Week 60 (Day 421)	>= 65	7	20.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	7	20.0	2	28.6	50.00	23.57	-161.77	261.77
Week 68 (Day 477)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	4	11.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	4	11.4	1	25.0	33.33	NE	NE	NE
Week 84 (Day 589)	>= 65	3	8.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	5.7	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	35	100.0	35	100.0	32.06	19.94	25.21	38.91
End of Study (LOCF)	>= 65	35	100.0	35	100.0	32.38	21.11	25.13	39.63
ECOG performance status									
Baseline	0	33	100.0	31	93.9	29.03	28.64	18.53	39.54
Week 4 (Day 29)	0	33	100.0	27	81.8	26.34	29.42	14.70	37.98
Week 8 (Day 57)	0	30	90.9	27	90.0	28.81	28.62	17.48	40.13
Week 12 (Day 85)	0	29	87.9	26	89.7	28.21	26.71	17.42	38.99
Week 16 (Day 113)	0	28	84.8	24	85.7	25.46	23.74	15.44	35.49
Week 20 (Day 141)	0	26	78.8	24	92.3	26.39	28.90	14.18	38.59
Week 24 (Day 169)	0	24	72.7	20	83.3	22.22	21.33	12.24	32.20
Week 28 (Day 197)	0	21	63.6	19	90.5	18.13	17.45	9.72	26.54

Week 32 (Day 225)	0	21	63.6	18	85.7	16.05	23.87	4.18	27.92
Week 36 (Day 253)	0	21	63.6	20	95.2	25.56	25.26	13.73	37.38
Week 40 (Day 281)	0	21	63.6	19	90.5	23.39	22.50	12.55	34.23
Week 44 (Day 309)	0	21	63.6	17	81.0	24.18	24.29	11.69	36.67
Week 48 (Day 337)	0	19	57.6	12	63.2	27.78	26.17	11.15	44.40
Week 52 (Day 365)	0	18	54.5	3	16.7	40.74	12.83	8.87	72.61
Week 56 (Day 393)	0	16	48.5	5	31.3	24.44	21.37	-2.09	50.98
Week 60 (Day 421)	0	16	48.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	0	16	48.5	5	31.3	17.78	28.97	-18.20	53.75
Week 68 (Day 477)	0	14	42.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	0	14	42.4	1	7.1	0.00	NE	NE	NE
Week 76 (Day 533)	0	12	36.4	1	8.3	22.22	NE	NE	NE
Week 80 (Day 561)	0	12	36.4	1	8.3	0.00	NE	NE	NE
Week 84 (Day 589)	0	10	30.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	9	27.3	1	11.1	22.22	NE	NE	NE
Week 92 (Day 645)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	9.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	3.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	33	100.0	33	100.0	34.01	29.65	23.49	44.52
End of Study (LOCF)	0	33	100.0	33	100.0	33.33	30.43	22.54	44.12
Baseline	1	79	100.0	76	96.2	32.31	21.33	27.44	37.18
Week 4 (Day 29)	1	79	100.0	67	84.8	27.03	18.37	22.55	31.51
Week 8 (Day 57)	1	70	88.6	65	92.9	25.13	18.77	20.48	29.78
Week 12 (Day 85)	1	68	86.1	64	94.1	25.09	18.57	20.45	29.73
Week 16 (Day 113)	1	67	84.8	61	91.0	24.41	20.87	19.06	29.75
Week 20 (Day 141)	1	63	79.7	59	93.7	24.29	22.74	18.37	30.22
Week 24 (Day 169)	1	57	72.2	53	93.0	22.01	20.73	16.30	27.73
Week 28 (Day 197)	1	53	67.1	50	94.3	18.44	19.26	12.97	23.92
Week 32 (Day 225)	1	50	63.3	45	90.0	25.68	21.82	19.12	32.23
Week 36 (Day 253)	1	50	63.3	45	90.0	23.21	19.22	17.44	28.98
Week 40 (Day 281)	1	46	58.2	40	87.0	22.22	22.08	15.16	29.28

Week 44 (Day 309)	1	43	54.4	41	95.3	23.85	25.04	15.95	31.75
Week 48 (Day 337)	1	39	49.4	21	53.8	22.75	21.79	12.83	32.67
Week 52 (Day 365)	1	27	34.2	4	14.8	11.11	12.83	-9.30	31.53
Week 56 (Day 393)	1	21	26.6	7	33.3	23.81	20.72	4.65	42.97
Week 60 (Day 421)	1	16	20.3	1	6.3	33.33	NE	NE	NE
Week 64 (Day 449)	1	15	19.0	4	26.7	19.44	16.67	-7.08	45.96
Week 68 (Day 477)	1	14	17.7	1	7.1	33.33	NE	NE	NE
Week 72 (Day 505)	1	14	17.7	3	21.4	14.81	16.97	-27.35	56.98
Week 76 (Day 533)	1	13	16.5	1	7.7	44.44	NE	NE	NE
Week 80 (Day 561)	1	13	16.5	5	38.5	22.22	15.71	2.71	41.73
Week 84 (Day 589)	1	8	10.1	1	12.5	22.22	NE	NE	NE
Week 88 (Day 617)	1	5	6.3	1	20.0	11.11	NE	NE	NE
Week 92 (Day 645)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	2.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	79	100.0	77	97.5	29.00	24.39	23.47	34.54
End of Study (LOCF)	1	79	100.0	77	97.5	27.27	23.19	22.01	32.54
Baseline	Missing	1	100.0	1	100.0	22.22	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	33.33	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	33.33	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	33.33	NE	NE	NE
Geographic region									
Baseline	USA	22	100.0	22	100.0	31.31	21.59	21.74	40.88
Week 4 (Day 29)	USA	22	100.0	18	81.8	28.40	29.82	13.57	43.22
Week 8 (Day 57)	USA	20	90.9	18	90.0	29.01	22.27	17.94	40.09
Week 12 (Day 85)	USA	20	90.9	19	95.0	28.65	19.71	19.16	38.15
Week 16 (Day 113)	USA	19	86.4	17	89.5	24.18	21.24	13.26	35.10
Week 20 (Day 141)	USA	19	86.4	17	89.5	28.10	28.09	13.66	42.55
Week 24 (Day 169)	USA	16	72.7	14	87.5	23.81	19.42	12.60	35.02
Week 28 (Day 197)	USA	15	68.2	12	80.0	15.74	14.57	6.48	25.00
Week 32 (Day 225)	USA	15	68.2	13	86.7	23.93	27.91	7.07	40.79
Week 36 (Day 253)	USA	15	68.2	13	86.7	23.93	22.15	10.55	37.32
Week 40 (Day 281)	USA	14	63.6	11	78.6	23.23	26.97	5.11	41.35

Week 44 (Day 309)	USA	13	59.1	11	84.6	23.23	29.59	3.36	43.11
Week 48 (Day 337)	USA	13	59.1	10	76.9	24.44	24.46	6.95	41.94
Week 52 (Day 365)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	USA	12	54.5	6	50.0	22.22	19.88	1.36	43.08
Week 60 (Day 421)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	11	50.0	4	36.4	8.33	16.67	-18.19	34.85
Week 68 (Day 477)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	10	45.5	1	10.0	0.00	NE	NE	NE
Week 76 (Day 533)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	10	45.5	2	20.0	33.33	0.00	NE	NE
Week 84 (Day 589)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	13.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	4.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	22	100.0	22	100.0	26.77	27.14	14.73	38.80
End of Study (LOCF)	USA	22	100.0	22	100.0	23.74	23.08	13.51	33.97
Baseline	Europe (EU)	32	100.0	29	90.6	38.31	25.47	28.62	48.00
Week 4 (Day 29)	Europe (EU)	32	100.0	25	78.1	32.44	22.20	23.28	41.61
Week 8 (Day 57)	Europe (EU)	29	90.6	25	86.2	33.78	26.35	22.90	44.65
Week 12 (Day 85)	Europe (EU)	26	81.3	24	92.3	31.25	24.01	21.11	41.39
Week 16 (Day 113)	Europe (EU)	25	78.1	20	80.0	32.78	22.65	22.18	43.38
Week 20 (Day 141)	Europe (EU)	23	71.9	22	95.7	34.34	25.64	22.98	45.71
Week 24 (Day 169)	Europe (EU)	21	65.6	20	95.2	30.00	23.11	19.18	40.82
Week 28 (Day 197)	Europe (EU)	20	62.5	20	100.0	26.11	20.79	16.38	35.84
Week 32 (Day 225)	Europe (EU)	18	56.3	16	88.9	24.31	19.12	14.11	34.50
Week 36 (Day 253)	Europe (EU)	18	56.3	17	94.4	25.49	22.83	13.75	37.23
Week 40 (Day 281)	Europe (EU)	17	53.1	16	94.1	20.83	18.09	11.20	30.47
Week 44 (Day 309)	Europe (EU)	17	53.1	14	82.4	29.37	24.50	15.22	43.51

Week 48 (Day 337)	Europe (EU)	14	43.8	10	71.4	31.11	17.21	18.80	43.42
Week 52 (Day 365)	Europe (EU)	13	40.6	3	23.1	40.74	12.83	8.87	72.61
Week 56 (Day 393)	Europe (EU)	11	34.4	5	45.5	24.44	24.09	-5.47	54.35
Week 60 (Day 421)	Europe (EU)	11	34.4	1	9.1	33.33	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	11	34.4	5	45.5	26.67	25.58	-5.09	58.43
Week 68 (Day 477)	Europe (EU)	10	31.3	1	10.0	33.33	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	10	31.3	3	30.0	14.81	16.97	-27.35	56.98
Week 76 (Day 533)	Europe (EU)	8	25.0	2	25.0	33.33	15.71	-107.85	174.51
Week 80 (Day 561)	Europe (EU)	8	25.0	4	50.0	11.11	15.71	-13.89	36.11
Week 84 (Day 589)	Europe (EU)	6	18.8	1	16.7	22.22	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	9.4	2	66.7	16.67	7.86	-53.92	87.26
Cycle 12 (LOCF)	Europe (EU)	32	100.0	31	96.9	38.35	27.19	28.38	48.33
End of Study (LOCF)	Europe (EU)	32	100.0	31	96.9	36.92	28.31	26.53	47.30
Baseline	Asia (AS)	59	100.0	57	96.6	27.68	22.72	21.65	33.71
Week 4 (Day 29)	Asia (AS)	59	100.0	52	88.1	23.72	18.01	18.70	28.73
Week 8 (Day 57)	Asia (AS)	52	88.1	49	94.2	21.32	18.40	16.03	26.60
Week 12 (Day 85)	Asia (AS)	51	86.4	47	92.2	22.22	19.79	16.41	28.03
Week 16 (Day 113)	Asia (AS)	51	86.4	48	94.1	21.53	20.81	15.49	27.57
Week 20 (Day 141)	Asia (AS)	47	79.7	44	93.6	18.94	21.11	12.52	25.36
Week 24 (Day 169)	Asia (AS)	44	74.6	39	88.6	17.38	19.04	11.21	23.55
Week 28 (Day 197)	Asia (AS)	39	66.1	37	94.9	15.02	17.80	9.08	20.95
Week 32 (Day 225)	Asia (AS)	38	64.4	34	89.5	21.90	22.64	14.00	29.79
Week 36 (Day 253)	Asia (AS)	38	64.4	35	92.1	23.17	20.41	16.16	30.19
Week 40 (Day 281)	Asia (AS)	36	61.0	32	88.9	23.26	22.64	15.10	31.43
Week 44 (Day 309)	Asia (AS)	34	57.6	33	97.1	21.89	23.32	13.62	30.15
Week 48 (Day 337)	Asia (AS)	31	52.5	13	41.9	19.66	26.51	3.64	35.68
Week 52 (Day 365)	Asia (AS)	20	33.9	4	20.0	11.11	12.83	-9.30	31.53
Week 56 (Day 393)	Asia (AS)	14	23.7	1	7.1	33.33	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	10.2	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	8.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	3.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	59	100.0	58	98.3	27.78	24.29	21.39	34.17
End of Study (LOCF)	Asia (AS)	59	100.0	58	98.3	27.01	24.19	20.65	33.37
Race/ethnicity									
Baseline	Asian	61	100.0	58	95.1	27.97	22.63	22.02	33.92
Week 4 (Day 29)	Asian	61	100.0	52	85.2	23.72	18.01	18.70	28.73
Week 8 (Day 57)	Asian	53	86.9	49	92.5	21.32	18.40	16.03	26.60
Week 12 (Day 85)	Asian	52	85.2	48	92.3	22.45	19.65	16.75	28.16
Week 16 (Day 113)	Asian	52	85.2	49	94.2	21.77	20.66	15.84	27.70
Week 20 (Day 141)	Asian	48	78.7	45	93.8	20.00	22.04	13.38	26.62
Week 24 (Day 169)	Asian	44	72.1	39	88.6	17.38	19.04	11.21	23.55
Week 28 (Day 197)	Asian	39	63.9	37	94.9	15.02	17.80	9.08	20.95
Week 32 (Day 225)	Asian	38	62.3	34	89.5	21.90	22.64	14.00	29.79
Week 36 (Day 253)	Asian	38	62.3	35	92.1	23.17	20.41	16.16	30.19
Week 40 (Day 281)	Asian	36	59.0	32	88.9	23.26	22.64	15.10	31.43
Week 44 (Day 309)	Asian	34	55.7	33	97.1	21.89	23.32	13.62	30.15
Week 48 (Day 337)	Asian	31	50.8	13	41.9	19.66	26.51	3.64	35.68
Week 52 (Day 365)	Asian	20	32.8	4	20.0	11.11	12.83	-9.30	31.53
Week 56 (Day 393)	Asian	14	23.0	1	7.1	33.33	NE	NE	NE
Week 60 (Day 421)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	9.8	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	8.2	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	3.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	61	100.0	59	96.7	28.44	24.61	22.02	34.85
End of Study (LOCF)	Asian	61	100.0	59	96.7	27.68	24.53	21.29	34.08
Baseline	Non-Asian	45	100.0	44	97.8	33.84	23.60	26.66	41.01
Week 4 (Day 29)	Non-Asian	45	100.0	39	86.7	29.06	22.17	21.87	36.25
Week 8 (Day 57)	Non-Asian	42	93.3	38	90.5	32.46	24.42	24.43	40.48
Week 12 (Day 85)	Non-Asian	39	86.7	37	94.9	29.88	21.41	22.74	37.02
Week 16 (Day 113)	Non-Asian	37	82.2	34	91.9	30.39	21.94	22.74	38.05
Week 20 (Day 141)	Non-Asian	36	80.0	34	94.4	32.03	27.18	22.54	41.51
Week 24 (Day 169)	Non-Asian	32	71.1	31	96.9	28.32	22.01	20.24	36.39
Week 28 (Day 197)	Non-Asian	30	66.7	28	93.3	22.62	19.48	15.07	30.17
Week 32 (Day 225)	Non-Asian	28	62.2	25	89.3	26.22	23.76	16.41	36.03
Week 36 (Day 253)	Non-Asian	28	62.2	26	92.9	23.08	19.35	15.26	30.89
Week 40 (Day 281)	Non-Asian	26	57.8	23	88.5	23.19	22.95	13.27	33.11
Week 44 (Day 309)	Non-Asian	25	55.6	21	84.0	27.51	28.24	14.66	40.37
Week 48 (Day 337)	Non-Asian	23	51.1	17	73.9	31.37	20.12	21.03	41.72
Week 52 (Day 365)	Non-Asian	21	46.7	3	14.3	40.74	12.83	8.87	72.61
Week 56 (Day 393)	Non-Asian	19	42.2	10	52.6	25.56	20.32	11.02	40.09
Week 60 (Day 421)	Non-Asian	19	42.2	1	5.3	33.33	NE	NE	NE
Week 64 (Day 449)	Non-Asian	18	40.0	7	38.9	22.22	24.85	-0.76	45.20
Week 68 (Day 477)	Non-Asian	17	37.8	1	5.9	33.33	NE	NE	NE
Week 72 (Day 505)	Non-Asian	17	37.8	3	17.6	11.11	19.25	-36.70	58.92
Week 76 (Day 533)	Non-Asian	15	33.3	2	13.3	33.33	15.71	-107.85	174.51
Week 80 (Day 561)	Non-Asian	15	33.3	5	33.3	15.56	16.85	-5.37	36.48
Week 84 (Day 589)	Non-Asian	10	22.2	1	10.0	22.22	NE	NE	NE
Week 88 (Day 617)	Non-Asian	7	15.6	2	28.6	16.67	7.86	-53.92	87.26
Week 92 (Day 645)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	45	100.0	45	100.0	33.09	27.57	24.80	41.37

End of Study (LOCF)	Non-Asian	45	100.0	45	100.0	31.36	26.30	23.46	39.26
Baseline	Unknown	7	100.0	6	85.7	44.44	28.11	14.95	73.94
Week 4 (Day 29)	Unknown	7	100.0	4	57.1	47.22	49.17	-31.02	125.46
Week 8 (Day 57)	Unknown	6	85.7	5	83.3	26.67	27.89	-7.96	61.30
Week 12 (Day 85)	Unknown	6	85.7	5	83.3	31.11	30.83	-7.17	69.39
Week 16 (Day 113)	Unknown	6	85.7	2	33.3	0.00	0.00	NE	NE
Week 20 (Day 141)	Unknown	5	71.4	4	80.0	19.44	13.98	-2.80	41.69
Week 24 (Day 169)	Unknown	5	71.4	3	60.0	18.52	16.97	-23.64	60.68
Week 28 (Day 197)	Unknown	5	71.4	4	80.0	19.44	18.98	-10.75	49.64
Week 32 (Day 225)	Unknown	5	71.4	4	80.0	11.11	12.83	-9.30	31.53
Week 36 (Day 253)	Unknown	5	71.4	4	80.0	36.11	37.82	-24.06	96.28
Week 40 (Day 281)	Unknown	5	71.4	4	80.0	13.89	10.64	-3.04	30.82
Week 44 (Day 309)	Unknown	5	71.4	4	80.0	22.22	15.71	-2.78	47.23
Week 48 (Day 337)	Unknown	4	57.1	3	75.0	7.41	12.83	-24.46	39.28
Week 52 (Day 365)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	4	57.1	1	25.0	0.00	NE	NE	NE
Week 60 (Day 421)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	4	57.1	2	50.0	5.56	7.86	-65.03	76.15
Week 68 (Day 477)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	3	42.9	1	33.3	11.11	NE	NE	NE
Week 76 (Day 533)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	3	42.9	1	33.3	33.33	NE	NE	NE
Week 84 (Day 589)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	14.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	7	100.0	7	100.0	31.75	28.28	5.60	57.90
End of Study (LOCF)	Unknown	7	100.0	7	100.0	26.98	30.67	-1.38	55.35
Number of prior antineoplastic systemic therapy lines I									
Baseline	1	60	100.0	57	95.0	32.94	24.57	26.42	39.46

Week 4 (Day 29)	1	60	100.0	50	83.3	27.11	22.69	20.66	33.56
Week 8 (Day 57)	1	54	90.0	49	90.7	26.30	20.50	20.42	32.19
Week 12 (Day 85)	1	52	86.7	48	92.3	27.66	20.99	21.57	33.76
Week 16 (Day 113)	1	51	85.0	46	90.2	26.81	22.54	20.12	33.50
Week 20 (Day 141)	1	48	80.0	43	89.6	25.84	25.40	18.02	33.66
Week 24 (Day 169)	1	43	71.7	39	90.7	22.51	20.63	15.82	29.19
Week 28 (Day 197)	1	38	63.3	34	89.5	18.63	19.67	11.76	25.49
Week 32 (Day 225)	1	35	58.3	29	82.9	22.61	23.09	13.82	31.39
Week 36 (Day 253)	1	35	58.3	31	88.6	25.45	21.12	17.70	33.19
Week 40 (Day 281)	1	32	53.3	27	84.4	23.05	22.21	14.26	31.83
Week 44 (Day 309)	1	32	53.3	27	84.4	26.34	28.44	15.09	37.59
Week 48 (Day 337)	1	27	45.0	16	59.3	26.39	23.61	13.81	38.97
Week 52 (Day 365)	1	23	38.3	5	21.7	22.22	23.57	-7.04	51.49
Week 56 (Day 393)	1	16	26.7	4	25.0	33.33	18.14	4.46	62.21
Week 60 (Day 421)	1	14	23.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	13	21.7	4	30.8	30.56	27.78	-13.65	74.76
Week 68 (Day 477)	1	12	20.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	12	20.0	1	8.3	0.00	NE	NE	NE
Week 76 (Day 533)	1	11	18.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	11	18.3	2	18.2	16.67	23.57	-195.10	228.44
Week 84 (Day 589)	1	9	15.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	1	8	13.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	1	3	5.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	1	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	60	100.0	58	96.7	31.80	26.45	24.85	38.75
End of Study (LOCF)	1	60	100.0	58	96.7	30.46	25.28	23.81	37.11
Baseline	>= 2	53	100.0	51	96.2	29.41	22.31	23.14	35.69
Week 4 (Day 29)	>= 2	53	100.0	45	84.9	26.67	21.11	20.32	33.01
Week 8 (Day 57)	>= 2	47	88.7	43	91.5	26.10	23.87	18.75	33.44
Week 12 (Day 85)	>= 2	45	84.9	42	93.3	24.07	21.38	17.41	30.74
Week 16 (Day 113)	>= 2	44	83.0	39	88.6	22.22	20.39	15.61	28.83

Week 20 (Day 141)	>= 2	41	77.4	40	97.6	23.89	23.81	16.27	31.50
Week 24 (Day 169)	>= 2	38	71.7	34	89.5	21.57	21.18	14.18	28.96
Week 28 (Day 197)	>= 2	36	67.9	35	97.2	18.10	17.89	11.95	24.24
Week 32 (Day 225)	>= 2	36	67.9	34	94.4	23.20	22.62	15.31	31.09
Week 36 (Day 253)	>= 2	36	67.9	34	94.4	22.55	21.27	15.13	29.97
Week 40 (Day 281)	>= 2	35	66.0	32	91.4	22.22	22.22	14.21	30.23
Week 44 (Day 309)	>= 2	32	60.4	31	96.9	21.86	20.98	14.17	29.56
Week 48 (Day 337)	>= 2	31	58.5	17	54.8	22.88	23.40	10.85	34.91
Week 52 (Day 365)	>= 2	22	41.5	2	9.1	27.78	7.86	-42.81	98.37
Week 56 (Day 393)	>= 2	21	39.6	8	38.1	19.44	20.36	2.42	36.46
Week 60 (Day 421)	>= 2	18	34.0	1	5.6	33.33	NE	NE	NE
Week 64 (Day 449)	>= 2	18	34.0	5	27.8	8.89	14.49	-9.10	26.88
Week 68 (Day 477)	>= 2	16	30.2	1	6.3	33.33	NE	NE	NE
Week 72 (Day 505)	>= 2	16	30.2	3	18.8	14.81	16.97	-27.35	56.98
Week 76 (Day 533)	>= 2	14	26.4	2	14.3	33.33	15.71	-107.85	174.51
Week 80 (Day 561)	>= 2	14	26.4	4	28.6	19.44	16.67	-7.08	45.96
Week 84 (Day 589)	>= 2	9	17.0	1	11.1	22.22	NE	NE	NE
Week 88 (Day 617)	>= 2	6	11.3	2	33.3	16.67	7.86	-53.92	87.26
Week 92 (Day 645)	>= 2	2	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 2	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 2	53	100.0	53	100.0	29.14	25.53	22.10	36.18
End of Study (LOCF)	>= 2	53	100.0	53	100.0	27.67	25.84	20.55	34.80

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TP_QSC30FA_SG.xls
27OCT2021 7:26

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Fatigue
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	64	59.3	49.8	68.1
	Cycle 12 (LOCF)	n/a	108	95.6	38	35.2	26.8	44.6
	End of Study (LOCF)	n/a	108	95.6	37	34.3	26.0	43.6
Sex	All visits	Female	67	59.3	41	61.2	49.2	72.0
		Male	41	36.3	23	56.1	41.0	70.1
	Cycle 12 (LOCF)	Female	67	59.3	21	31.3	21.5	43.2
		Male	41	36.3	17	41.5	27.8	56.6
	End of Study (LOCF)	Female	67	59.3	22	32.8	22.8	44.7
		Male	41	36.3	15	36.6	23.6	51.9
Age	All visits	< 65	73	64.6	42	57.5	46.1	68.2
		>= 65	35	31.0	22	62.9	46.3	76.8
	Cycle 12 (LOCF)	< 65	73	64.6	24	32.9	23.2	44.3
		>= 65	35	31.0	14	40.0	25.6	56.4
	End of Study (LOCF)	< 65	73	64.6	23	31.5	22.0	42.9
		>= 65	35	31.0	14	40.0	25.6	56.4
ECOG performance status	All visits	0	31	27.4	22	71.0	53.4	83.9
		1	76	67.3	41	53.9	42.8	64.7
		Missing	1	0.9	1	100.0	20.7	100.0
	Cycle 12 (LOCF)	0	31	27.4	10	32.3	18.6	49.9
		1	76	67.3	27	35.5	25.7	46.7
		Missing	1	0.9	1	100.0	20.7	100.0
	End of Study (LOCF)	0	31	27.4	12	38.7	23.7	56.2
		1	76	67.3	24	31.6	22.2	42.7
		Missing	1	0.9	1	100.0	20.7	100.0
Geographic region	All visits	USA	22	19.5	15	68.2	47.3	83.6
		Europe (EU)	29	25.7	17	58.6	40.7	74.5
		Asia (AS)	57	50.4	32	56.1	43.3	68.2
	Cycle 12 (LOCF)	USA	22	19.5	5	22.7	10.1	43.4
		Europe (EU)	29	25.7	9	31.0	17.3	49.2
		Asia (AS)	57	50.4	24	42.1	30.2	55.0
	End of Study (LOCF)	USA	22	19.5	6	27.3	13.2	48.2
		Europe (EU)	29	25.7	9	31.0	17.3	49.2
		Asia (AS)	57	50.4	22	38.6	27.1	51.6
Race/ethnicity	All visits	Asian	58	51.3	33	56.9	44.1	68.8
		Non-Asian	44	38.9	29	65.9	51.1	78.1
		Unknown	6	5.3	2	33.3	9.7	70.0
	Cycle 12 (LOCF)	Asian	58	51.3	25	43.1	31.2	55.9

		Non-Asian	44	38.9	13	29.5	18.2	44.2
		Unknown	6	5.3	0	0.0	0.0	39.0
	End of Study (LOCF)	Asian	58	51.3	23	39.7	28.1	52.5
		Non-Asian	44	38.9	14	31.8	20.0	46.6
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	35	61.4	48.4	72.9
		>= 2	51	45.1	29	56.9	43.3	69.5
	Cycle 12 (LOCF)	1	57	50.4	21	36.8	25.5	49.8
		>= 2	51	45.1	17	33.3	22.0	47.0
	End of Study (LOCF)	1	57	50.4	19	33.3	22.5	46.3
		>= 2	51	45.1	18	35.3	23.6	49.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30FA_W10_SG.xls
15OCT2021 13:33

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Fatigue
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

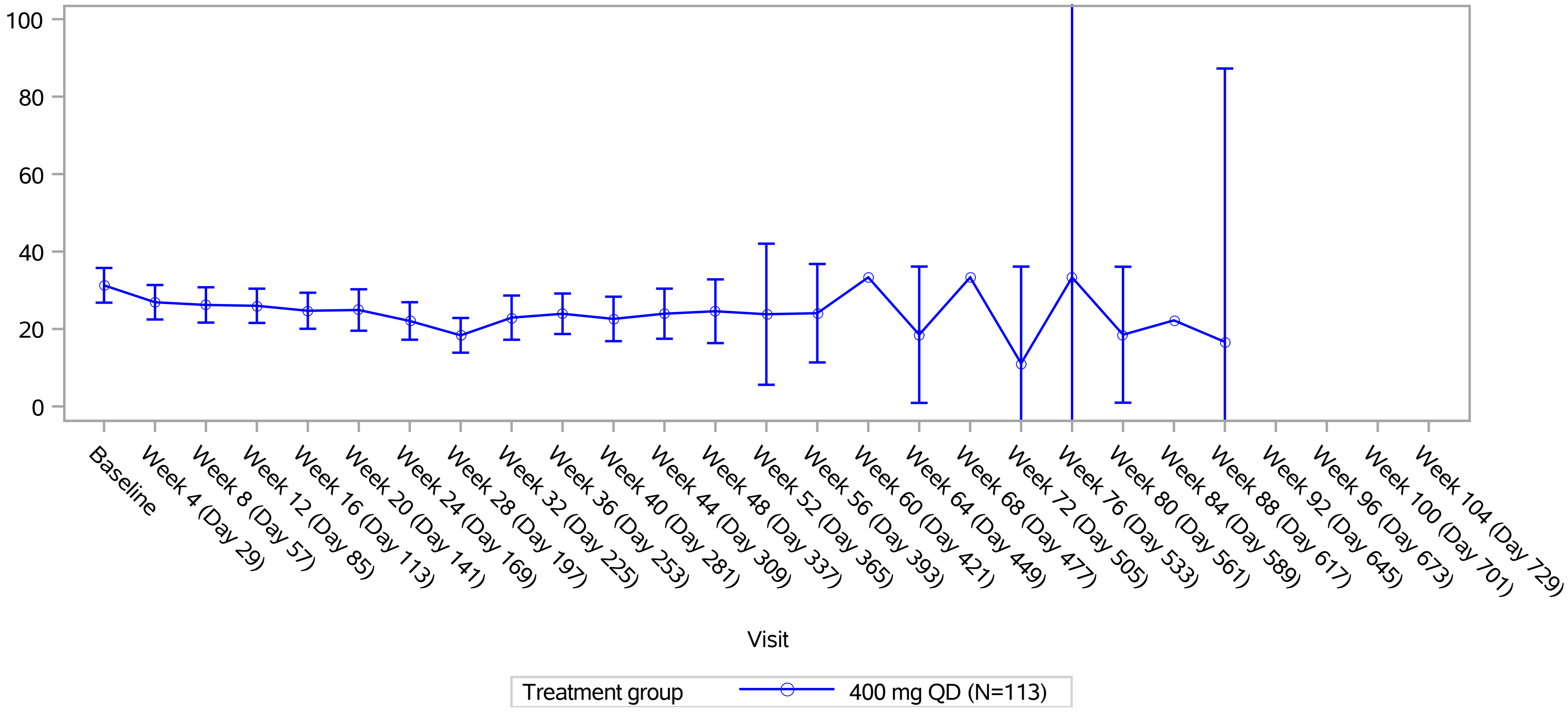
			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	40	37.0	28.5	46.4
	Cycle 12 (LOCF)	n/a	108	95.6	22	20.4	13.9	28.9
	End of Study (LOCF)	n/a	108	95.6	22	20.4	13.9	28.9
Sex	All visits	Female	67	59.3	25	37.3	26.7	49.3
		Male	41	36.3	15	36.6	23.6	51.9
	Cycle 12 (LOCF)	Female	67	59.3	14	20.9	12.9	32.1
		Male	41	36.3	8	19.5	10.2	34.0
	End of Study (LOCF)	Female	67	59.3	15	22.4	14.1	33.7
		Male	41	36.3	7	17.1	8.5	31.3
Age	All visits	< 65	73	64.6	28	38.4	28.1	49.8
		>= 65	35	31.0	12	34.3	20.8	50.8
	Cycle 12 (LOCF)	< 65	73	64.6	17	23.3	15.1	34.2
		>= 65	35	31.0	5	14.3	6.3	29.4
	End of Study (LOCF)	< 65	73	64.6	16	21.9	14.0	32.7
		>= 65	35	31.0	6	17.1	8.1	32.7
ECOG performance status	All visits	0	31	27.4	15	48.4	32.0	65.2
		1	76	67.3	25	32.9	23.4	44.1
		Missing	1	0.9	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	31	27.4	10	32.3	18.6	49.9
		1	76	67.3	12	15.8	9.3	25.6
		Missing	1	0.9	0	0.0	0.0	79.3
	End of Study (LOCF)	0	31	27.4	11	35.5	21.1	53.1
		1	76	67.3	11	14.5	8.3	24.1
		Missing	1	0.9	0	0.0	0.0	79.3
Geographic region	All visits	USA	22	19.5	7	31.8	16.4	52.7
		Europe (EU)	29	25.7	12	41.4	25.5	59.3
		Asia (AS)	57	50.4	21	36.8	25.5	49.8
	Cycle 12 (LOCF)	USA	22	19.5	2	9.1	2.5	27.8
		Europe (EU)	29	25.7	6	20.7	9.8	38.4
		Asia (AS)	57	50.4	14	24.6	15.2	37.1
	End of Study (LOCF)	USA	22	19.5	1	4.5	0.8	21.8
		Europe (EU)	29	25.7	7	24.1	12.2	42.1
		Asia (AS)	57	50.4	14	24.6	15.2	37.1
Race/ethnicity	All visits	Asian	58	51.3	22	37.9	26.6	50.8
		Non-Asian	44	38.9	17	38.6	25.7	53.4
		Unknown	6	5.3	1	16.7	3.0	56.4
	Cycle 12 (LOCF)	Asian	58	51.3	15	25.9	16.3	38.4

		Non-Asian	44	38.9	7	15.9	7.9	29.4
		Unknown	6	5.3	0	0.0	0.0	39.0
	End of Study (LOCF)	Asian	58	51.3	15	25.9	16.3	38.4
		Non-Asian	44	38.9	7	15.9	7.9	29.4
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	22	38.6	27.1	51.6
		>= 2	51	45.1	18	35.3	23.6	49.0
	Cycle 12 (LOCF)	1	57	50.4	11	19.3	11.1	31.3
		>= 2	51	45.1	11	21.6	12.5	34.6
	End of Study (LOCF)	1	57	50.4	11	19.3	11.1	31.3
		>= 2	51	45.1	11	21.6	12.5	34.6

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30FA_W15_SG.xls
15OCT2021 13:23

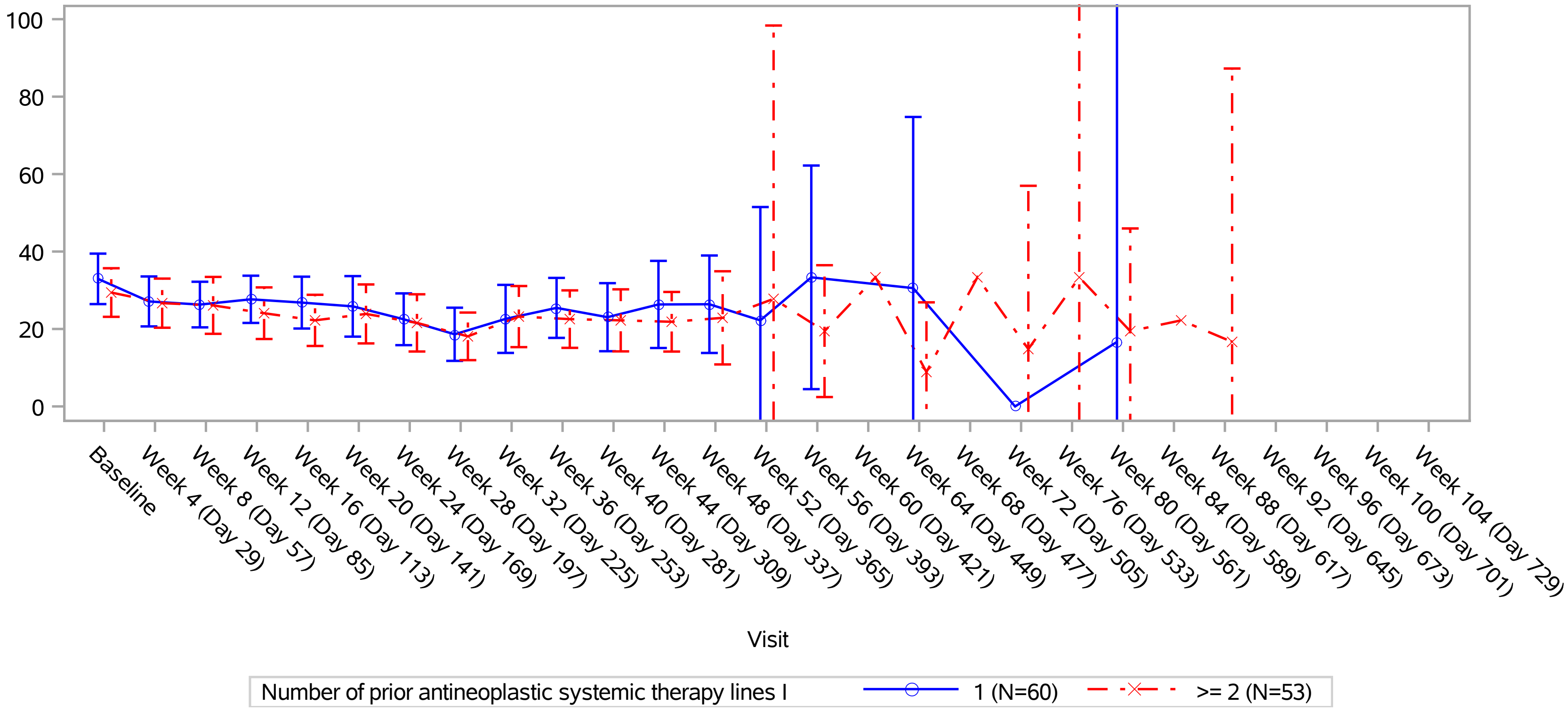
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Fatigue
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30FA.pdf
15OCT2021 17:16

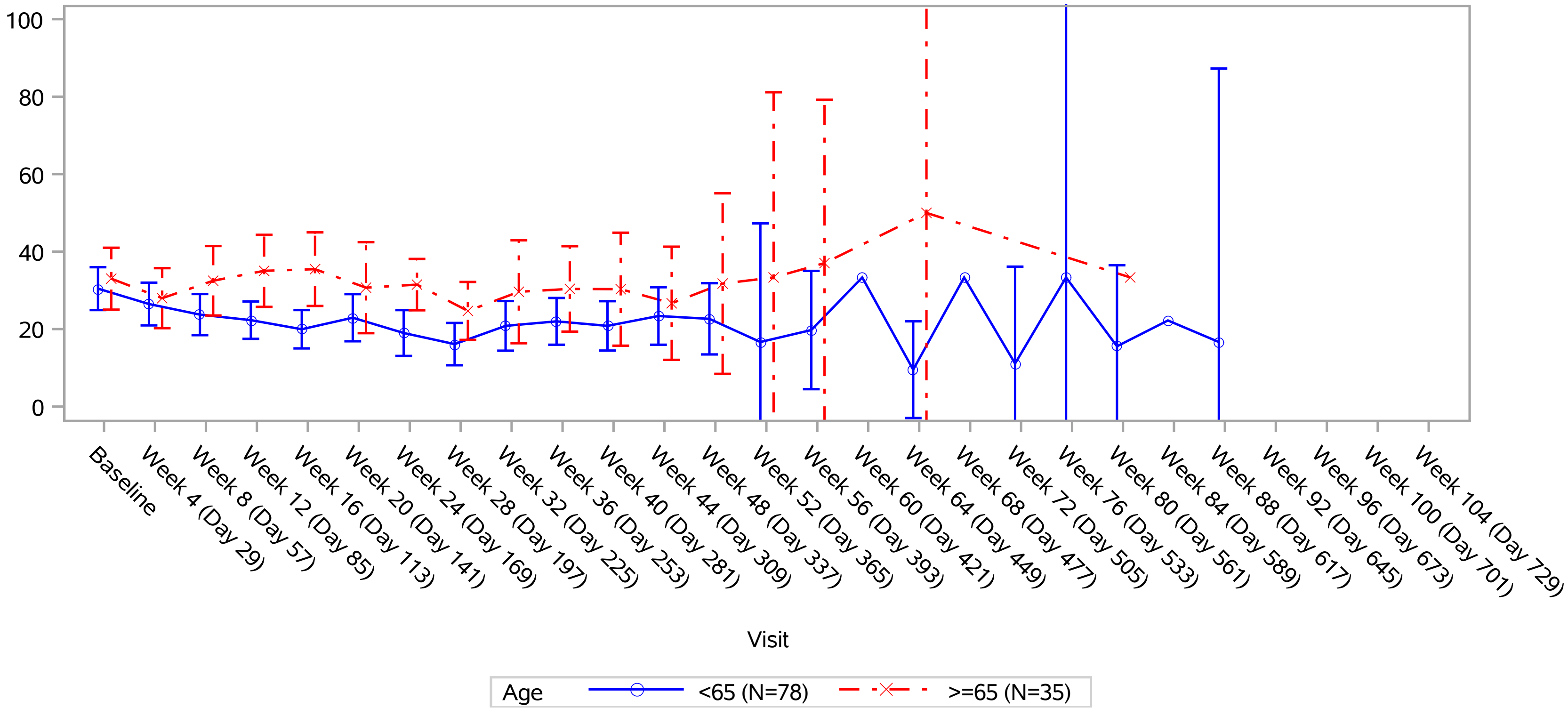
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Fatigue
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30FA_PRTHL1.pdf
15OCT2021 20:07

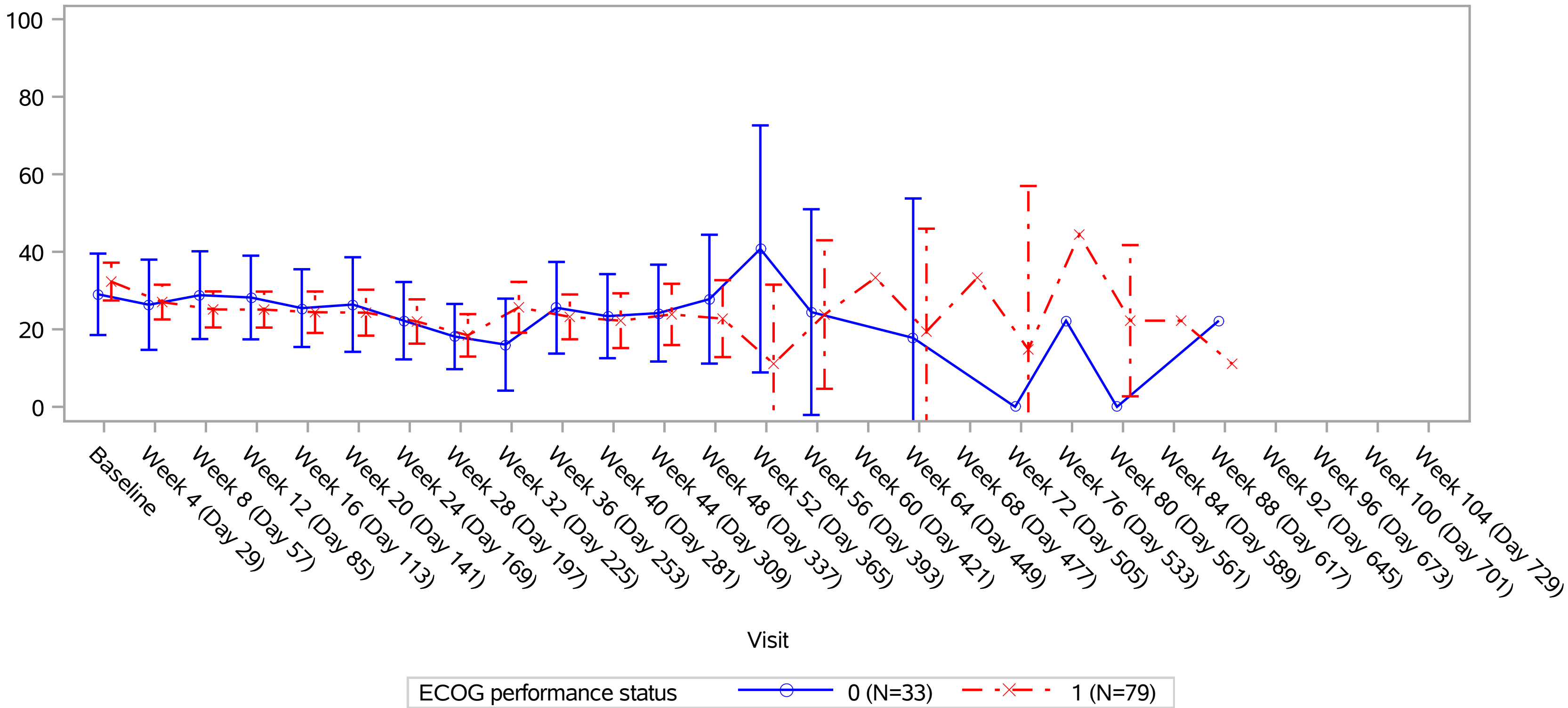
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Fatigue
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30FA_SGAGE65.pdf
15OCT2021 17:45

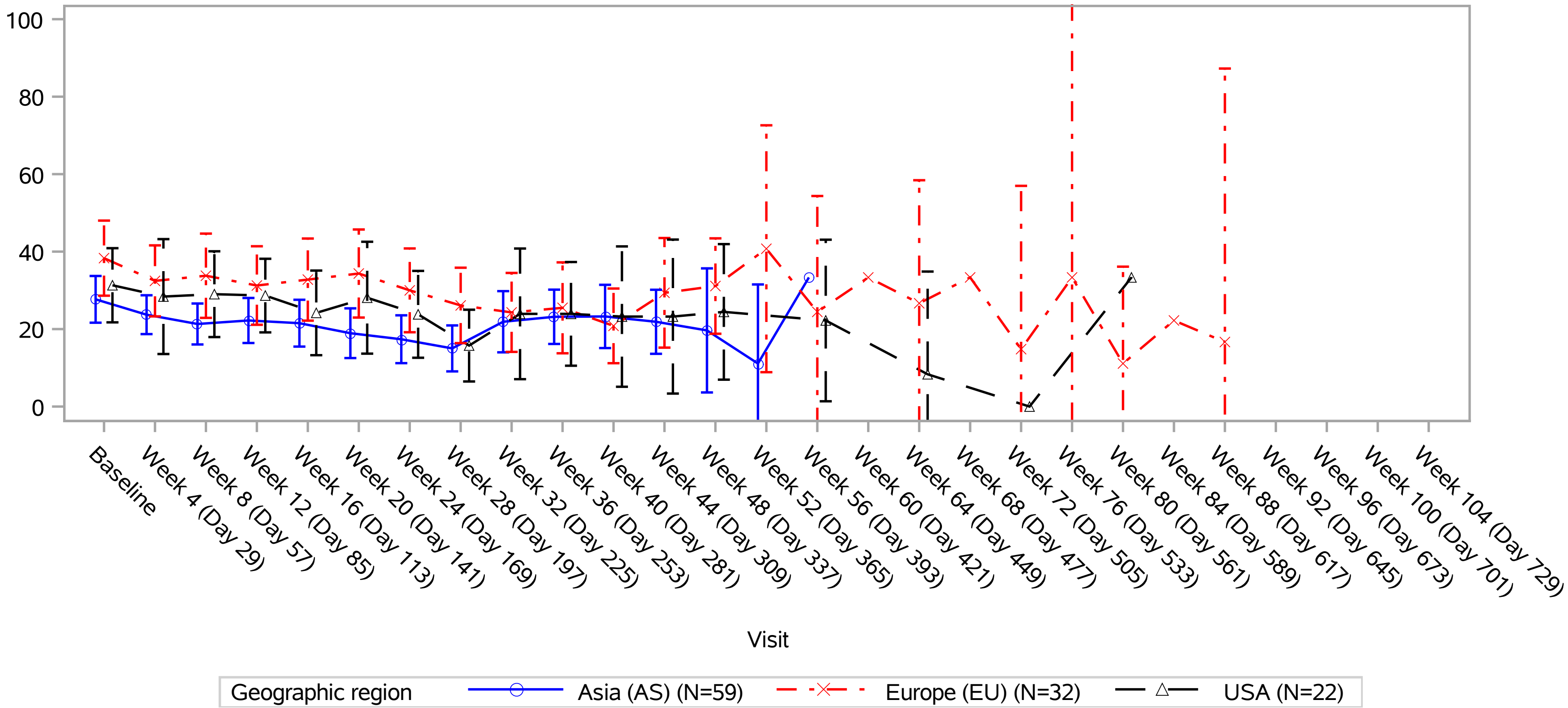
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Fatigue
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30FA_SGECOG.pdf
15OCT2021 18:15

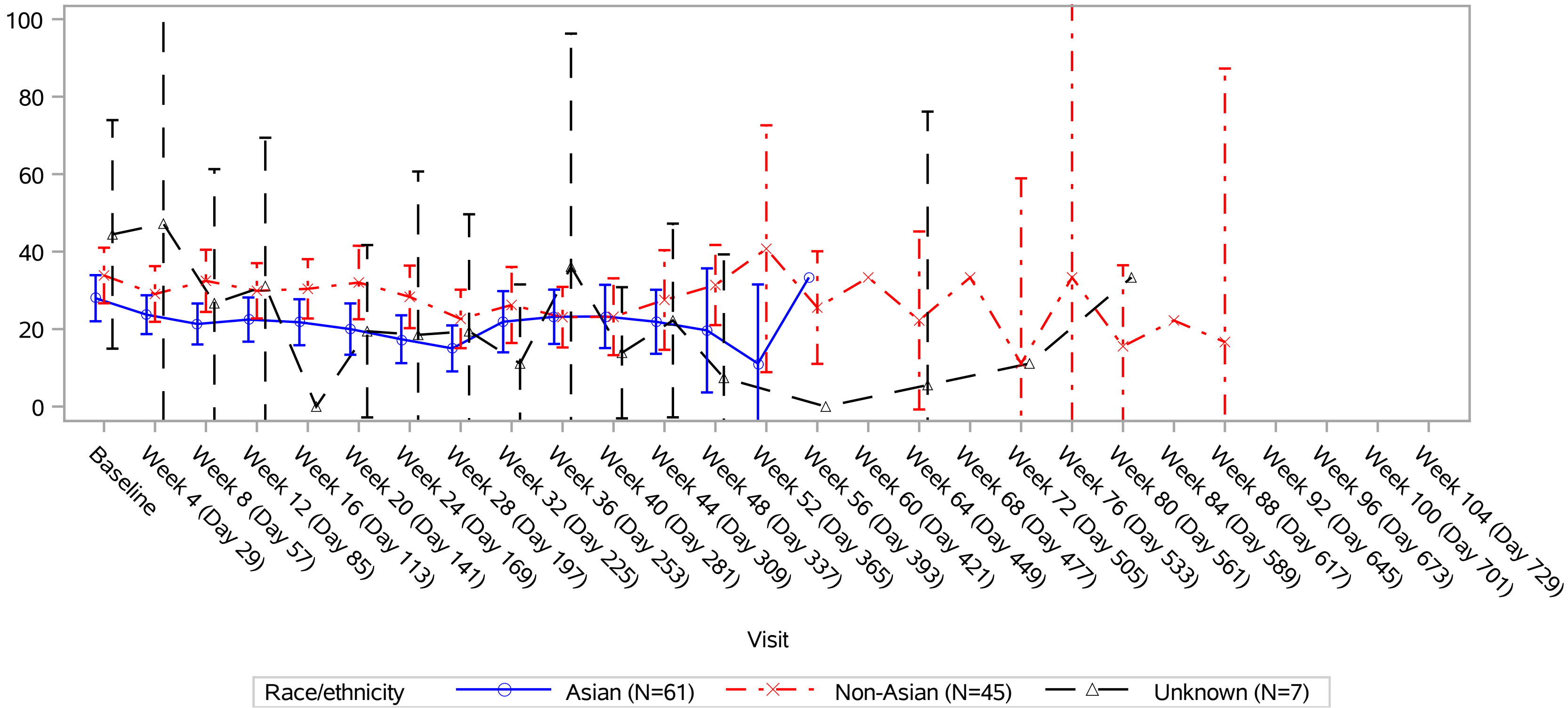
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Fatigue
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30FA_SGGEO.pdf
15OCT2021 18:46

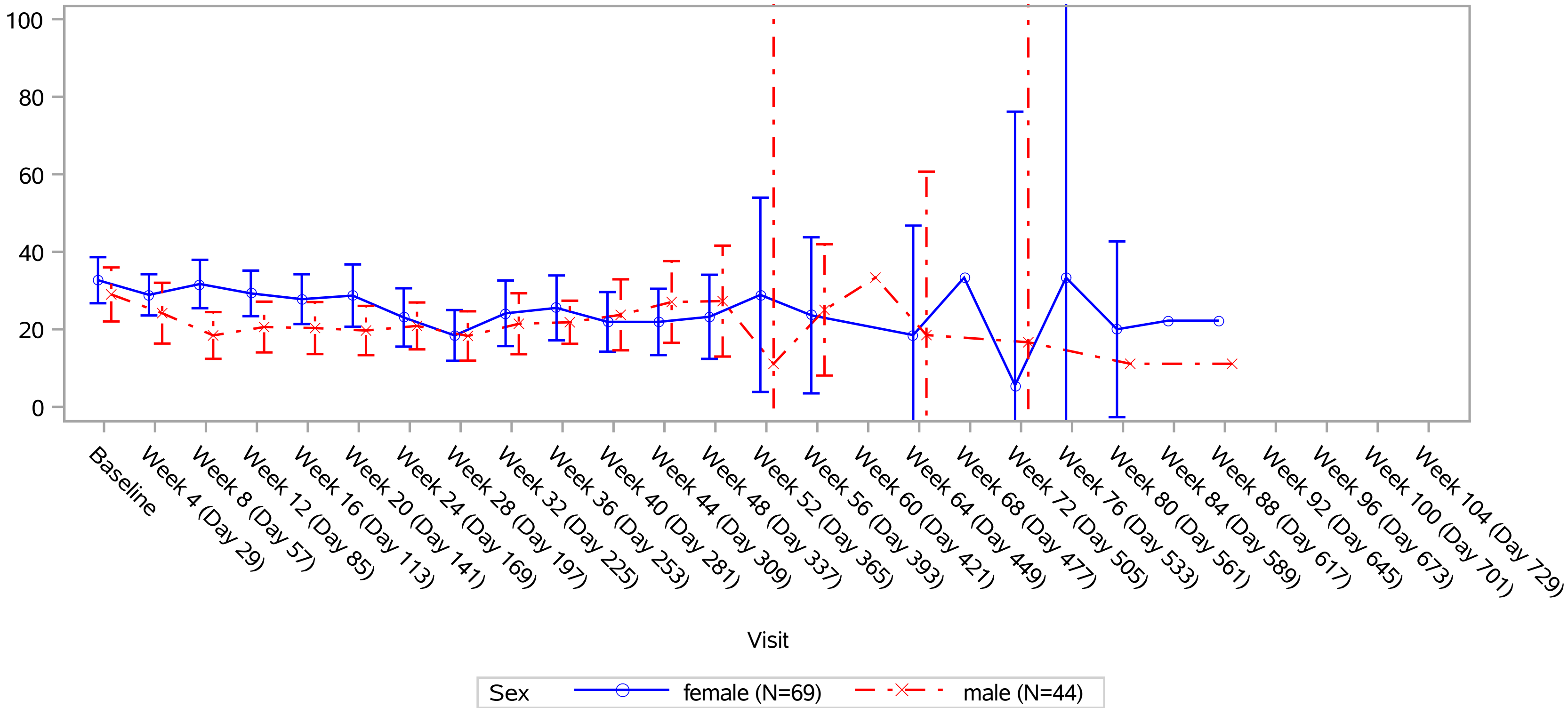
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Fatigue
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30FA_SGRE.pdf
15OCT2021 19:17

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Fatigue
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30FA_SGSEX.pdf
15OCT2021 19:47

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Nausea and vomiting
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=113)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	113	100.0	108	95.6	8.49	17.13	5.22	11.75
Week 4 (Day 29)	n/a	113	100.0	95	84.1	4.21	10.86	2.00	6.42
Week 8 (Day 57)	n/a	101	89.4	92	91.1	3.99	10.59	1.79	6.18
Week 12 (Day 85)	n/a	97	85.8	90	92.8	2.22	9.08	0.32	4.12
Week 16 (Day 113)	n/a	95	84.1	85	89.5	3.33	9.20	1.35	5.32
Week 20 (Day 141)	n/a	89	78.8	83	93.3	3.21	9.90	1.05	5.37
Week 24 (Day 169)	n/a	81	71.7	73	90.1	3.20	12.93	0.18	6.21
Week 28 (Day 197)	n/a	74	65.5	69	93.2	5.31	12.94	2.21	8.42
Week 32 (Day 225)	n/a	71	62.8	63	88.7	3.97	12.24	0.89	7.05
Week 36 (Day 253)	n/a	71	62.8	65	91.5	3.08	8.79	0.90	5.25
Week 40 (Day 281)	n/a	67	59.3	59	88.1	3.67	11.19	0.76	6.59
Week 44 (Day 309)	n/a	64	56.6	58	90.6	6.61	17.37	2.04	11.18
Week 48 (Day 337)	n/a	58	51.3	33	56.9	5.05	14.12	0.04	10.06
Week 52 (Day 365)	n/a	45	39.8	7	15.6	4.76	12.60	-6.89	16.41
Week 56 (Day 393)	n/a	37	32.7	12	32.4	2.78	6.49	-1.34	6.90
Week 60 (Day 421)	n/a	32	28.3	1	3.1	0.00	NE	NE	NE
Week 64 (Day 449)	n/a	31	27.4	9	29.0	1.85	5.56	-2.42	6.12
Week 68 (Day 477)	n/a	28	24.8	1	3.6	16.67	NE	NE	NE
Week 72 (Day 505)	n/a	28	24.8	4	14.3	0.00	0.00	NE	NE
Week 76 (Day 533)	n/a	25	22.1	2	8.0	8.33	11.79	-97.55	114.22
Week 80 (Day 561)	n/a	25	22.1	6	24.0	0.00	0.00	NE	NE
Week 84 (Day 589)	n/a	18	15.9	1	5.6	0.00	NE	NE	NE
Week 88 (Day 617)	n/a	14	12.4	2	14.3	0.00	0.00	NE	NE
Week 92 (Day 645)	n/a	7	6.2	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	5.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	2.7	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	113	100.0	111	98.2	8.26	18.92	4.70	11.82
End of Study (LOCF)	n/a	113	100.0	111	98.2	7.36	18.76	3.83	10.89
Sex									
Baseline	Female	69	100.0	67	97.1	8.21	17.97	3.83	12.59
Week 4 (Day 29)	Female	69	100.0	55	79.7	5.45	12.45	2.09	8.82
Week 8 (Day 57)	Female	63	91.3	54	85.7	5.86	13.01	2.31	9.42
Week 12 (Day 85)	Female	60	87.0	56	93.3	3.57	11.33	0.54	6.61
Week 16 (Day 113)	Female	58	84.1	50	86.2	4.67	10.67	1.63	7.70
Week 20 (Day 141)	Female	53	76.8	48	90.6	4.86	11.89	1.41	8.31
Week 24 (Day 169)	Female	47	68.1	40	85.1	4.17	16.34	-1.06	9.39
Week 28 (Day 197)	Female	42	60.9	38	90.5	7.89	15.37	2.84	12.95
Week 32 (Day 225)	Female	42	60.9	35	83.3	6.19	15.70	0.80	11.58
Week 36 (Day 253)	Female	42	60.9	37	88.1	4.50	10.13	1.13	7.88
Week 40 (Day 281)	Female	41	59.4	37	90.2	4.95	12.95	0.64	9.27
Week 44 (Day 309)	Female	41	59.4	35	85.4	9.05	20.35	2.06	16.04
Week 48 (Day 337)	Female	37	53.6	22	59.5	7.58	16.85	0.11	15.04
Week 52 (Day 365)	Female	29	42.0	5	17.2	6.67	14.91	-11.84	25.18
Week 56 (Day 393)	Female	24	34.8	8	33.3	4.17	7.72	-2.28	10.62
Week 60 (Day 421)	Female	22	31.9	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Female	22	31.9	6	27.3	2.78	6.80	-4.36	9.92
Week 68 (Day 477)	Female	20	29.0	1	5.0	16.67	NE	NE	NE
Week 72 (Day 505)	Female	20	29.0	2	10.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Female	18	26.1	2	11.1	8.33	11.79	-97.55	114.22
Week 80 (Day 561)	Female	18	26.1	5	27.8	0.00	0.00	NE	NE
Week 84 (Day 589)	Female	12	17.4	1	8.3	0.00	NE	NE	NE
Week 88 (Day 617)	Female	9	13.0	1	11.1	0.00	NE	NE	NE
Week 92 (Day 645)	Female	6	8.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	7.2	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	2.9	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	1.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	69	100.0	68	98.6	11.03	22.23	5.65	16.41
End of Study (LOCF)	Female	69	100.0	68	98.6	10.29	22.68	4.80	15.78
Baseline	Male	44	100.0	41	93.2	8.94	15.85	3.94	13.95
Week 4 (Day 29)	Male	44	100.0	40	90.9	2.50	8.05	-0.07	5.07
Week 8 (Day 57)	Male	38	86.4	38	100.0	1.32	4.55	-0.18	2.81
Week 12 (Day 85)	Male	37	84.1	34	91.9	0.00	0.00	NE	NE
Week 16 (Day 113)	Male	37	84.1	35	94.6	1.43	6.22	-0.71	3.57
Week 20 (Day 141)	Male	36	81.8	35	97.2	0.95	5.63	-0.98	2.89
Week 24 (Day 169)	Male	34	77.3	33	97.1	2.02	6.92	-0.43	4.47
Week 28 (Day 197)	Male	32	72.7	31	96.9	2.15	8.32	-0.90	5.20
Week 32 (Day 225)	Male	29	65.9	28	96.6	1.19	4.37	-0.50	2.89
Week 36 (Day 253)	Male	29	65.9	28	96.6	1.19	6.30	-1.25	3.63
Week 40 (Day 281)	Male	26	59.1	22	84.6	1.52	7.11	-1.64	4.67
Week 44 (Day 309)	Male	23	52.3	23	100.0	2.90	10.84	-1.79	7.59
Week 48 (Day 337)	Male	21	47.7	11	52.4	0.00	0.00	NE	NE
Week 52 (Day 365)	Male	16	36.4	2	12.5	0.00	0.00	NE	NE
Week 56 (Day 393)	Male	13	29.5	4	30.8	0.00	0.00	NE	NE
Week 60 (Day 421)	Male	10	22.7	1	10.0	0.00	NE	NE	NE
Week 64 (Day 449)	Male	9	20.5	3	33.3	0.00	0.00	NE	NE
Week 68 (Day 477)	Male	8	18.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	8	18.2	2	25.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Male	7	15.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	7	15.9	1	14.3	0.00	NE	NE	NE
Week 84 (Day 589)	Male	6	13.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	5	11.4	1	20.0	0.00	NE	NE	NE
Week 92 (Day 645)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	44	100.0	43	97.7	3.88	10.81	0.55	7.20
End of Study (LOCF)	Male	44	100.0	43	97.7	2.71	8.08	0.23	5.20
Age									

Baseline	< 65	78	100.0	73	93.6	8.90	19.06	4.46	13.35
Week 4 (Day 29)	< 65	78	100.0	68	87.2	2.94	8.11	0.98	4.91
Week 8 (Day 57)	< 65	73	93.6	66	90.4	2.27	7.67	0.39	4.16
Week 12 (Day 85)	< 65	71	91.0	64	90.1	1.04	6.56	-0.60	2.68
Week 16 (Day 113)	< 65	69	88.5	59	85.5	1.98	6.98	0.16	3.80
Week 20 (Day 141)	< 65	65	83.3	62	95.4	2.96	9.79	0.47	5.44
Week 24 (Day 169)	< 65	59	75.6	55	93.2	1.82	6.15	0.16	3.48
Week 28 (Day 197)	< 65	55	70.5	51	92.7	5.56	13.61	1.73	9.38
Week 32 (Day 225)	< 65	53	67.9	48	90.6	3.47	12.38	-0.12	7.07
Week 36 (Day 253)	< 65	53	67.9	50	94.3	3.33	9.52	0.63	6.04
Week 40 (Day 281)	< 65	52	66.7	48	92.3	2.43	10.31	-0.56	5.42
Week 44 (Day 309)	< 65	52	66.7	48	92.3	6.60	17.78	1.43	11.76
Week 48 (Day 337)	< 65	47	60.3	26	55.3	3.21	9.45	-0.61	7.02
Week 52 (Day 365)	< 65	36	46.2	4	11.1	0.00	0.00	NE	NE
Week 56 (Day 393)	< 65	30	38.5	9	30.0	0.00	0.00	NE	NE
Week 60 (Day 421)	< 65	25	32.1	1	4.0	0.00	NE	NE	NE
Week 64 (Day 449)	< 65	24	30.8	7	29.2	0.00	0.00	NE	NE
Week 68 (Day 477)	< 65	22	28.2	1	4.5	16.67	NE	NE	NE
Week 72 (Day 505)	< 65	22	28.2	4	18.2	0.00	0.00	NE	NE
Week 76 (Day 533)	< 65	21	26.9	2	9.5	8.33	11.79	-97.55	114.22
Week 80 (Day 561)	< 65	21	26.9	5	23.8	0.00	0.00	NE	NE
Week 84 (Day 589)	< 65	15	19.2	1	6.7	0.00	NE	NE	NE
Week 88 (Day 617)	< 65	12	15.4	2	16.7	0.00	0.00	NE	NE
Week 92 (Day 645)	< 65	6	7.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	6.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	78	100.0	76	97.4	6.80	17.04	2.91	10.69
End of Study (LOCF)	< 65	78	100.0	76	97.4	5.26	15.92	1.63	8.90
Baseline	>= 65	35	100.0	35	100.0	7.62	12.36	3.37	11.86
Week 4 (Day 29)	>= 65	35	100.0	27	77.1	7.41	15.56	1.25	13.56
Week 8 (Day 57)	>= 65	28	80.0	26	92.9	8.33	15.09	2.24	14.43
Week 12 (Day 85)	>= 65	26	74.3	26	100.0	5.13	13.14	-0.18	10.44

Week 16 (Day 113)	>= 65	26	74.3	26	100.0	6.41	12.54	1.35	11.48
Week 20 (Day 141)	>= 65	24	68.6	21	87.5	3.97	10.41	-0.77	8.71
Week 24 (Day 169)	>= 65	22	62.9	18	81.8	7.41	23.72	-4.39	19.20
Week 28 (Day 197)	>= 65	19	54.3	18	94.7	4.63	11.15	-0.92	10.18
Week 32 (Day 225)	>= 65	18	51.4	15	83.3	5.56	12.06	-1.12	12.24
Week 36 (Day 253)	>= 65	18	51.4	15	83.3	2.22	5.86	-1.03	5.47
Week 40 (Day 281)	>= 65	15	42.9	11	73.3	9.09	13.67	-0.09	18.27
Week 44 (Day 309)	>= 65	12	34.3	10	83.3	6.67	16.10	-4.85	18.19
Week 48 (Day 337)	>= 65	11	31.4	7	63.6	11.90	24.93	-11.16	34.96
Week 52 (Day 365)	>= 65	9	25.7	3	33.3	11.11	19.25	-36.70	58.92
Week 56 (Day 393)	>= 65	7	20.0	3	42.9	11.11	9.62	-12.79	35.01
Week 60 (Day 421)	>= 65	7	20.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	7	20.0	2	28.6	8.33	11.79	-97.55	114.22
Week 68 (Day 477)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	4	11.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	4	11.4	1	25.0	0.00	NE	NE	NE
Week 84 (Day 589)	>= 65	3	8.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	5.7	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	35	100.0	35	100.0	11.43	22.42	3.73	19.13
End of Study (LOCF)	>= 65	35	100.0	35	100.0	11.90	23.42	3.86	19.95
ECOG performance status									
Baseline	0	33	100.0	31	93.9	4.84	14.40	-0.44	10.12
Week 4 (Day 29)	0	33	100.0	27	81.8	5.56	10.34	1.47	9.64
Week 8 (Day 57)	0	30	90.9	27	90.0	4.32	11.87	-0.37	9.02
Week 12 (Day 85)	0	29	87.9	26	89.7	4.49	12.07	-0.39	9.36
Week 16 (Day 113)	0	28	84.8	24	85.7	4.86	11.50	0.00	9.72
Week 20 (Day 141)	0	26	78.8	24	92.3	4.17	8.86	0.43	7.91
Week 24 (Day 169)	0	24	72.7	20	83.3	5.83	22.47	-4.69	16.35
Week 28 (Day 197)	0	21	63.6	19	90.5	7.02	16.96	-1.16	15.19

Week 32 (Day 225)	0	21	63.6	18	85.7	1.85	7.86	-2.06	5.76
Week 36 (Day 253)	0	21	63.6	20	95.2	2.50	6.11	-0.36	5.36
Week 40 (Day 281)	0	21	63.6	19	90.5	2.63	8.36	-1.40	6.66
Week 44 (Day 309)	0	21	63.6	17	81.0	6.86	15.66	-1.19	14.91
Week 48 (Day 337)	0	19	57.6	12	63.2	6.94	19.41	-5.39	19.28
Week 52 (Day 365)	0	18	54.5	3	16.7	11.11	19.25	-36.70	58.92
Week 56 (Day 393)	0	16	48.5	5	31.3	3.33	7.45	-5.92	12.59
Week 60 (Day 421)	0	16	48.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	0	16	48.5	5	31.3	3.33	7.45	-5.92	12.59
Week 68 (Day 477)	0	14	42.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	0	14	42.4	1	7.1	0.00	NE	NE	NE
Week 76 (Day 533)	0	12	36.4	1	8.3	0.00	NE	NE	NE
Week 80 (Day 561)	0	12	36.4	1	8.3	0.00	NE	NE	NE
Week 84 (Day 589)	0	10	30.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	9	27.3	1	11.1	0.00	NE	NE	NE
Week 92 (Day 645)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	9.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	3.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	33	100.0	33	100.0	9.60	21.26	2.06	17.13
End of Study (LOCF)	0	33	100.0	33	100.0	8.08	21.70	0.39	15.78
Baseline	1	79	100.0	76	96.2	9.87	18.09	5.73	14.00
Week 4 (Day 29)	1	79	100.0	67	84.8	3.73	11.17	1.01	6.46
Week 8 (Day 57)	1	70	88.6	65	92.9	3.85	10.11	1.34	6.35
Week 12 (Day 85)	1	68	86.1	64	94.1	1.30	7.46	-0.56	3.16
Week 16 (Day 113)	1	67	84.8	61	91.0	2.73	8.15	0.64	4.82
Week 20 (Day 141)	1	63	79.7	59	93.7	2.82	10.34	0.13	5.52
Week 24 (Day 169)	1	57	72.2	53	93.0	2.20	6.57	0.39	4.01
Week 28 (Day 197)	1	53	67.1	50	94.3	4.67	11.19	1.49	7.85
Week 32 (Day 225)	1	50	63.3	45	90.0	4.81	13.59	0.73	8.90
Week 36 (Day 253)	1	50	63.3	45	90.0	3.33	9.80	0.39	6.28
Week 40 (Day 281)	1	46	58.2	40	87.0	4.17	12.37	0.21	8.12

Week 44 (Day 309)	1	43	54.4	41	95.3	6.50	18.21	0.76	12.25
Week 48 (Day 337)	1	39	49.4	21	53.8	3.97	10.41	-0.77	8.71
Week 52 (Day 365)	1	27	34.2	4	14.8	0.00	0.00	NE	NE
Week 56 (Day 393)	1	21	26.6	7	33.3	2.38	6.30	-3.45	8.21
Week 60 (Day 421)	1	16	20.3	1	6.3	0.00	NE	NE	NE
Week 64 (Day 449)	1	15	19.0	4	26.7	0.00	0.00	NE	NE
Week 68 (Day 477)	1	14	17.7	1	7.1	16.67	NE	NE	NE
Week 72 (Day 505)	1	14	17.7	3	21.4	0.00	0.00	NE	NE
Week 76 (Day 533)	1	13	16.5	1	7.7	16.67	NE	NE	NE
Week 80 (Day 561)	1	13	16.5	5	38.5	0.00	0.00	NE	NE
Week 84 (Day 589)	1	8	10.1	1	12.5	0.00	NE	NE	NE
Week 88 (Day 617)	1	5	6.3	1	20.0	0.00	NE	NE	NE
Week 92 (Day 645)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	2.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	79	100.0	77	97.5	7.79	18.05	3.69	11.89
End of Study (LOCF)	1	79	100.0	77	97.5	7.14	17.61	3.15	11.14
Baseline	Missing	1	100.0	1	100.0	16.67	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Geographic region									
Baseline	USA	22	100.0	22	100.0	6.82	13.27	0.93	12.70
Week 4 (Day 29)	USA	22	100.0	18	81.8	7.41	17.36	-1.23	16.04
Week 8 (Day 57)	USA	20	90.9	18	90.0	5.56	14.00	-1.41	12.52
Week 12 (Day 85)	USA	20	90.9	19	95.0	1.75	7.65	-1.93	5.44
Week 16 (Day 113)	USA	19	86.4	17	89.5	3.92	11.07	-1.77	9.61
Week 20 (Day 141)	USA	19	86.4	17	89.5	2.94	6.55	-0.43	6.31
Week 24 (Day 169)	USA	16	72.7	14	87.5	3.57	9.65	-2.00	9.14
Week 28 (Day 197)	USA	15	68.2	12	80.0	5.56	10.86	-1.34	12.45
Week 32 (Day 225)	USA	15	68.2	13	86.7	2.56	6.26	-1.22	6.35
Week 36 (Day 253)	USA	15	68.2	13	86.7	2.56	6.26	-1.22	6.35
Week 40 (Day 281)	USA	14	63.6	11	78.6	4.55	7.78	-0.68	9.78

Week 44 (Day 309)	USA	13	59.1	11	84.6	10.61	18.67	-1.94	23.15
Week 48 (Day 337)	USA	13	59.1	10	76.9	3.33	10.54	-4.21	10.87
Week 52 (Day 365)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	USA	12	54.5	6	50.0	2.78	6.80	-4.36	9.92
Week 60 (Day 421)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	11	50.0	4	36.4	0.00	0.00	NE	NE
Week 68 (Day 477)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	10	45.5	1	10.0	0.00	NE	NE	NE
Week 76 (Day 533)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	10	45.5	2	20.0	0.00	0.00	NE	NE
Week 84 (Day 589)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	13.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	4.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	22	100.0	22	100.0	9.85	19.69	1.12	18.58
End of Study (LOCF)	USA	22	100.0	22	100.0	4.55	15.59	-2.36	11.46
Baseline	Europe (EU)	32	100.0	29	90.6	6.32	15.05	0.60	12.05
Week 4 (Day 29)	Europe (EU)	32	100.0	25	78.1	3.33	8.33	-0.11	6.77
Week 8 (Day 57)	Europe (EU)	29	90.6	25	86.2	5.33	13.37	-0.18	10.85
Week 12 (Day 85)	Europe (EU)	26	81.3	24	92.3	3.47	10.97	-1.16	8.10
Week 16 (Day 113)	Europe (EU)	25	78.1	20	80.0	5.00	12.21	-0.72	10.72
Week 20 (Day 141)	Europe (EU)	23	71.9	22	95.7	4.55	9.17	0.48	8.61
Week 24 (Day 169)	Europe (EU)	21	65.6	20	95.2	6.67	22.56	-3.89	17.22
Week 28 (Day 197)	Europe (EU)	20	62.5	20	100.0	8.33	17.52	0.13	16.53
Week 32 (Day 225)	Europe (EU)	18	56.3	16	88.9	7.29	18.23	-2.42	17.00
Week 36 (Day 253)	Europe (EU)	18	56.3	17	94.4	2.94	6.55	-0.43	6.31
Week 40 (Day 281)	Europe (EU)	17	53.1	16	94.1	2.08	5.69	-0.95	5.12
Week 44 (Day 309)	Europe (EU)	17	53.1	14	82.4	7.14	18.16	-3.34	17.63

Week 48 (Day 337)	Europe (EU)	14	43.8	10	71.4	6.67	11.65	-1.67	15.00
Week 52 (Day 365)	Europe (EU)	13	40.6	3	23.1	11.11	19.25	-36.70	58.92
Week 56 (Day 393)	Europe (EU)	11	34.4	5	45.5	3.33	7.45	-5.92	12.59
Week 60 (Day 421)	Europe (EU)	11	34.4	1	9.1	0.00	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	11	34.4	5	45.5	3.33	7.45	-5.92	12.59
Week 68 (Day 477)	Europe (EU)	10	31.3	1	10.0	16.67	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	10	31.3	3	30.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Europe (EU)	8	25.0	2	25.0	8.33	11.79	-97.55	114.22
Week 80 (Day 561)	Europe (EU)	8	25.0	4	50.0	0.00	0.00	NE	NE
Week 84 (Day 589)	Europe (EU)	6	18.8	1	16.7	0.00	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	9.4	2	66.7	0.00	0.00	NE	NE
Cycle 12 (LOCF)	Europe (EU)	32	100.0	31	96.9	9.68	22.27	1.51	17.85
End of Study (LOCF)	Europe (EU)	32	100.0	31	96.9	9.68	22.68	1.36	18.00
Baseline	Asia (AS)	59	100.0	57	96.6	10.23	19.35	5.10	15.37
Week 4 (Day 29)	Asia (AS)	59	100.0	52	88.1	3.53	8.94	1.04	6.01
Week 8 (Day 57)	Asia (AS)	52	88.1	49	94.2	2.72	7.09	0.68	4.76
Week 12 (Day 85)	Asia (AS)	51	86.4	47	92.2	1.77	8.68	-0.77	4.32
Week 16 (Day 113)	Asia (AS)	51	86.4	48	94.1	2.43	6.87	0.44	4.42
Week 20 (Day 141)	Asia (AS)	47	79.7	44	93.6	2.65	11.33	-0.79	6.10
Week 24 (Day 169)	Asia (AS)	44	74.6	39	88.6	1.28	4.50	-0.18	2.74
Week 28 (Day 197)	Asia (AS)	39	66.1	37	94.9	3.60	10.49	0.10	7.10
Week 32 (Day 225)	Asia (AS)	38	64.4	34	89.5	2.94	10.44	-0.70	6.58
Week 36 (Day 253)	Asia (AS)	38	64.4	35	92.1	3.33	10.54	-0.29	6.95
Week 40 (Day 281)	Asia (AS)	36	61.0	32	88.9	4.17	14.04	-0.90	9.23
Week 44 (Day 309)	Asia (AS)	34	57.6	33	97.1	5.05	16.92	-0.95	11.05
Week 48 (Day 337)	Asia (AS)	31	52.5	13	41.9	5.13	18.49	-6.05	16.30
Week 52 (Day 365)	Asia (AS)	20	33.9	4	20.0	0.00	0.00	NE	NE
Week 56 (Day 393)	Asia (AS)	14	23.7	1	7.1	0.00	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	10.2	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	8.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	3.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	59	100.0	58	98.3	6.90	16.82	2.47	11.32
End of Study (LOCF)	Asia (AS)	59	100.0	58	98.3	7.18	17.69	2.53	11.84
Race/ethnicity									
Baseline	Asian	61	100.0	58	95.1	10.63	19.42	5.53	15.74
Week 4 (Day 29)	Asian	61	100.0	52	85.2	3.53	8.94	1.04	6.01
Week 8 (Day 57)	Asian	53	86.9	49	92.5	2.72	7.09	0.68	4.76
Week 12 (Day 85)	Asian	52	85.2	48	92.3	1.74	8.59	-0.76	4.23
Week 16 (Day 113)	Asian	52	85.2	49	94.2	2.38	6.80	0.43	4.34
Week 20 (Day 141)	Asian	48	78.7	45	93.8	2.59	11.21	-0.78	5.96
Week 24 (Day 169)	Asian	44	72.1	39	88.6	1.28	4.50	-0.18	2.74
Week 28 (Day 197)	Asian	39	63.9	37	94.9	3.60	10.49	0.10	7.10
Week 32 (Day 225)	Asian	38	62.3	34	89.5	2.94	10.44	-0.70	6.58
Week 36 (Day 253)	Asian	38	62.3	35	92.1	3.33	10.54	-0.29	6.95
Week 40 (Day 281)	Asian	36	59.0	32	88.9	4.17	14.04	-0.90	9.23
Week 44 (Day 309)	Asian	34	55.7	33	97.1	5.05	16.92	-0.95	11.05
Week 48 (Day 337)	Asian	31	50.8	13	41.9	5.13	18.49	-6.05	16.30
Week 52 (Day 365)	Asian	20	32.8	4	20.0	0.00	0.00	NE	NE
Week 56 (Day 393)	Asian	14	23.0	1	7.1	0.00	NE	NE	NE
Week 60 (Day 421)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	9.8	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	8.2	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	3.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	61	100.0	59	96.7	6.78	16.70	2.43	11.13
End of Study (LOCF)	Asian	61	100.0	59	96.7	7.06	17.56	2.49	11.64
Baseline	Non-Asian	45	100.0	44	97.8	6.44	14.47	2.04	10.84
Week 4 (Day 29)	Non-Asian	45	100.0	39	86.7	5.13	13.33	0.81	9.45
Week 8 (Day 57)	Non-Asian	42	93.3	38	90.5	6.14	14.20	1.47	10.81
Week 12 (Day 85)	Non-Asian	39	86.7	37	94.9	3.15	10.27	-0.27	6.58
Week 16 (Day 113)	Non-Asian	37	82.2	34	91.9	4.90	11.98	0.72	9.08
Week 20 (Day 141)	Non-Asian	36	80.0	34	94.4	3.92	8.27	1.04	6.81
Week 24 (Day 169)	Non-Asian	32	71.1	31	96.9	5.91	19.03	-1.06	12.89
Week 28 (Day 197)	Non-Asian	30	66.7	28	93.3	5.95	11.31	1.57	10.34
Week 32 (Day 225)	Non-Asian	28	62.2	25	89.3	6.00	15.12	-0.24	12.24
Week 36 (Day 253)	Non-Asian	28	62.2	26	92.9	3.21	6.70	0.50	5.91
Week 40 (Day 281)	Non-Asian	26	57.8	23	88.5	3.62	7.03	0.58	6.66
Week 44 (Day 309)	Non-Asian	25	55.6	21	84.0	8.73	18.72	0.21	17.25
Week 48 (Day 337)	Non-Asian	23	51.1	17	73.9	5.88	11.70	-0.13	11.90
Week 52 (Day 365)	Non-Asian	21	46.7	3	14.3	11.11	19.25	-36.70	58.92
Week 56 (Day 393)	Non-Asian	19	42.2	10	52.6	3.33	7.03	-1.69	8.36
Week 60 (Day 421)	Non-Asian	19	42.2	1	5.3	0.00	NE	NE	NE
Week 64 (Day 449)	Non-Asian	18	40.0	7	38.9	2.38	6.30	-3.45	8.21
Week 68 (Day 477)	Non-Asian	17	37.8	1	5.9	16.67	NE	NE	NE
Week 72 (Day 505)	Non-Asian	17	37.8	3	17.6	0.00	0.00	NE	NE
Week 76 (Day 533)	Non-Asian	15	33.3	2	13.3	8.33	11.79	-97.55	114.22
Week 80 (Day 561)	Non-Asian	15	33.3	5	33.3	0.00	0.00	NE	NE
Week 84 (Day 589)	Non-Asian	10	22.2	1	10.0	0.00	NE	NE	NE
Week 88 (Day 617)	Non-Asian	7	15.6	2	28.6	0.00	0.00	NE	NE
Week 92 (Day 645)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	45	100.0	45	100.0	10.74	22.23	4.06	17.42

End of Study (LOCF)	Non-Asian	45	100.0	45	100.0	8.89	21.50	2.43	15.35
Baseline	Unknown	7	100.0	6	85.7	2.78	6.80	-4.36	9.92
Week 4 (Day 29)	Unknown	7	100.0	4	57.1	4.17	8.33	-9.09	17.43
Week 8 (Day 57)	Unknown	6	85.7	5	83.3	0.00	0.00	NE	NE
Week 12 (Day 85)	Unknown	6	85.7	5	83.3	0.00	0.00	NE	NE
Week 16 (Day 113)	Unknown	6	85.7	2	33.3	0.00	0.00	NE	NE
Week 20 (Day 141)	Unknown	5	71.4	4	80.0	4.17	8.33	-9.09	17.43
Week 24 (Day 169)	Unknown	5	71.4	3	60.0	0.00	0.00	NE	NE
Week 28 (Day 197)	Unknown	5	71.4	4	80.0	16.67	33.33	-36.37	69.71
Week 32 (Day 225)	Unknown	5	71.4	4	80.0	0.00	0.00	NE	NE
Week 36 (Day 253)	Unknown	5	71.4	4	80.0	0.00	0.00	NE	NE
Week 40 (Day 281)	Unknown	5	71.4	4	80.0	0.00	0.00	NE	NE
Week 44 (Day 309)	Unknown	5	71.4	4	80.0	8.33	16.67	-18.19	34.85
Week 48 (Day 337)	Unknown	4	57.1	3	75.0	0.00	0.00	NE	NE
Week 52 (Day 365)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	4	57.1	1	25.0	0.00	NE	NE	NE
Week 60 (Day 421)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	4	57.1	2	50.0	0.00	0.00	NE	NE
Week 68 (Day 477)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	3	42.9	1	33.3	0.00	NE	NE	NE
Week 76 (Day 533)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	3	42.9	1	33.3	0.00	NE	NE	NE
Week 84 (Day 589)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	14.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	7	100.0	7	100.0	4.76	12.60	-6.89	16.41
End of Study (LOCF)	Unknown	7	100.0	7	100.0	0.00	0.00	NE	NE
Number of prior antineoplastic systemic therapy lines I									
Baseline	1	60	100.0	57	95.0	9.06	16.39	4.72	13.41

Week 4 (Day 29)	1	60	100.0	50	83.3	4.33	12.05	0.91	7.76
Week 8 (Day 57)	1	54	90.0	49	90.7	5.78	12.98	2.05	9.51
Week 12 (Day 85)	1	52	86.7	48	92.3	2.08	8.85	-0.49	4.65
Week 16 (Day 113)	1	51	85.0	46	90.2	3.26	9.70	0.38	6.14
Week 20 (Day 141)	1	48	80.0	43	89.6	1.94	6.52	-0.07	3.94
Week 24 (Day 169)	1	43	71.7	39	90.7	4.27	16.98	-1.23	9.78
Week 28 (Day 197)	1	38	63.3	34	89.5	6.86	14.86	1.68	12.05
Week 32 (Day 225)	1	35	58.3	29	82.9	4.02	13.84	-1.24	9.29
Week 36 (Day 253)	1	35	58.3	31	88.6	1.08	4.16	-0.45	2.60
Week 40 (Day 281)	1	32	53.3	27	84.4	1.23	4.45	-0.53	2.99
Week 44 (Day 309)	1	32	53.3	27	84.4	6.79	16.83	0.13	13.45
Week 48 (Day 337)	1	27	45.0	16	59.3	3.13	9.07	-1.71	7.96
Week 52 (Day 365)	1	23	38.3	5	21.7	6.67	14.91	-11.84	25.18
Week 56 (Day 393)	1	16	26.7	4	25.0	8.33	9.62	-6.98	23.64
Week 60 (Day 421)	1	14	23.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	13	21.7	4	30.8	4.17	8.33	-9.09	17.43
Week 68 (Day 477)	1	12	20.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	12	20.0	1	8.3	0.00	NE	NE	NE
Week 76 (Day 533)	1	11	18.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	11	18.3	2	18.2	0.00	0.00	NE	NE
Week 84 (Day 589)	1	9	15.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	1	8	13.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	1	3	5.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	1	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	60	100.0	58	96.7	9.77	20.24	4.45	15.09
End of Study (LOCF)	1	60	100.0	58	96.7	8.62	19.56	3.48	13.76
Baseline	>= 2	53	100.0	51	96.2	7.84	18.06	2.76	12.92
Week 4 (Day 29)	>= 2	53	100.0	45	84.9	4.07	9.51	1.22	6.93
Week 8 (Day 57)	>= 2	47	88.7	43	91.5	1.94	6.52	-0.07	3.94
Week 12 (Day 85)	>= 2	45	84.9	42	93.3	2.38	9.44	-0.56	5.32
Week 16 (Day 113)	>= 2	44	83.0	39	88.6	3.42	8.70	0.60	6.24

Week 20 (Day 141)	>= 2	41	77.4	40	97.6	4.58	12.51	0.58	8.58
Week 24 (Day 169)	>= 2	38	71.7	34	89.5	1.96	5.45	0.06	3.86
Week 28 (Day 197)	>= 2	36	67.9	35	97.2	3.81	10.76	0.11	7.51
Week 32 (Day 225)	>= 2	36	67.9	34	94.4	3.92	10.90	0.12	7.73
Week 36 (Day 253)	>= 2	36	67.9	34	94.4	4.90	11.26	0.97	8.83
Week 40 (Day 281)	>= 2	35	66.0	32	91.4	5.73	14.42	0.53	10.93
Week 44 (Day 309)	>= 2	32	60.4	31	96.9	6.45	18.09	-0.18	13.09
Week 48 (Day 337)	>= 2	31	58.5	17	54.8	6.86	17.74	-2.26	15.98
Week 52 (Day 365)	>= 2	22	41.5	2	9.1	0.00	0.00	NE	NE
Week 56 (Day 393)	>= 2	21	39.6	8	38.1	0.00	0.00	NE	NE
Week 60 (Day 421)	>= 2	18	34.0	1	5.6	0.00	NE	NE	NE
Week 64 (Day 449)	>= 2	18	34.0	5	27.8	0.00	0.00	NE	NE
Week 68 (Day 477)	>= 2	16	30.2	1	6.3	16.67	NE	NE	NE
Week 72 (Day 505)	>= 2	16	30.2	3	18.8	0.00	0.00	NE	NE
Week 76 (Day 533)	>= 2	14	26.4	2	14.3	8.33	11.79	-97.55	114.22
Week 80 (Day 561)	>= 2	14	26.4	4	28.6	0.00	0.00	NE	NE
Week 84 (Day 589)	>= 2	9	17.0	1	11.1	0.00	NE	NE	NE
Week 88 (Day 617)	>= 2	6	11.3	2	33.3	0.00	0.00	NE	NE
Week 92 (Day 645)	>= 2	2	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 2	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 2	53	100.0	53	100.0	6.60	17.40	1.81	11.40
End of Study (LOCF)	>= 2	53	100.0	53	100.0	5.97	17.93	1.03	10.92

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TP_QSC30NV_SG.xls
27OCT2021 7:28

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Nausea and vomiting
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	34	31.5	23.5	40.7
	Cycle 12 (LOCF)	n/a	108	95.6	17	15.7	10.1	23.8
	End of Study (LOCF)	n/a	108	95.6	13	12.0	7.2	19.5
Sex	All visits	Female	67	59.3	25	37.3	26.7	49.3
		Male	41	36.3	9	22.0	12.0	36.7
	Cycle 12 (LOCF)	Female	67	59.3	13	19.4	11.7	30.4
		Male	41	36.3	4	9.8	3.9	22.5
	End of Study (LOCF)	Female	67	59.3	10	14.9	8.3	25.3
		Male	41	36.3	3	7.3	2.5	19.4
Age	All visits	< 65	73	64.6	22	30.1	20.8	41.4
		>= 65	35	31.0	12	34.3	20.8	50.8
	Cycle 12 (LOCF)	< 65	73	64.6	9	12.3	6.6	21.8
		>= 65	35	31.0	8	22.9	12.1	39.0
	End of Study (LOCF)	< 65	73	64.6	5	6.8	3.0	15.1
		>= 65	35	31.0	8	22.9	12.1	39.0
ECOG performance status	All visits	0	31	27.4	15	48.4	32.0	65.2
		1	76	67.3	19	25.0	16.6	35.8
		Missing	1	0.9	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	31	27.4	7	22.6	11.4	39.8
		1	76	67.3	10	13.2	7.3	22.6
		Missing	1	0.9	0	0.0	0.0	79.3
	End of Study (LOCF)	0	31	27.4	5	16.1	7.1	32.6
		1	76	67.3	8	10.5	5.4	19.4
		Missing	1	0.9	0	0.0	0.0	79.3
Geographic region	All visits	USA	22	19.5	9	40.9	23.3	61.3
		Europe (EU)	29	25.7	12	41.4	25.5	59.3
		Asia (AS)	57	50.4	13	22.8	13.8	35.2
	Cycle 12 (LOCF)	USA	22	19.5	5	22.7	10.1	43.4
		Europe (EU)	29	25.7	5	17.2	7.6	34.5
		Asia (AS)	57	50.4	7	12.3	6.1	23.2
	End of Study (LOCF)	USA	22	19.5	2	9.1	2.5	27.8
		Europe (EU)	29	25.7	4	13.8	5.5	30.6
		Asia (AS)	57	50.4	7	12.3	6.1	23.2
Race/ethnicity	All visits	Asian	58	51.3	13	22.4	13.6	34.7
		Non-Asian	44	38.9	18	40.9	27.7	55.6
		Unknown	6	5.3	3	50.0	18.8	81.2
	Cycle 12 (LOCF)	Asian	58	51.3	7	12.1	6.0	22.9

		Non-Asian	44	38.9	9	20.5	11.2	34.5
		Unknown	6	5.3	1	16.7	3.0	56.4
	End of Study (LOCF)	Asian	58	51.3	7	12.1	6.0	22.9
		Non-Asian	44	38.9	6	13.6	6.4	26.7
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	18	31.6	21.0	44.5
		>= 2	51	45.1	16	31.4	20.3	45.0
	Cycle 12 (LOCF)	1	57	50.4	10	17.5	9.8	29.4
		>= 2	51	45.1	7	13.7	6.8	25.7
	End of Study (LOCF)	1	57	50.4	8	14.0	7.3	25.3
		>= 2	51	45.1	5	9.8	4.3	21.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30NV_W10_SG.xls
15OCT2021 13:35

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Nausea and vomiting
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

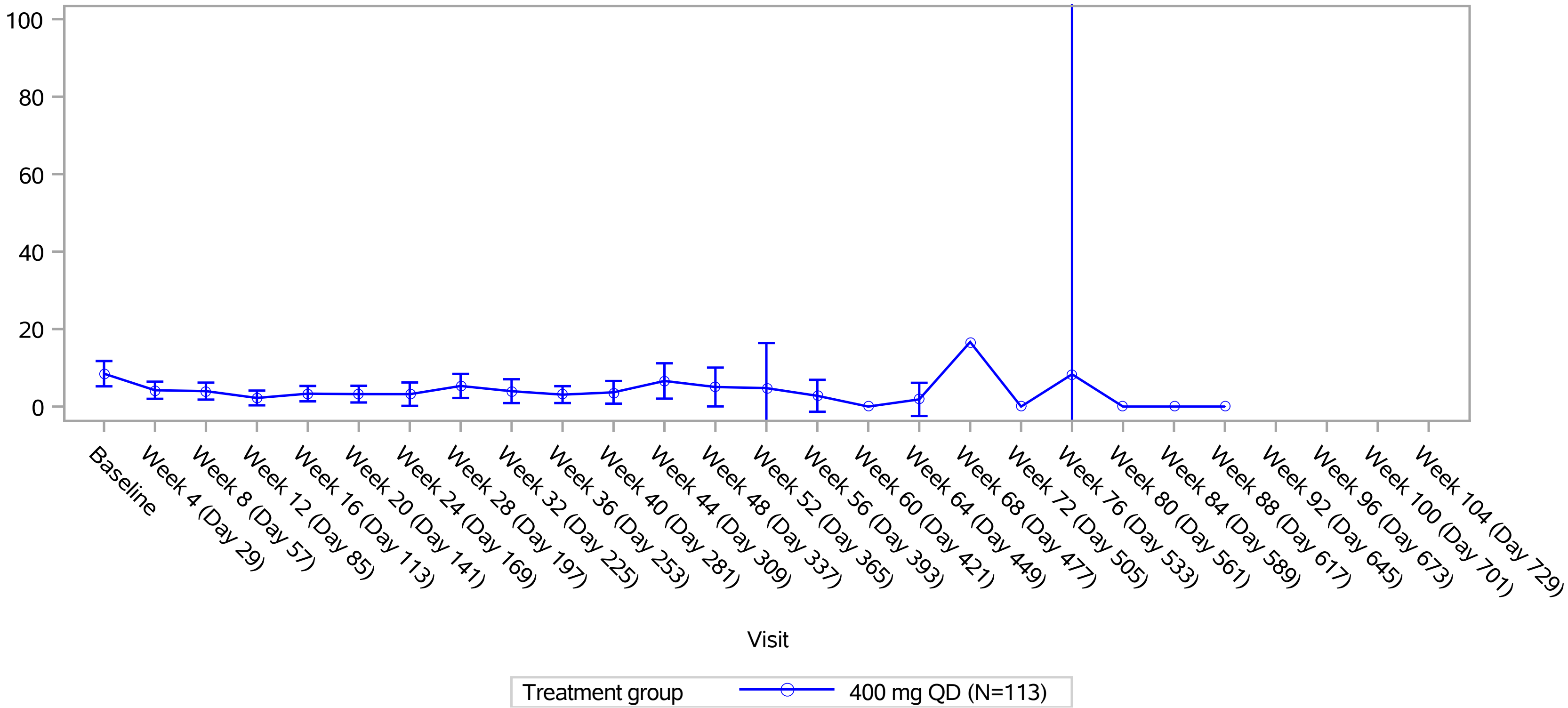
			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	34	31.5	23.5	40.7
	Cycle 12 (LOCF)	n/a	108	95.6	17	15.7	10.1	23.8
	End of Study (LOCF)	n/a	108	95.6	13	12.0	7.2	19.5
Sex	All visits	Female	67	59.3	25	37.3	26.7	49.3
		Male	41	36.3	9	22.0	12.0	36.7
	Cycle 12 (LOCF)	Female	67	59.3	13	19.4	11.7	30.4
		Male	41	36.3	4	9.8	3.9	22.5
	End of Study (LOCF)	Female	67	59.3	10	14.9	8.3	25.3
		Male	41	36.3	3	7.3	2.5	19.4
Age	All visits	< 65	73	64.6	22	30.1	20.8	41.4
		>= 65	35	31.0	12	34.3	20.8	50.8
	Cycle 12 (LOCF)	< 65	73	64.6	9	12.3	6.6	21.8
		>= 65	35	31.0	8	22.9	12.1	39.0
	End of Study (LOCF)	< 65	73	64.6	5	6.8	3.0	15.1
		>= 65	35	31.0	8	22.9	12.1	39.0
ECOG performance status	All visits	0	31	27.4	15	48.4	32.0	65.2
		1	76	67.3	19	25.0	16.6	35.8
		Missing	1	0.9	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	31	27.4	7	22.6	11.4	39.8
		1	76	67.3	10	13.2	7.3	22.6
		Missing	1	0.9	0	0.0	0.0	79.3
	End of Study (LOCF)	0	31	27.4	5	16.1	7.1	32.6
		1	76	67.3	8	10.5	5.4	19.4
		Missing	1	0.9	0	0.0	0.0	79.3
Geographic region	All visits	USA	22	19.5	9	40.9	23.3	61.3
		Europe (EU)	29	25.7	12	41.4	25.5	59.3
		Asia (AS)	57	50.4	13	22.8	13.8	35.2
	Cycle 12 (LOCF)	USA	22	19.5	5	22.7	10.1	43.4
		Europe (EU)	29	25.7	5	17.2	7.6	34.5
		Asia (AS)	57	50.4	7	12.3	6.1	23.2
	End of Study (LOCF)	USA	22	19.5	2	9.1	2.5	27.8
		Europe (EU)	29	25.7	4	13.8	5.5	30.6
		Asia (AS)	57	50.4	7	12.3	6.1	23.2
Race/ethnicity	All visits	Asian	58	51.3	13	22.4	13.6	34.7
		Non-Asian	44	38.9	18	40.9	27.7	55.6
		Unknown	6	5.3	3	50.0	18.8	81.2
	Cycle 12 (LOCF)	Asian	58	51.3	7	12.1	6.0	22.9

		Non-Asian	44	38.9	9	20.5	11.2	34.5
		Unknown	6	5.3	1	16.7	3.0	56.4
	End of Study (LOCF)	Asian	58	51.3	7	12.1	6.0	22.9
		Non-Asian	44	38.9	6	13.6	6.4	26.7
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	18	31.6	21.0	44.5
		>= 2	51	45.1	16	31.4	20.3	45.0
	Cycle 12 (LOCF)	1	57	50.4	10	17.5	9.8	29.4
		>= 2	51	45.1	7	13.7	6.8	25.7
	End of Study (LOCF)	1	57	50.4	8	14.0	7.3	25.3
		>= 2	51	45.1	5	9.8	4.3	21.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30NV_W15_SG.xls
15OCT2021 13:25

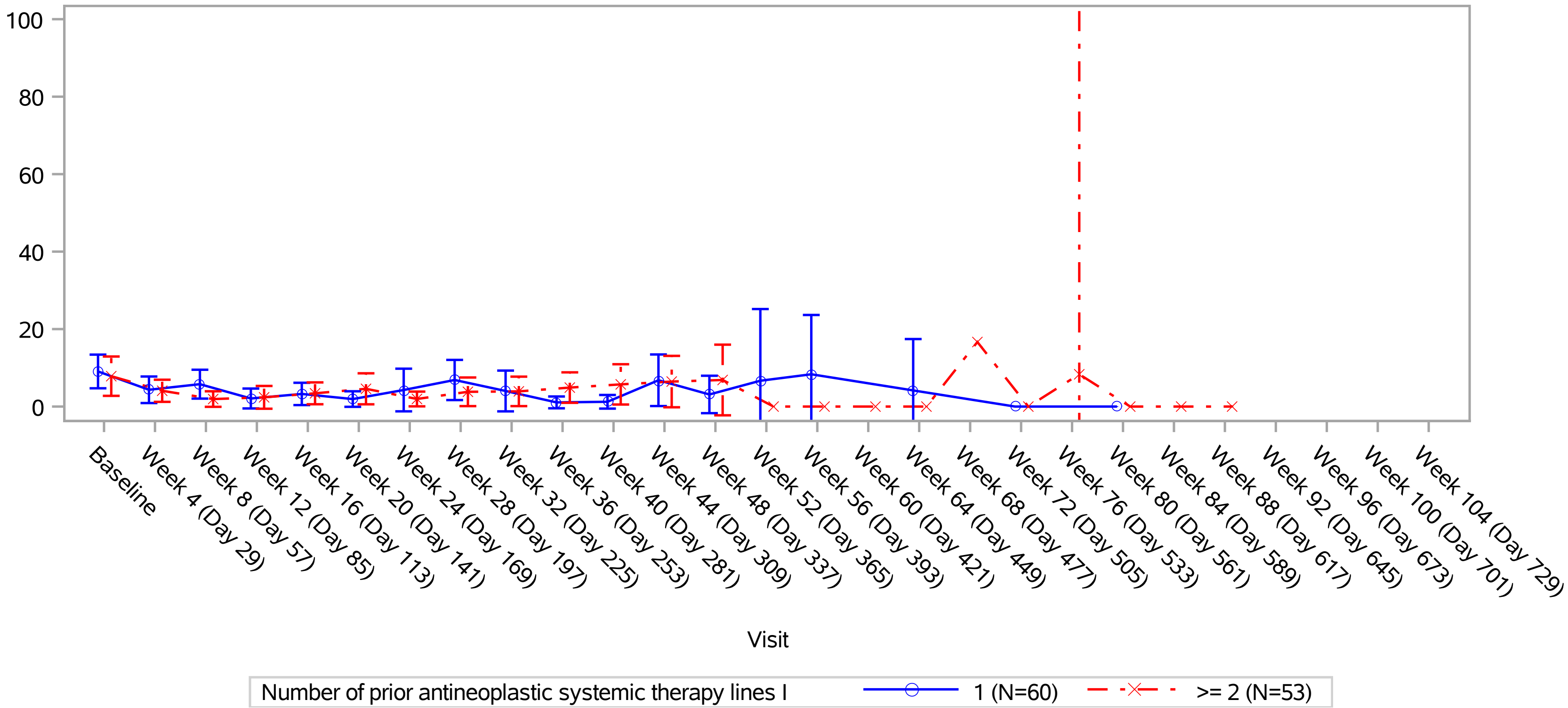
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Nausea and vomiting
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30NV.pdf
15OCT2021 17:17

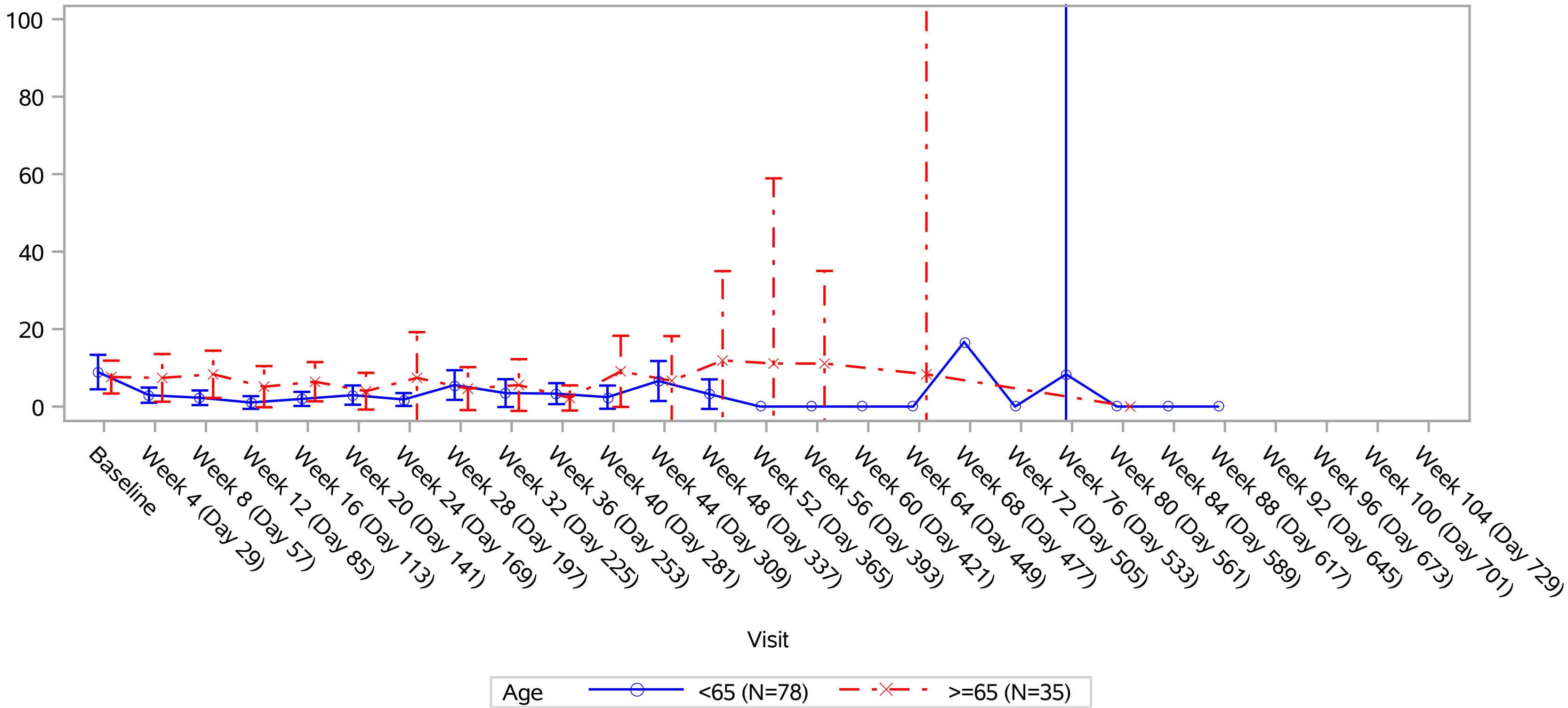
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Nausea and vomiting
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30NV_PRTHL1.pdf
15OCT2021 20:09

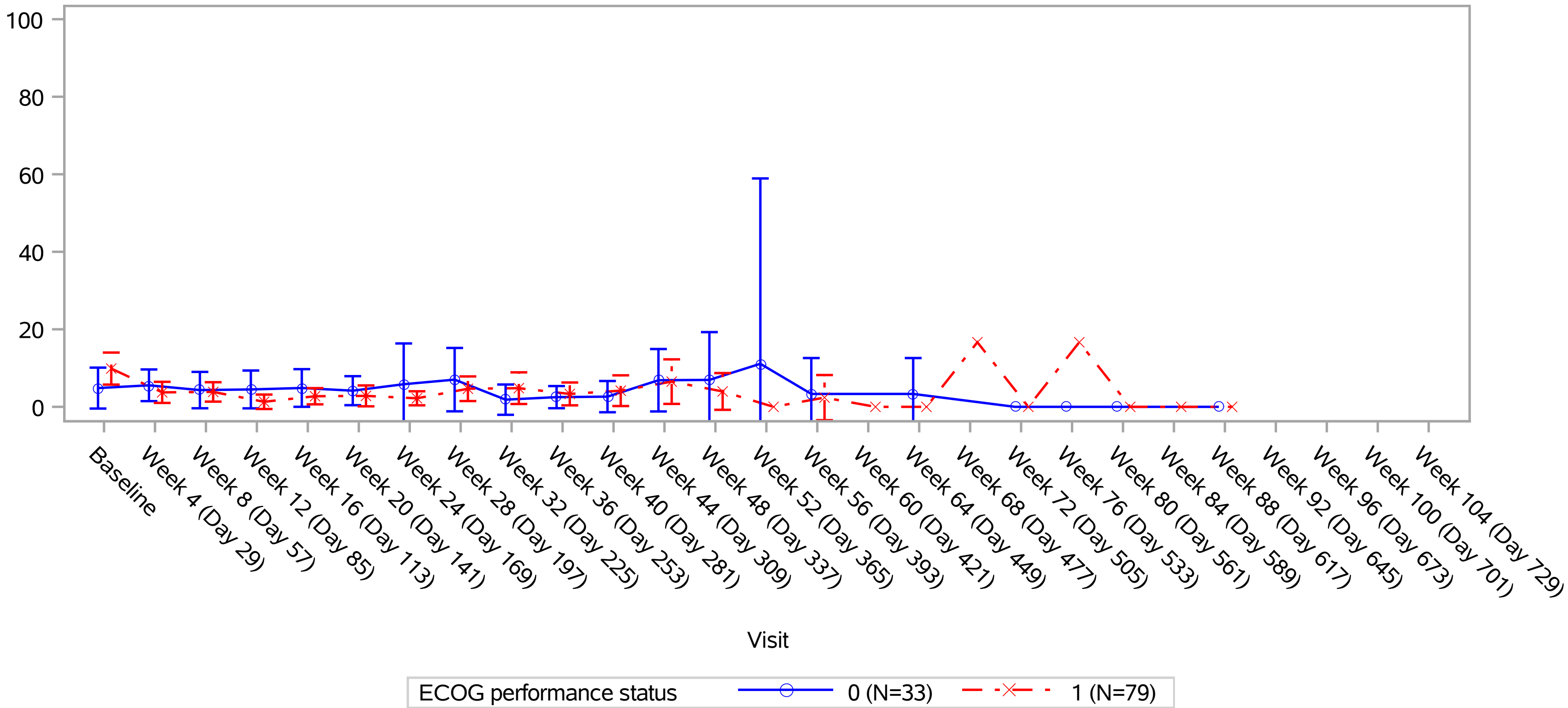
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Nausea and vomiting
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30NV_SGAGE65.pdf
15OCT2021 17:46

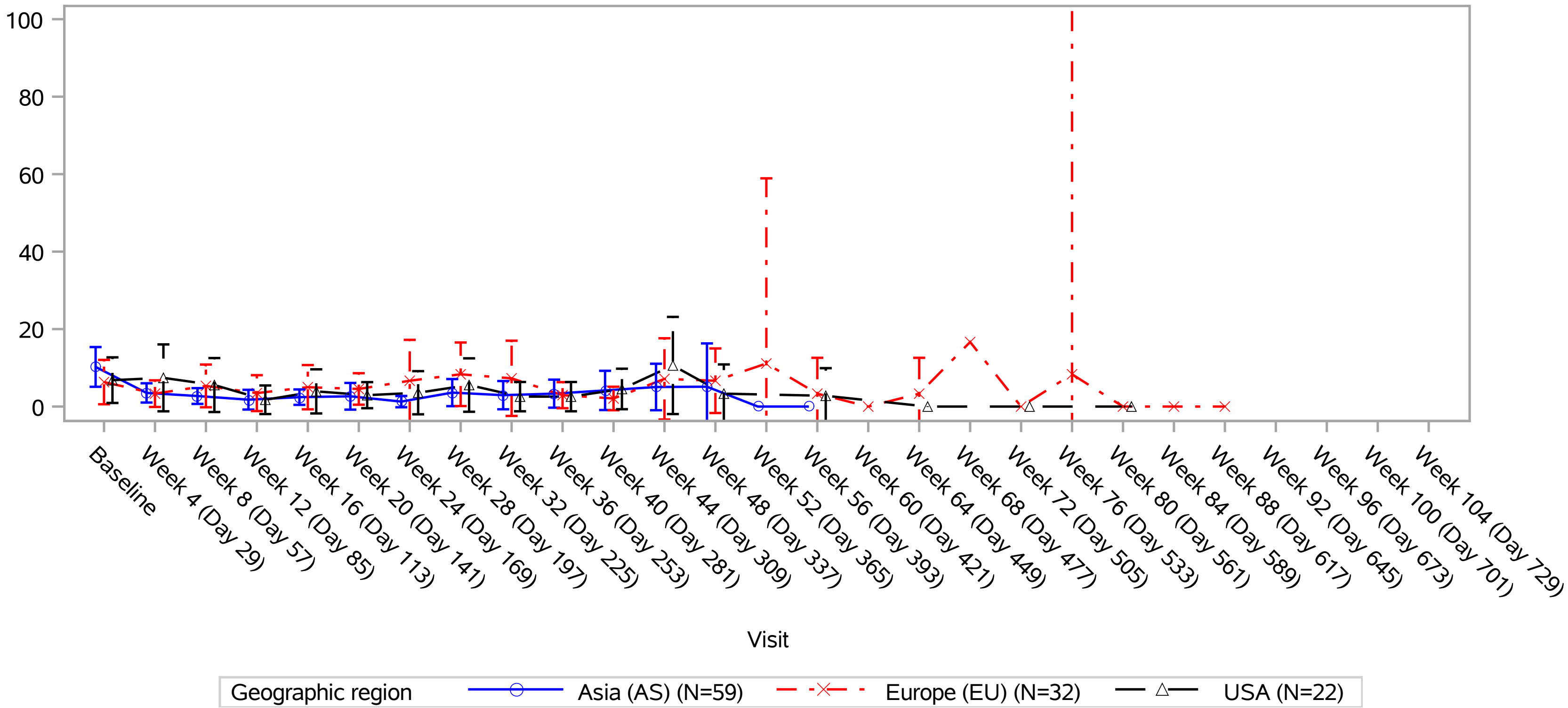
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Nausea and vomiting
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30NV_SGECOG.pdf
15OCT2021 18:16

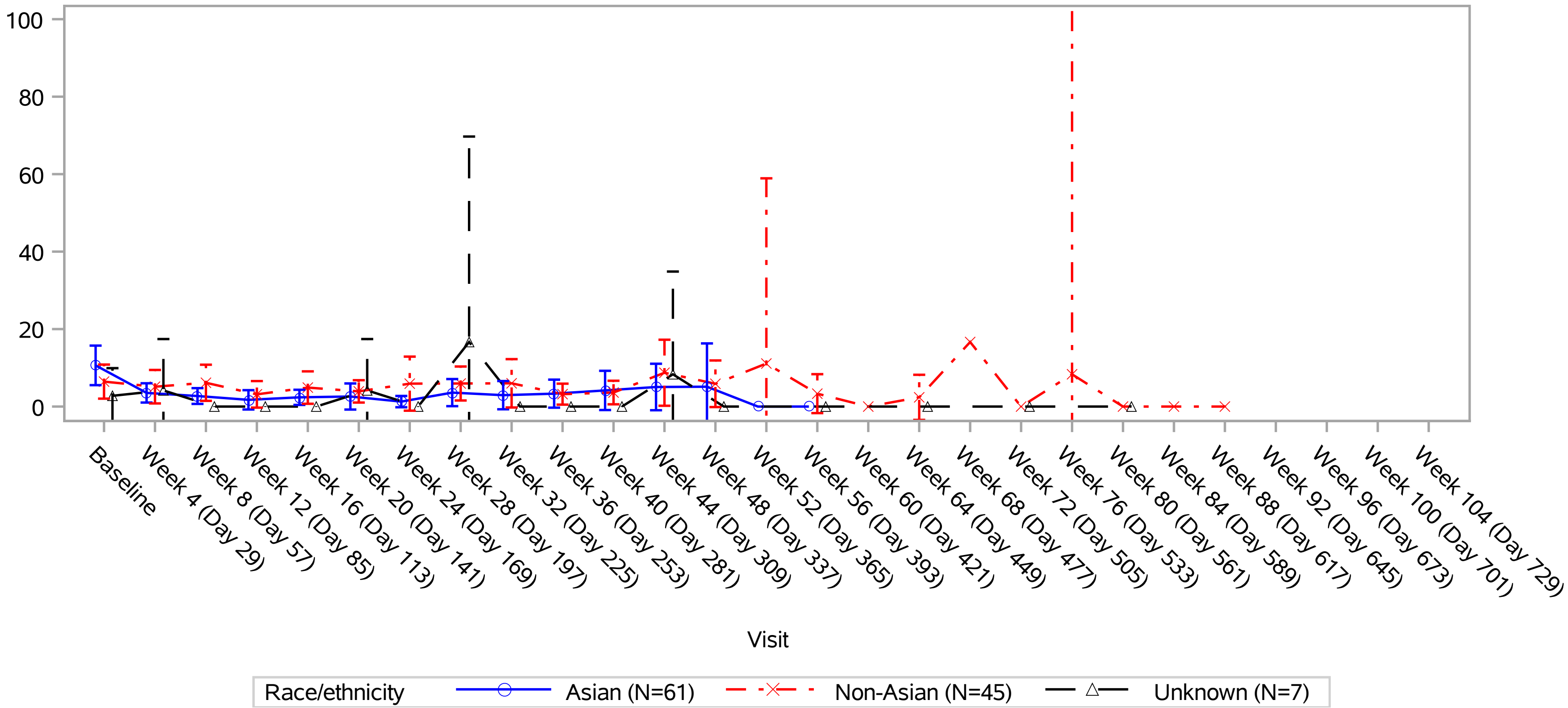
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Nausea and vomiting
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30NV_SGGEO.pdf
15OCT2021 18:48

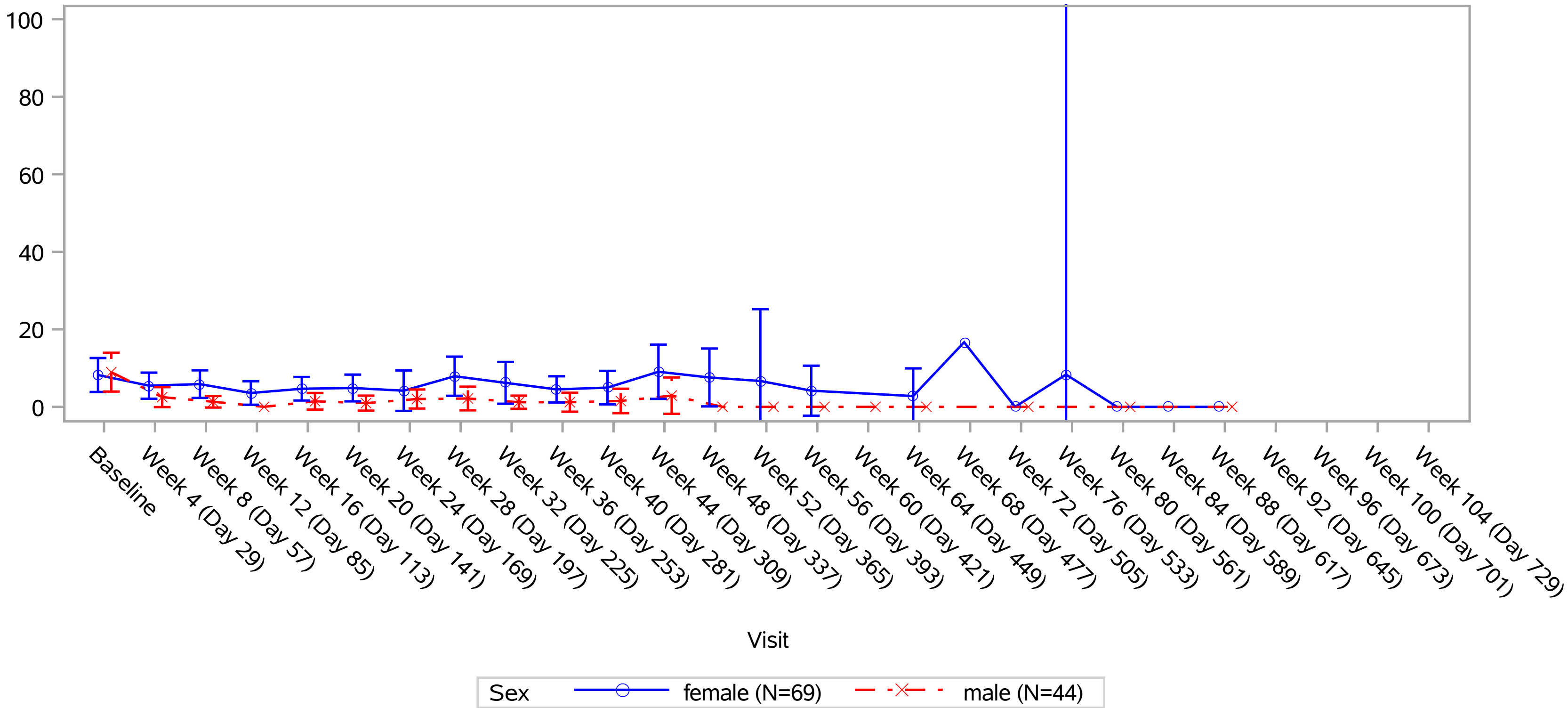
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Nausea and vomiting
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30NV_SGRE.pdf
15OCT2021 19:18

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Nausea and vomiting
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30NV_SGSEX.pdf
15OCT2021 19:49

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Pain
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=113)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	113	100.0	108	95.6	25.00	27.67	19.72	30.28
Week 4 (Day 29)	n/a	113	100.0	95	84.1	15.96	23.31	11.22	20.71
Week 8 (Day 57)	n/a	101	89.4	92	91.1	11.59	19.57	7.54	15.65
Week 12 (Day 85)	n/a	97	85.8	90	92.8	12.78	19.68	8.66	16.90
Week 16 (Day 113)	n/a	95	84.1	85	89.5	11.18	17.33	7.44	14.91
Week 20 (Day 141)	n/a	89	78.8	83	93.3	12.65	20.26	8.23	17.07
Week 24 (Day 169)	n/a	81	71.7	73	90.1	10.05	15.15	6.51	13.58
Week 28 (Day 197)	n/a	74	65.5	69	93.2	14.98	21.23	9.88	20.07
Week 32 (Day 225)	n/a	71	62.8	63	88.7	13.76	22.90	7.99	19.52
Week 36 (Day 253)	n/a	71	62.8	65	91.5	12.82	20.36	7.77	17.87
Week 40 (Day 281)	n/a	67	59.3	59	88.1	13.28	20.24	8.00	18.55
Week 44 (Day 309)	n/a	64	56.6	58	90.6	14.08	22.69	8.12	20.05
Week 48 (Day 337)	n/a	58	51.3	33	56.9	14.14	18.22	7.68	20.60
Week 52 (Day 365)	n/a	45	39.8	7	15.6	14.29	17.82	-2.19	30.76
Week 56 (Day 393)	n/a	37	32.7	12	32.4	19.44	26.43	2.65	36.24
Week 60 (Day 421)	n/a	32	28.3	1	3.1	0.00	NE	NE	NE
Week 64 (Day 449)	n/a	31	27.4	9	29.0	18.52	22.74	1.04	36.00
Week 68 (Day 477)	n/a	28	24.8	1	3.6	0.00	NE	NE	NE
Week 72 (Day 505)	n/a	28	24.8	4	14.3	0.00	0.00	NE	NE
Week 76 (Day 533)	n/a	25	22.1	2	8.0	16.67	23.57	-195.10	228.44
Week 80 (Day 561)	n/a	25	22.1	6	24.0	11.11	17.21	-6.95	29.18
Week 84 (Day 589)	n/a	18	15.9	1	5.6	16.67	NE	NE	NE
Week 88 (Day 617)	n/a	14	12.4	2	14.3	0.00	0.00	NE	NE
Week 92 (Day 645)	n/a	7	6.2	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	5.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	2.7	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	113	100.0	111	98.2	17.72	25.35	12.95	22.49
End of Study (LOCF)	n/a	113	100.0	111	98.2	18.47	24.35	13.89	23.05
Sex									
Baseline	Female	69	100.0	67	97.1	27.36	27.78	20.59	34.14
Week 4 (Day 29)	Female	69	100.0	55	79.7	16.97	23.68	10.57	23.37
Week 8 (Day 57)	Female	63	91.3	54	85.7	13.89	19.36	8.61	19.17
Week 12 (Day 85)	Female	60	87.0	56	93.3	14.29	20.46	8.81	19.76
Week 16 (Day 113)	Female	58	84.1	50	86.2	13.67	19.25	8.20	19.14
Week 20 (Day 141)	Female	53	76.8	48	90.6	15.28	23.53	8.45	22.11
Week 24 (Day 169)	Female	47	68.1	40	85.1	9.17	13.05	4.99	13.34
Week 28 (Day 197)	Female	42	60.9	38	90.5	16.67	22.26	9.35	23.98
Week 32 (Day 225)	Female	42	60.9	35	83.3	15.71	22.12	8.12	23.31
Week 36 (Day 253)	Female	42	60.9	37	88.1	11.26	16.69	5.70	16.83
Week 40 (Day 281)	Female	41	59.4	37	90.2	12.61	18.17	6.55	18.67
Week 44 (Day 309)	Female	41	59.4	35	85.4	13.81	19.59	7.08	20.54
Week 48 (Day 337)	Female	37	53.6	22	59.5	15.15	19.86	6.35	23.96
Week 52 (Day 365)	Female	29	42.0	5	17.2	16.67	20.41	-8.68	42.01
Week 56 (Day 393)	Female	24	34.8	8	33.3	14.58	18.77	-1.11	30.27
Week 60 (Day 421)	Female	22	31.9	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Female	22	31.9	6	27.3	22.22	25.09	-4.11	48.56
Week 68 (Day 477)	Female	20	29.0	1	5.0	0.00	NE	NE	NE
Week 72 (Day 505)	Female	20	29.0	2	10.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Female	18	26.1	2	11.1	16.67	23.57	-195.10	228.44
Week 80 (Day 561)	Female	18	26.1	5	27.8	13.33	18.26	-9.34	36.00
Week 84 (Day 589)	Female	12	17.4	1	8.3	16.67	NE	NE	NE
Week 88 (Day 617)	Female	9	13.0	1	11.1	0.00	NE	NE	NE
Week 92 (Day 645)	Female	6	8.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	7.2	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	2.9	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	1.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	69	100.0	68	98.6	15.93	22.93	10.38	21.48
End of Study (LOCF)	Female	69	100.0	68	98.6	17.65	23.37	11.99	23.30
Baseline	Male	44	100.0	41	93.2	21.14	27.39	12.49	29.78
Week 4 (Day 29)	Male	44	100.0	40	90.9	14.58	23.02	7.22	21.94
Week 8 (Day 57)	Male	38	86.4	38	100.0	8.33	19.66	1.87	14.80
Week 12 (Day 85)	Male	37	84.1	34	91.9	10.29	18.36	3.89	16.70
Week 16 (Day 113)	Male	37	84.1	35	94.6	7.62	13.61	2.94	12.30
Week 20 (Day 141)	Male	36	81.8	35	97.2	9.05	14.20	4.17	13.93
Week 24 (Day 169)	Male	34	77.3	33	97.1	11.11	17.51	4.90	17.32
Week 28 (Day 197)	Male	32	72.7	31	96.9	12.90	20.05	5.55	20.26
Week 32 (Day 225)	Male	29	65.9	28	96.6	11.31	24.03	1.99	20.63
Week 36 (Day 253)	Male	29	65.9	28	96.6	14.88	24.57	5.35	24.41
Week 40 (Day 281)	Male	26	59.1	22	84.6	14.39	23.74	3.87	24.92
Week 44 (Day 309)	Male	23	52.3	23	100.0	14.49	27.20	2.73	26.26
Week 48 (Day 337)	Male	21	47.7	11	52.4	12.12	15.08	1.99	22.25
Week 52 (Day 365)	Male	16	36.4	2	12.5	8.33	11.79	-97.55	114.22
Week 56 (Day 393)	Male	13	29.5	4	30.8	29.17	39.38	-33.50	91.83
Week 60 (Day 421)	Male	10	22.7	1	10.0	0.00	NE	NE	NE
Week 64 (Day 449)	Male	9	20.5	3	33.3	11.11	19.25	-36.70	58.92
Week 68 (Day 477)	Male	8	18.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	8	18.2	2	25.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Male	7	15.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	7	15.9	1	14.3	0.00	NE	NE	NE
Week 84 (Day 589)	Male	6	13.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	5	11.4	1	20.0	0.00	NE	NE	NE
Week 92 (Day 645)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	44	100.0	43	97.7	20.54	28.83	11.67	29.42
End of Study (LOCF)	Male	44	100.0	43	97.7	19.77	26.04	11.75	27.78
Age									

Baseline	< 65	78	100.0	73	93.6	26.94	29.35	20.09	33.79
Week 4 (Day 29)	< 65	78	100.0	68	87.2	15.44	23.27	9.81	21.07
Week 8 (Day 57)	< 65	73	93.6	66	90.4	12.12	18.38	7.60	16.64
Week 12 (Day 85)	< 65	71	91.0	64	90.1	12.50	16.80	8.30	16.70
Week 16 (Day 113)	< 65	69	88.5	59	85.5	11.02	17.12	6.55	15.48
Week 20 (Day 141)	< 65	65	83.3	62	95.4	13.17	21.37	7.75	18.60
Week 24 (Day 169)	< 65	59	75.6	55	93.2	11.21	15.73	6.96	15.46
Week 28 (Day 197)	< 65	55	70.5	51	92.7	15.69	22.21	9.44	21.93
Week 32 (Day 225)	< 65	53	67.9	48	90.6	11.81	22.27	5.34	18.27
Week 36 (Day 253)	< 65	53	67.9	50	94.3	9.33	16.20	4.73	13.94
Week 40 (Day 281)	< 65	52	66.7	48	92.3	12.15	20.26	6.27	18.04
Week 44 (Day 309)	< 65	52	66.7	48	92.3	12.50	21.05	6.39	18.61
Week 48 (Day 337)	< 65	47	60.3	26	55.3	12.18	16.03	5.71	18.65
Week 52 (Day 365)	< 65	36	46.2	4	11.1	4.17	8.33	-9.09	17.43
Week 56 (Day 393)	< 65	30	38.5	9	30.0	11.11	18.63	-3.21	25.43
Week 60 (Day 421)	< 65	25	32.1	1	4.0	0.00	NE	NE	NE
Week 64 (Day 449)	< 65	24	30.8	7	29.2	11.90	15.85	-2.76	26.57
Week 68 (Day 477)	< 65	22	28.2	1	4.5	0.00	NE	NE	NE
Week 72 (Day 505)	< 65	22	28.2	4	18.2	0.00	0.00	NE	NE
Week 76 (Day 533)	< 65	21	26.9	2	9.5	16.67	23.57	-195.10	228.44
Week 80 (Day 561)	< 65	21	26.9	5	23.8	6.67	14.91	-11.84	25.18
Week 84 (Day 589)	< 65	15	19.2	1	6.7	16.67	NE	NE	NE
Week 88 (Day 617)	< 65	12	15.4	2	16.7	0.00	0.00	NE	NE
Week 92 (Day 645)	< 65	6	7.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	6.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	78	100.0	76	97.4	16.45	25.02	10.73	22.16
End of Study (LOCF)	< 65	78	100.0	76	97.4	16.67	22.77	11.46	21.87
Baseline	>= 65	35	100.0	35	100.0	20.95	23.69	12.82	29.09
Week 4 (Day 29)	>= 65	35	100.0	27	77.1	17.28	23.79	7.87	26.69
Week 8 (Day 57)	>= 65	28	80.0	26	92.9	10.26	22.65	1.11	19.40
Week 12 (Day 85)	>= 65	26	74.3	26	100.0	13.46	25.83	3.03	23.89

Week 16 (Day 113)	>= 65	26	74.3	26	100.0	11.54	18.12	4.22	18.86
Week 20 (Day 141)	>= 65	24	68.6	21	87.5	11.11	16.94	3.40	18.82
Week 24 (Day 169)	>= 65	22	62.9	18	81.8	6.48	12.96	0.04	12.93
Week 28 (Day 197)	>= 65	19	54.3	18	94.7	12.96	18.57	3.73	22.20
Week 32 (Day 225)	>= 65	18	51.4	15	83.3	20.00	24.56	6.40	33.60
Week 36 (Day 253)	>= 65	18	51.4	15	83.3	24.44	28.08	8.90	39.99
Week 40 (Day 281)	>= 65	15	42.9	11	73.3	18.18	20.35	4.51	31.85
Week 44 (Day 309)	>= 65	12	34.3	10	83.3	21.67	29.45	0.60	42.73
Week 48 (Day 337)	>= 65	11	31.4	7	63.6	21.43	24.93	-1.63	44.49
Week 52 (Day 365)	>= 65	9	25.7	3	33.3	27.78	19.25	-20.03	75.59
Week 56 (Day 393)	>= 65	7	20.0	3	42.9	44.44	34.69	-41.74	130.63
Week 60 (Day 421)	>= 65	7	20.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	7	20.0	2	28.6	41.67	35.36	-275.99	359.32
Week 68 (Day 477)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	4	11.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	4	11.4	1	25.0	33.33	NE	NE	NE
Week 84 (Day 589)	>= 65	3	8.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	5.7	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	35	100.0	35	100.0	20.48	26.22	11.47	29.48
End of Study (LOCF)	>= 65	35	100.0	35	100.0	22.38	27.40	12.97	31.79
ECOG performance status									
Baseline	0	33	100.0	31	93.9	25.81	27.50	15.72	35.89
Week 4 (Day 29)	0	33	100.0	27	81.8	24.69	31.14	12.37	37.01
Week 8 (Day 57)	0	30	90.9	27	90.0	16.67	24.02	7.16	26.17
Week 12 (Day 85)	0	29	87.9	26	89.7	18.59	20.72	10.22	26.96
Week 16 (Day 113)	0	28	84.8	24	85.7	15.28	23.53	5.34	25.21
Week 20 (Day 141)	0	26	78.8	24	92.3	13.89	21.23	4.92	22.86
Week 24 (Day 169)	0	24	72.7	20	83.3	9.17	12.65	3.25	15.09
Week 28 (Day 197)	0	21	63.6	19	90.5	15.79	25.14	3.67	27.91

Week 32 (Day 225)	0	21	63.6	18	85.7	9.26	18.28	0.17	18.35
Week 36 (Day 253)	0	21	63.6	20	95.2	10.83	21.13	0.94	20.72
Week 40 (Day 281)	0	21	63.6	19	90.5	12.28	16.52	4.32	20.24
Week 44 (Day 309)	0	21	63.6	17	81.0	15.69	23.91	3.39	27.98
Week 48 (Day 337)	0	19	57.6	12	63.2	18.06	21.86	4.17	31.94
Week 52 (Day 365)	0	18	54.5	3	16.7	16.67	28.87	-55.04	88.38
Week 56 (Day 393)	0	16	48.5	5	31.3	26.67	34.56	-16.25	69.58
Week 60 (Day 421)	0	16	48.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	0	16	48.5	5	31.3	26.67	27.89	-7.96	61.30
Week 68 (Day 477)	0	14	42.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	0	14	42.4	1	7.1	0.00	NE	NE	NE
Week 76 (Day 533)	0	12	36.4	1	8.3	33.33	NE	NE	NE
Week 80 (Day 561)	0	12	36.4	1	8.3	0.00	NE	NE	NE
Week 84 (Day 589)	0	10	30.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	9	27.3	1	11.1	0.00	NE	NE	NE
Week 92 (Day 645)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	9.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	3.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	33	100.0	33	100.0	18.69	27.25	9.03	28.35
End of Study (LOCF)	0	33	100.0	33	100.0	21.72	28.71	11.54	31.90
Baseline	1	79	100.0	76	96.2	24.78	28.09	18.36	31.20
Week 4 (Day 29)	1	79	100.0	67	84.8	12.44	18.65	7.89	16.99
Week 8 (Day 57)	1	70	88.6	65	92.9	9.49	17.17	5.23	13.74
Week 12 (Day 85)	1	68	86.1	64	94.1	10.42	18.90	5.70	15.14
Week 16 (Day 113)	1	67	84.8	61	91.0	9.56	14.10	5.95	13.17
Week 20 (Day 141)	1	63	79.7	59	93.7	12.15	20.02	6.93	17.36
Week 24 (Day 169)	1	57	72.2	53	93.0	10.38	16.09	5.94	14.81
Week 28 (Day 197)	1	53	67.1	50	94.3	14.67	19.82	9.03	20.30
Week 32 (Day 225)	1	50	63.3	45	90.0	15.56	24.46	8.21	22.91
Week 36 (Day 253)	1	50	63.3	45	90.0	13.70	20.19	7.64	19.77
Week 40 (Day 281)	1	46	58.2	40	87.0	13.75	21.97	6.72	20.78

Week 44 (Day 309)	1	43	54.4	41	95.3	13.41	22.43	6.34	20.49
Week 48 (Day 337)	1	39	49.4	21	53.8	11.90	15.94	4.65	19.16
Week 52 (Day 365)	1	27	34.2	4	14.8	12.50	8.33	-0.76	25.76
Week 56 (Day 393)	1	21	26.6	7	33.3	14.29	20.25	-4.44	33.01
Week 60 (Day 421)	1	16	20.3	1	6.3	0.00	NE	NE	NE
Week 64 (Day 449)	1	15	19.0	4	26.7	8.33	9.62	-6.98	23.64
Week 68 (Day 477)	1	14	17.7	1	7.1	0.00	NE	NE	NE
Week 72 (Day 505)	1	14	17.7	3	21.4	0.00	0.00	NE	NE
Week 76 (Day 533)	1	13	16.5	1	7.7	0.00	NE	NE	NE
Week 80 (Day 561)	1	13	16.5	5	38.5	13.33	18.26	-9.34	36.00
Week 84 (Day 589)	1	8	10.1	1	12.5	16.67	NE	NE	NE
Week 88 (Day 617)	1	5	6.3	1	20.0	0.00	NE	NE	NE
Week 92 (Day 645)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	2.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	79	100.0	77	97.5	17.32	24.84	11.68	22.96
End of Study (LOCF)	1	79	100.0	77	97.5	17.10	22.45	12.00	22.20
Baseline	Missing	1	100.0	1	100.0	16.67	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	16.67	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	16.67	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	16.67	NE	NE	NE
Geographic region									
Baseline	USA	22	100.0	22	100.0	25.76	28.51	13.12	38.40
Week 4 (Day 29)	USA	22	100.0	18	81.8	25.00	29.84	10.16	39.84
Week 8 (Day 57)	USA	20	90.9	18	90.0	12.96	25.28	0.39	25.53
Week 12 (Day 85)	USA	20	90.9	19	95.0	14.91	26.00	2.38	27.44
Week 16 (Day 113)	USA	19	86.4	17	89.5	9.80	16.73	1.20	18.40
Week 20 (Day 141)	USA	19	86.4	17	89.5	17.65	24.63	4.98	30.31
Week 24 (Day 169)	USA	16	72.7	14	87.5	8.33	14.25	0.11	16.56
Week 28 (Day 197)	USA	15	68.2	12	80.0	8.33	16.67	-2.26	18.92
Week 32 (Day 225)	USA	15	68.2	13	86.7	21.79	32.90	1.91	41.68
Week 36 (Day 253)	USA	15	68.2	13	86.7	20.51	30.55	2.05	38.97
Week 40 (Day 281)	USA	14	63.6	11	78.6	21.21	30.81	0.51	41.91

Week 44 (Day 309)	USA	13	59.1	11	84.6	24.24	36.03	0.04	48.45
Week 48 (Day 337)	USA	13	59.1	10	76.9	15.00	16.57	3.14	26.86
Week 52 (Day 365)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	USA	12	54.5	6	50.0	30.56	32.35	-3.39	64.50
Week 60 (Day 421)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	11	50.0	4	36.4	12.50	15.96	-12.89	37.89
Week 68 (Day 477)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	10	45.5	1	10.0	0.00	NE	NE	NE
Week 76 (Day 533)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	10	45.5	2	20.0	33.33	0.00	NE	NE
Week 84 (Day 589)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	13.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	4.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	22	100.0	22	100.0	25.00	32.43	10.62	39.38
End of Study (LOCF)	USA	22	100.0	22	100.0	24.24	27.08	12.23	36.25
Baseline	Europe (EU)	32	100.0	29	90.6	32.18	30.19	20.70	43.67
Week 4 (Day 29)	Europe (EU)	32	100.0	25	78.1	19.33	24.85	9.08	29.59
Week 8 (Day 57)	Europe (EU)	29	90.6	25	86.2	19.33	24.38	9.27	29.40
Week 12 (Day 85)	Europe (EU)	26	81.3	24	92.3	15.28	19.61	7.00	23.56
Week 16 (Day 113)	Europe (EU)	25	78.1	20	80.0	20.83	25.29	9.00	32.67
Week 20 (Day 141)	Europe (EU)	23	71.9	22	95.7	17.42	22.70	7.36	27.49
Week 24 (Day 169)	Europe (EU)	21	65.6	20	95.2	15.00	17.85	6.64	23.36
Week 28 (Day 197)	Europe (EU)	20	62.5	20	100.0	23.33	27.78	10.33	36.34
Week 32 (Day 225)	Europe (EU)	18	56.3	16	88.9	14.58	21.84	2.95	26.22
Week 36 (Day 253)	Europe (EU)	18	56.3	17	94.4	10.78	15.52	2.80	18.77
Week 40 (Day 281)	Europe (EU)	17	53.1	16	94.1	10.42	17.08	1.32	19.52
Week 44 (Day 309)	Europe (EU)	17	53.1	14	82.4	15.48	21.15	3.27	27.69

Week 48 (Day 337)	Europe (EU)	14	43.8	10	71.4	18.33	18.34	5.21	31.45
Week 52 (Day 365)	Europe (EU)	13	40.6	3	23.1	16.67	28.87	-55.04	88.38
Week 56 (Day 393)	Europe (EU)	11	34.4	5	45.5	10.00	14.91	-8.51	28.51
Week 60 (Day 421)	Europe (EU)	11	34.4	1	9.1	0.00	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	11	34.4	5	45.5	23.33	27.89	-11.30	57.96
Week 68 (Day 477)	Europe (EU)	10	31.3	1	10.0	0.00	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	10	31.3	3	30.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Europe (EU)	8	25.0	2	25.0	16.67	23.57	-195.10	228.44
Week 80 (Day 561)	Europe (EU)	8	25.0	4	50.0	0.00	0.00	NE	NE
Week 84 (Day 589)	Europe (EU)	6	18.8	1	16.7	16.67	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	9.4	2	66.7	0.00	0.00	NE	NE
Cycle 12 (LOCF)	Europe (EU)	32	100.0	31	96.9	19.35	25.85	9.87	28.84
End of Study (LOCF)	Europe (EU)	32	100.0	31	96.9	20.97	26.86	11.11	30.82
Baseline	Asia (AS)	59	100.0	57	96.6	21.05	25.69	14.24	27.87
Week 4 (Day 29)	Asia (AS)	59	100.0	52	88.1	11.22	18.88	5.96	16.47
Week 8 (Day 57)	Asia (AS)	52	88.1	49	94.2	7.14	12.27	3.62	10.67
Week 12 (Day 85)	Asia (AS)	51	86.4	47	92.2	10.64	16.82	5.70	15.58
Week 16 (Day 113)	Asia (AS)	51	86.4	48	94.1	7.64	11.38	4.33	10.94
Week 20 (Day 141)	Asia (AS)	47	79.7	44	93.6	8.33	16.27	3.39	13.28
Week 24 (Day 169)	Asia (AS)	44	74.6	39	88.6	8.12	13.72	3.67	12.57
Week 28 (Day 197)	Asia (AS)	39	66.1	37	94.9	12.61	17.31	6.84	18.38
Week 32 (Day 225)	Asia (AS)	38	64.4	34	89.5	10.29	18.36	3.89	16.70
Week 36 (Day 253)	Asia (AS)	38	64.4	35	92.1	10.95	17.59	4.91	17.00
Week 40 (Day 281)	Asia (AS)	36	61.0	32	88.9	11.98	17.06	5.83	18.13
Week 44 (Day 309)	Asia (AS)	34	57.6	33	97.1	10.10	16.64	4.20	16.00
Week 48 (Day 337)	Asia (AS)	31	52.5	13	41.9	10.26	19.88	-1.76	22.27
Week 52 (Day 365)	Asia (AS)	20	33.9	4	20.0	12.50	8.33	-0.76	25.76
Week 56 (Day 393)	Asia (AS)	14	23.7	1	7.1	0.00	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	10.2	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	8.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	3.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	59	100.0	58	98.3	14.08	21.58	8.41	19.76
End of Study (LOCF)	Asia (AS)	59	100.0	58	98.3	14.94	21.56	9.27	20.61
Race/ethnicity									
Baseline	Asian	61	100.0	58	95.1	21.84	26.16	14.96	28.72
Week 4 (Day 29)	Asian	61	100.0	52	85.2	11.22	18.88	5.96	16.47
Week 8 (Day 57)	Asian	53	86.9	49	92.5	7.14	12.27	3.62	10.67
Week 12 (Day 85)	Asian	52	85.2	48	92.3	11.11	16.96	6.19	16.04
Week 16 (Day 113)	Asian	52	85.2	49	94.2	8.16	11.85	4.76	11.57
Week 20 (Day 141)	Asian	48	78.7	45	93.8	9.63	18.29	4.14	15.12
Week 24 (Day 169)	Asian	44	72.1	39	88.6	8.12	13.72	3.67	12.57
Week 28 (Day 197)	Asian	39	63.9	37	94.9	12.61	17.31	6.84	18.38
Week 32 (Day 225)	Asian	38	62.3	34	89.5	10.29	18.36	3.89	16.70
Week 36 (Day 253)	Asian	38	62.3	35	92.1	10.95	17.59	4.91	17.00
Week 40 (Day 281)	Asian	36	59.0	32	88.9	11.98	17.06	5.83	18.13
Week 44 (Day 309)	Asian	34	55.7	33	97.1	10.10	16.64	4.20	16.00
Week 48 (Day 337)	Asian	31	50.8	13	41.9	10.26	19.88	-1.76	22.27
Week 52 (Day 365)	Asian	20	32.8	4	20.0	12.50	8.33	-0.76	25.76
Week 56 (Day 393)	Asian	14	23.0	1	7.1	0.00	NE	NE	NE
Week 60 (Day 421)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	9.8	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	8.2	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	3.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	61	100.0	59	96.7	14.97	22.47	9.12	20.83
End of Study (LOCF)	Asian	61	100.0	59	96.7	15.82	22.41	9.98	21.66
Baseline	Non-Asian	45	100.0	44	97.8	28.41	27.51	20.05	36.77
Week 4 (Day 29)	Non-Asian	45	100.0	39	86.7	18.38	22.55	11.06	25.69
Week 8 (Day 57)	Non-Asian	42	93.3	38	90.5	14.04	21.76	6.88	21.19
Week 12 (Day 85)	Non-Asian	39	86.7	37	94.9	13.51	21.81	6.24	20.79
Week 16 (Day 113)	Non-Asian	37	82.2	34	91.9	16.18	22.65	8.27	24.08
Week 20 (Day 141)	Non-Asian	36	80.0	34	94.4	16.67	22.84	8.70	24.64
Week 24 (Day 169)	Non-Asian	32	71.1	31	96.9	12.37	17.20	6.06	18.67
Week 28 (Day 197)	Non-Asian	30	66.7	28	93.3	16.07	22.90	7.19	24.95
Week 32 (Day 225)	Non-Asian	28	62.2	25	89.3	19.33	28.74	7.47	31.20
Week 36 (Day 253)	Non-Asian	28	62.2	26	92.9	16.03	24.26	6.23	25.82
Week 40 (Day 281)	Non-Asian	26	57.8	23	88.5	15.94	24.86	5.19	26.69
Week 44 (Day 309)	Non-Asian	25	55.6	21	84.0	22.22	29.97	8.58	35.86
Week 48 (Day 337)	Non-Asian	23	51.1	17	73.9	19.61	16.91	10.91	28.30
Week 52 (Day 365)	Non-Asian	21	46.7	3	14.3	16.67	28.87	-55.04	88.38
Week 56 (Day 393)	Non-Asian	19	42.2	10	52.6	23.33	27.44	3.70	42.96
Week 60 (Day 421)	Non-Asian	19	42.2	1	5.3	0.00	NE	NE	NE
Week 64 (Day 449)	Non-Asian	18	40.0	7	38.9	21.43	24.93	-1.63	44.49
Week 68 (Day 477)	Non-Asian	17	37.8	1	5.9	0.00	NE	NE	NE
Week 72 (Day 505)	Non-Asian	17	37.8	3	17.6	0.00	0.00	NE	NE
Week 76 (Day 533)	Non-Asian	15	33.3	2	13.3	16.67	23.57	-195.10	228.44
Week 80 (Day 561)	Non-Asian	15	33.3	5	33.3	13.33	18.26	-9.34	36.00
Week 84 (Day 589)	Non-Asian	10	22.2	1	10.0	16.67	NE	NE	NE
Week 88 (Day 617)	Non-Asian	7	15.6	2	28.6	0.00	0.00	NE	NE
Week 92 (Day 645)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	45	100.0	45	100.0	21.85	28.83	13.19	30.51

End of Study (LOCF)	Non-Asian	45	100.0	45	100.0	22.59	26.63	14.59	30.59
Baseline	Unknown	7	100.0	6	85.7	30.56	42.71	-14.26	75.38
Week 4 (Day 29)	Unknown	7	100.0	4	57.1	54.17	45.90	-18.86	127.20
Week 8 (Day 57)	Unknown	6	85.7	5	83.3	36.67	38.01	-10.52	83.86
Week 12 (Day 85)	Unknown	6	85.7	5	83.3	23.33	27.89	-11.30	57.96
Week 16 (Day 113)	Unknown	6	85.7	2	33.3	0.00	0.00	NE	NE
Week 20 (Day 141)	Unknown	5	71.4	4	80.0	12.50	15.96	-12.89	37.89
Week 24 (Day 169)	Unknown	5	71.4	3	60.0	11.11	9.62	-12.79	35.01
Week 28 (Day 197)	Unknown	5	71.4	4	80.0	29.17	39.38	-33.50	91.83
Week 32 (Day 225)	Unknown	5	71.4	4	80.0	8.33	9.62	-6.98	23.64
Week 36 (Day 253)	Unknown	5	71.4	4	80.0	8.33	16.67	-18.19	34.85
Week 40 (Day 281)	Unknown	5	71.4	4	80.0	8.33	16.67	-18.19	34.85
Week 44 (Day 309)	Unknown	5	71.4	4	80.0	4.17	8.33	-9.09	17.43
Week 48 (Day 337)	Unknown	4	57.1	3	75.0	0.00	0.00	NE	NE
Week 52 (Day 365)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	4	57.1	1	25.0	0.00	NE	NE	NE
Week 60 (Day 421)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	4	57.1	2	50.0	8.33	11.79	-97.55	114.22
Week 68 (Day 477)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	3	42.9	1	33.3	0.00	NE	NE	NE
Week 76 (Day 533)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	3	42.9	1	33.3	0.00	NE	NE	NE
Week 84 (Day 589)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	14.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	7	100.0	7	100.0	14.29	24.40	-8.28	36.85
End of Study (LOCF)	Unknown	7	100.0	7	100.0	14.29	24.40	-8.28	36.85
Number of prior antineoplastic systemic therapy lines I									
Baseline	1	60	100.0	57	95.0	26.02	29.88	18.09	33.95

Week 4 (Day 29)	1		60	100.0	50	83.3	15.00	22.14	8.71	21.29
Week 8 (Day 57)	1		54	90.0	49	90.7	12.59	19.99	6.84	18.33
Week 12 (Day 85)	1		52	86.7	48	92.3	11.81	19.13	6.25	17.36
Week 16 (Day 113)	1		51	85.0	46	90.2	13.04	20.76	6.88	19.21
Week 20 (Day 141)	1		48	80.0	43	89.6	13.18	20.10	6.99	19.37
Week 24 (Day 169)	1		43	71.7	39	90.7	11.54	16.73	6.11	16.96
Week 28 (Day 197)	1		38	63.3	34	89.5	17.16	24.09	8.75	25.56
Week 32 (Day 225)	1		35	58.3	29	82.9	16.67	26.73	6.50	26.83
Week 36 (Day 253)	1		35	58.3	31	88.6	13.44	19.92	6.14	20.75
Week 40 (Day 281)	1		32	53.3	27	84.4	15.43	23.54	6.12	24.74
Week 44 (Day 309)	1		32	53.3	27	84.4	17.28	24.67	7.53	27.04
Week 48 (Day 337)	1		27	45.0	16	59.3	15.63	16.63	6.76	24.49
Week 52 (Day 365)	1		23	38.3	5	21.7	16.67	20.41	-8.68	42.01
Week 56 (Day 393)	1		16	26.7	4	25.0	20.83	15.96	-4.56	46.22
Week 60 (Day 421)	1		14	23.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1		13	21.7	4	30.8	29.17	28.46	-16.13	74.46
Week 68 (Day 477)	1		12	20.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1		12	20.0	1	8.3	0.00	NE	NE	NE
Week 76 (Day 533)	1		11	18.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1		11	18.3	2	18.2	16.67	23.57	-195.10	228.44
Week 84 (Day 589)	1		9	15.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	1		8	13.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	1		5	8.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1		5	8.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	1		3	5.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	1		1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1		60	100.0	58	96.7	19.25	26.27	12.35	26.16
End of Study (LOCF)	1		60	100.0	58	96.7	18.97	24.27	12.58	25.35
Baseline	>= 2		53	100.0	51	96.2	23.86	25.22	16.76	30.95
Week 4 (Day 29)	>= 2		53	100.0	45	84.9	17.04	24.74	9.60	24.47
Week 8 (Day 57)	>= 2		47	88.7	43	91.5	10.47	19.25	4.54	16.39
Week 12 (Day 85)	>= 2		45	84.9	42	93.3	13.89	20.47	7.51	20.27
Week 16 (Day 113)	>= 2		44	83.0	39	88.6	8.97	12.00	5.09	12.86

Week 20 (Day 141)	>= 2	41	77.4	40	97.6	12.08	20.67	5.47	18.69
Week 24 (Day 169)	>= 2	38	71.7	34	89.5	8.33	13.14	3.75	12.92
Week 28 (Day 197)	>= 2	36	67.9	35	97.2	12.86	18.12	6.63	19.08
Week 32 (Day 225)	>= 2	36	67.9	34	94.4	11.27	19.12	4.60	17.95
Week 36 (Day 253)	>= 2	36	67.9	34	94.4	12.25	21.05	4.91	19.60
Week 40 (Day 281)	>= 2	35	66.0	32	91.4	11.46	17.16	5.27	17.65
Week 44 (Day 309)	>= 2	32	60.4	31	96.9	11.29	20.81	3.66	18.92
Week 48 (Day 337)	>= 2	31	58.5	17	54.8	12.75	20.01	2.46	23.03
Week 52 (Day 365)	>= 2	22	41.5	2	9.1	8.33	11.79	-97.55	114.22
Week 56 (Day 393)	>= 2	21	39.6	8	38.1	18.75	31.42	-7.52	45.02
Week 60 (Day 421)	>= 2	18	34.0	1	5.6	0.00	NE	NE	NE
Week 64 (Day 449)	>= 2	18	34.0	5	27.8	10.00	14.91	-8.51	28.51
Week 68 (Day 477)	>= 2	16	30.2	1	6.3	0.00	NE	NE	NE
Week 72 (Day 505)	>= 2	16	30.2	3	18.8	0.00	0.00	NE	NE
Week 76 (Day 533)	>= 2	14	26.4	2	14.3	16.67	23.57	-195.10	228.44
Week 80 (Day 561)	>= 2	14	26.4	4	28.6	8.33	16.67	-18.19	34.85
Week 84 (Day 589)	>= 2	9	17.0	1	11.1	16.67	NE	NE	NE
Week 88 (Day 617)	>= 2	6	11.3	2	33.3	0.00	0.00	NE	NE
Week 92 (Day 645)	>= 2	2	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 2	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 2	53	100.0	53	100.0	16.04	24.45	9.30	22.78
End of Study (LOCF)	>= 2	53	100.0	53	100.0	17.92	24.64	11.13	24.72

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TP_QSC30PA_SG.xls
27OCT2021 7:28

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Pain
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	41	38.0	29.4	47.4
	Cycle 12 (LOCF)	n/a	108	95.6	17	15.7	10.1	23.8
	End of Study (LOCF)	n/a	108	95.6	20	18.5	12.3	26.9
Sex	All visits	Female	67	59.3	22	32.8	22.8	44.7
		Male	41	36.3	19	46.3	32.1	61.3
	Cycle 12 (LOCF)	Female	67	59.3	6	9.0	4.2	18.2
		Male	41	36.3	11	26.8	15.7	41.9
	End of Study (LOCF)	Female	67	59.3	10	14.9	8.3	25.3
		Male	41	36.3	10	24.4	13.8	39.3
Age	All visits	< 65	73	64.6	26	35.6	25.6	47.1
		>= 65	35	31.0	15	42.9	28.0	59.1
	Cycle 12 (LOCF)	< 65	73	64.6	9	12.3	6.6	21.8
		>= 65	35	31.0	8	22.9	12.1	39.0
	End of Study (LOCF)	< 65	73	64.6	11	15.1	8.6	25.0
		>= 65	35	31.0	9	25.7	14.2	42.1
ECOG performance status	All visits	0	31	27.4	12	38.7	23.7	56.2
		1	76	67.3	29	38.2	28.1	49.4
		Missing	1	0.9	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	31	27.4	5	16.1	7.1	32.6
		1	76	67.3	12	15.8	9.3	25.6
		Missing	1	0.9	0	0.0	0.0	79.3
	End of Study (LOCF)	0	31	27.4	7	22.6	11.4	39.8
		1	76	67.3	13	17.1	10.3	27.1
		Missing	1	0.9	0	0.0	0.0	79.3
Geographic region	All visits	USA	22	19.5	10	45.5	26.9	65.3
		Europe (EU)	29	25.7	9	31.0	17.3	49.2
		Asia (AS)	57	50.4	22	38.6	27.1	51.6
	Cycle 12 (LOCF)	USA	22	19.5	4	18.2	7.3	38.5
		Europe (EU)	29	25.7	3	10.3	3.6	26.4
		Asia (AS)	57	50.4	10	17.5	9.8	29.4
	End of Study (LOCF)	USA	22	19.5	6	27.3	13.2	48.2
		Europe (EU)	29	25.7	4	13.8	5.5	30.6
		Asia (AS)	57	50.4	10	17.5	9.8	29.4
Race/ethnicity	All visits	Asian	58	51.3	22	37.9	26.6	50.8
		Non-Asian	44	38.9	18	40.9	27.7	55.6
		Unknown	6	5.3	1	16.7	3.0	56.4
	Cycle 12 (LOCF)	Asian	58	51.3	10	17.2	9.6	28.9

		Non-Asian	44	38.9	7	15.9	7.9	29.4
		Unknown	6	5.3	0	0.0	0.0	39.0
	End of Study (LOCF)	Asian	58	51.3	10	17.2	9.6	28.9
		Non-Asian	44	38.9	10	22.7	12.8	37.0
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	22	38.6	27.1	51.6
		>= 2	51	45.1	19	37.3	25.3	51.0
	Cycle 12 (LOCF)	1	57	50.4	9	15.8	8.5	27.4
		>= 2	51	45.1	8	15.7	8.2	28.0
	End of Study (LOCF)	1	57	50.4	9	15.8	8.5	27.4
		>= 2	51	45.1	11	21.6	12.5	34.6

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30PA_W10_SG.xls
15OCT2021 13:36

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Pain
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

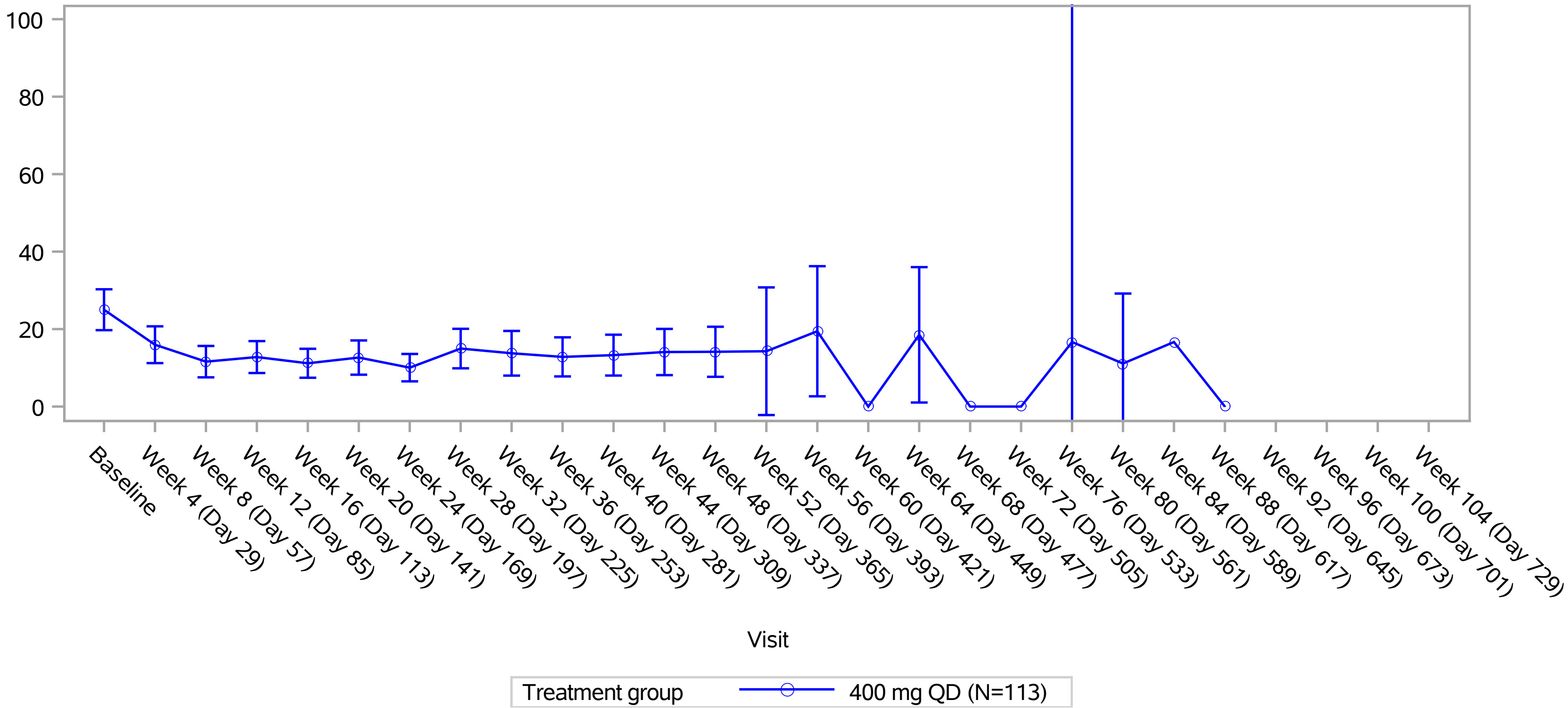
			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	41	38.0	29.4	47.4
	Cycle 12 (LOCF)	n/a	108	95.6	17	15.7	10.1	23.8
	End of Study (LOCF)	n/a	108	95.6	20	18.5	12.3	26.9
Sex	All visits	Female	67	59.3	22	32.8	22.8	44.7
		Male	41	36.3	19	46.3	32.1	61.3
	Cycle 12 (LOCF)	Female	67	59.3	6	9.0	4.2	18.2
		Male	41	36.3	11	26.8	15.7	41.9
	End of Study (LOCF)	Female	67	59.3	10	14.9	8.3	25.3
		Male	41	36.3	10	24.4	13.8	39.3
Age	All visits	< 65	73	64.6	26	35.6	25.6	47.1
		>= 65	35	31.0	15	42.9	28.0	59.1
	Cycle 12 (LOCF)	< 65	73	64.6	9	12.3	6.6	21.8
		>= 65	35	31.0	8	22.9	12.1	39.0
	End of Study (LOCF)	< 65	73	64.6	11	15.1	8.6	25.0
		>= 65	35	31.0	9	25.7	14.2	42.1
ECOG performance status	All visits	0	31	27.4	12	38.7	23.7	56.2
		1	76	67.3	29	38.2	28.1	49.4
		Missing	1	0.9	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	31	27.4	5	16.1	7.1	32.6
		1	76	67.3	12	15.8	9.3	25.6
		Missing	1	0.9	0	0.0	0.0	79.3
	End of Study (LOCF)	0	31	27.4	7	22.6	11.4	39.8
		1	76	67.3	13	17.1	10.3	27.1
		Missing	1	0.9	0	0.0	0.0	79.3
Geographic region	All visits	USA	22	19.5	10	45.5	26.9	65.3
		Europe (EU)	29	25.7	9	31.0	17.3	49.2
		Asia (AS)	57	50.4	22	38.6	27.1	51.6
	Cycle 12 (LOCF)	USA	22	19.5	4	18.2	7.3	38.5
		Europe (EU)	29	25.7	3	10.3	3.6	26.4
		Asia (AS)	57	50.4	10	17.5	9.8	29.4
	End of Study (LOCF)	USA	22	19.5	6	27.3	13.2	48.2
		Europe (EU)	29	25.7	4	13.8	5.5	30.6
		Asia (AS)	57	50.4	10	17.5	9.8	29.4
Race/ethnicity	All visits	Asian	58	51.3	22	37.9	26.6	50.8
		Non-Asian	44	38.9	18	40.9	27.7	55.6
		Unknown	6	5.3	1	16.7	3.0	56.4
	Cycle 12 (LOCF)	Asian	58	51.3	10	17.2	9.6	28.9

		Non-Asian	44	38.9	7	15.9	7.9	29.4
		Unknown	6	5.3	0	0.0	0.0	39.0
	End of Study (LOCF)	Asian	58	51.3	10	17.2	9.6	28.9
		Non-Asian	44	38.9	10	22.7	12.8	37.0
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	22	38.6	27.1	51.6
		>= 2	51	45.1	19	37.3	25.3	51.0
	Cycle 12 (LOCF)	1	57	50.4	9	15.8	8.5	27.4
		>= 2	51	45.1	8	15.7	8.2	28.0
	End of Study (LOCF)	1	57	50.4	9	15.8	8.5	27.4
		>= 2	51	45.1	11	21.6	12.5	34.6

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30PA_W15_SG.xls
15OCT2021 13:25

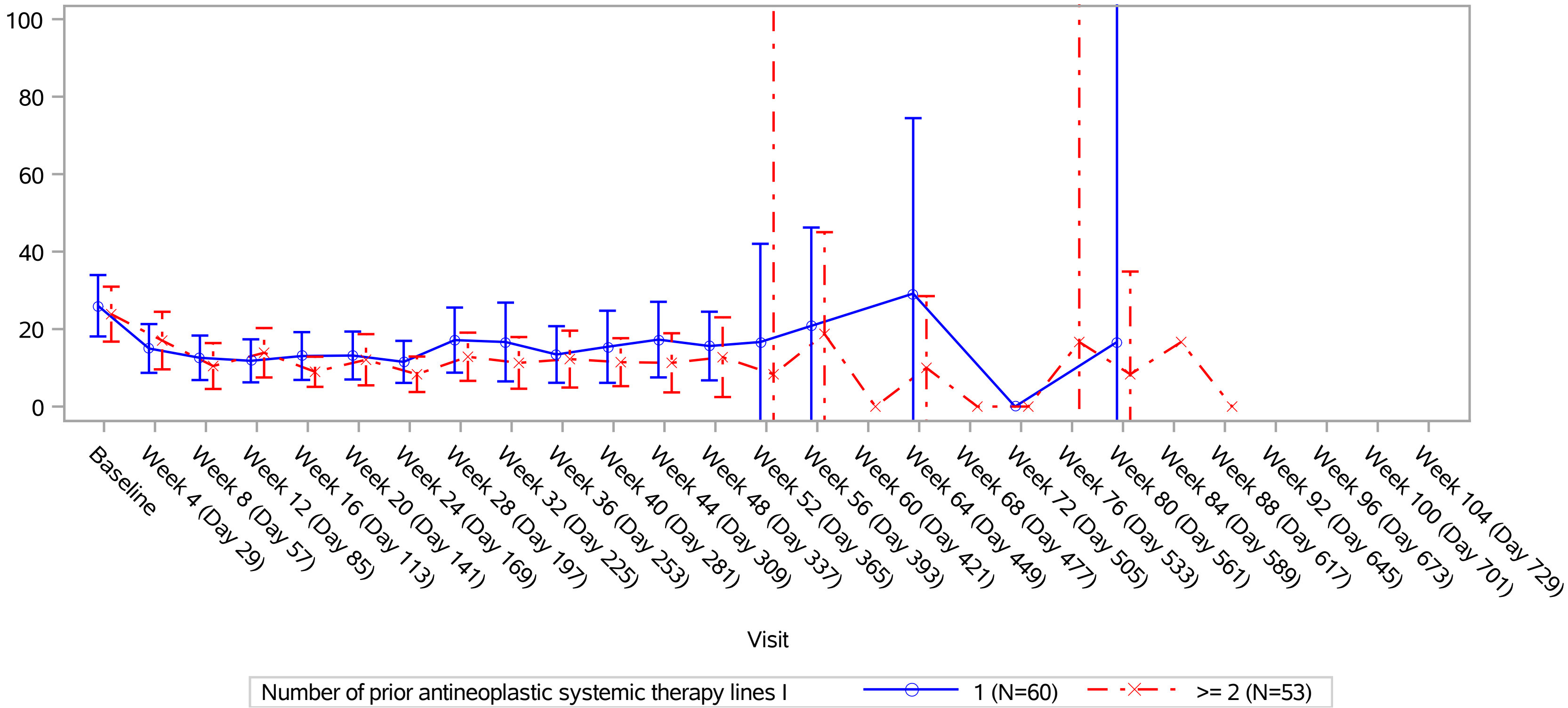
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Pain
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30PA.pdf
15OCT2021 17:18

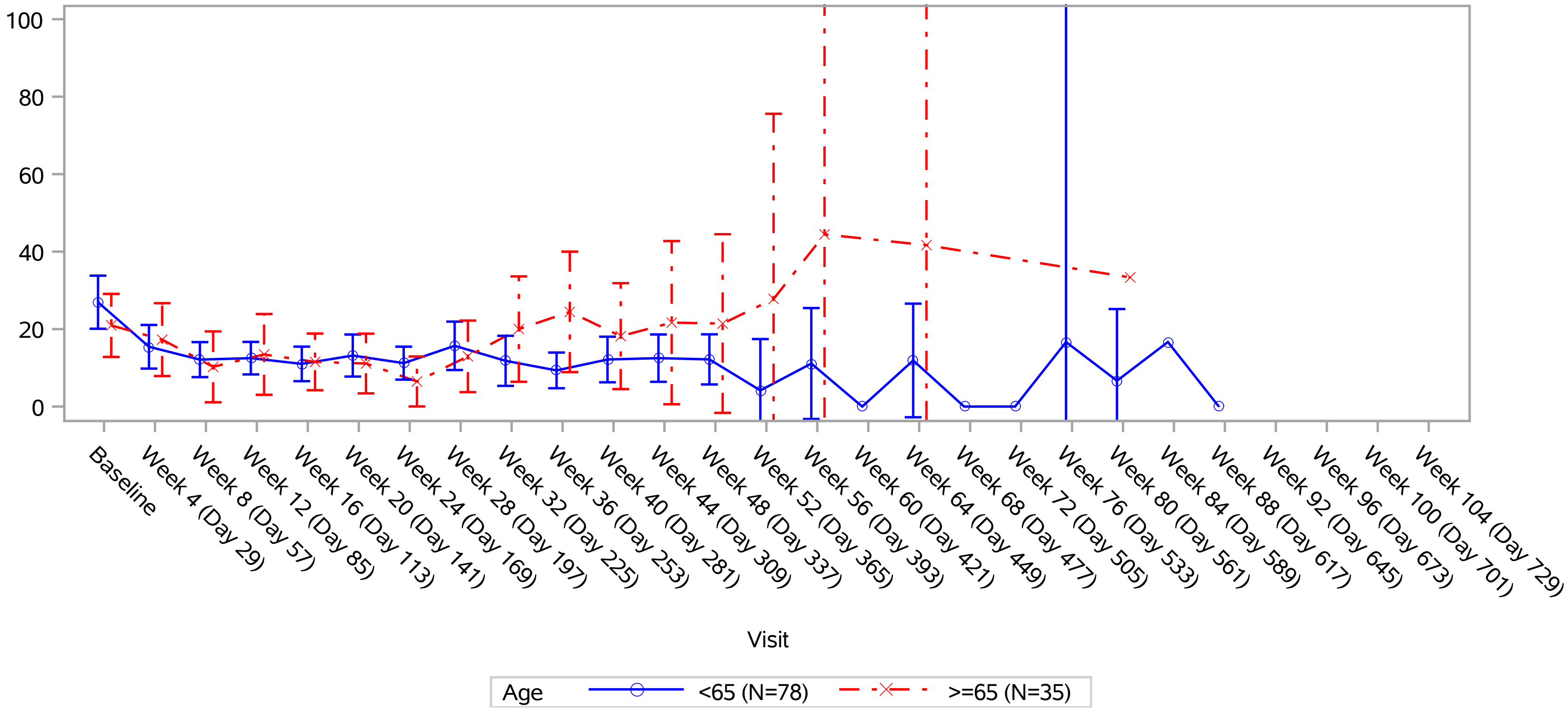
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Pain
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30PA_PRTHL1.pdf
15OCT2021 20:09

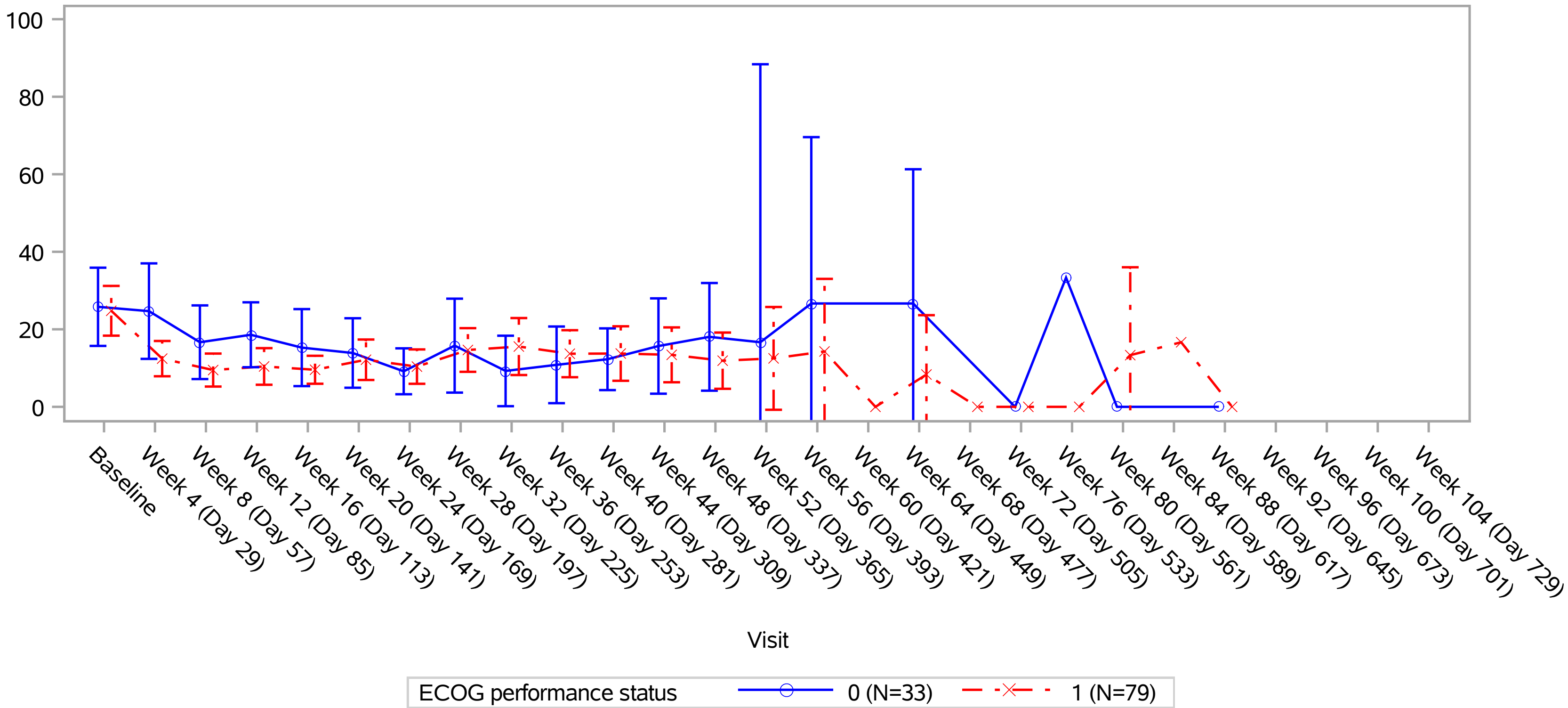
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Pain
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30PA_SGAGE65.pdf
15OCT2021 17:47

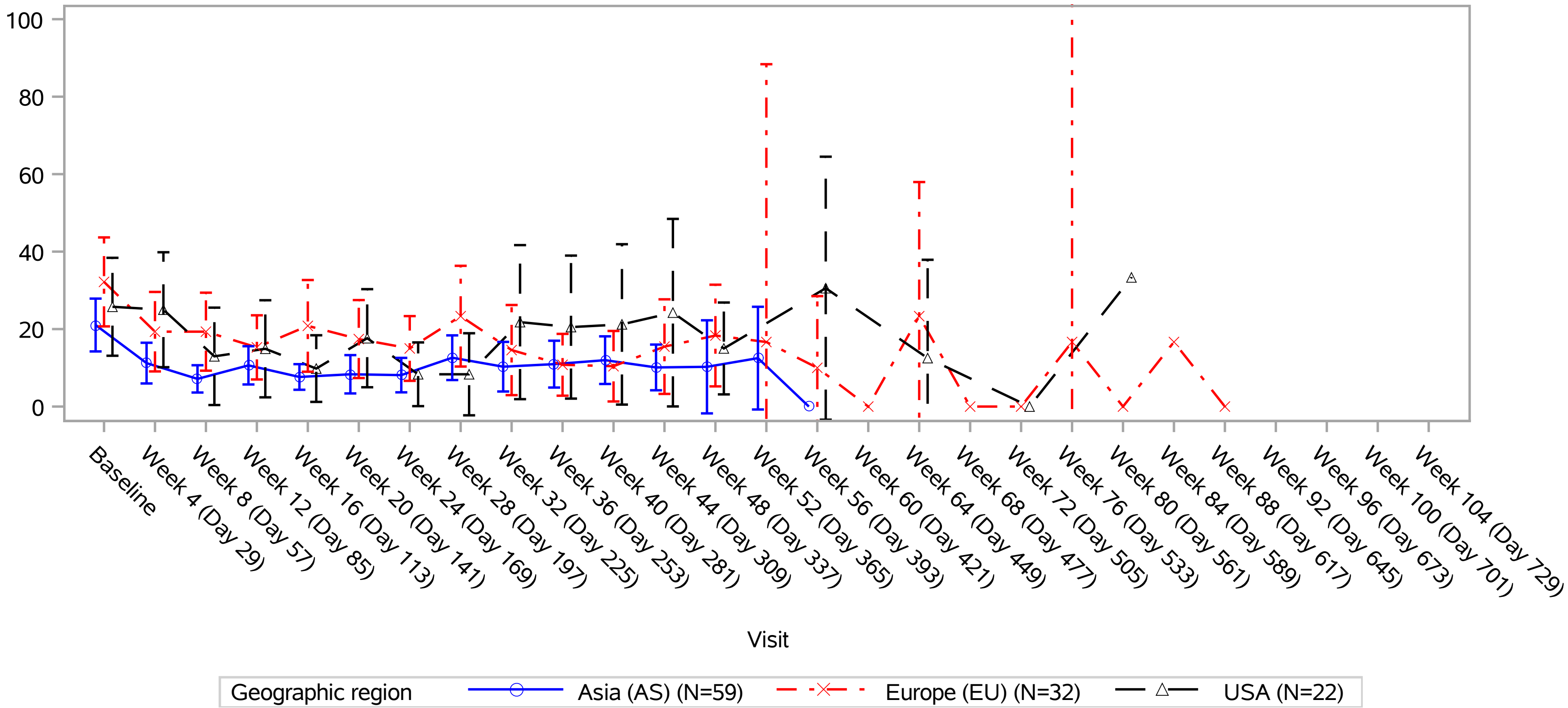
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Pain
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30PA_SGECOG.pdf
15OCT2021 18:17

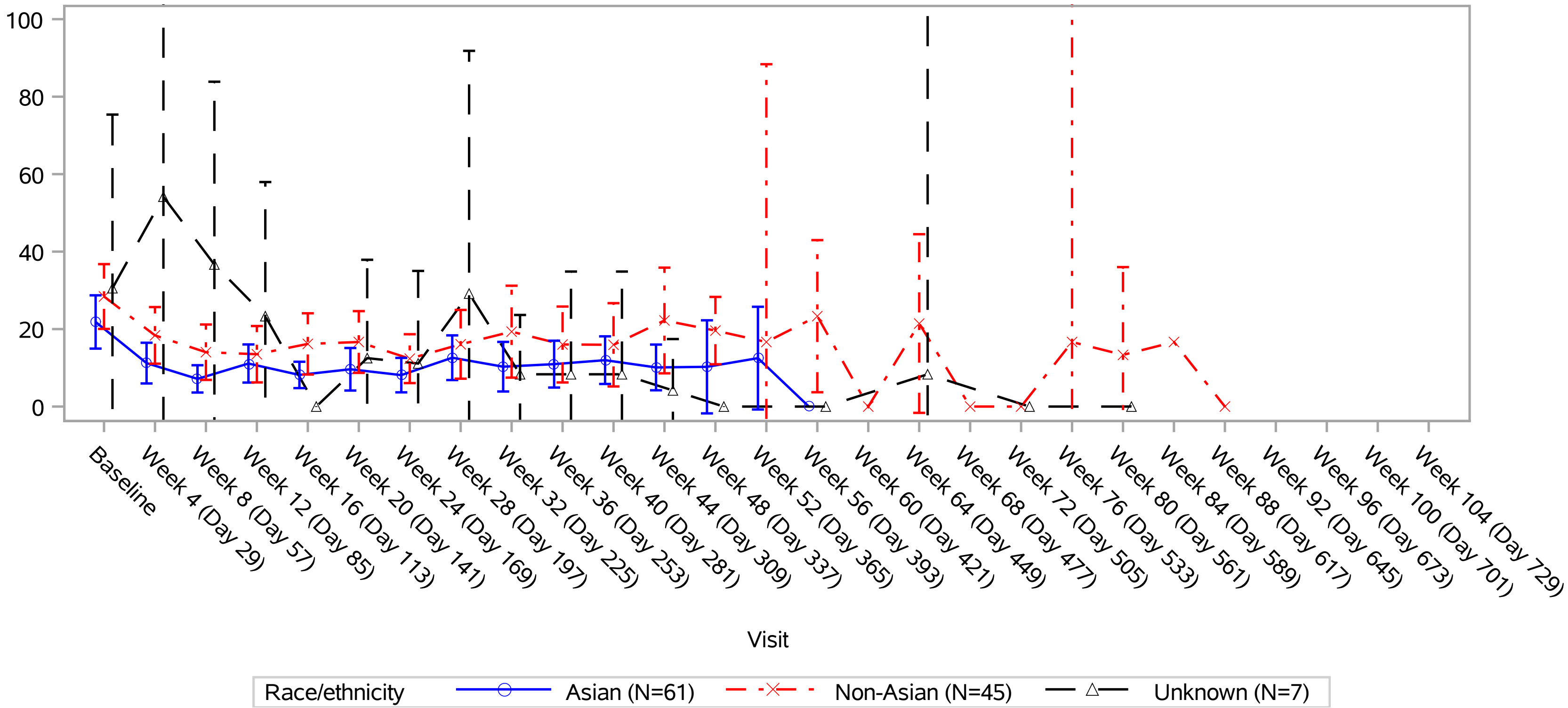
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Pain
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30PA_SGGEO.pdf
15OCT2021 18:48

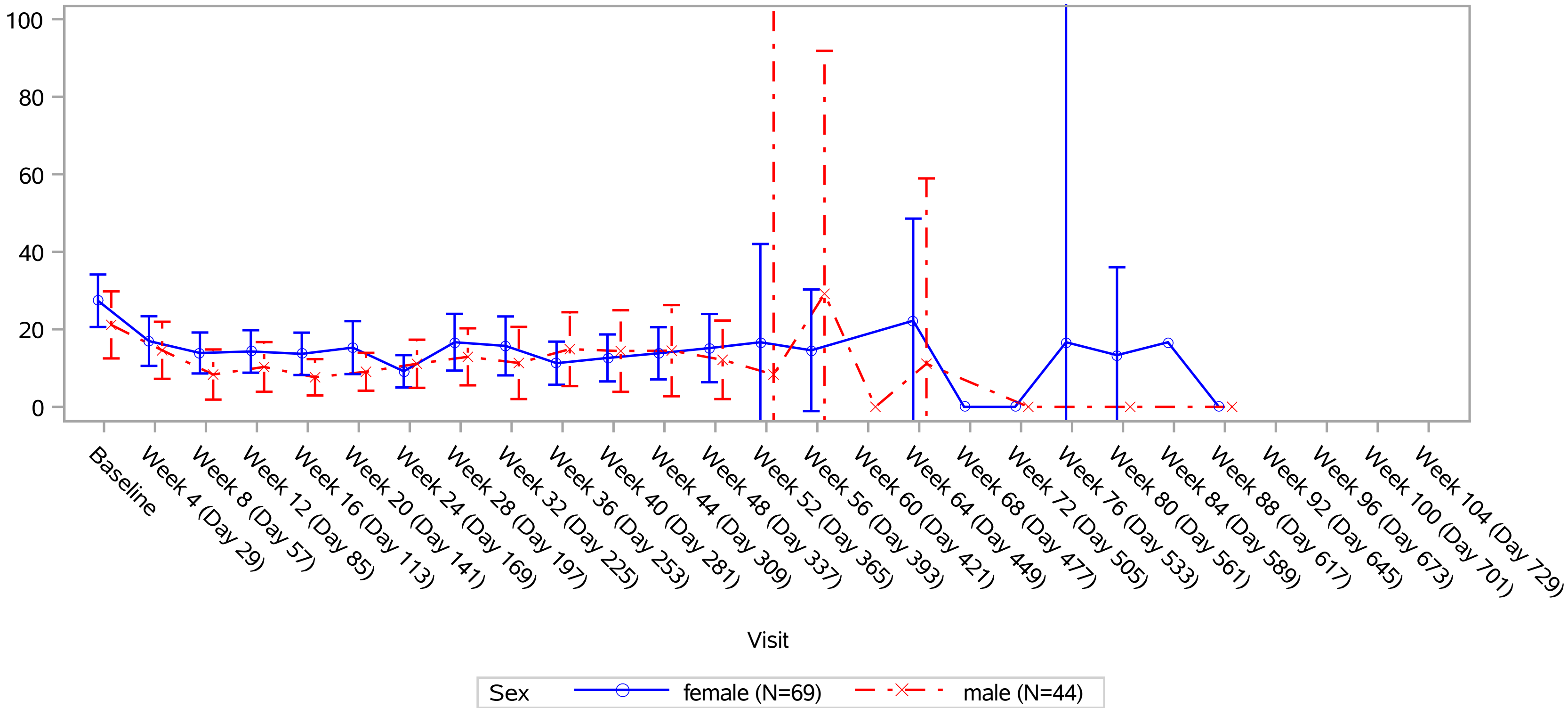
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Pain
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30PA_SGRE.pdf
15OCT2021 19:19

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Pain
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30PA_SGSEX.pdf
15OCT2021 19:49

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Physical functioning
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=113)							
		Patients				Statistics			
Name Visit	Level	in study¹	%	with value¹	%	mean²	SD	CI LL	CI UL
All									
Baseline	n/a	113	100.0	108	95.6	76.79	22.22	72.55	81.03
Week 4 (Day 29)	n/a	113	100.0	95	84.1	84.70	18.22	80.99	88.41
Week 8 (Day 57)	n/a	101	89.4	92	91.1	83.26	16.67	79.81	86.71
Week 12 (Day 85)	n/a	97	85.8	90	92.8	85.19	16.57	81.72	88.65
Week 16 (Day 113)	n/a	95	84.1	85	89.5	82.67	17.55	78.88	86.45
Week 20 (Day 141)	n/a	89	78.8	83	93.3	82.65	20.11	78.26	87.04
Week 24 (Day 169)	n/a	81	71.7	73	90.1	85.21	15.72	81.54	88.87
Week 28 (Day 197)	n/a	74	65.5	69	93.2	86.06	16.74	82.04	90.09
Week 32 (Day 225)	n/a	71	62.8	63	88.7	84.44	19.42	79.55	89.33
Week 36 (Day 253)	n/a	71	62.8	65	91.5	86.87	15.85	82.94	90.80
Week 40 (Day 281)	n/a	67	59.3	59	88.1	87.77	17.68	83.16	92.38
Week 44 (Day 309)	n/a	64	56.6	58	90.6	84.94	18.88	79.98	89.91
Week 48 (Day 337)	n/a	58	51.3	33	56.9	84.85	19.02	78.10	91.59
Week 52 (Day 365)	n/a	45	39.8	7	15.6	82.86	10.08	73.54	92.18
Week 56 (Day 393)	n/a	37	32.7	12	32.4	88.33	10.30	81.79	94.88
Week 60 (Day 421)	n/a	32	28.3	1	3.1	86.67	NE	NE	NE
Week 64 (Day 449)	n/a	31	27.4	9	29.0	90.37	10.06	82.64	98.10
Week 68 (Day 477)	n/a	28	24.8	1	3.6	80.00	NE	NE	NE
Week 72 (Day 505)	n/a	28	24.8	4	14.3	95.00	10.00	79.09	110.91
Week 76 (Day 533)	n/a	25	22.1	2	8.0	83.33	4.71	40.98	125.69
Week 80 (Day 561)	n/a	25	22.1	6	24.0	92.22	10.68	81.01	103.43
Week 84 (Day 589)	n/a	18	15.9	1	5.6	66.67	NE	NE	NE
Week 88 (Day 617)	n/a	14	12.4	2	14.3	90.00	4.71	47.65	132.35
Week 92 (Day 645)	n/a	7	6.2	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	5.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	2.7	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	113	100.0	111	98.2	78.56	23.34	74.17	82.95
End of Study (LOCF)	n/a	113	100.0	111	98.2	79.22	22.72	74.95	83.49
Sex									
Baseline	Female	69	100.0	67	97.1	75.62	21.00	70.50	80.75
Week 4 (Day 29)	Female	69	100.0	55	79.7	82.67	19.98	77.26	88.07
Week 8 (Day 57)	Female	63	91.3	54	85.7	80.00	18.72	74.89	85.11
Week 12 (Day 85)	Female	60	87.0	56	93.3	83.33	17.80	78.57	88.10
Week 16 (Day 113)	Female	58	84.1	50	86.2	79.33	19.48	73.80	84.87
Week 20 (Day 141)	Female	53	76.8	48	90.6	80.56	22.51	74.02	87.09
Week 24 (Day 169)	Female	47	68.1	40	85.1	84.50	17.76	78.82	90.18
Week 28 (Day 197)	Female	42	60.9	38	90.5	85.39	19.08	79.12	91.67
Week 32 (Day 225)	Female	42	60.9	35	83.3	82.48	23.66	74.35	90.60
Week 36 (Day 253)	Female	42	60.9	37	88.1	87.93	18.58	81.73	94.12
Week 40 (Day 281)	Female	41	59.4	37	90.2	88.42	17.32	82.65	94.20
Week 44 (Day 309)	Female	41	59.4	35	85.4	84.57	19.32	77.93	91.21
Week 48 (Day 337)	Female	37	53.6	22	59.5	84.85	20.69	75.67	94.02
Week 52 (Day 365)	Female	29	42.0	5	17.2	81.33	10.95	67.73	94.94
Week 56 (Day 393)	Female	24	34.8	8	33.3	88.33	10.54	79.52	97.15
Week 60 (Day 421)	Female	22	31.9	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Female	22	31.9	6	27.3	90.00	11.74	77.68	102.32
Week 68 (Day 477)	Female	20	29.0	1	5.0	80.00	NE	NE	NE
Week 72 (Day 505)	Female	20	29.0	2	10.0	100.00	0.00	NE	NE
Week 76 (Day 533)	Female	18	26.1	2	11.1	83.33	4.71	40.98	125.69
Week 80 (Day 561)	Female	18	26.1	5	27.8	92.00	11.93	77.19	106.81
Week 84 (Day 589)	Female	12	17.4	1	8.3	66.67	NE	NE	NE
Week 88 (Day 617)	Female	9	13.0	1	11.1	86.67	NE	NE	NE
Week 92 (Day 645)	Female	6	8.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	7.2	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	2.9	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	1.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	69	100.0	68	98.6	77.45	23.83	71.68	83.22
End of Study (LOCF)	Female	69	100.0	68	98.6	78.33	24.03	72.52	84.15
Baseline	Male	44	100.0	41	93.2	78.70	24.23	71.05	86.35
Week 4 (Day 29)	Male	44	100.0	40	90.9	87.50	15.26	82.62	92.38
Week 8 (Day 57)	Male	38	86.4	38	100.0	87.89	11.99	83.95	91.84
Week 12 (Day 85)	Male	37	84.1	34	91.9	88.24	14.03	83.34	93.13
Week 16 (Day 113)	Male	37	84.1	35	94.6	87.43	13.21	82.89	91.97
Week 20 (Day 141)	Male	36	81.8	35	97.2	85.52	16.13	79.98	91.06
Week 24 (Day 169)	Male	34	77.3	33	97.1	86.06	13.06	81.43	90.69
Week 28 (Day 197)	Male	32	72.7	31	96.9	86.88	13.61	81.89	91.87
Week 32 (Day 225)	Male	29	65.9	28	96.6	86.90	12.24	82.16	91.65
Week 36 (Day 253)	Male	29	65.9	28	96.6	85.48	11.48	81.02	89.93
Week 40 (Day 281)	Male	26	59.1	22	84.6	86.67	18.63	78.41	94.93
Week 44 (Day 309)	Male	23	52.3	23	100.0	85.51	18.60	77.46	93.55
Week 48 (Day 337)	Male	21	47.7	11	52.4	84.85	16.08	74.05	95.65
Week 52 (Day 365)	Male	16	36.4	2	12.5	86.67	9.43	1.96	171.37
Week 56 (Day 393)	Male	13	29.5	4	30.8	88.33	11.39	70.22	106.45
Week 60 (Day 421)	Male	10	22.7	1	10.0	86.67	NE	NE	NE
Week 64 (Day 449)	Male	9	20.5	3	33.3	91.11	7.70	71.99	110.23
Week 68 (Day 477)	Male	8	18.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	8	18.2	2	25.0	90.00	14.14	-37.06	217.06
Week 76 (Day 533)	Male	7	15.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	7	15.9	1	14.3	93.33	NE	NE	NE
Week 84 (Day 589)	Male	6	13.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	5	11.4	1	20.0	93.33	NE	NE	NE
Week 92 (Day 645)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	44	100.0	43	97.7	80.31	22.72	73.32	87.30
End of Study (LOCF)	Male	44	100.0	43	97.7	80.62	20.67	74.26	86.98
Age									

Baseline	< 65	78	100.0	73	93.6	77.44	22.10	72.29	82.60
Week 4 (Day 29)	< 65	78	100.0	68	87.2	85.98	17.09	81.84	90.12
Week 8 (Day 57)	< 65	73	93.6	66	90.4	86.67	13.59	83.33	90.01
Week 12 (Day 85)	< 65	71	91.0	64	90.1	88.54	12.87	85.33	91.76
Week 16 (Day 113)	< 65	69	88.5	59	85.5	87.46	13.28	84.00	90.92
Week 20 (Day 141)	< 65	65	83.3	62	95.4	85.16	19.22	80.28	90.04
Week 24 (Day 169)	< 65	59	75.6	55	93.2	87.52	14.35	83.64	91.39
Week 28 (Day 197)	< 65	55	70.5	51	92.7	88.73	14.81	84.56	92.89
Week 32 (Day 225)	< 65	53	67.9	48	90.6	87.22	18.39	81.88	92.56
Week 36 (Day 253)	< 65	53	67.9	50	94.3	89.47	13.13	85.73	93.20
Week 40 (Day 281)	< 65	52	66.7	48	92.3	89.97	15.12	85.57	94.36
Week 44 (Day 309)	< 65	52	66.7	48	92.3	86.25	16.92	81.34	91.16
Week 48 (Day 337)	< 65	47	60.3	26	55.3	87.95	13.07	82.67	93.23
Week 52 (Day 365)	< 65	36	46.2	4	11.1	88.33	10.00	72.42	104.25
Week 56 (Day 393)	< 65	30	38.5	9	30.0	91.11	10.00	83.42	98.80
Week 60 (Day 421)	< 65	25	32.1	1	4.0	86.67	NE	NE	NE
Week 64 (Day 449)	< 65	24	30.8	7	29.2	94.29	7.13	87.69	100.88
Week 68 (Day 477)	< 65	22	28.2	1	4.5	80.00	NE	NE	NE
Week 72 (Day 505)	< 65	22	28.2	4	18.2	95.00	10.00	79.09	110.91
Week 76 (Day 533)	< 65	21	26.9	2	9.5	83.33	4.71	40.98	125.69
Week 80 (Day 561)	< 65	21	26.9	5	23.8	93.33	11.55	79.00	107.67
Week 84 (Day 589)	< 65	15	19.2	1	6.7	66.67	NE	NE	NE
Week 88 (Day 617)	< 65	12	15.4	2	16.7	90.00	4.71	47.65	132.35
Week 92 (Day 645)	< 65	6	7.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	6.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	78	100.0	76	97.4	80.35	23.42	75.00	85.70
End of Study (LOCF)	< 65	78	100.0	76	97.4	81.49	22.35	76.38	86.60
Baseline	>= 65	35	100.0	35	100.0	75.43	22.74	67.62	83.24
Week 4 (Day 29)	>= 65	35	100.0	27	77.1	81.48	20.78	73.26	89.70
Week 8 (Day 57)	>= 65	28	80.0	26	92.9	74.62	20.57	66.31	82.92
Week 12 (Day 85)	>= 65	26	74.3	26	100.0	76.92	21.44	68.27	85.58

Week 16 (Day 113)	>= 65	26	74.3	26	100.0	71.79	21.19	63.24	80.35
Week 20 (Day 141)	>= 65	24	68.6	21	87.5	75.24	21.31	65.54	84.94
Week 24 (Day 169)	>= 65	22	62.9	18	81.8	78.15	17.98	69.21	87.09
Week 28 (Day 197)	>= 65	19	54.3	18	94.7	78.52	19.88	68.63	88.40
Week 32 (Day 225)	>= 65	18	51.4	15	83.3	75.56	20.57	64.16	86.95
Week 36 (Day 253)	>= 65	18	51.4	15	83.3	78.22	21.00	66.59	89.85
Week 40 (Day 281)	>= 65	15	42.9	11	73.3	78.18	24.78	61.53	94.83
Week 44 (Day 309)	>= 65	12	34.3	10	83.3	78.67	26.63	59.62	97.72
Week 48 (Day 337)	>= 65	11	31.4	7	63.6	73.33	31.97	43.76	102.90
Week 52 (Day 365)	>= 65	9	25.7	3	33.3	75.56	3.85	65.99	85.12
Week 56 (Day 393)	>= 65	7	20.0	3	42.9	80.00	6.67	63.44	96.56
Week 60 (Day 421)	>= 65	7	20.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	7	20.0	2	28.6	76.67	4.71	34.31	119.02
Week 68 (Day 477)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	4	11.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	4	11.4	1	25.0	86.67	NE	NE	NE
Week 84 (Day 589)	>= 65	3	8.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	5.7	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	35	100.0	35	100.0	74.67	23.03	66.76	82.58
End of Study (LOCF)	>= 65	35	100.0	35	100.0	74.29	23.05	66.37	82.20
ECOG performance status									
Baseline	0	33	100.0	31	93.9	80.65	24.36	71.71	89.58
Week 4 (Day 29)	0	33	100.0	27	81.8	81.98	27.48	71.11	92.84
Week 8 (Day 57)	0	30	90.9	27	90.0	81.73	22.92	72.66	90.79
Week 12 (Day 85)	0	29	87.9	26	89.7	85.13	21.02	76.64	93.62
Week 16 (Day 113)	0	28	84.8	24	85.7	84.44	23.73	74.43	94.46
Week 20 (Day 141)	0	26	78.8	24	92.3	84.44	23.65	74.46	94.43
Week 24 (Day 169)	0	24	72.7	20	83.3	88.00	20.24	78.53	97.47
Week 28 (Day 197)	0	21	63.6	19	90.5	86.32	21.71	75.85	96.78

Week 32 (Day 225)	0	21	63.6	18	85.7	84.81	29.27	70.26	99.37
Week 36 (Day 253)	0	21	63.6	20	95.2	89.00	19.26	79.99	98.01
Week 40 (Day 281)	0	21	63.6	19	90.5	87.63	20.50	77.75	97.51
Week 44 (Day 309)	0	21	63.6	17	81.0	83.14	26.68	69.42	96.85
Week 48 (Day 337)	0	19	57.6	12	63.2	81.67	27.14	64.43	98.91
Week 52 (Day 365)	0	18	54.5	3	16.7	77.78	3.85	68.22	87.34
Week 56 (Day 393)	0	16	48.5	5	31.3	88.00	11.93	73.19	102.81
Week 60 (Day 421)	0	16	48.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	0	16	48.5	5	31.3	89.33	11.16	75.48	103.18
Week 68 (Day 477)	0	14	42.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	0	14	42.4	1	7.1	100.00	NE	NE	NE
Week 76 (Day 533)	0	12	36.4	1	8.3	86.67	NE	NE	NE
Week 80 (Day 561)	0	12	36.4	1	8.3	100.00	NE	NE	NE
Week 84 (Day 589)	0	10	30.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	9	27.3	1	11.1	86.67	NE	NE	NE
Week 92 (Day 645)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	9.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	3.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	33	100.0	33	100.0	75.76	28.08	65.80	85.71
End of Study (LOCF)	0	33	100.0	33	100.0	76.36	26.67	66.91	85.82
Baseline	1	79	100.0	76	96.2	75.00	21.31	70.13	79.87
Week 4 (Day 29)	1	79	100.0	67	84.8	85.67	13.04	82.49	88.85
Week 8 (Day 57)	1	70	88.6	65	92.9	83.90	13.43	80.57	87.23
Week 12 (Day 85)	1	68	86.1	64	94.1	85.21	14.57	81.57	88.85
Week 16 (Day 113)	1	67	84.8	61	91.0	81.97	14.62	78.22	85.71
Week 20 (Day 141)	1	63	79.7	59	93.7	81.92	18.65	77.06	86.78
Week 24 (Day 169)	1	57	72.2	53	93.0	84.15	13.73	80.37	87.93
Week 28 (Day 197)	1	53	67.1	50	94.3	85.97	14.69	81.79	90.14
Week 32 (Day 225)	1	50	63.3	45	90.0	84.30	14.15	80.04	88.55
Week 36 (Day 253)	1	50	63.3	45	90.0	85.93	14.23	81.65	90.20
Week 40 (Day 281)	1	46	58.2	40	87.0	87.83	16.46	82.57	93.10

Week 44 (Day 309)	1	43	54.4	41	95.3	85.69	14.87	81.00	90.39
Week 48 (Day 337)	1	39	49.4	21	53.8	86.67	12.82	80.83	92.50
Week 52 (Day 365)	1	27	34.2	4	14.8	86.67	12.17	67.30	106.03
Week 56 (Day 393)	1	21	26.6	7	33.3	88.57	9.97	79.35	97.80
Week 60 (Day 421)	1	16	20.3	1	6.3	86.67	NE	NE	NE
Week 64 (Day 449)	1	15	19.0	4	26.7	91.67	10.00	75.75	107.58
Week 68 (Day 477)	1	14	17.7	1	7.1	80.00	NE	NE	NE
Week 72 (Day 505)	1	14	17.7	3	21.4	93.33	11.55	64.65	122.02
Week 76 (Day 533)	1	13	16.5	1	7.7	80.00	NE	NE	NE
Week 80 (Day 561)	1	13	16.5	5	38.5	90.67	11.16	76.82	104.52
Week 84 (Day 589)	1	8	10.1	1	12.5	66.67	NE	NE	NE
Week 88 (Day 617)	1	5	6.3	1	20.0	93.33	NE	NE	NE
Week 92 (Day 645)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	2.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	79	100.0	77	97.5	79.57	21.20	74.75	84.38
End of Study (LOCF)	1	79	100.0	77	97.5	80.26	20.98	75.50	85.02
Baseline	Missing	1	100.0	1	100.0	93.33	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	93.33	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	93.33	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	93.33	NE	NE	NE
Geographic region									
Baseline	USA	22	100.0	22	100.0	76.36	21.94	66.64	86.09
Week 4 (Day 29)	USA	22	100.0	18	81.8	85.56	22.20	74.52	96.60
Week 8 (Day 57)	USA	20	90.9	18	90.0	84.44	15.34	76.82	92.07
Week 12 (Day 85)	USA	20	90.9	19	95.0	89.82	14.63	82.77	96.88
Week 16 (Day 113)	USA	19	86.4	17	89.5	84.31	16.99	75.58	93.05
Week 20 (Day 141)	USA	19	86.4	17	89.5	84.31	19.14	74.47	94.15
Week 24 (Day 169)	USA	16	72.7	14	87.5	89.52	9.68	83.93	95.11
Week 28 (Day 197)	USA	15	68.2	12	80.0	90.00	11.19	82.89	97.11
Week 32 (Day 225)	USA	15	68.2	13	86.7	78.97	27.87	62.13	95.81
Week 36 (Day 253)	USA	15	68.2	13	86.7	87.69	15.83	78.12	97.26
Week 40 (Day 281)	USA	14	63.6	11	78.6	87.12	23.71	71.19	103.05

Week 44 (Day 309)	USA	13	59.1	11	84.6	84.85	17.66	72.98	96.71
Week 48 (Day 337)	USA	13	59.1	10	76.9	88.67	15.09	77.87	99.46
Week 52 (Day 365)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	USA	12	54.5	6	50.0	86.67	11.93	74.15	99.18
Week 60 (Day 421)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	11	50.0	4	36.4	91.67	10.00	75.75	107.58
Week 68 (Day 477)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	10	45.5	1	10.0	100.00	NE	NE	NE
Week 76 (Day 533)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	10	45.5	2	20.0	80.00	9.43	-4.71	164.71
Week 84 (Day 589)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	13.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	4.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	22	100.0	22	100.0	79.39	25.02	68.30	90.49
End of Study (LOCF)	USA	22	100.0	22	100.0	80.00	24.17	69.28	90.72
Baseline	Europe (EU)	32	100.0	29	90.6	75.63	24.25	66.41	84.86
Week 4 (Day 29)	Europe (EU)	32	100.0	25	78.1	82.67	19.15	74.76	90.57
Week 8 (Day 57)	Europe (EU)	29	90.6	25	86.2	80.00	19.91	71.78	88.22
Week 12 (Day 85)	Europe (EU)	26	81.3	24	92.3	82.50	20.03	74.04	90.96
Week 16 (Day 113)	Europe (EU)	25	78.1	20	80.0	80.33	21.79	70.14	90.53
Week 20 (Day 141)	Europe (EU)	23	71.9	22	95.7	80.61	22.05	70.83	90.38
Week 24 (Day 169)	Europe (EU)	21	65.6	20	95.2	81.00	22.40	70.52	91.48
Week 28 (Day 197)	Europe (EU)	20	62.5	20	100.0	84.58	17.68	76.31	92.86
Week 32 (Day 225)	Europe (EU)	18	56.3	16	88.9	89.17	11.89	82.83	95.50
Week 36 (Day 253)	Europe (EU)	18	56.3	17	94.4	90.98	8.14	86.79	95.17
Week 40 (Day 281)	Europe (EU)	17	53.1	16	94.1	91.25	9.95	85.95	96.55
Week 44 (Day 309)	Europe (EU)	17	53.1	14	82.4	84.76	15.78	75.65	93.87

Week 48 (Day 337)	Europe (EU)	14	43.8	10	71.4	84.67	12.59	75.66	93.67
Week 52 (Day 365)	Europe (EU)	13	40.6	3	23.1	77.78	3.85	68.22	87.34
Week 56 (Day 393)	Europe (EU)	11	34.4	5	45.5	89.33	10.11	76.78	101.89
Week 60 (Day 421)	Europe (EU)	11	34.4	1	9.1	86.67	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	11	34.4	5	45.5	89.33	11.16	75.48	103.18
Week 68 (Day 477)	Europe (EU)	10	31.3	1	10.0	80.00	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	10	31.3	3	30.0	93.33	11.55	64.65	122.02
Week 76 (Day 533)	Europe (EU)	8	25.0	2	25.0	83.33	4.71	40.98	125.69
Week 80 (Day 561)	Europe (EU)	8	25.0	4	50.0	98.33	3.33	93.03	103.64
Week 84 (Day 589)	Europe (EU)	6	18.8	1	16.7	66.67	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	9.4	2	66.7	90.00	4.71	47.65	132.35
Cycle 12 (LOCF)	Europe (EU)	32	100.0	31	96.9	75.91	24.38	66.97	84.86
End of Study (LOCF)	Europe (EU)	32	100.0	31	96.9	77.20	24.45	68.24	86.17
Baseline	Asia (AS)	59	100.0	57	96.6	77.54	21.63	71.81	83.28
Week 4 (Day 29)	Asia (AS)	59	100.0	52	88.1	85.38	16.49	80.79	89.98
Week 8 (Day 57)	Asia (AS)	52	88.1	49	94.2	84.49	15.42	80.06	88.92
Week 12 (Day 85)	Asia (AS)	51	86.4	47	92.2	84.68	15.29	80.19	89.17
Week 16 (Day 113)	Asia (AS)	51	86.4	48	94.1	83.06	16.04	78.40	87.71
Week 20 (Day 141)	Asia (AS)	47	79.7	44	93.6	83.03	19.84	77.00	89.06
Week 24 (Day 169)	Asia (AS)	44	74.6	39	88.6	85.81	12.99	81.60	90.02
Week 28 (Day 197)	Asia (AS)	39	66.1	37	94.9	85.59	17.88	79.62	91.55
Week 32 (Day 225)	Asia (AS)	38	64.4	34	89.5	84.31	18.41	77.89	90.74
Week 36 (Day 253)	Asia (AS)	38	64.4	35	92.1	84.57	18.42	78.24	90.90
Week 40 (Day 281)	Asia (AS)	36	61.0	32	88.9	86.25	18.62	79.54	92.96
Week 44 (Day 309)	Asia (AS)	34	57.6	33	97.1	85.05	20.89	77.64	92.46
Week 48 (Day 337)	Asia (AS)	31	52.5	13	41.9	82.05	25.59	66.59	97.51
Week 52 (Day 365)	Asia (AS)	20	33.9	4	20.0	86.67	12.17	67.30	106.03
Week 56 (Day 393)	Asia (AS)	14	23.7	1	7.1	93.33	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	10.2	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	8.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	3.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	59	100.0	58	98.3	79.66	22.42	73.76	85.55
End of Study (LOCF)	Asia (AS)	59	100.0	58	98.3	80.00	21.52	74.34	85.66
Race/ethnicity									
Baseline	Asian	61	100.0	58	95.1	77.13	21.67	71.43	82.82
Week 4 (Day 29)	Asian	61	100.0	52	85.2	85.38	16.49	80.79	89.98
Week 8 (Day 57)	Asian	53	86.9	49	92.5	84.49	15.42	80.06	88.92
Week 12 (Day 85)	Asian	52	85.2	48	92.3	84.58	15.14	80.19	88.98
Week 16 (Day 113)	Asian	52	85.2	49	94.2	82.86	15.93	78.28	87.43
Week 20 (Day 141)	Asian	48	78.7	45	93.8	82.96	19.62	77.07	88.86
Week 24 (Day 169)	Asian	44	72.1	39	88.6	85.81	12.99	81.60	90.02
Week 28 (Day 197)	Asian	39	63.9	37	94.9	85.59	17.88	79.62	91.55
Week 32 (Day 225)	Asian	38	62.3	34	89.5	84.31	18.41	77.89	90.74
Week 36 (Day 253)	Asian	38	62.3	35	92.1	84.57	18.42	78.24	90.90
Week 40 (Day 281)	Asian	36	59.0	32	88.9	86.25	18.62	79.54	92.96
Week 44 (Day 309)	Asian	34	55.7	33	97.1	85.05	20.89	77.64	92.46
Week 48 (Day 337)	Asian	31	50.8	13	41.9	82.05	25.59	66.59	97.51
Week 52 (Day 365)	Asian	20	32.8	4	20.0	86.67	12.17	67.30	106.03
Week 56 (Day 393)	Asian	14	23.0	1	7.1	93.33	NE	NE	NE
Week 60 (Day 421)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	9.8	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	8.2	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	3.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	61	100.0	59	96.7	79.66	22.23	73.87	85.45
End of Study (LOCF)	Asian	61	100.0	59	96.7	80.00	21.33	74.44	85.56
Baseline	Non-Asian	45	100.0	44	97.8	78.48	20.73	72.18	84.79
Week 4 (Day 29)	Non-Asian	45	100.0	39	86.7	85.13	17.73	79.38	90.88
Week 8 (Day 57)	Non-Asian	42	93.3	38	90.5	81.23	18.72	75.08	87.38
Week 12 (Day 85)	Non-Asian	39	86.7	37	94.9	85.41	19.11	79.04	91.78
Week 16 (Day 113)	Non-Asian	37	82.2	34	91.9	81.37	19.88	74.43	88.31
Week 20 (Day 141)	Non-Asian	36	80.0	34	94.4	81.37	21.64	73.82	88.92
Week 24 (Day 169)	Non-Asian	32	71.1	31	96.9	83.87	19.15	76.85	90.90
Week 28 (Day 197)	Non-Asian	30	66.7	28	93.3	87.32	15.20	81.43	93.21
Week 32 (Day 225)	Non-Asian	28	62.2	25	89.3	86.93	13.81	81.23	92.63
Week 36 (Day 253)	Non-Asian	28	62.2	26	92.9	89.23	12.66	84.12	94.34
Week 40 (Day 281)	Non-Asian	26	57.8	23	88.5	88.91	17.92	81.16	96.66
Week 44 (Day 309)	Non-Asian	25	55.6	21	84.0	84.13	17.57	76.13	92.13
Week 48 (Day 337)	Non-Asian	23	51.1	17	73.9	85.10	14.25	77.77	92.42
Week 52 (Day 365)	Non-Asian	21	46.7	3	14.3	77.78	3.85	68.22	87.34
Week 56 (Day 393)	Non-Asian	19	42.2	10	52.6	86.67	10.42	79.21	94.12
Week 60 (Day 421)	Non-Asian	19	42.2	1	5.3	86.67	NE	NE	NE
Week 64 (Day 449)	Non-Asian	18	40.0	7	38.9	89.52	10.79	79.55	99.50
Week 68 (Day 477)	Non-Asian	17	37.8	1	5.9	80.00	NE	NE	NE
Week 72 (Day 505)	Non-Asian	17	37.8	3	17.6	93.33	11.55	64.65	122.02
Week 76 (Day 533)	Non-Asian	15	33.3	2	13.3	83.33	4.71	40.98	125.69
Week 80 (Day 561)	Non-Asian	15	33.3	5	33.3	90.67	11.16	76.82	104.52
Week 84 (Day 589)	Non-Asian	10	22.2	1	10.0	66.67	NE	NE	NE
Week 88 (Day 617)	Non-Asian	7	15.6	2	28.6	90.00	4.71	47.65	132.35
Week 92 (Day 645)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	45	100.0	45	100.0	77.33	23.33	70.32	84.34

End of Study (LOCF)	Non-Asian	45	100.0	45	100.0	78.07	22.68	71.26	84.89
Baseline	Unknown	7	100.0	6	85.7	61.11	34.62	24.78	97.44
Week 4 (Day 29)	Unknown	7	100.0	4	57.1	71.67	39.39	8.98	134.35
Week 8 (Day 57)	Unknown	6	85.7	5	83.3	86.67	12.47	71.18	102.15
Week 12 (Day 85)	Unknown	6	85.7	5	83.3	89.33	10.11	76.78	101.89
Week 16 (Day 113)	Unknown	6	85.7	2	33.3	100.00	0.00	NE	NE
Week 20 (Day 141)	Unknown	5	71.4	4	80.0	90.00	12.77	69.69	110.31
Week 24 (Day 169)	Unknown	5	71.4	3	60.0	91.11	10.18	65.81	116.41
Week 28 (Day 197)	Unknown	5	71.4	4	80.0	81.67	19.91	49.99	113.34
Week 32 (Day 225)	Unknown	5	71.4	4	80.0	70.00	46.98	-4.76	144.76
Week 36 (Day 253)	Unknown	5	71.4	4	80.0	91.67	6.38	81.51	101.82
Week 40 (Day 281)	Unknown	5	71.4	4	80.0	93.33	5.44	84.67	101.99
Week 44 (Day 309)	Unknown	5	71.4	4	80.0	88.33	6.38	78.18	98.49
Week 48 (Day 337)	Unknown	4	57.1	3	75.0	95.56	3.85	85.99	105.12
Week 52 (Day 365)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	4	57.1	1	25.0	100.00	NE	NE	NE
Week 60 (Day 421)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	4	57.1	2	50.0	93.33	9.43	8.63	178.04
Week 68 (Day 477)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	3	42.9	1	33.3	100.00	NE	NE	NE
Week 76 (Day 533)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	3	42.9	1	33.3	100.00	NE	NE	NE
Week 84 (Day 589)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	14.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	7	100.0	7	100.0	77.14	34.61	45.13	109.15
End of Study (LOCF)	Unknown	7	100.0	7	100.0	80.00	35.69	46.99	113.01
Number of prior antineoplastic systemic therapy lines I									
Baseline	1	60	100.0	57	95.0	75.56	21.32	69.90	81.21

Week 4 (Day 29)	1	60	100.0	50	83.3	86.27	16.19	81.67	90.87
Week 8 (Day 57)	1	54	90.0	49	90.7	82.04	15.94	77.46	86.62
Week 12 (Day 85)	1	52	86.7	48	92.3	82.64	17.70	77.50	87.78
Week 16 (Day 113)	1	51	85.0	46	90.2	80.72	18.66	75.18	86.27
Week 20 (Day 141)	1	48	80.0	43	89.6	82.95	19.32	77.00	88.89
Week 24 (Day 169)	1	43	71.7	39	90.7	84.96	17.49	79.29	90.63
Week 28 (Day 197)	1	38	63.3	34	89.5	86.27	14.86	81.09	91.46
Week 32 (Day 225)	1	35	58.3	29	82.9	83.45	20.52	75.64	91.25
Week 36 (Day 253)	1	35	58.3	31	88.6	88.82	11.34	84.66	92.98
Week 40 (Day 281)	1	32	53.3	27	84.4	88.83	16.73	82.21	95.45
Week 44 (Day 309)	1	32	53.3	27	84.4	85.68	19.54	77.95	93.41
Week 48 (Day 337)	1	27	45.0	16	59.3	81.67	14.91	73.72	89.61
Week 52 (Day 365)	1	23	38.3	5	21.7	84.00	12.11	68.96	99.04
Week 56 (Day 393)	1	16	26.7	4	25.0	88.33	8.39	74.99	101.68
Week 60 (Day 421)	1	14	23.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	13	21.7	4	30.8	85.00	11.39	66.88	103.12
Week 68 (Day 477)	1	12	20.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	12	20.0	1	8.3	100.00	NE	NE	NE
Week 76 (Day 533)	1	11	18.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	11	18.3	2	18.2	93.33	9.43	8.63	178.04
Week 84 (Day 589)	1	9	15.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	1	8	13.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	1	3	5.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	1	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	60	100.0	58	96.7	78.85	21.09	73.31	84.40
End of Study (LOCF)	1	60	100.0	58	96.7	79.66	19.40	74.55	84.76
Baseline	>= 2	53	100.0	51	96.2	78.17	23.33	71.61	84.73
Week 4 (Day 29)	>= 2	53	100.0	45	84.9	82.96	20.28	76.87	89.06
Week 8 (Day 57)	>= 2	47	88.7	43	91.5	84.65	17.55	79.25	90.05
Week 12 (Day 85)	>= 2	45	84.9	42	93.3	88.10	14.84	83.47	92.72
Week 16 (Day 113)	>= 2	44	83.0	39	88.6	84.96	16.09	79.74	90.17

Week 20 (Day 141)	>= 2	41	77.4	40	97.6	82.33	21.17	75.56	89.10
Week 24 (Day 169)	>= 2	38	71.7	34	89.5	85.49	13.68	80.72	90.26
Week 28 (Day 197)	>= 2	36	67.9	35	97.2	85.86	18.61	79.46	92.25
Week 32 (Day 225)	>= 2	36	67.9	34	94.4	85.29	18.70	78.77	91.82
Week 36 (Day 253)	>= 2	36	67.9	34	94.4	85.10	19.07	78.44	91.75
Week 40 (Day 281)	>= 2	35	66.0	32	91.4	86.88	18.66	80.15	93.60
Week 44 (Day 309)	>= 2	32	60.4	31	96.9	84.30	18.58	77.48	91.12
Week 48 (Day 337)	>= 2	31	58.5	17	54.8	87.84	22.27	76.40	99.29
Week 52 (Day 365)	>= 2	22	41.5	2	9.1	80.00	0.00	NE	NE
Week 56 (Day 393)	>= 2	21	39.6	8	38.1	88.33	11.68	78.57	98.10
Week 60 (Day 421)	>= 2	18	34.0	1	5.6	86.67	NE	NE	NE
Week 64 (Day 449)	>= 2	18	34.0	5	27.8	94.67	7.30	85.60	103.73
Week 68 (Day 477)	>= 2	16	30.2	1	6.3	80.00	NE	NE	NE
Week 72 (Day 505)	>= 2	16	30.2	3	18.8	93.33	11.55	64.65	122.02
Week 76 (Day 533)	>= 2	14	26.4	2	14.3	83.33	4.71	40.98	125.69
Week 80 (Day 561)	>= 2	14	26.4	4	28.6	91.67	12.62	71.59	111.75
Week 84 (Day 589)	>= 2	9	17.0	1	11.1	66.67	NE	NE	NE
Week 88 (Day 617)	>= 2	6	11.3	2	33.3	90.00	4.71	47.65	132.35
Week 92 (Day 645)	>= 2	2	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 2	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 2	53	100.0	53	100.0	78.24	25.79	71.13	85.35
End of Study (LOCF)	>= 2	53	100.0	53	100.0	78.74	26.05	71.56	85.92

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
¹ in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
² mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TP_QSC30PF_SG.xls
27OCT2021 7:29

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Physical functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	48	44.4	35.4	53.8
	Cycle 12 (LOCF)	n/a	108	95.6	25	23.1	16.2	31.9
	End of Study (LOCF)	n/a	108	95.6	25	23.1	16.2	31.9
Sex	All visits	Female	67	59.3	30	44.8	33.5	56.6
		Male	41	36.3	18	43.9	29.9	59.0
	Cycle 12 (LOCF)	Female	67	59.3	14	20.9	12.9	32.1
		Male	41	36.3	11	26.8	15.7	41.9
	End of Study (LOCF)	Female	67	59.3	13	19.4	11.7	30.4
		Male	41	36.3	12	29.3	17.6	44.5
Age	All visits	< 65	73	64.6	31	42.5	31.8	53.9
		>= 65	35	31.0	17	48.6	33.0	64.4
	Cycle 12 (LOCF)	< 65	73	64.6	17	23.3	15.1	34.2
		>= 65	35	31.0	8	22.9	12.1	39.0
	End of Study (LOCF)	< 65	73	64.6	15	20.5	12.9	31.2
		>= 65	35	31.0	10	28.6	16.3	45.1
ECOG performance status	All visits	0	31	27.4	18	58.1	40.8	73.6
		1	76	67.3	30	39.5	29.2	50.7
		Missing	1	0.9	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	31	27.4	10	32.3	18.6	49.9
		1	76	67.3	15	19.7	12.3	30.0
		Missing	1	0.9	0	0.0	0.0	79.3
	End of Study (LOCF)	0	31	27.4	10	32.3	18.6	49.9
		1	76	67.3	15	19.7	12.3	30.0
		Missing	1	0.9	0	0.0	0.0	79.3
Geographic region	All visits	USA	22	19.5	10	45.5	26.9	65.3
		Europe (EU)	29	25.7	16	55.2	37.5	71.6
		Asia (AS)	57	50.4	22	38.6	27.1	51.6
	Cycle 12 (LOCF)	USA	22	19.5	4	18.2	7.3	38.5
		Europe (EU)	29	25.7	8	27.6	14.7	45.7
		Asia (AS)	57	50.4	13	22.8	13.8	35.2
	End of Study (LOCF)	USA	22	19.5	3	13.6	4.7	33.3
		Europe (EU)	29	25.7	7	24.1	12.2	42.1
		Asia (AS)	57	50.4	15	26.3	16.6	39.0
Race/ethnicity	All visits	Asian	58	51.3	22	37.9	26.6	50.8
		Non-Asian	44	38.9	23	52.3	37.9	66.2
		Unknown	6	5.3	3	50.0	18.8	81.2
	Cycle 12 (LOCF)	Asian	58	51.3	13	22.4	13.6	34.7

		Non-Asian	44	38.9	12	27.3	16.3	41.8
		Unknown	6	5.3	0	0.0	0.0	39.0
	End of Study (LOCF)	Asian	58	51.3	15	25.9	16.3	38.4
		Non-Asian	44	38.9	10	22.7	12.8	37.0
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	25	43.9	31.8	56.7
		>= 2	51	45.1	23	45.1	32.3	58.6
	Cycle 12 (LOCF)	1	57	50.4	12	21.1	12.5	33.3
		>= 2	51	45.1	13	25.5	15.5	38.9
	End of Study (LOCF)	1	57	50.4	10	17.5	9.8	29.4
		>= 2	51	45.1	15	29.4	18.7	43.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30PF_W10_SG.xls
15OCT2021 13:36

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Physical functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

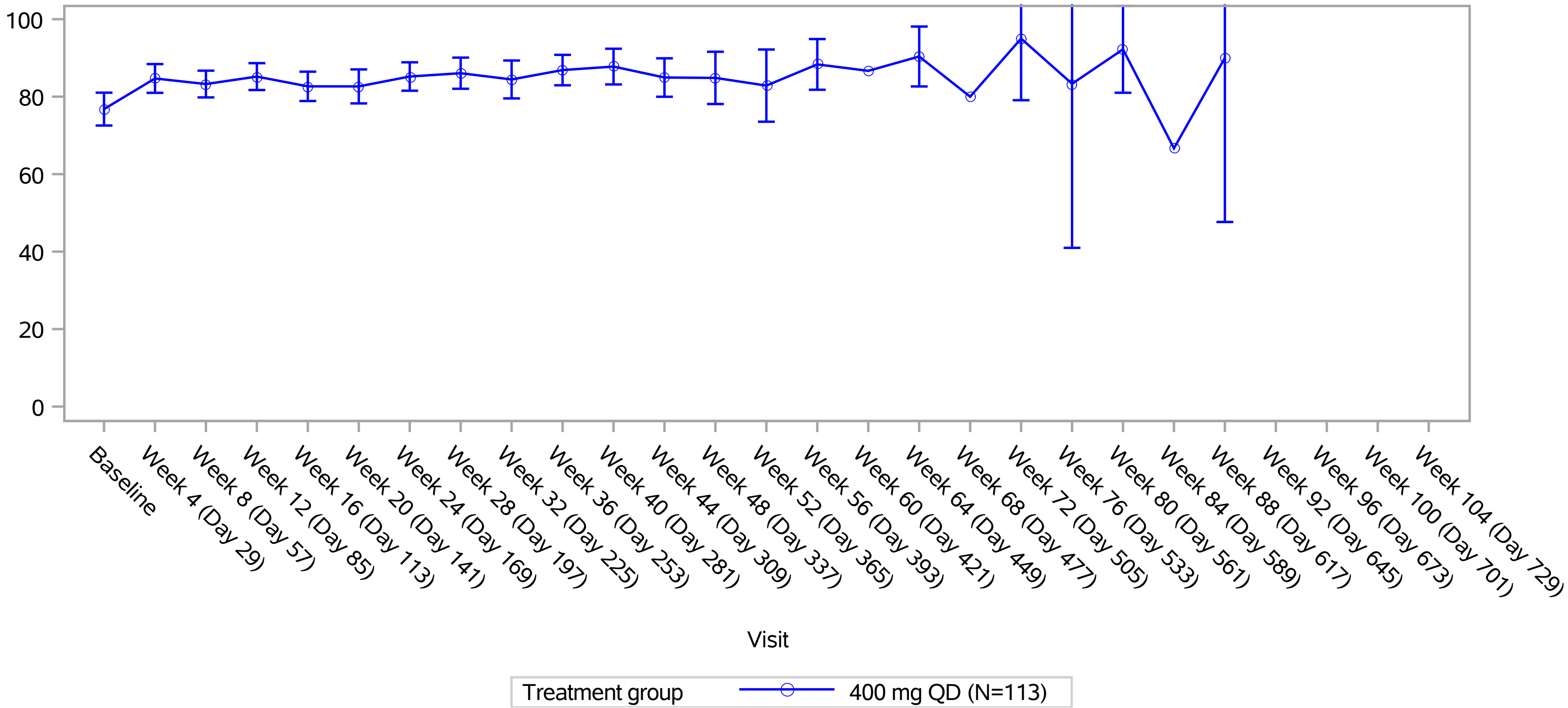
			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	34	31.5	23.5	40.7
	Cycle 12 (LOCF)	n/a	108	95.6	20	18.5	12.3	26.9
	End of Study (LOCF)	n/a	108	95.6	17	15.7	10.1	23.8
Sex	All visits	Female	67	59.3	21	31.3	21.5	43.2
		Male	41	36.3	13	31.7	19.6	47.0
	Cycle 12 (LOCF)	Female	67	59.3	12	17.9	10.6	28.7
		Male	41	36.3	8	19.5	10.2	34.0
	End of Study (LOCF)	Female	67	59.3	10	14.9	8.3	25.3
		Male	41	36.3	7	17.1	8.5	31.3
Age	All visits	< 65	73	64.6	22	30.1	20.8	41.4
		>= 65	35	31.0	12	34.3	20.8	50.8
	Cycle 12 (LOCF)	< 65	73	64.6	14	19.2	11.8	29.7
		>= 65	35	31.0	6	17.1	8.1	32.7
	End of Study (LOCF)	< 65	73	64.6	11	15.1	8.6	25.0
		>= 65	35	31.0	6	17.1	8.1	32.7
ECOG performance status	All visits	0	31	27.4	12	38.7	23.7	56.2
		1	76	67.3	22	28.9	20.0	40.0
		Missing	1	0.9	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	31	27.4	9	29.0	16.1	46.6
		1	76	67.3	11	14.5	8.3	24.1
		Missing	1	0.9	0	0.0	0.0	79.3
	End of Study (LOCF)	0	31	27.4	9	29.0	16.1	46.6
		1	76	67.3	8	10.5	5.4	19.4
		Missing	1	0.9	0	0.0	0.0	79.3
Geographic region	All visits	USA	22	19.5	8	36.4	19.7	57.0
		Europe (EU)	29	25.7	10	34.5	19.9	52.7
		Asia (AS)	57	50.4	16	28.1	18.1	40.8
	Cycle 12 (LOCF)	USA	22	19.5	3	13.6	4.7	33.3
		Europe (EU)	29	25.7	8	27.6	14.7	45.7
		Asia (AS)	57	50.4	9	15.8	8.5	27.4
	End of Study (LOCF)	USA	22	19.5	2	9.1	2.5	27.8
		Europe (EU)	29	25.7	6	20.7	9.8	38.4
		Asia (AS)	57	50.4	9	15.8	8.5	27.4
Race/ethnicity	All visits	Asian	58	51.3	16	27.6	17.8	40.2
		Non-Asian	44	38.9	16	36.4	23.8	51.1
		Unknown	6	5.3	2	33.3	9.7	70.0
	Cycle 12 (LOCF)	Asian	58	51.3	9	15.5	8.4	26.9

		Non-Asian	44	38.9	11	25.0	14.6	39.4
		Unknown	6	5.3	0	0.0	0.0	39.0
	End of Study (LOCF)	Asian	58	51.3	9	15.5	8.4	26.9
		Non-Asian	44	38.9	8	18.2	9.5	32.0
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	16	28.1	18.1	40.8
		>= 2	51	45.1	18	35.3	23.6	49.0
	Cycle 12 (LOCF)	1	57	50.4	9	15.8	8.5	27.4
		>= 2	51	45.1	11	21.6	12.5	34.6
	End of Study (LOCF)	1	57	50.4	7	12.3	6.1	23.2
		>= 2	51	45.1	10	19.6	11.0	32.5

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30PF_W15_SG.xls
15OCT2021 13:26

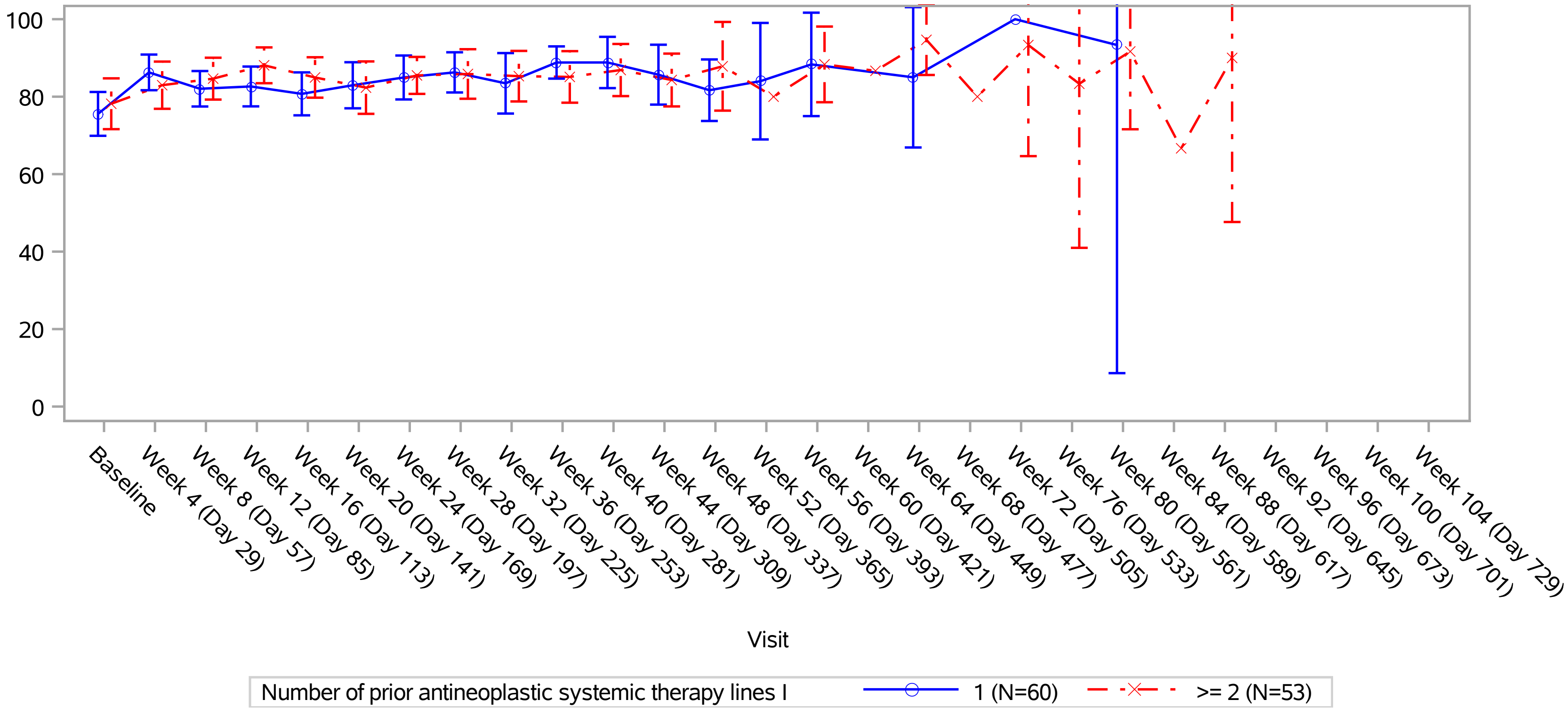
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Physical functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30PF.pdf
15OCT2021 17:19

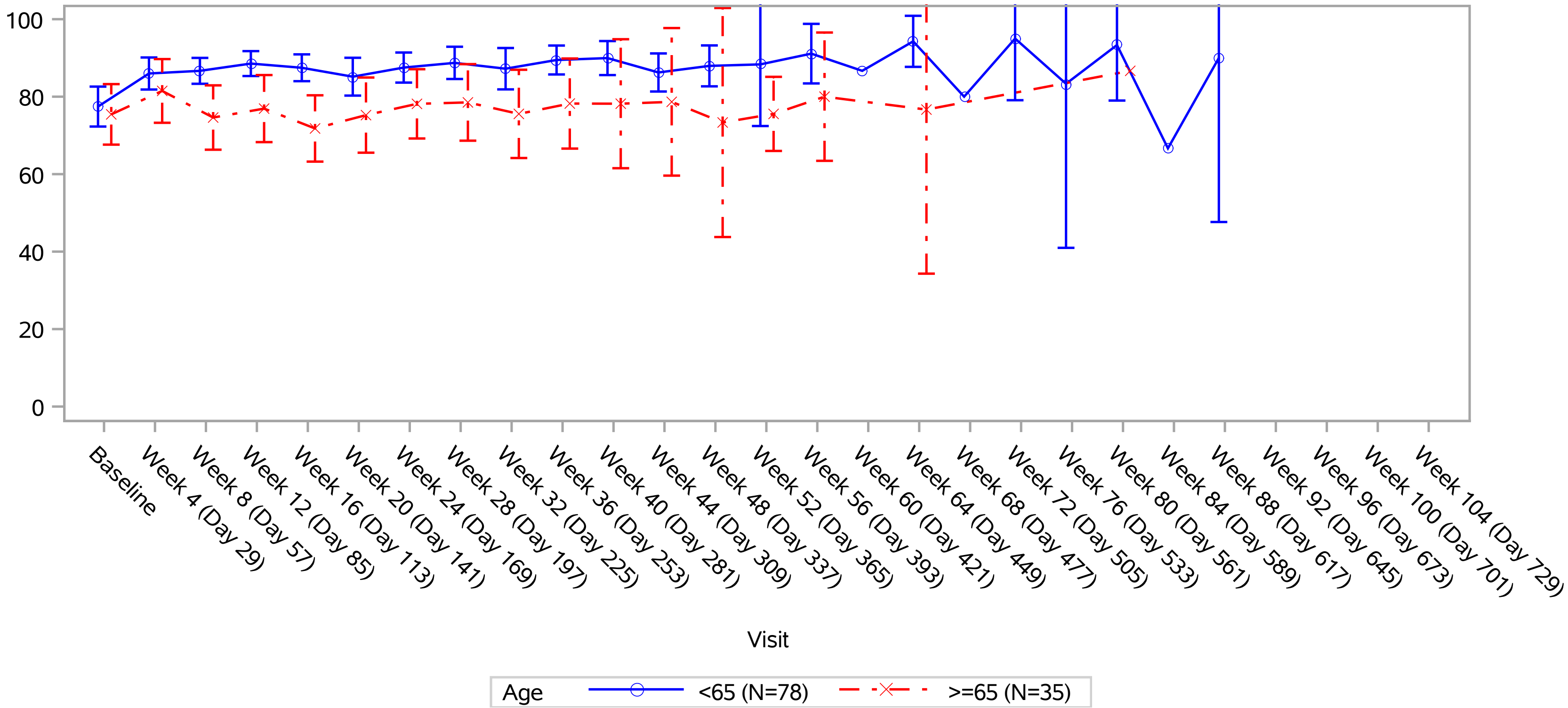
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Physical functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30PF_PRTHL1.pdf
15OCT2021 20:10

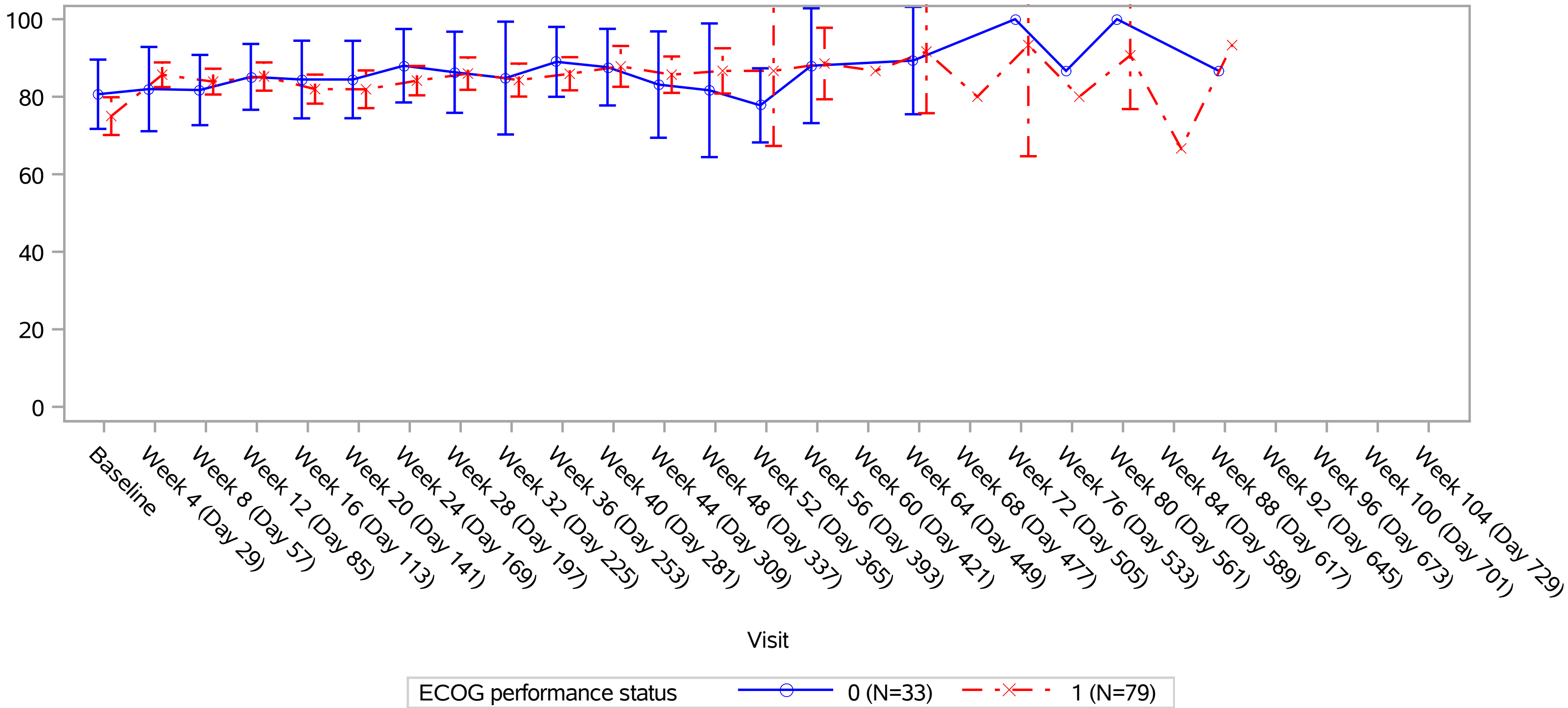
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Physical functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30PF_SGAGE65.pdf
15OCT2021 17:48

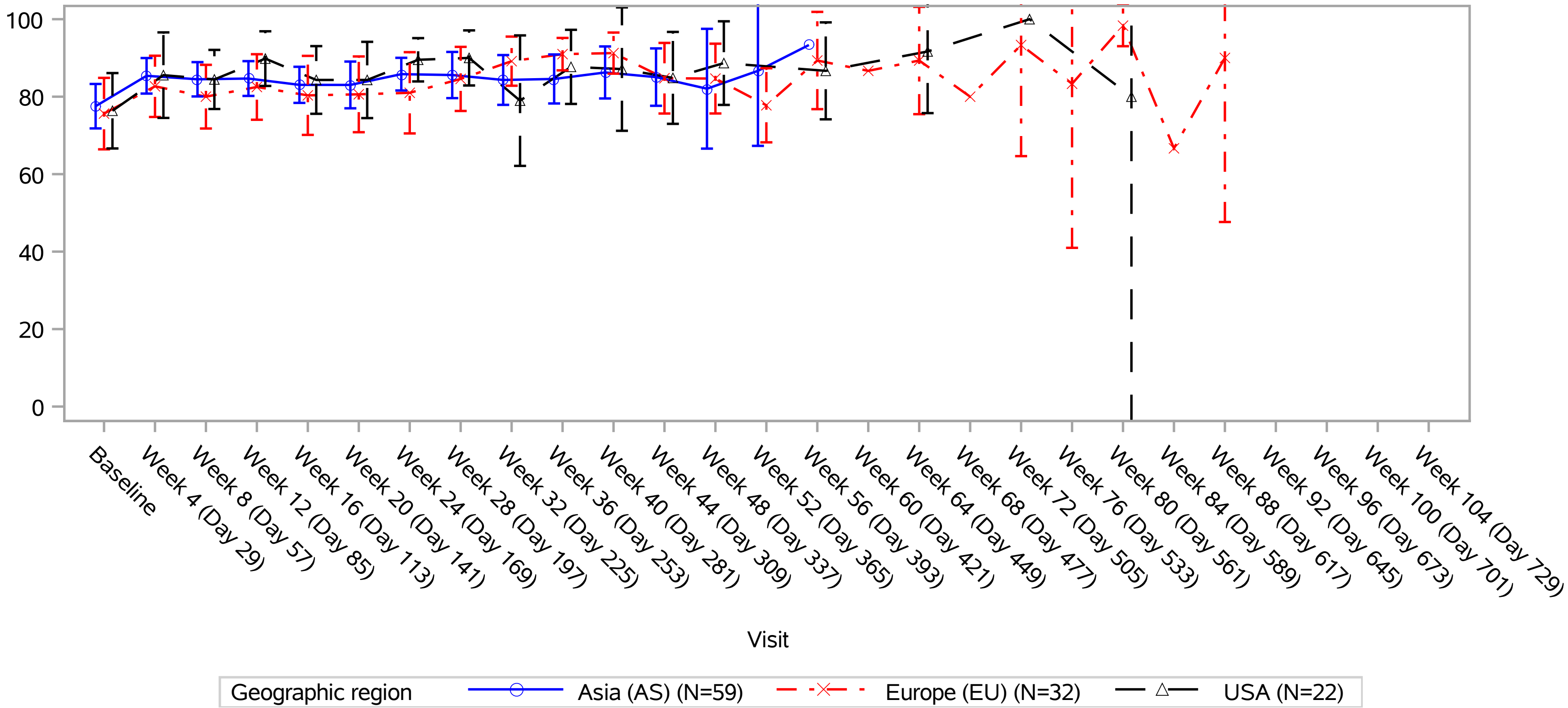
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Physical functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30PF_SGECOG.pdf
15OCT2021 18:18

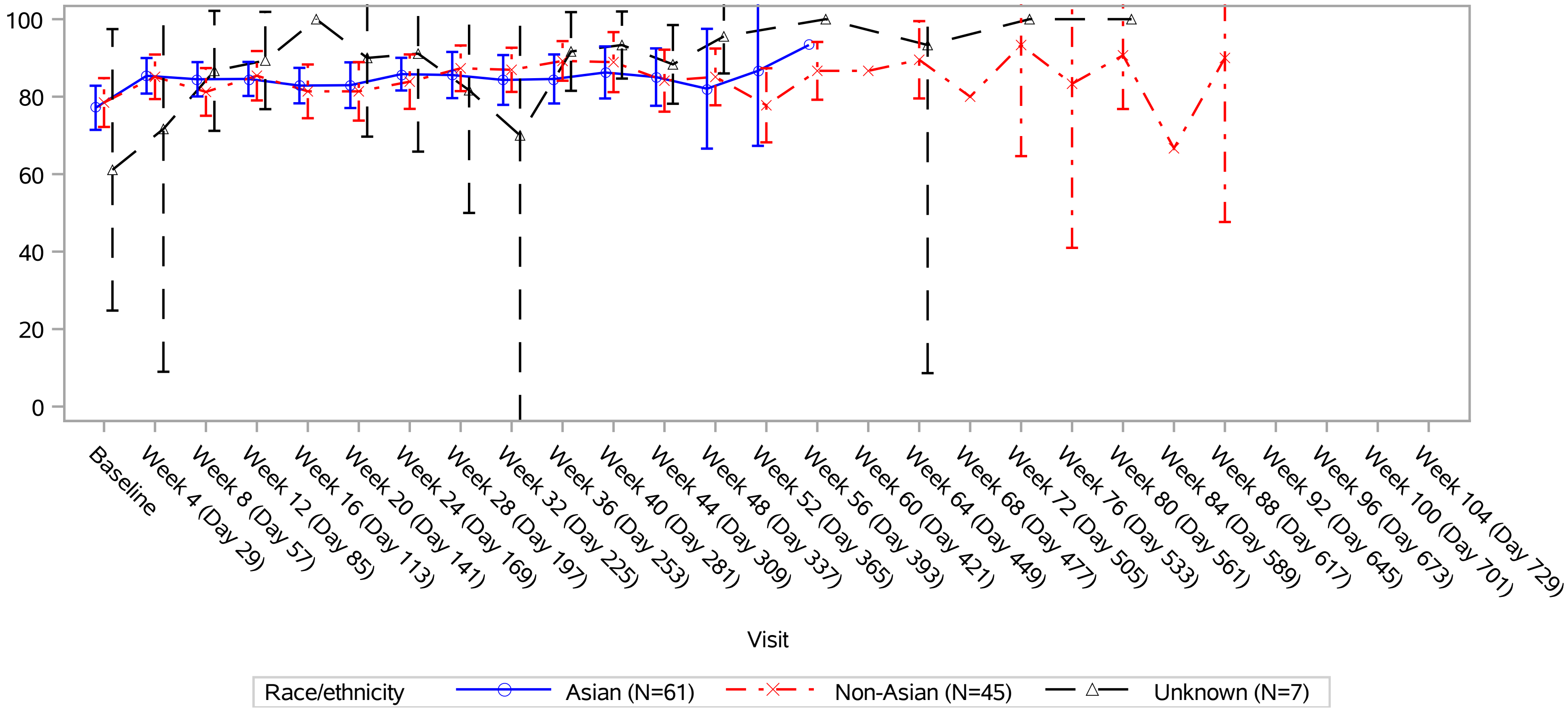
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Physical functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30PF_SGGEO.pdf
15OCT2021 18:49

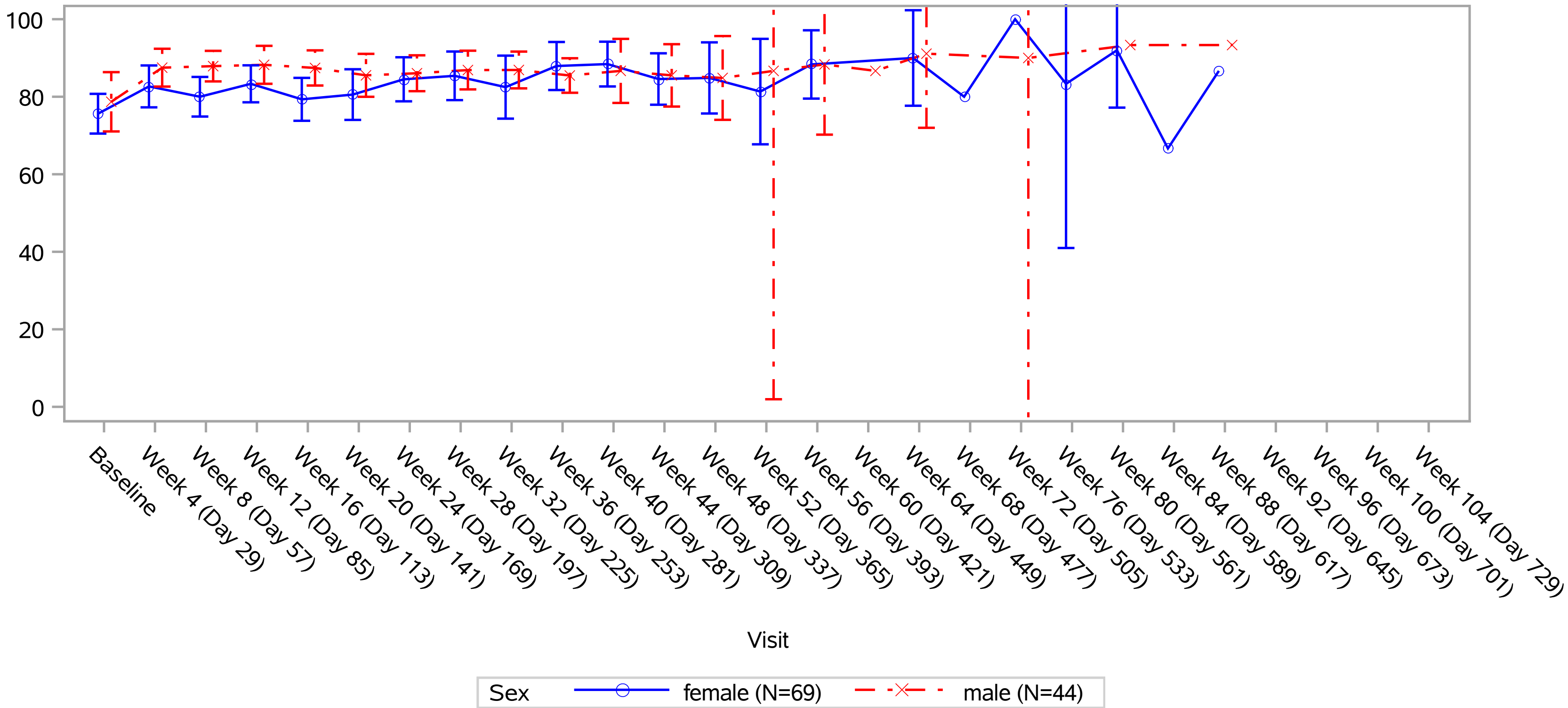
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Physical functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30PF_SGRE.pdf
15OCT2021 19:19

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Physical functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30PF_SGSEX.pdf
15OCT2021 19:50

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Global health status
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=113)							
		Patients				Statistics			
Name Visit	Level	in study¹	%	with value¹	%	mean²	SD	CI LL	CI UL
All									
Baseline	n/a	113	100.0	108	95.6	61.34	23.99	56.77	65.92
Week 4 (Day 29)	n/a	113	100.0	95	84.1	68.16	20.73	63.93	72.38
Week 8 (Day 57)	n/a	101	89.4	92	91.1	70.38	19.43	66.36	74.40
Week 12 (Day 85)	n/a	97	85.8	90	92.8	72.69	19.47	68.61	76.76
Week 16 (Day 113)	n/a	95	84.1	85	89.5	69.61	20.92	65.10	74.12
Week 20 (Day 141)	n/a	89	78.8	83	93.3	69.88	21.65	65.15	74.61
Week 24 (Day 169)	n/a	81	71.7	73	90.1	73.86	17.86	69.69	78.02
Week 28 (Day 197)	n/a	74	65.5	69	93.2	72.95	18.55	68.49	77.40
Week 32 (Day 225)	n/a	71	62.8	63	88.7	70.90	21.05	65.60	76.20
Week 36 (Day 253)	n/a	71	62.8	65	91.5	71.03	20.79	65.87	76.18
Week 40 (Day 281)	n/a	67	59.3	59	88.1	72.46	21.29	66.91	78.01
Week 44 (Day 309)	n/a	64	56.6	58	90.6	70.26	22.08	64.45	76.06
Week 48 (Day 337)	n/a	58	51.3	33	56.9	71.72	21.44	64.11	79.32
Week 52 (Day 365)	n/a	45	39.8	7	15.6	70.24	13.49	57.77	82.71
Week 56 (Day 393)	n/a	37	32.7	12	32.4	72.92	21.94	58.98	86.86
Week 60 (Day 421)	n/a	32	28.3	1	3.1	83.33	NE	NE	NE
Week 64 (Day 449)	n/a	31	27.4	9	29.0	64.81	31.40	40.68	88.95
Week 68 (Day 477)	n/a	28	24.8	1	3.6	58.33	NE	NE	NE
Week 72 (Day 505)	n/a	28	24.8	4	14.3	87.50	10.76	70.38	104.62
Week 76 (Day 533)	n/a	25	22.1	2	8.0	58.33	11.79	-47.55	164.22
Week 80 (Day 561)	n/a	25	22.1	6	24.0	77.78	14.59	62.46	93.09
Week 84 (Day 589)	n/a	18	15.9	1	5.6	50.00	NE	NE	NE
Week 88 (Day 617)	n/a	14	12.4	2	14.3	83.33	23.57	-128.44	295.10
Week 92 (Day 645)	n/a	7	6.2	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	5.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	2.7	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	113	100.0	111	98.2	65.62	22.39	61.40	69.83
End of Study (LOCF)	n/a	113	100.0	111	98.2	66.22	22.50	61.98	70.45
Sex									
Baseline	Female	69	100.0	67	97.1	61.69	24.10	55.81	67.57
Week 4 (Day 29)	Female	69	100.0	55	79.7	69.24	19.50	63.97	74.51
Week 8 (Day 57)	Female	63	91.3	54	85.7	70.22	21.82	64.26	76.17
Week 12 (Day 85)	Female	60	87.0	56	93.3	70.83	21.20	65.16	76.51
Week 16 (Day 113)	Female	58	84.1	50	86.2	67.50	21.77	61.31	73.69
Week 20 (Day 141)	Female	53	76.8	48	90.6	69.44	24.51	62.33	76.56
Week 24 (Day 169)	Female	47	68.1	40	85.1	75.42	19.70	69.12	81.72
Week 28 (Day 197)	Female	42	60.9	38	90.5	73.25	21.41	66.21	80.28
Week 32 (Day 225)	Female	42	60.9	35	83.3	71.67	23.85	63.48	79.86
Week 36 (Day 253)	Female	42	60.9	37	88.1	71.17	23.45	63.35	78.99
Week 40 (Day 281)	Female	41	59.4	37	90.2	75.23	20.92	68.25	82.20
Week 44 (Day 309)	Female	41	59.4	35	85.4	73.10	21.59	65.68	80.51
Week 48 (Day 337)	Female	37	53.6	22	59.5	75.38	21.59	65.81	84.95
Week 52 (Day 365)	Female	29	42.0	5	17.2	71.67	11.18	57.78	85.55
Week 56 (Day 393)	Female	24	34.8	8	33.3	79.17	20.89	61.70	96.63
Week 60 (Day 421)	Female	22	31.9	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Female	22	31.9	6	27.3	62.50	37.91	22.71	102.29
Week 68 (Day 477)	Female	20	29.0	1	5.0	58.33	NE	NE	NE
Week 72 (Day 505)	Female	20	29.0	2	10.0	91.67	11.79	-14.22	197.55
Week 76 (Day 533)	Female	18	26.1	2	11.1	58.33	11.79	-47.55	164.22
Week 80 (Day 561)	Female	18	26.1	5	27.8	78.33	16.24	58.16	98.50
Week 84 (Day 589)	Female	12	17.4	1	8.3	50.00	NE	NE	NE
Week 88 (Day 617)	Female	9	13.0	1	11.1	100.00	NE	NE	NE
Week 92 (Day 645)	Female	6	8.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	7.2	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	2.9	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	1.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	69	100.0	68	98.6	66.05	22.64	60.57	71.53
End of Study (LOCF)	Female	69	100.0	68	98.6	66.67	23.66	60.94	72.39
Baseline	Male	44	100.0	41	93.2	60.77	24.10	53.17	68.38
Week 4 (Day 29)	Male	44	100.0	40	90.9	66.67	22.49	59.47	73.86
Week 8 (Day 57)	Male	38	86.4	38	100.0	70.61	15.71	65.45	75.78
Week 12 (Day 85)	Male	37	84.1	34	91.9	75.74	16.07	70.13	81.34
Week 16 (Day 113)	Male	37	84.1	35	94.6	72.62	19.55	65.90	79.34
Week 20 (Day 141)	Male	36	81.8	35	97.2	70.48	17.31	64.53	76.42
Week 24 (Day 169)	Male	34	77.3	33	97.1	71.97	15.42	66.50	77.44
Week 28 (Day 197)	Male	32	72.7	31	96.9	72.58	14.62	67.22	77.94
Week 32 (Day 225)	Male	29	65.9	28	96.6	69.94	17.32	63.22	76.66
Week 36 (Day 253)	Male	29	65.9	28	96.6	70.83	17.05	64.22	77.44
Week 40 (Day 281)	Male	26	59.1	22	84.6	67.80	21.56	58.24	77.36
Week 44 (Day 309)	Male	23	52.3	23	100.0	65.94	22.60	56.17	75.72
Week 48 (Day 337)	Male	21	47.7	11	52.4	64.39	20.10	50.89	77.90
Week 52 (Day 365)	Male	16	36.4	2	12.5	66.67	23.57	-145.10	278.44
Week 56 (Day 393)	Male	13	29.5	4	30.8	60.42	20.83	27.27	93.57
Week 60 (Day 421)	Male	10	22.7	1	10.0	83.33	NE	NE	NE
Week 64 (Day 449)	Male	9	20.5	3	33.3	69.44	17.35	26.35	112.54
Week 68 (Day 477)	Male	8	18.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	8	18.2	2	25.0	83.33	11.79	-22.55	189.22
Week 76 (Day 533)	Male	7	15.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	7	15.9	1	14.3	75.00	NE	NE	NE
Week 84 (Day 589)	Male	6	13.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	5	11.4	1	20.0	66.67	NE	NE	NE
Week 92 (Day 645)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	44	100.0	43	97.7	64.92	22.24	58.08	71.77
End of Study (LOCF)	Male	44	100.0	43	97.7	65.50	20.78	59.11	71.90
Age									

Baseline	< 65	78	100.0	73	93.6	59.36	24.17	53.72	65.00
Week 4 (Day 29)	< 65	78	100.0	68	87.2	68.26	19.81	63.47	73.05
Week 8 (Day 57)	< 65	73	93.6	66	90.4	72.10	18.23	67.62	76.58
Week 12 (Day 85)	< 65	71	91.0	64	90.1	74.09	16.67	69.92	78.25
Week 16 (Day 113)	< 65	69	88.5	59	85.5	72.18	18.99	67.23	77.12
Week 20 (Day 141)	< 65	65	83.3	62	95.4	70.70	22.11	65.08	76.31
Week 24 (Day 169)	< 65	59	75.6	55	93.2	74.55	19.07	69.39	79.70
Week 28 (Day 197)	< 65	55	70.5	51	92.7	74.18	18.80	68.90	79.47
Week 32 (Day 225)	< 65	53	67.9	48	90.6	74.13	19.54	68.46	79.81
Week 36 (Day 253)	< 65	53	67.9	50	94.3	72.17	21.67	66.01	78.32
Week 40 (Day 281)	< 65	52	66.7	48	92.3	74.13	21.28	67.95	80.31
Week 44 (Day 309)	< 65	52	66.7	48	92.3	70.66	22.21	64.21	77.11
Week 48 (Day 337)	< 65	47	60.3	26	55.3	73.72	20.23	65.55	81.89
Week 52 (Day 365)	< 65	36	46.2	4	11.1	70.83	15.96	45.44	96.22
Week 56 (Day 393)	< 65	30	38.5	9	30.0	77.78	19.98	62.42	93.14
Week 60 (Day 421)	< 65	25	32.1	1	4.0	83.33	NE	NE	NE
Week 64 (Day 449)	< 65	24	30.8	7	29.2	67.86	33.48	36.89	98.82
Week 68 (Day 477)	< 65	22	28.2	1	4.5	58.33	NE	NE	NE
Week 72 (Day 505)	< 65	22	28.2	4	18.2	87.50	10.76	70.38	104.62
Week 76 (Day 533)	< 65	21	26.9	2	9.5	58.33	11.79	-47.55	164.22
Week 80 (Day 561)	< 65	21	26.9	5	23.8	76.67	16.03	56.76	96.57
Week 84 (Day 589)	< 65	15	19.2	1	6.7	50.00	NE	NE	NE
Week 88 (Day 617)	< 65	12	15.4	2	16.7	83.33	23.57	-128.44	295.10
Week 92 (Day 645)	< 65	6	7.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	6.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	78	100.0	76	97.4	67.00	22.38	61.88	72.11
End of Study (LOCF)	< 65	78	100.0	76	97.4	68.53	21.84	63.54	73.52
Baseline	>= 65	35	100.0	35	100.0	65.48	23.41	57.44	73.52
Week 4 (Day 29)	>= 65	35	100.0	27	77.1	67.90	23.31	58.68	77.12
Week 8 (Day 57)	>= 65	28	80.0	26	92.9	66.03	21.98	57.15	74.90
Week 12 (Day 85)	>= 65	26	74.3	26	100.0	69.23	25.14	59.08	79.39

Week 16 (Day 113)	>= 65	26	74.3	26	100.0	63.78	24.15	54.03	73.53
Week 20 (Day 141)	>= 65	24	68.6	21	87.5	67.46	20.57	58.10	76.82
Week 24 (Day 169)	>= 65	22	62.9	18	81.8	71.76	13.75	64.92	78.60
Week 28 (Day 197)	>= 65	19	54.3	18	94.7	69.44	17.85	60.57	78.32
Week 32 (Day 225)	>= 65	18	51.4	15	83.3	60.56	23.03	47.80	73.31
Week 36 (Day 253)	>= 65	18	51.4	15	83.3	67.22	17.67	57.44	77.01
Week 40 (Day 281)	>= 65	15	42.9	11	73.3	65.15	20.69	51.25	79.05
Week 44 (Day 309)	>= 65	12	34.3	10	83.3	68.33	22.50	52.24	84.43
Week 48 (Day 337)	>= 65	11	31.4	7	63.6	64.29	25.78	40.44	88.13
Week 52 (Day 365)	>= 65	9	25.7	3	33.3	69.44	12.73	37.82	101.07
Week 56 (Day 393)	>= 65	7	20.0	3	42.9	58.33	25.00	-3.77	120.44
Week 60 (Day 421)	>= 65	7	20.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	7	20.0	2	28.6	54.17	29.46	-210.55	318.88
Week 68 (Day 477)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	4	11.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	4	11.4	1	25.0	83.33	NE	NE	NE
Week 84 (Day 589)	>= 65	3	8.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	5.7	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	35	100.0	35	100.0	62.62	22.45	54.91	70.33
End of Study (LOCF)	>= 65	35	100.0	35	100.0	61.19	23.39	53.16	69.23
ECOG performance status									
Baseline	0	33	100.0	31	93.9	65.86	23.61	57.20	74.52
Week 4 (Day 29)	0	33	100.0	27	81.8	61.73	26.88	51.09	72.36
Week 8 (Day 57)	0	30	90.9	27	90.0	67.59	23.04	58.48	76.71
Week 12 (Day 85)	0	29	87.9	26	89.7	70.51	20.71	62.15	78.88
Week 16 (Day 113)	0	28	84.8	24	85.7	66.32	20.63	57.61	75.03
Week 20 (Day 141)	0	26	78.8	24	92.3	67.36	23.43	57.47	77.26
Week 24 (Day 169)	0	24	72.7	20	83.3	72.92	18.71	64.16	81.67
Week 28 (Day 197)	0	21	63.6	19	90.5	73.25	19.95	63.63	82.86

Week 32 (Day 225)	0	21	63.6	18	85.7	74.54	21.48	63.86	85.22
Week 36 (Day 253)	0	21	63.6	20	95.2	69.58	23.61	58.53	80.63
Week 40 (Day 281)	0	21	63.6	19	90.5	69.74	22.77	58.76	80.71
Week 44 (Day 309)	0	21	63.6	17	81.0	69.61	21.23	58.69	80.53
Week 48 (Day 337)	0	19	57.6	12	63.2	67.36	28.53	49.24	85.49
Week 52 (Day 365)	0	18	54.5	3	16.7	69.44	12.73	37.82	101.07
Week 56 (Day 393)	0	16	48.5	5	31.3	66.67	25.69	34.77	98.56
Week 60 (Day 421)	0	16	48.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	0	16	48.5	5	31.3	70.00	27.39	36.00	104.00
Week 68 (Day 477)	0	14	42.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	0	14	42.4	1	7.1	91.67	NE	NE	NE
Week 76 (Day 533)	0	12	36.4	1	8.3	66.67	NE	NE	NE
Week 80 (Day 561)	0	12	36.4	1	8.3	83.33	NE	NE	NE
Week 84 (Day 589)	0	10	30.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	9	27.3	1	11.1	100.00	NE	NE	NE
Week 92 (Day 645)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	9.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	3.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	33	100.0	33	100.0	61.62	25.76	52.48	70.75
End of Study (LOCF)	0	33	100.0	33	100.0	61.62	28.48	51.52	71.72
Baseline	1	79	100.0	76	96.2	59.32	24.15	53.80	64.84
Week 4 (Day 29)	1	79	100.0	67	84.8	70.65	17.43	66.40	74.90
Week 8 (Day 57)	1	70	88.6	65	92.9	71.54	17.79	67.13	75.95
Week 12 (Day 85)	1	68	86.1	64	94.1	73.57	19.05	68.81	78.33
Week 16 (Day 113)	1	67	84.8	61	91.0	70.90	21.06	65.51	76.30
Week 20 (Day 141)	1	63	79.7	59	93.7	70.90	21.01	65.43	76.38
Week 24 (Day 169)	1	57	72.2	53	93.0	74.21	17.70	69.34	79.09
Week 28 (Day 197)	1	53	67.1	50	94.3	72.83	18.20	67.66	78.00
Week 32 (Day 225)	1	50	63.3	45	90.0	69.44	20.95	63.15	75.74
Week 36 (Day 253)	1	50	63.3	45	90.0	71.67	19.66	65.76	77.57
Week 40 (Day 281)	1	46	58.2	40	87.0	73.75	20.72	67.12	80.38

Week 44 (Day 309)	1	43	54.4	41	95.3	70.53	22.68	63.37	77.69
Week 48 (Day 337)	1	39	49.4	21	53.8	74.21	16.44	66.72	81.69
Week 52 (Day 365)	1	27	34.2	4	14.8	70.83	15.96	45.44	96.22
Week 56 (Day 393)	1	21	26.6	7	33.3	77.38	19.67	59.19	95.57
Week 60 (Day 421)	1	16	20.3	1	6.3	83.33	NE	NE	NE
Week 64 (Day 449)	1	15	19.0	4	26.7	58.33	39.09	-3.86	120.53
Week 68 (Day 477)	1	14	17.7	1	7.1	58.33	NE	NE	NE
Week 72 (Day 505)	1	14	17.7	3	21.4	86.11	12.73	54.49	117.73
Week 76 (Day 533)	1	13	16.5	1	7.7	50.00	NE	NE	NE
Week 80 (Day 561)	1	13	16.5	5	38.5	76.67	16.03	56.76	96.57
Week 84 (Day 589)	1	8	10.1	1	12.5	50.00	NE	NE	NE
Week 88 (Day 617)	1	5	6.3	1	20.0	66.67	NE	NE	NE
Week 92 (Day 645)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	2.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	79	100.0	77	97.5	67.21	20.87	62.47	71.94
End of Study (LOCF)	1	79	100.0	77	97.5	68.07	19.42	63.67	72.48
Baseline	Missing	1	100.0	1	100.0	75.00	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	75.00	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	75.00	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	75.00	NE	NE	NE
Geographic region									
Baseline	USA	22	100.0	22	100.0	69.32	21.42	59.82	78.82
Week 4 (Day 29)	USA	22	100.0	18	81.8	75.93	25.87	63.06	88.79
Week 8 (Day 57)	USA	20	90.9	18	90.0	79.17	16.97	70.73	87.61
Week 12 (Day 85)	USA	20	90.9	19	95.0	75.88	20.95	65.78	85.98
Week 16 (Day 113)	USA	19	86.4	17	89.5	78.43	16.94	69.72	87.14
Week 20 (Day 141)	USA	19	86.4	17	89.5	77.45	19.93	67.20	87.70
Week 24 (Day 169)	USA	16	72.7	14	87.5	84.52	13.81	76.55	92.50
Week 28 (Day 197)	USA	15	68.2	12	80.0	82.64	14.85	73.21	92.07
Week 32 (Day 225)	USA	15	68.2	13	86.7	77.56	21.08	64.83	90.30
Week 36 (Day 253)	USA	15	68.2	13	86.7	76.92	19.29	65.27	88.58
Week 40 (Day 281)	USA	14	63.6	11	78.6	74.24	28.00	55.43	93.05

Week 44 (Day 309)	USA	13	59.1	11	84.6	71.97	26.16	54.40	89.54
Week 48 (Day 337)	USA	13	59.1	10	76.9	81.67	17.92	68.85	94.48
Week 52 (Day 365)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	USA	12	54.5	6	50.0	75.00	27.39	46.26	103.74
Week 60 (Day 421)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	11	50.0	4	36.4	85.42	10.49	68.73	102.10
Week 68 (Day 477)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	10	45.5	1	10.0	91.67	NE	NE	NE
Week 76 (Day 533)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	10	45.5	2	20.0	70.83	17.68	-87.99	229.66
Week 84 (Day 589)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	13.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	4.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	22	100.0	22	100.0	72.73	20.76	63.52	81.93
End of Study (LOCF)	USA	22	100.0	22	100.0	76.52	16.99	68.98	84.05
Baseline	Europe (EU)	32	100.0	29	90.6	59.48	23.96	50.37	68.60
Week 4 (Day 29)	Europe (EU)	32	100.0	25	78.1	63.67	19.82	55.49	71.85
Week 8 (Day 57)	Europe (EU)	29	90.6	25	86.2	64.67	21.69	55.71	73.62
Week 12 (Day 85)	Europe (EU)	26	81.3	24	92.3	69.10	18.30	61.37	76.83
Week 16 (Day 113)	Europe (EU)	25	78.1	20	80.0	65.00	22.56	54.44	75.56
Week 20 (Day 141)	Europe (EU)	23	71.9	22	95.7	63.26	23.24	52.95	73.56
Week 24 (Day 169)	Europe (EU)	21	65.6	20	95.2	66.25	19.96	56.91	75.59
Week 28 (Day 197)	Europe (EU)	20	62.5	20	100.0	66.67	19.12	57.72	75.61
Week 32 (Day 225)	Europe (EU)	18	56.3	16	88.9	67.19	20.96	56.02	78.36
Week 36 (Day 253)	Europe (EU)	18	56.3	17	94.4	64.71	24.21	52.26	77.15
Week 40 (Day 281)	Europe (EU)	17	53.1	16	94.1	68.75	20.07	58.06	79.44
Week 44 (Day 309)	Europe (EU)	17	53.1	14	82.4	66.67	23.11	53.32	80.01

Week 48 (Day 337)	Europe (EU)	14	43.8	10	71.4	69.17	17.15	56.90	81.43
Week 52 (Day 365)	Europe (EU)	13	40.6	3	23.1	69.44	12.73	37.82	101.07
Week 56 (Day 393)	Europe (EU)	11	34.4	5	45.5	71.67	19.18	47.85	95.49
Week 60 (Day 421)	Europe (EU)	11	34.4	1	9.1	83.33	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	11	34.4	5	45.5	48.33	33.54	6.69	89.98
Week 68 (Day 477)	Europe (EU)	10	31.3	1	10.0	58.33	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	10	31.3	3	30.0	86.11	12.73	54.49	117.73
Week 76 (Day 533)	Europe (EU)	8	25.0	2	25.0	58.33	11.79	-47.55	164.22
Week 80 (Day 561)	Europe (EU)	8	25.0	4	50.0	81.25	14.23	58.60	103.90
Week 84 (Day 589)	Europe (EU)	6	18.8	1	16.7	50.00	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	9.4	2	66.7	83.33	23.57	-128.44	295.10
Cycle 12 (LOCF)	Europe (EU)	32	100.0	31	96.9	61.29	24.20	52.41	70.17
End of Study (LOCF)	Europe (EU)	32	100.0	31	96.9	62.10	24.61	53.07	71.12
Baseline	Asia (AS)	59	100.0	57	96.6	59.21	24.68	52.66	65.76
Week 4 (Day 29)	Asia (AS)	59	100.0	52	88.1	67.63	18.79	62.40	72.86
Week 8 (Day 57)	Asia (AS)	52	88.1	49	94.2	70.07	18.24	64.83	75.31
Week 12 (Day 85)	Asia (AS)	51	86.4	47	92.2	73.23	19.58	67.48	78.97
Week 16 (Day 113)	Asia (AS)	51	86.4	48	94.1	68.40	20.98	62.31	74.49
Week 20 (Day 141)	Asia (AS)	47	79.7	44	93.6	70.27	20.91	63.91	76.62
Week 24 (Day 169)	Asia (AS)	44	74.6	39	88.6	73.93	16.35	68.63	79.23
Week 28 (Day 197)	Asia (AS)	39	66.1	37	94.9	73.20	18.33	67.09	79.31
Week 32 (Day 225)	Asia (AS)	38	64.4	34	89.5	70.10	21.13	62.72	77.47
Week 36 (Day 253)	Asia (AS)	38	64.4	35	92.1	71.90	19.29	65.28	78.53
Week 40 (Day 281)	Asia (AS)	36	61.0	32	88.9	73.70	19.76	66.58	80.82
Week 44 (Day 309)	Asia (AS)	34	57.6	33	97.1	71.21	20.74	63.86	78.57
Week 48 (Day 337)	Asia (AS)	31	52.5	13	41.9	66.03	25.34	50.72	81.34
Week 52 (Day 365)	Asia (AS)	20	33.9	4	20.0	70.83	15.96	45.44	96.22
Week 56 (Day 393)	Asia (AS)	14	23.7	1	7.1	66.67	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	10.2	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	8.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	3.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	59	100.0	58	98.3	65.23	21.69	59.53	70.93
End of Study (LOCF)	Asia (AS)	59	100.0	58	98.3	64.51	22.33	58.64	70.38
Race/ethnicity									
Baseline	Asian	61	100.0	58	95.1	58.76	24.70	52.27	65.26
Week 4 (Day 29)	Asian	61	100.0	52	85.2	67.63	18.79	62.40	72.86
Week 8 (Day 57)	Asian	53	86.9	49	92.5	70.07	18.24	64.83	75.31
Week 12 (Day 85)	Asian	52	85.2	48	92.3	73.44	19.42	67.80	79.08
Week 16 (Day 113)	Asian	52	85.2	49	94.2	68.03	20.93	62.02	74.04
Week 20 (Day 141)	Asian	48	78.7	45	93.8	70.19	20.68	63.97	76.40
Week 24 (Day 169)	Asian	44	72.1	39	88.6	73.93	16.35	68.63	79.23
Week 28 (Day 197)	Asian	39	63.9	37	94.9	73.20	18.33	67.09	79.31
Week 32 (Day 225)	Asian	38	62.3	34	89.5	70.10	21.13	62.72	77.47
Week 36 (Day 253)	Asian	38	62.3	35	92.1	71.90	19.29	65.28	78.53
Week 40 (Day 281)	Asian	36	59.0	32	88.9	73.70	19.76	66.58	80.82
Week 44 (Day 309)	Asian	34	55.7	33	97.1	71.21	20.74	63.86	78.57
Week 48 (Day 337)	Asian	31	50.8	13	41.9	66.03	25.34	50.72	81.34
Week 52 (Day 365)	Asian	20	32.8	4	20.0	70.83	15.96	45.44	96.22
Week 56 (Day 393)	Asian	14	23.0	1	7.1	66.67	NE	NE	NE
Week 60 (Day 421)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	9.8	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	8.2	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	3.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	61	100.0	59	96.7	65.25	21.51	59.65	70.86
End of Study (LOCF)	Asian	61	100.0	59	96.7	64.55	22.13	58.78	70.32
Baseline	Non-Asian	45	100.0	44	97.8	65.72	22.46	58.89	72.55
Week 4 (Day 29)	Non-Asian	45	100.0	39	86.7	70.30	21.01	63.49	77.11
Week 8 (Day 57)	Non-Asian	42	93.3	38	90.5	70.39	21.37	63.37	77.42
Week 12 (Day 85)	Non-Asian	39	86.7	37	94.9	71.62	20.08	64.93	78.31
Week 16 (Day 113)	Non-Asian	37	82.2	34	91.9	70.59	20.95	63.28	77.90
Week 20 (Day 141)	Non-Asian	36	80.0	34	94.4	68.14	23.07	60.09	76.19
Week 24 (Day 169)	Non-Asian	32	71.1	31	96.9	72.85	19.95	65.53	80.17
Week 28 (Day 197)	Non-Asian	30	66.7	28	93.3	74.11	16.41	67.74	80.47
Week 32 (Day 225)	Non-Asian	28	62.2	25	89.3	70.00	22.05	60.90	79.10
Week 36 (Day 253)	Non-Asian	28	62.2	26	92.9	70.83	21.89	61.99	79.67
Week 40 (Day 281)	Non-Asian	26	57.8	23	88.5	68.12	23.92	57.77	78.46
Week 44 (Day 309)	Non-Asian	25	55.6	21	84.0	67.06	25.88	55.28	78.85
Week 48 (Day 337)	Non-Asian	23	51.1	17	73.9	74.02	18.61	64.45	83.59
Week 52 (Day 365)	Non-Asian	21	46.7	3	14.3	69.44	12.73	37.82	101.07
Week 56 (Day 393)	Non-Asian	19	42.2	10	52.6	72.50	23.91	55.39	89.61
Week 60 (Day 421)	Non-Asian	19	42.2	1	5.3	83.33	NE	NE	NE
Week 64 (Day 449)	Non-Asian	18	40.0	7	38.9	59.52	34.17	27.93	91.12
Week 68 (Day 477)	Non-Asian	17	37.8	1	5.9	58.33	NE	NE	NE
Week 72 (Day 505)	Non-Asian	17	37.8	3	17.6	88.89	12.73	57.27	120.51
Week 76 (Day 533)	Non-Asian	15	33.3	2	13.3	58.33	11.79	-47.55	164.22
Week 80 (Day 561)	Non-Asian	15	33.3	5	33.3	80.00	15.14	61.20	98.80
Week 84 (Day 589)	Non-Asian	10	22.2	1	10.0	50.00	NE	NE	NE
Week 88 (Day 617)	Non-Asian	7	15.6	2	28.6	83.33	23.57	-128.44	295.10
Week 92 (Day 645)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	45	100.0	45	100.0	64.63	24.31	57.33	71.93

End of Study (LOCF)	Non-Asian	45	100.0	45	100.0	67.04	23.70	59.92	74.16
Baseline	Unknown	7	100.0	6	85.7	54.17	26.74	26.10	82.23
Week 4 (Day 29)	Unknown	7	100.0	4	57.1	54.17	39.38	-8.50	116.83
Week 8 (Day 57)	Unknown	6	85.7	5	83.3	73.33	19.00	49.74	96.93
Week 12 (Day 85)	Unknown	6	85.7	5	83.3	73.33	19.00	49.74	96.93
Week 16 (Day 113)	Unknown	6	85.7	2	33.3	91.67	11.79	-14.22	197.55
Week 20 (Day 141)	Unknown	5	71.4	4	80.0	81.25	21.92	46.38	116.12
Week 24 (Day 169)	Unknown	5	71.4	3	60.0	83.33	16.67	41.93	124.74
Week 28 (Day 197)	Unknown	5	71.4	4	80.0	62.50	34.36	7.83	117.17
Week 32 (Day 225)	Unknown	5	71.4	4	80.0	83.33	11.79	64.58	102.09
Week 36 (Day 253)	Unknown	5	71.4	4	80.0	64.58	30.71	15.71	113.45
Week 40 (Day 281)	Unknown	5	71.4	4	80.0	87.50	8.33	74.24	100.76
Week 44 (Day 309)	Unknown	5	71.4	4	80.0	79.17	4.81	71.51	86.82
Week 48 (Day 337)	Unknown	4	57.1	3	75.0	83.33	16.67	41.93	124.74
Week 52 (Day 365)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	4	57.1	1	25.0	83.33	NE	NE	NE
Week 60 (Day 421)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	4	57.1	2	50.0	83.33	0.00	NE	NE
Week 68 (Day 477)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	3	42.9	1	33.3	83.33	NE	NE	NE
Week 76 (Day 533)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	3	42.9	1	33.3	66.67	NE	NE	NE
Week 84 (Day 589)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	14.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	7	100.0	7	100.0	75.00	16.67	59.59	90.41
End of Study (LOCF)	Unknown	7	100.0	7	100.0	75.00	17.35	58.96	91.04
Number of prior antineoplastic systemic therapy lines I									
Baseline	1	60	100.0	57	95.0	63.60	22.36	57.66	69.53

Week 4 (Day 29)	1	60	100.0	50	83.3	67.00	20.75	61.10	72.90
Week 8 (Day 57)	1	54	90.0	49	90.7	70.24	19.98	64.50	75.98
Week 12 (Day 85)	1	52	86.7	48	92.3	71.53	19.44	65.88	77.17
Week 16 (Day 113)	1	51	85.0	46	90.2	69.02	20.00	63.08	74.96
Week 20 (Day 141)	1	48	80.0	43	89.6	68.80	21.68	62.13	75.47
Week 24 (Day 169)	1	43	71.7	39	90.7	73.72	17.58	68.02	79.42
Week 28 (Day 197)	1	38	63.3	34	89.5	72.79	16.83	66.92	78.67
Week 32 (Day 225)	1	35	58.3	29	82.9	69.54	20.93	61.58	77.50
Week 36 (Day 253)	1	35	58.3	31	88.6	67.47	20.34	60.01	74.93
Week 40 (Day 281)	1	32	53.3	27	84.4	70.99	21.97	62.30	79.68
Week 44 (Day 309)	1	32	53.3	27	84.4	66.05	24.34	56.42	75.68
Week 48 (Day 337)	1	27	45.0	16	59.3	69.27	18.44	59.45	79.10
Week 52 (Day 365)	1	23	38.3	5	21.7	68.33	14.91	49.82	86.84
Week 56 (Day 393)	1	16	26.7	4	25.0	70.83	14.43	47.87	93.80
Week 60 (Day 421)	1	14	23.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	13	21.7	4	30.8	60.42	22.95	23.90	96.93
Week 68 (Day 477)	1	12	20.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	12	20.0	1	8.3	91.67	NE	NE	NE
Week 76 (Day 533)	1	11	18.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	11	18.3	2	18.2	83.33	0.00	NE	NE
Week 84 (Day 589)	1	9	15.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	1	8	13.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	1	3	5.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	1	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	60	100.0	58	96.7	64.80	22.02	59.01	70.59
End of Study (LOCF)	1	60	100.0	58	96.7	66.52	20.74	61.07	71.98
Baseline	>= 2	53	100.0	51	96.2	58.82	25.68	51.60	66.05
Week 4 (Day 29)	>= 2	53	100.0	45	84.9	69.44	20.87	63.17	75.71
Week 8 (Day 57)	>= 2	47	88.7	43	91.5	70.54	19.02	64.69	76.39
Week 12 (Day 85)	>= 2	45	84.9	42	93.3	74.01	19.67	67.88	80.14
Week 16 (Day 113)	>= 2	44	83.0	39	88.6	70.30	22.20	63.10	77.49

Week 20 (Day 141)	>= 2	41	77.4	40	97.6	71.04	21.84	64.06	78.03
Week 24 (Day 169)	>= 2	38	71.7	34	89.5	74.02	18.44	67.59	80.45
Week 28 (Day 197)	>= 2	36	67.9	35	97.2	73.10	20.32	66.11	80.08
Week 32 (Day 225)	>= 2	36	67.9	34	94.4	72.06	21.41	64.59	79.53
Week 36 (Day 253)	>= 2	36	67.9	34	94.4	74.26	20.96	66.95	81.58
Week 40 (Day 281)	>= 2	35	66.0	32	91.4	73.70	20.97	66.14	81.26
Week 44 (Day 309)	>= 2	32	60.4	31	96.9	73.92	19.57	66.75	81.10
Week 48 (Day 337)	>= 2	31	58.5	17	54.8	74.02	24.27	61.54	86.50
Week 52 (Day 365)	>= 2	22	41.5	2	9.1	75.00	11.79	-30.89	180.89
Week 56 (Day 393)	>= 2	21	39.6	8	38.1	73.96	25.76	52.42	95.49
Week 60 (Day 421)	>= 2	18	34.0	1	5.6	83.33	NE	NE	NE
Week 64 (Day 449)	>= 2	18	34.0	5	27.8	68.33	39.26	19.58	117.09
Week 68 (Day 477)	>= 2	16	30.2	1	6.3	58.33	NE	NE	NE
Week 72 (Day 505)	>= 2	16	30.2	3	18.8	86.11	12.73	54.49	117.73
Week 76 (Day 533)	>= 2	14	26.4	2	14.3	58.33	11.79	-47.55	164.22
Week 80 (Day 561)	>= 2	14	26.4	4	28.6	75.00	18.00	46.35	103.65
Week 84 (Day 589)	>= 2	9	17.0	1	11.1	50.00	NE	NE	NE
Week 88 (Day 617)	>= 2	6	11.3	2	33.3	83.33	23.57	-128.44	295.10
Week 92 (Day 645)	>= 2	2	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 2	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 2	53	100.0	53	100.0	66.51	22.97	60.18	72.84
End of Study (LOCF)	>= 2	53	100.0	53	100.0	65.88	24.47	59.13	72.63

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TP_QSC30QL_SG.xls
27OCT2021 7:30

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Global health status
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	49	45.4	36.3	54.8
	Cycle 12 (LOCF)	n/a	108	95.6	25	23.1	16.2	31.9
	End of Study (LOCF)	n/a	108	95.6	25	23.1	16.2	31.9
Sex	All visits	Female	67	59.3	31	46.3	34.9	58.1
		Male	41	36.3	18	43.9	29.9	59.0
	Cycle 12 (LOCF)	Female	67	59.3	15	22.4	14.1	33.7
		Male	41	36.3	10	24.4	13.8	39.3
	End of Study (LOCF)	Female	67	59.3	14	20.9	12.9	32.1
		Male	41	36.3	11	26.8	15.7	41.9
Age	All visits	< 65	73	64.6	32	43.8	33.0	55.2
		>= 65	35	31.0	17	48.6	33.0	64.4
	Cycle 12 (LOCF)	< 65	73	64.6	16	21.9	14.0	32.7
		>= 65	35	31.0	9	25.7	14.2	42.1
	End of Study (LOCF)	< 65	73	64.6	15	20.5	12.9	31.2
		>= 65	35	31.0	10	28.6	16.3	45.1
ECOG performance status	All visits	0	31	27.4	20	64.5	46.9	78.9
		1	76	67.3	29	38.2	28.1	49.4
		Missing	1	0.9	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	31	27.4	11	35.5	21.1	53.1
		1	76	67.3	14	18.4	11.3	28.6
		Missing	1	0.9	0	0.0	0.0	79.3
	End of Study (LOCF)	0	31	27.4	12	38.7	23.7	56.2
		1	76	67.3	13	17.1	10.3	27.1
		Missing	1	0.9	0	0.0	0.0	79.3
Geographic region	All visits	USA	22	19.5	8	36.4	19.7	57.0
		Europe (EU)	29	25.7	18	62.1	44.0	77.3
		Asia (AS)	57	50.4	23	40.4	28.6	53.3
	Cycle 12 (LOCF)	USA	22	19.5	2	9.1	2.5	27.8
		Europe (EU)	29	25.7	9	31.0	17.3	49.2
		Asia (AS)	57	50.4	14	24.6	15.2	37.1
	End of Study (LOCF)	USA	22	19.5	2	9.1	2.5	27.8
		Europe (EU)	29	25.7	9	31.0	17.3	49.2
		Asia (AS)	57	50.4	14	24.6	15.2	37.1
Race/ethnicity	All visits	Asian	58	51.3	23	39.7	28.1	52.5
		Non-Asian	44	38.9	24	54.5	40.1	68.3
		Unknown	6	5.3	2	33.3	9.7	70.0
	Cycle 12 (LOCF)	Asian	58	51.3	14	24.1	15.0	36.5

		Non-Asian	44	38.9	11	25.0	14.6	39.4
		Unknown	6	5.3	0	0.0	0.0	39.0
	End of Study (LOCF)	Asian	58	51.3	14	24.1	15.0	36.5
		Non-Asian	44	38.9	11	25.0	14.6	39.4
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	28	49.1	36.6	61.7
		>= 2	51	45.1	21	41.2	28.8	54.8
	Cycle 12 (LOCF)	1	57	50.4	13	22.8	13.8	35.2
		>= 2	51	45.1	12	23.5	14.0	36.8
	End of Study (LOCF)	1	57	50.4	12	21.1	12.5	33.3
		>= 2	51	45.1	13	25.5	15.5	38.9

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30QL_W10_SG.xls
15OCT2021 13:37

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Global health status
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

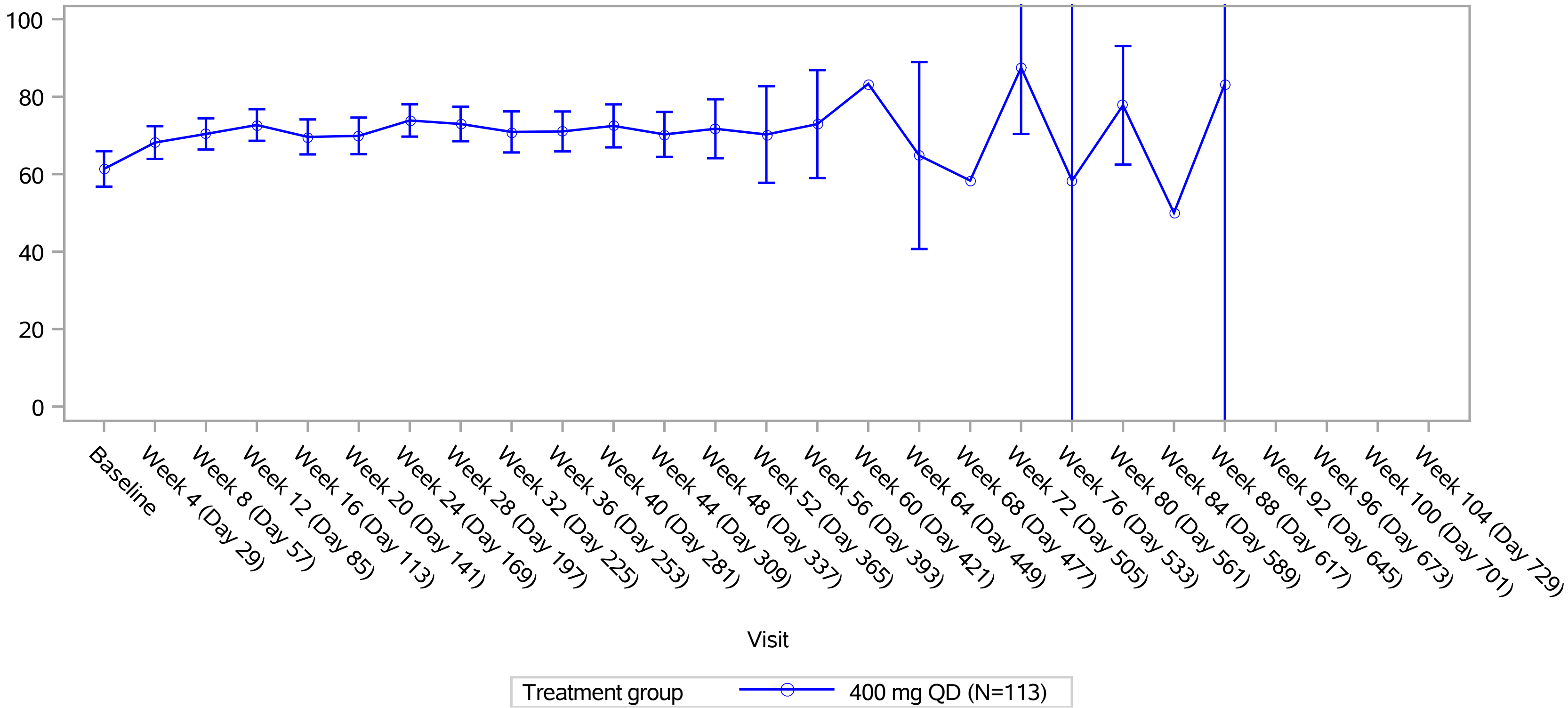
			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	49	45.4	36.3	54.8
	Cycle 12 (LOCF)	n/a	108	95.6	25	23.1	16.2	31.9
	End of Study (LOCF)	n/a	108	95.6	25	23.1	16.2	31.9
Sex	All visits	Female	67	59.3	31	46.3	34.9	58.1
		Male	41	36.3	18	43.9	29.9	59.0
	Cycle 12 (LOCF)	Female	67	59.3	15	22.4	14.1	33.7
		Male	41	36.3	10	24.4	13.8	39.3
	End of Study (LOCF)	Female	67	59.3	14	20.9	12.9	32.1
		Male	41	36.3	11	26.8	15.7	41.9
Age	All visits	< 65	73	64.6	32	43.8	33.0	55.2
		>= 65	35	31.0	17	48.6	33.0	64.4
	Cycle 12 (LOCF)	< 65	73	64.6	16	21.9	14.0	32.7
		>= 65	35	31.0	9	25.7	14.2	42.1
	End of Study (LOCF)	< 65	73	64.6	15	20.5	12.9	31.2
		>= 65	35	31.0	10	28.6	16.3	45.1
ECOG performance status	All visits	0	31	27.4	20	64.5	46.9	78.9
		1	76	67.3	29	38.2	28.1	49.4
		Missing	1	0.9	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	31	27.4	11	35.5	21.1	53.1
		1	76	67.3	14	18.4	11.3	28.6
		Missing	1	0.9	0	0.0	0.0	79.3
	End of Study (LOCF)	0	31	27.4	12	38.7	23.7	56.2
		1	76	67.3	13	17.1	10.3	27.1
		Missing	1	0.9	0	0.0	0.0	79.3
Geographic region	All visits	USA	22	19.5	8	36.4	19.7	57.0
		Europe (EU)	29	25.7	18	62.1	44.0	77.3
		Asia (AS)	57	50.4	23	40.4	28.6	53.3
	Cycle 12 (LOCF)	USA	22	19.5	2	9.1	2.5	27.8
		Europe (EU)	29	25.7	9	31.0	17.3	49.2
		Asia (AS)	57	50.4	14	24.6	15.2	37.1
	End of Study (LOCF)	USA	22	19.5	2	9.1	2.5	27.8
		Europe (EU)	29	25.7	9	31.0	17.3	49.2
		Asia (AS)	57	50.4	14	24.6	15.2	37.1
Race/ethnicity	All visits	Asian	58	51.3	23	39.7	28.1	52.5
		Non-Asian	44	38.9	24	54.5	40.1	68.3
		Unknown	6	5.3	2	33.3	9.7	70.0
	Cycle 12 (LOCF)	Asian	58	51.3	14	24.1	15.0	36.5

		Non-Asian	44	38.9	11	25.0	14.6	39.4
		Unknown	6	5.3	0	0.0	0.0	39.0
	End of Study (LOCF)	Asian	58	51.3	14	24.1	15.0	36.5
		Non-Asian	44	38.9	11	25.0	14.6	39.4
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	28	49.1	36.6	61.7
		>= 2	51	45.1	21	41.2	28.8	54.8
	Cycle 12 (LOCF)	1	57	50.4	13	22.8	13.8	35.2
		>= 2	51	45.1	12	23.5	14.0	36.8
	End of Study (LOCF)	1	57	50.4	12	21.1	12.5	33.3
		>= 2	51	45.1	13	25.5	15.5	38.9

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30QL_W15_SG.xls
15OCT2021 13:27

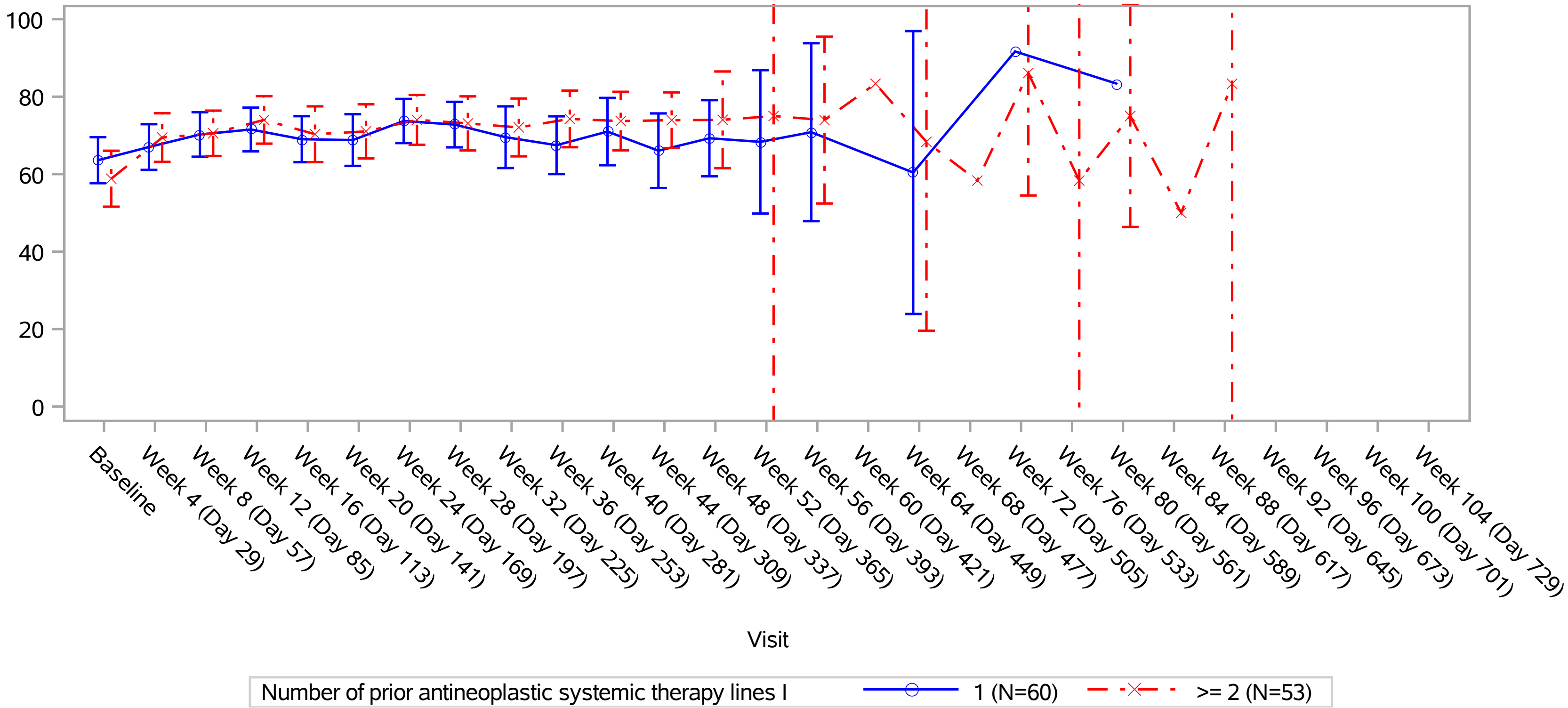
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Global health status
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30QL.pdf
15OCT2021 17:19

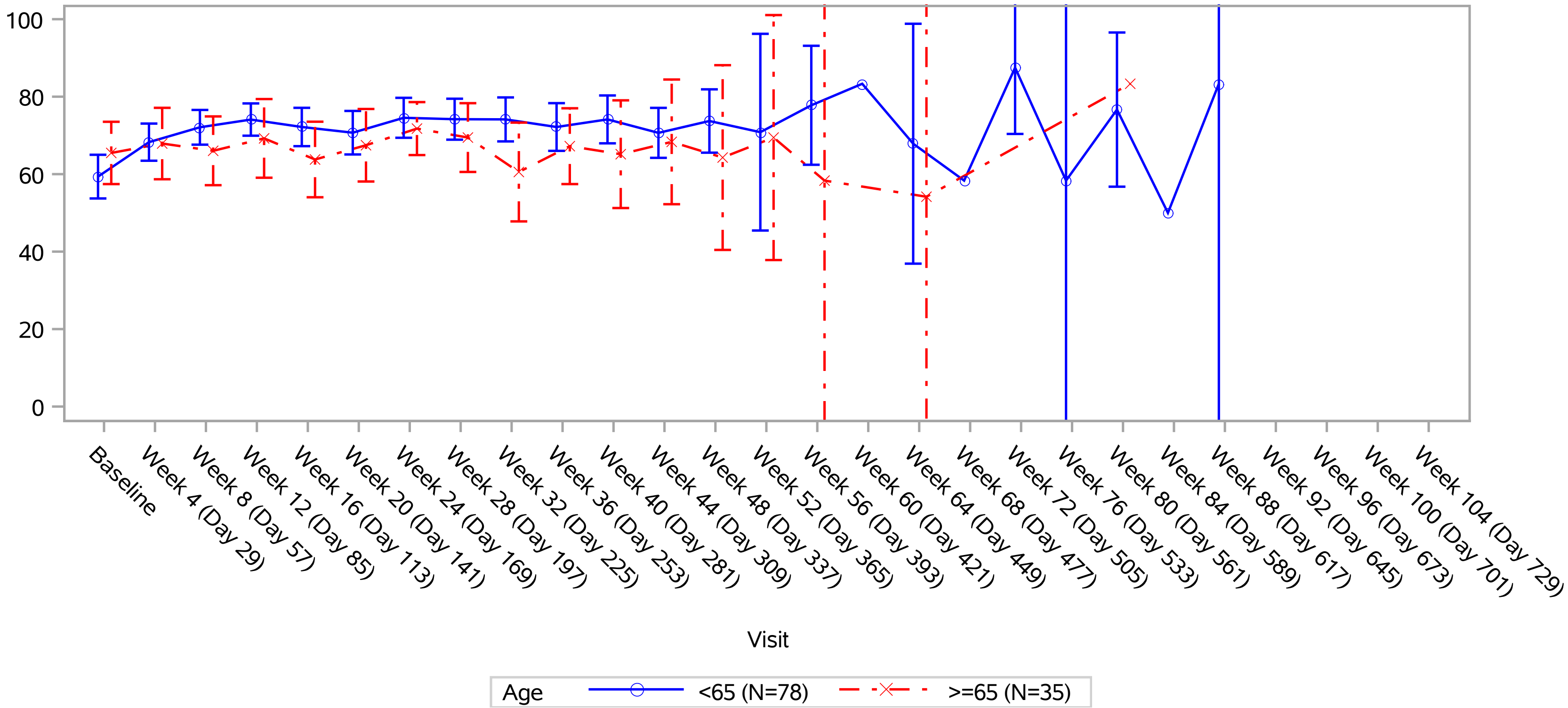
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Global health status
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30QL_PRTHL1.pdf
15OCT2021 20:11

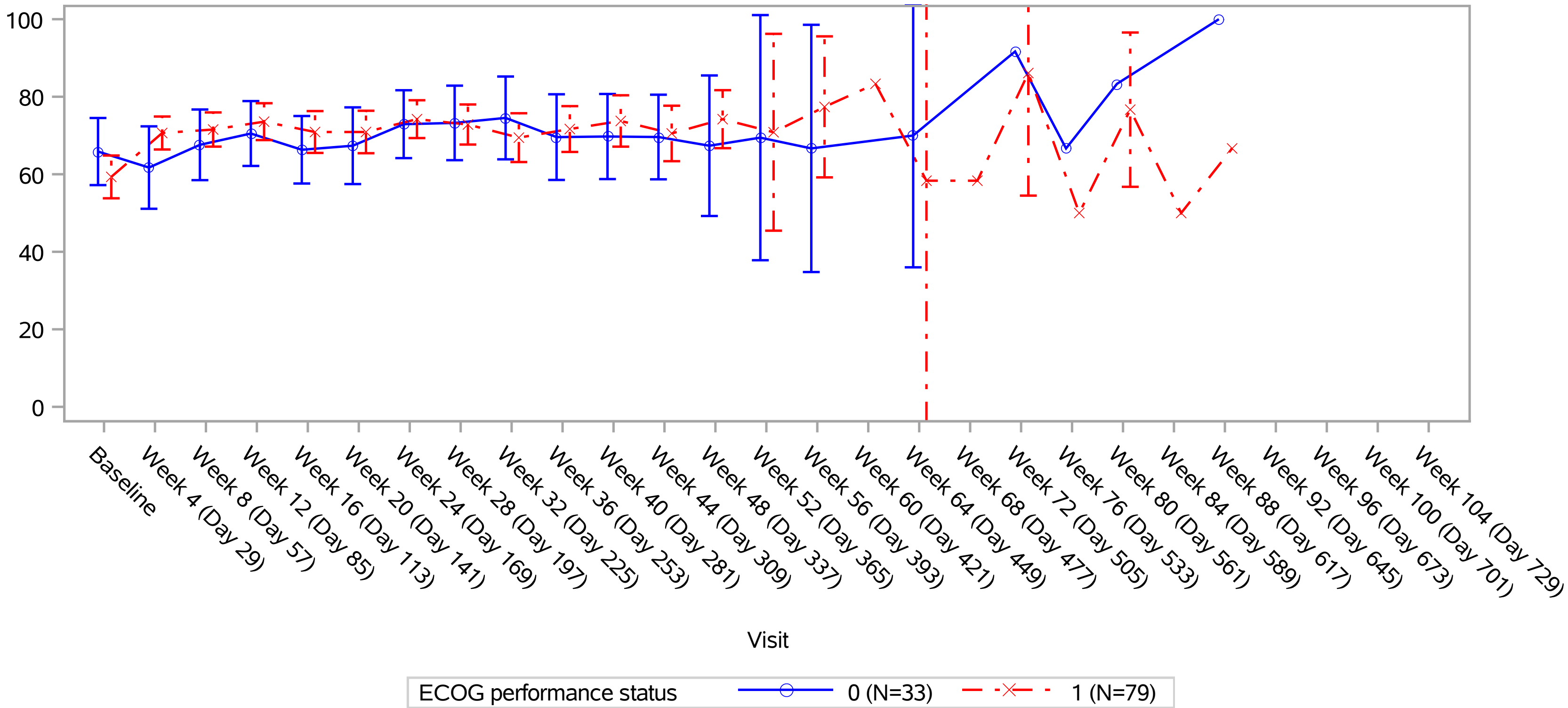
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Global health status
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30QL_SGAGE65.pdf
15OCT2021 17:48

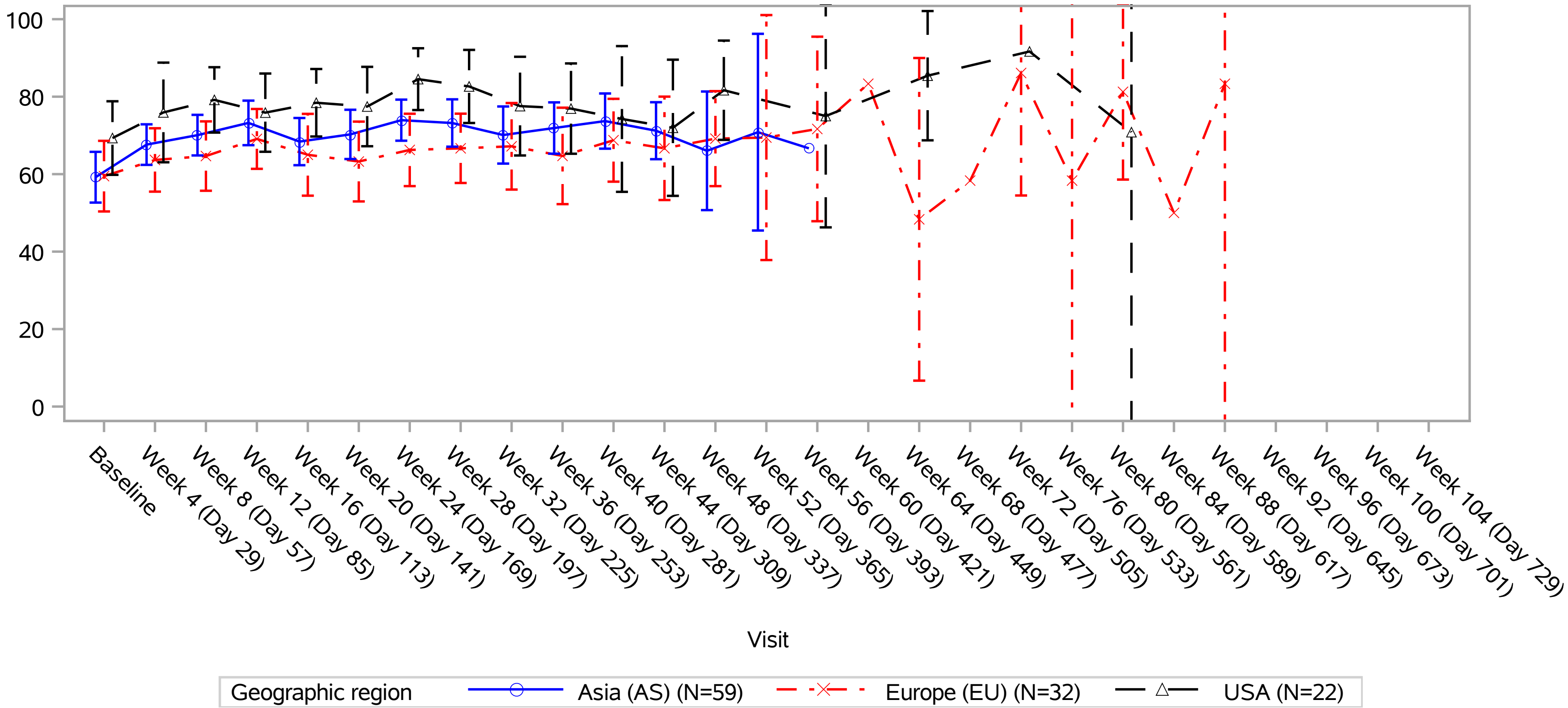
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Global health status
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30QL_SGECOG.pdf
15OCT2021 18:19

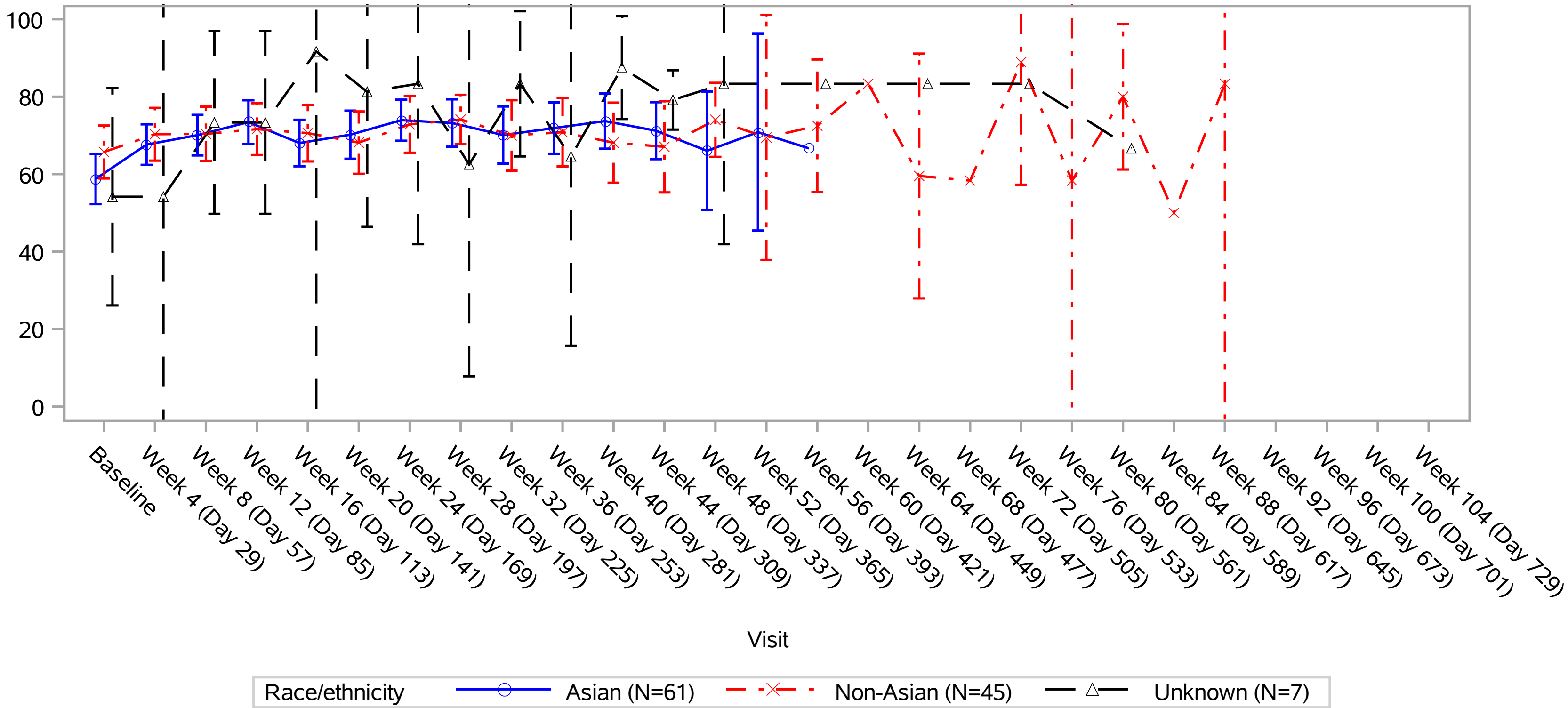
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Global health status
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30QL_SGGEO.pdf
15OCT2021 18:50

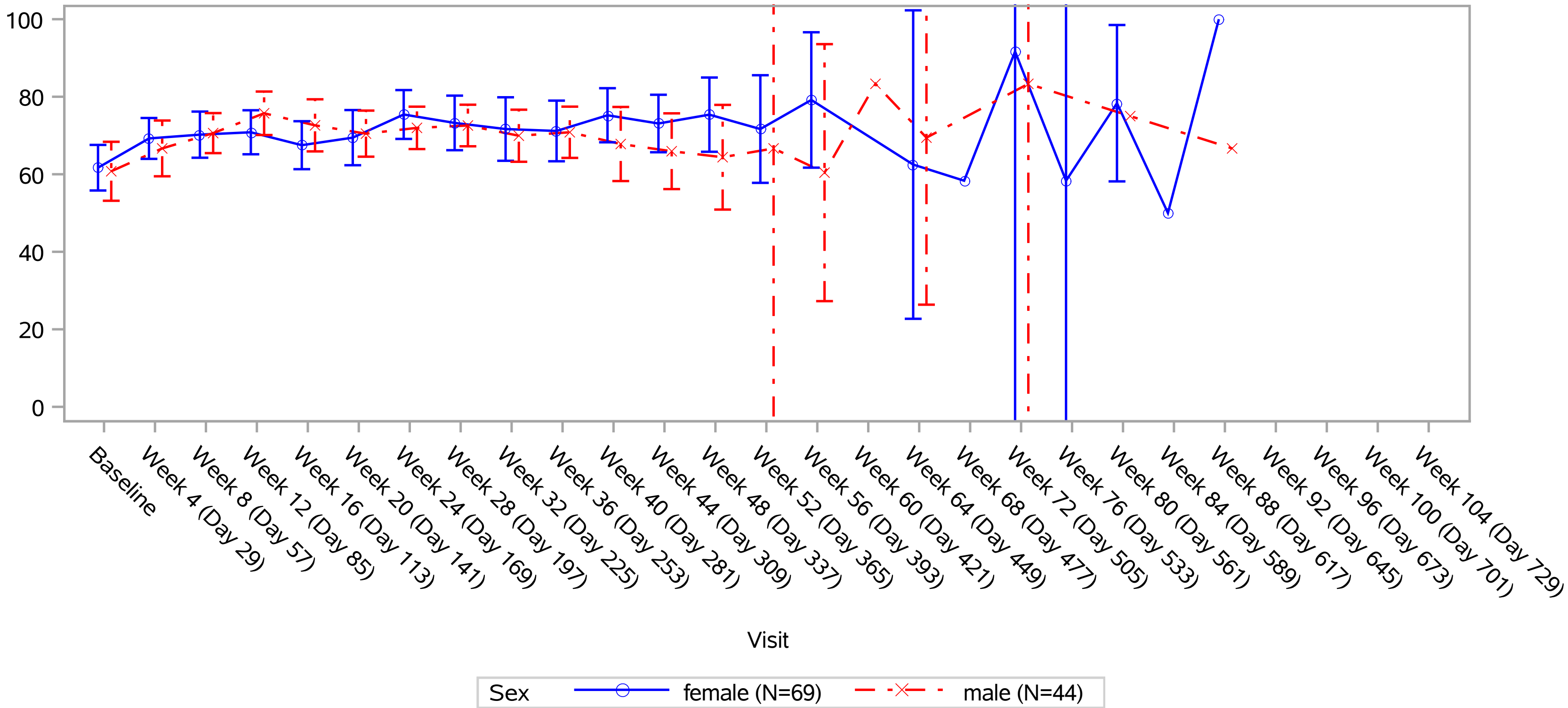
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Global health status
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30QL_SGRE.pdf
15OCT2021 19:20

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Global health status
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30QL_SGSEX.pdf
15OCT2021 19:51

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Role functioning
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=113)							
		Patients				Statistics			
Name Visit	Level	in study¹	%	with value¹	%	mean²	SD	CI LL	CI UL
All									
Baseline	n/a	113	100.0	108	95.6	71.60	30.42	65.80	77.41
Week 4 (Day 29)	n/a	113	100.0	95	84.1	80.18	25.65	74.95	85.40
Week 8 (Day 57)	n/a	101	89.4	92	91.1	80.62	24.74	75.49	85.74
Week 12 (Day 85)	n/a	97	85.8	90	92.8	80.74	22.33	76.06	85.42
Week 16 (Day 113)	n/a	95	84.1	85	89.5	78.82	22.48	73.98	83.67
Week 20 (Day 141)	n/a	89	78.8	83	93.3	77.31	27.12	71.39	83.23
Week 24 (Day 169)	n/a	81	71.7	73	90.1	83.11	22.31	77.90	88.31
Week 28 (Day 197)	n/a	74	65.5	69	93.2	81.40	24.18	75.59	87.21
Week 32 (Day 225)	n/a	71	62.8	63	88.7	78.57	24.21	72.47	84.67
Week 36 (Day 253)	n/a	71	62.8	65	91.5	79.23	23.76	73.34	85.12
Week 40 (Day 281)	n/a	67	59.3	59	88.1	82.77	24.36	76.42	89.12
Week 44 (Day 309)	n/a	64	56.6	58	90.6	79.60	26.31	72.68	86.52
Week 48 (Day 337)	n/a	58	51.3	33	56.9	85.35	25.26	76.40	94.31
Week 52 (Day 365)	n/a	45	39.8	7	15.6	90.48	13.11	78.35	102.60
Week 56 (Day 393)	n/a	37	32.7	12	32.4	87.50	21.47	73.86	101.14
Week 60 (Day 421)	n/a	32	28.3	1	3.1	100.00	NE	NE	NE
Week 64 (Day 449)	n/a	31	27.4	9	29.0	92.59	12.11	83.29	101.90
Week 68 (Day 477)	n/a	28	24.8	1	3.6	66.67	NE	NE	NE
Week 72 (Day 505)	n/a	28	24.8	4	14.3	95.83	8.33	82.57	109.09
Week 76 (Day 533)	n/a	25	22.1	2	8.0	66.67	0.00	NE	NE
Week 80 (Day 561)	n/a	25	22.1	6	24.0	83.33	18.26	64.17	102.49
Week 84 (Day 589)	n/a	18	15.9	1	5.6	66.67	NE	NE	NE
Week 88 (Day 617)	n/a	14	12.4	2	14.3	100.00	0.00	NE	NE
Week 92 (Day 645)	n/a	7	6.2	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	5.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	2.7	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	113	100.0	111	98.2	74.32	29.37	68.80	79.85
End of Study (LOCF)	n/a	113	100.0	111	98.2	74.92	28.33	69.60	80.25
Sex									
Baseline	Female	69	100.0	67	97.1	69.65	30.97	62.10	77.21
Week 4 (Day 29)	Female	69	100.0	55	79.7	78.48	26.96	71.20	85.77
Week 8 (Day 57)	Female	63	91.3	54	85.7	80.56	27.04	73.18	87.94
Week 12 (Day 85)	Female	60	87.0	56	93.3	80.95	24.29	74.45	87.46
Week 16 (Day 113)	Female	58	84.1	50	86.2	77.33	23.99	70.52	84.15
Week 20 (Day 141)	Female	53	76.8	48	90.6	76.39	31.48	67.25	85.53
Week 24 (Day 169)	Female	47	68.1	40	85.1	84.58	23.69	77.01	92.16
Week 28 (Day 197)	Female	42	60.9	38	90.5	82.02	25.81	73.53	90.50
Week 32 (Day 225)	Female	42	60.9	35	83.3	80.95	25.29	72.26	89.64
Week 36 (Day 253)	Female	42	60.9	37	88.1	80.63	27.08	71.60	89.66
Week 40 (Day 281)	Female	41	59.4	37	90.2	84.23	25.14	75.85	92.62
Week 44 (Day 309)	Female	41	59.4	35	85.4	81.43	27.64	71.93	90.92
Week 48 (Day 337)	Female	37	53.6	22	59.5	86.36	27.04	74.38	98.35
Week 52 (Day 365)	Female	29	42.0	5	17.2	90.00	14.91	71.49	108.51
Week 56 (Day 393)	Female	24	34.8	8	33.3	93.75	12.40	83.38	104.12
Week 60 (Day 421)	Female	22	31.9	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Female	22	31.9	6	27.3	94.44	8.61	85.41	103.48
Week 68 (Day 477)	Female	20	29.0	1	5.0	66.67	NE	NE	NE
Week 72 (Day 505)	Female	20	29.0	2	10.0	100.00	0.00	NE	NE
Week 76 (Day 533)	Female	18	26.1	2	11.1	66.67	0.00	NE	NE
Week 80 (Day 561)	Female	18	26.1	5	27.8	80.00	18.26	57.33	102.67
Week 84 (Day 589)	Female	12	17.4	1	8.3	66.67	NE	NE	NE
Week 88 (Day 617)	Female	9	13.0	1	11.1	100.00	NE	NE	NE
Week 92 (Day 645)	Female	6	8.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	7.2	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	2.9	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	1.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	69	100.0	68	98.6	75.25	30.54	67.85	82.64
End of Study (LOCF)	Female	69	100.0	68	98.6	76.23	29.41	69.11	83.34
Baseline	Male	44	100.0	41	93.2	74.80	29.61	65.45	84.14
Week 4 (Day 29)	Male	44	100.0	40	90.9	82.50	23.86	74.87	90.13
Week 8 (Day 57)	Male	38	86.4	38	100.0	80.70	21.41	73.66	87.74
Week 12 (Day 85)	Male	37	84.1	34	91.9	80.39	19.01	73.76	87.03
Week 16 (Day 113)	Male	37	84.1	35	94.6	80.95	20.27	73.99	87.92
Week 20 (Day 141)	Male	36	81.8	35	97.2	78.57	20.04	71.69	85.45
Week 24 (Day 169)	Male	34	77.3	33	97.1	81.31	20.73	73.96	88.66
Week 28 (Day 197)	Male	32	72.7	31	96.9	80.65	22.40	72.43	88.86
Week 32 (Day 225)	Male	29	65.9	28	96.6	75.60	22.90	66.72	84.47
Week 36 (Day 253)	Male	29	65.9	28	96.6	77.38	18.82	70.08	84.68
Week 40 (Day 281)	Male	26	59.1	22	84.6	80.30	23.37	69.94	90.66
Week 44 (Day 309)	Male	23	52.3	23	100.0	76.81	24.48	66.22	87.40
Week 48 (Day 337)	Male	21	47.7	11	52.4	83.33	22.36	68.31	98.36
Week 52 (Day 365)	Male	16	36.4	2	12.5	91.67	11.79	-14.22	197.55
Week 56 (Day 393)	Male	13	29.5	4	30.8	75.00	31.91	24.22	125.78
Week 60 (Day 421)	Male	10	22.7	1	10.0	100.00	NE	NE	NE
Week 64 (Day 449)	Male	9	20.5	3	33.3	88.89	19.25	41.08	136.70
Week 68 (Day 477)	Male	8	18.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	8	18.2	2	25.0	91.67	11.79	-14.22	197.55
Week 76 (Day 533)	Male	7	15.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	7	15.9	1	14.3	100.00	NE	NE	NE
Week 84 (Day 589)	Male	6	13.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	5	11.4	1	20.0	100.00	NE	NE	NE
Week 92 (Day 645)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	44	100.0	43	97.7	72.87	27.70	64.34	81.39
End of Study (LOCF)	Male	44	100.0	43	97.7	72.87	26.73	64.64	81.10
Age									

Baseline	< 65	78	100.0	73	93.6	69.86	30.64	62.71	77.01
Week 4 (Day 29)	< 65	78	100.0	68	87.2	80.15	25.96	73.86	86.43
Week 8 (Day 57)	< 65	73	93.6	66	90.4	84.34	23.37	78.60	90.09
Week 12 (Day 85)	< 65	71	91.0	64	90.1	82.03	19.99	77.04	87.02
Week 16 (Day 113)	< 65	69	88.5	59	85.5	81.92	19.64	76.80	87.04
Week 20 (Day 141)	< 65	65	83.3	62	95.4	79.03	26.81	72.22	85.84
Week 24 (Day 169)	< 65	59	75.6	55	93.2	84.55	20.75	78.94	90.16
Week 28 (Day 197)	< 65	55	70.5	51	92.7	84.31	22.21	78.07	90.56
Week 32 (Day 225)	< 65	53	67.9	48	90.6	82.29	22.12	75.87	88.72
Week 36 (Day 253)	< 65	53	67.9	50	94.3	83.67	22.21	77.36	89.98
Week 40 (Day 281)	< 65	52	66.7	48	92.3	84.37	23.17	77.65	91.10
Week 44 (Day 309)	< 65	52	66.7	48	92.3	80.90	25.73	73.43	88.37
Week 48 (Day 337)	< 65	47	60.3	26	55.3	86.54	21.61	77.81	95.27
Week 52 (Day 365)	< 65	36	46.2	4	11.1	95.83	8.33	82.57	109.09
Week 56 (Day 393)	< 65	30	38.5	9	30.0	90.74	14.70	79.44	102.04
Week 60 (Day 421)	< 65	25	32.1	1	4.0	100.00	NE	NE	NE
Week 64 (Day 449)	< 65	24	30.8	7	29.2	92.86	13.11	80.73	104.98
Week 68 (Day 477)	< 65	22	28.2	1	4.5	66.67	NE	NE	NE
Week 72 (Day 505)	< 65	22	28.2	4	18.2	95.83	8.33	82.57	109.09
Week 76 (Day 533)	< 65	21	26.9	2	9.5	66.67	0.00	NE	NE
Week 80 (Day 561)	< 65	21	26.9	5	23.8	86.67	18.26	64.00	109.34
Week 84 (Day 589)	< 65	15	19.2	1	6.7	66.67	NE	NE	NE
Week 88 (Day 617)	< 65	12	15.4	2	16.7	100.00	0.00	NE	NE
Week 92 (Day 645)	< 65	6	7.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	6.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	78	100.0	76	97.4	75.44	29.87	68.61	82.26
End of Study (LOCF)	< 65	78	100.0	76	97.4	77.19	28.13	70.76	83.62
Baseline	>= 65	35	100.0	35	100.0	75.24	30.08	64.91	85.57
Week 4 (Day 29)	>= 65	35	100.0	27	77.1	80.25	25.33	70.23	90.27
Week 8 (Day 57)	>= 65	28	80.0	26	92.9	71.15	26.06	60.63	81.68
Week 12 (Day 85)	>= 65	26	74.3	26	100.0	77.56	27.46	66.47	88.66

Week 16 (Day 113)	>= 65	26	74.3	26	100.0	71.79	26.99	60.90	82.69
Week 20 (Day 141)	>= 65	24	68.6	21	87.5	72.22	28.05	59.45	84.99
Week 24 (Day 169)	>= 65	22	62.9	18	81.8	78.70	26.69	65.43	91.98
Week 28 (Day 197)	>= 65	19	54.3	18	94.7	73.15	28.09	59.18	87.12
Week 32 (Day 225)	>= 65	18	51.4	15	83.3	66.67	27.46	51.46	81.87
Week 36 (Day 253)	>= 65	18	51.4	15	83.3	64.44	23.46	51.45	77.43
Week 40 (Day 281)	>= 65	15	42.9	11	73.3	75.76	29.22	56.13	95.38
Week 44 (Day 309)	>= 65	12	34.3	10	83.3	73.33	29.61	52.15	94.51
Week 48 (Day 337)	>= 65	11	31.4	7	63.6	80.95	37.80	46.00	115.91
Week 52 (Day 365)	>= 65	9	25.7	3	33.3	83.33	16.67	41.93	124.74
Week 56 (Day 393)	>= 65	7	20.0	3	42.9	77.78	38.49	-17.84	173.39
Week 60 (Day 421)	>= 65	7	20.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	7	20.0	2	28.6	91.67	11.79	-14.22	197.55
Week 68 (Day 477)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	4	11.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	4	11.4	1	25.0	66.67	NE	NE	NE
Week 84 (Day 589)	>= 65	3	8.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	5.7	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	35	100.0	35	100.0	71.90	28.52	62.11	81.70
End of Study (LOCF)	>= 65	35	100.0	35	100.0	70.00	28.53	60.20	79.80
ECOG performance status									
Baseline	0	33	100.0	31	93.9	76.34	31.85	64.66	88.03
Week 4 (Day 29)	0	33	100.0	27	81.8	72.84	35.85	58.66	87.02
Week 8 (Day 57)	0	30	90.9	27	90.0	70.37	36.50	55.93	84.81
Week 12 (Day 85)	0	29	87.9	26	89.7	76.92	27.92	65.65	88.20
Week 16 (Day 113)	0	28	84.8	24	85.7	79.17	27.91	67.38	90.95
Week 20 (Day 141)	0	26	78.8	24	92.3	74.31	34.75	59.63	88.98
Week 24 (Day 169)	0	24	72.7	20	83.3	83.33	24.78	71.74	94.93
Week 28 (Day 197)	0	21	63.6	19	90.5	80.70	29.01	66.72	94.68

Week 32 (Day 225)	0	21	63.6	18	85.7	78.70	27.89	64.83	92.57
Week 36 (Day 253)	0	21	63.6	20	95.2	80.00	28.92	66.47	93.53
Week 40 (Day 281)	0	21	63.6	19	90.5	84.21	24.52	72.39	96.03
Week 44 (Day 309)	0	21	63.6	17	81.0	80.39	28.40	65.79	95.00
Week 48 (Day 337)	0	19	57.6	12	63.2	79.17	32.66	58.41	99.92
Week 52 (Day 365)	0	18	54.5	3	16.7	94.44	9.62	70.54	118.35
Week 56 (Day 393)	0	16	48.5	5	31.3	80.00	29.81	42.98	117.02
Week 60 (Day 421)	0	16	48.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	0	16	48.5	5	31.3	90.00	14.91	71.49	108.51
Week 68 (Day 477)	0	14	42.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	0	14	42.4	1	7.1	100.00	NE	NE	NE
Week 76 (Day 533)	0	12	36.4	1	8.3	66.67	NE	NE	NE
Week 80 (Day 561)	0	12	36.4	1	8.3	100.00	NE	NE	NE
Week 84 (Day 589)	0	10	30.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	9	27.3	1	11.1	100.00	NE	NE	NE
Week 92 (Day 645)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	9.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	3.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	33	100.0	33	100.0	69.19	35.14	56.73	81.65
End of Study (LOCF)	0	33	100.0	33	100.0	68.69	34.80	56.35	81.03
Baseline	1	79	100.0	76	96.2	69.52	29.99	62.67	76.37
Week 4 (Day 29)	1	79	100.0	67	84.8	83.33	19.89	78.48	88.18
Week 8 (Day 57)	1	70	88.6	65	92.9	84.87	16.33	80.83	88.92
Week 12 (Day 85)	1	68	86.1	64	94.1	82.29	19.67	77.38	87.21
Week 16 (Day 113)	1	67	84.8	61	91.0	78.69	20.21	73.51	83.87
Week 20 (Day 141)	1	63	79.7	59	93.7	78.53	23.58	72.39	84.68
Week 24 (Day 169)	1	57	72.2	53	93.0	83.02	21.56	77.08	88.96
Week 28 (Day 197)	1	53	67.1	50	94.3	81.67	22.40	75.30	88.03
Week 32 (Day 225)	1	50	63.3	45	90.0	78.52	22.92	71.63	85.41
Week 36 (Day 253)	1	50	63.3	45	90.0	78.89	21.44	72.45	85.33
Week 40 (Day 281)	1	46	58.2	40	87.0	82.08	24.57	74.22	89.94

Week 44 (Day 309)	1	43	54.4	41	95.3	79.27	25.76	71.14	87.40
Week 48 (Day 337)	1	39	49.4	21	53.8	88.89	19.95	79.81	97.97
Week 52 (Day 365)	1	27	34.2	4	14.8	87.50	15.96	62.11	112.89
Week 56 (Day 393)	1	21	26.6	7	33.3	92.86	13.11	80.73	104.98
Week 60 (Day 421)	1	16	20.3	1	6.3	100.00	NE	NE	NE
Week 64 (Day 449)	1	15	19.0	4	26.7	95.83	8.33	82.57	109.09
Week 68 (Day 477)	1	14	17.7	1	7.1	66.67	NE	NE	NE
Week 72 (Day 505)	1	14	17.7	3	21.4	94.44	9.62	70.54	118.35
Week 76 (Day 533)	1	13	16.5	1	7.7	66.67	NE	NE	NE
Week 80 (Day 561)	1	13	16.5	5	38.5	80.00	18.26	57.33	102.67
Week 84 (Day 589)	1	8	10.1	1	12.5	66.67	NE	NE	NE
Week 88 (Day 617)	1	5	6.3	1	20.0	100.00	NE	NE	NE
Week 92 (Day 645)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	2.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	79	100.0	77	97.5	76.62	26.66	70.57	82.68
End of Study (LOCF)	1	79	100.0	77	97.5	77.71	25.02	72.03	83.38
Baseline	Missing	1	100.0	1	100.0	83.33	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	66.67	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	66.67	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	66.67	NE	NE	NE
Geographic region									
Baseline	USA	22	100.0	22	100.0	65.15	30.39	51.68	78.63
Week 4 (Day 29)	USA	22	100.0	18	81.8	84.26	28.85	69.91	98.61
Week 8 (Day 57)	USA	20	90.9	18	90.0	87.04	15.71	79.22	94.85
Week 12 (Day 85)	USA	20	90.9	19	95.0	87.72	20.67	77.76	97.68
Week 16 (Day 113)	USA	19	86.4	17	89.5	79.41	20.01	69.12	89.70
Week 20 (Day 141)	USA	19	86.4	17	89.5	83.33	23.57	71.21	95.45
Week 24 (Day 169)	USA	16	72.7	14	87.5	89.29	15.48	80.35	98.22
Week 28 (Day 197)	USA	15	68.2	12	80.0	86.11	19.89	73.47	98.75
Week 32 (Day 225)	USA	15	68.2	13	86.7	76.92	27.67	60.20	93.64
Week 36 (Day 253)	USA	15	68.2	13	86.7	75.64	23.19	61.63	89.65
Week 40 (Day 281)	USA	14	63.6	11	78.6	86.36	30.57	65.83	106.90

Week 44 (Day 309)	USA	13	59.1	11	84.6	78.79	27.98	59.99	97.58
Week 48 (Day 337)	USA	13	59.1	10	76.9	85.00	22.84	68.66	101.34
Week 52 (Day 365)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	USA	12	54.5	6	50.0	83.33	27.89	54.07	112.60
Week 60 (Day 421)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	11	50.0	4	36.4	100.00	0.00	NE	NE
Week 68 (Day 477)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	10	45.5	1	10.0	100.00	NE	NE	NE
Week 76 (Day 533)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	10	45.5	2	20.0	66.67	0.00	NE	NE
Week 84 (Day 589)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	13.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	4.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	22	100.0	22	100.0	77.27	29.79	64.06	90.48
End of Study (LOCF)	USA	22	100.0	22	100.0	78.03	29.27	65.05	91.01
Baseline	Europe (EU)	32	100.0	29	90.6	66.09	34.64	52.91	79.27
Week 4 (Day 29)	Europe (EU)	32	100.0	25	78.1	70.67	26.48	59.74	81.60
Week 8 (Day 57)	Europe (EU)	29	90.6	25	86.2	72.00	35.59	57.31	86.69
Week 12 (Day 85)	Europe (EU)	26	81.3	24	92.3	74.31	25.53	63.53	85.09
Week 16 (Day 113)	Europe (EU)	25	78.1	20	80.0	75.00	29.37	61.25	88.75
Week 20 (Day 141)	Europe (EU)	23	71.9	22	95.7	65.91	33.52	51.05	80.77
Week 24 (Day 169)	Europe (EU)	21	65.6	20	95.2	75.00	28.87	61.49	88.51
Week 28 (Day 197)	Europe (EU)	20	62.5	20	100.0	79.17	25.86	67.06	91.27
Week 32 (Day 225)	Europe (EU)	18	56.3	16	88.9	81.25	19.12	71.06	91.44
Week 36 (Day 253)	Europe (EU)	18	56.3	17	94.4	81.37	22.73	69.68	93.06
Week 40 (Day 281)	Europe (EU)	17	53.1	16	94.1	84.38	20.61	73.39	95.36
Week 44 (Day 309)	Europe (EU)	17	53.1	14	82.4	78.57	28.06	62.37	94.77

Week 48 (Day 337)	Europe (EU)	14	43.8	10	71.4	85.00	25.40	66.83	103.17
Week 52 (Day 365)	Europe (EU)	13	40.6	3	23.1	94.44	9.62	70.54	118.35
Week 56 (Day 393)	Europe (EU)	11	34.4	5	45.5	90.00	14.91	71.49	108.51
Week 60 (Day 421)	Europe (EU)	11	34.4	1	9.1	100.00	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	11	34.4	5	45.5	86.67	13.94	69.35	103.98
Week 68 (Day 477)	Europe (EU)	10	31.3	1	10.0	66.67	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	10	31.3	3	30.0	94.44	9.62	70.54	118.35
Week 76 (Day 533)	Europe (EU)	8	25.0	2	25.0	66.67	0.00	NE	NE
Week 80 (Day 561)	Europe (EU)	8	25.0	4	50.0	91.67	16.67	65.15	118.19
Week 84 (Day 589)	Europe (EU)	6	18.8	1	16.7	66.67	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	9.4	2	66.7	100.00	0.00	NE	NE
Cycle 12 (LOCF)	Europe (EU)	32	100.0	31	96.9	68.28	33.98	55.82	80.74
End of Study (LOCF)	Europe (EU)	32	100.0	31	96.9	68.82	32.13	57.03	80.60
Baseline	Asia (AS)	59	100.0	57	96.6	76.90	27.59	69.58	84.22
Week 4 (Day 29)	Asia (AS)	59	100.0	52	88.1	83.33	23.34	76.84	89.83
Week 8 (Day 57)	Asia (AS)	52	88.1	49	94.2	82.65	19.53	77.04	88.26
Week 12 (Day 85)	Asia (AS)	51	86.4	47	92.2	81.21	20.74	75.12	87.30
Week 16 (Day 113)	Asia (AS)	51	86.4	48	94.1	80.21	20.24	74.33	86.09
Week 20 (Day 141)	Asia (AS)	47	79.7	44	93.6	80.68	23.55	73.52	87.84
Week 24 (Day 169)	Asia (AS)	44	74.6	39	88.6	85.04	19.79	78.63	91.46
Week 28 (Day 197)	Asia (AS)	39	66.1	37	94.9	81.08	24.90	72.78	89.38
Week 32 (Day 225)	Asia (AS)	38	64.4	34	89.5	77.94	25.53	69.03	86.85
Week 36 (Day 253)	Asia (AS)	38	64.4	35	92.1	79.52	24.95	70.95	88.09
Week 40 (Day 281)	Asia (AS)	36	61.0	32	88.9	80.73	24.36	71.95	89.51
Week 44 (Day 309)	Asia (AS)	34	57.6	33	97.1	80.30	25.84	71.14	89.46
Week 48 (Day 337)	Asia (AS)	31	52.5	13	41.9	85.90	28.74	68.53	103.27
Week 52 (Day 365)	Asia (AS)	20	33.9	4	20.0	87.50	15.96	62.11	112.89
Week 56 (Day 393)	Asia (AS)	14	23.7	1	7.1	100.00	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	10.2	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	8.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	3.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	59	100.0	58	98.3	76.44	26.50	69.47	83.40
End of Study (LOCF)	Asia (AS)	59	100.0	58	98.3	77.01	25.71	70.25	83.77
Race/ethnicity									
Baseline	Asian	61	100.0	58	95.1	76.72	27.38	69.52	83.92
Week 4 (Day 29)	Asian	61	100.0	52	85.2	83.33	23.34	76.84	89.83
Week 8 (Day 57)	Asian	53	86.9	49	92.5	82.65	19.53	77.04	88.26
Week 12 (Day 85)	Asian	52	85.2	48	92.3	80.90	20.63	74.91	86.89
Week 16 (Day 113)	Asian	52	85.2	49	94.2	79.93	20.12	74.15	85.71
Week 20 (Day 141)	Asian	48	78.7	45	93.8	81.11	23.46	74.06	88.16
Week 24 (Day 169)	Asian	44	72.1	39	88.6	85.04	19.79	78.63	91.46
Week 28 (Day 197)	Asian	39	63.9	37	94.9	81.08	24.90	72.78	89.38
Week 32 (Day 225)	Asian	38	62.3	34	89.5	77.94	25.53	69.03	86.85
Week 36 (Day 253)	Asian	38	62.3	35	92.1	79.52	24.95	70.95	88.09
Week 40 (Day 281)	Asian	36	59.0	32	88.9	80.73	24.36	71.95	89.51
Week 44 (Day 309)	Asian	34	55.7	33	97.1	80.30	25.84	71.14	89.46
Week 48 (Day 337)	Asian	31	50.8	13	41.9	85.90	28.74	68.53	103.27
Week 52 (Day 365)	Asian	20	32.8	4	20.0	87.50	15.96	62.11	112.89
Week 56 (Day 393)	Asian	14	23.0	1	7.1	100.00	NE	NE	NE
Week 60 (Day 421)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	9.8	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	8.2	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	3.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	61	100.0	59	96.7	76.84	26.45	69.94	83.73
End of Study (LOCF)	Asian	61	100.0	59	96.7	77.40	25.66	70.71	84.09
Baseline	Non-Asian	45	100.0	44	97.8	68.18	31.09	58.73	77.63
Week 4 (Day 29)	Non-Asian	45	100.0	39	86.7	79.06	25.28	70.86	87.26
Week 8 (Day 57)	Non-Asian	42	93.3	38	90.5	78.95	28.13	69.70	88.19
Week 12 (Day 85)	Non-Asian	39	86.7	37	94.9	81.98	23.69	74.08	89.88
Week 16 (Day 113)	Non-Asian	37	82.2	34	91.9	75.98	25.69	67.02	84.94
Week 20 (Day 141)	Non-Asian	36	80.0	34	94.4	71.57	31.66	60.52	82.61
Week 24 (Day 169)	Non-Asian	32	71.1	31	96.9	80.11	25.61	70.71	89.50
Week 28 (Day 197)	Non-Asian	30	66.7	28	93.3	83.93	21.51	75.59	92.27
Week 32 (Day 225)	Non-Asian	28	62.2	25	89.3	78.00	23.92	68.13	87.87
Week 36 (Day 253)	Non-Asian	28	62.2	26	92.9	80.77	20.38	72.54	89.00
Week 40 (Day 281)	Non-Asian	26	57.8	23	88.5	84.78	26.07	73.51	96.06
Week 44 (Day 309)	Non-Asian	25	55.6	21	84.0	75.40	28.68	62.34	88.45
Week 48 (Day 337)	Non-Asian	23	51.1	17	73.9	82.35	24.63	69.69	95.02
Week 52 (Day 365)	Non-Asian	21	46.7	3	14.3	94.44	9.62	70.54	118.35
Week 56 (Day 393)	Non-Asian	19	42.2	10	52.6	85.00	22.84	68.66	101.34
Week 60 (Day 421)	Non-Asian	19	42.2	1	5.3	100.00	NE	NE	NE
Week 64 (Day 449)	Non-Asian	18	40.0	7	38.9	92.86	13.11	80.73	104.98
Week 68 (Day 477)	Non-Asian	17	37.8	1	5.9	66.67	NE	NE	NE
Week 72 (Day 505)	Non-Asian	17	37.8	3	17.6	94.44	9.62	70.54	118.35
Week 76 (Day 533)	Non-Asian	15	33.3	2	13.3	66.67	0.00	NE	NE
Week 80 (Day 561)	Non-Asian	15	33.3	5	33.3	86.67	18.26	64.00	109.34
Week 84 (Day 589)	Non-Asian	10	22.2	1	10.0	66.67	NE	NE	NE
Week 88 (Day 617)	Non-Asian	7	15.6	2	28.6	100.00	0.00	NE	NE
Week 92 (Day 645)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	45	100.0	45	100.0	71.11	31.46	61.66	80.56

End of Study (LOCF)	Non-Asian	45	100.0	45	100.0	72.22	29.94	63.23	81.22
Baseline	Unknown	7	100.0	6	85.7	47.22	42.71	2.40	92.04
Week 4 (Day 29)	Unknown	7	100.0	4	57.1	50.00	43.03	-18.48	118.48
Week 8 (Day 57)	Unknown	6	85.7	5	83.3	73.33	43.46	19.37	127.30
Week 12 (Day 85)	Unknown	6	85.7	5	83.3	70.00	29.81	32.98	107.02
Week 16 (Day 113)	Unknown	6	85.7	2	33.3	100.00	0.00	NE	NE
Week 20 (Day 141)	Unknown	5	71.4	4	80.0	83.33	19.25	52.71	113.96
Week 24 (Day 169)	Unknown	5	71.4	3	60.0	88.89	19.25	41.08	136.70
Week 28 (Day 197)	Unknown	5	71.4	4	80.0	66.67	36.00	9.38	123.96
Week 32 (Day 225)	Unknown	5	71.4	4	80.0	87.50	15.96	62.11	112.89
Week 36 (Day 253)	Unknown	5	71.4	4	80.0	66.67	36.00	9.38	123.96
Week 40 (Day 281)	Unknown	5	71.4	4	80.0	87.50	15.96	62.11	112.89
Week 44 (Day 309)	Unknown	5	71.4	4	80.0	95.83	8.33	82.57	109.09
Week 48 (Day 337)	Unknown	4	57.1	3	75.0	100.00	0.00	NE	NE
Week 52 (Day 365)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	4	57.1	1	25.0	100.00	NE	NE	NE
Week 60 (Day 421)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	4	57.1	2	50.0	91.67	11.79	-14.22	197.55
Week 68 (Day 477)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	3	42.9	1	33.3	100.00	NE	NE	NE
Week 76 (Day 533)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	3	42.9	1	33.3	66.67	NE	NE	NE
Week 84 (Day 589)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	14.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	7	100.0	7	100.0	73.81	40.66	36.20	111.42
End of Study (LOCF)	Unknown	7	100.0	7	100.0	71.43	40.50	33.97	108.88
Number of prior antineoplastic systemic therapy lines I									
Baseline	1	60	100.0	57	95.0	68.13	30.74	59.97	76.29

Week 4 (Day 29)	1	60	100.0	50	83.3	80.67	22.93	74.15	87.18
Week 8 (Day 57)	1	54	90.0	49	90.7	81.29	22.98	74.69	87.89
Week 12 (Day 85)	1	52	86.7	48	92.3	78.82	23.00	72.14	85.50
Week 16 (Day 113)	1	51	85.0	46	90.2	76.81	24.96	69.40	84.22
Week 20 (Day 141)	1	48	80.0	43	89.6	77.52	29.74	68.37	86.67
Week 24 (Day 169)	1	43	71.7	39	90.7	81.62	24.72	73.61	89.64
Week 28 (Day 197)	1	38	63.3	34	89.5	82.35	24.25	73.89	90.82
Week 32 (Day 225)	1	35	58.3	29	82.9	78.74	24.76	69.32	88.15
Week 36 (Day 253)	1	35	58.3	31	88.6	77.96	22.11	69.85	86.07
Week 40 (Day 281)	1	32	53.3	27	84.4	82.10	24.86	72.26	91.93
Week 44 (Day 309)	1	32	53.3	27	84.4	76.54	28.22	65.38	87.71
Week 48 (Day 337)	1	27	45.0	16	59.3	83.33	25.09	69.96	96.70
Week 52 (Day 365)	1	23	38.3	5	21.7	90.00	14.91	71.49	108.51
Week 56 (Day 393)	1	16	26.7	4	25.0	91.67	16.67	65.15	118.19
Week 60 (Day 421)	1	14	23.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	13	21.7	4	30.8	87.50	15.96	62.11	112.89
Week 68 (Day 477)	1	12	20.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	12	20.0	1	8.3	100.00	NE	NE	NE
Week 76 (Day 533)	1	11	18.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	11	18.3	2	18.2	83.33	23.57	-128.44	295.10
Week 84 (Day 589)	1	9	15.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	1	8	13.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	1	3	5.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	1	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	60	100.0	58	96.7	73.56	28.62	66.04	81.09
End of Study (LOCF)	1	60	100.0	58	96.7	75.00	26.54	68.02	81.98
Baseline	>= 2	53	100.0	51	96.2	75.49	29.88	67.09	83.89
Week 4 (Day 29)	>= 2	53	100.0	45	84.9	79.63	28.62	71.03	88.23
Week 8 (Day 57)	>= 2	47	88.7	43	91.5	79.84	26.86	71.58	88.11
Week 12 (Day 85)	>= 2	45	84.9	42	93.3	82.94	21.62	76.20	89.67
Week 16 (Day 113)	>= 2	44	83.0	39	88.6	81.20	19.19	74.98	87.42

Week 20 (Day 141)	>= 2	41	77.4	40	97.6	77.08	24.37	69.29	84.88
Week 24 (Day 169)	>= 2	38	71.7	34	89.5	84.80	19.41	78.03	91.57
Week 28 (Day 197)	>= 2	36	67.9	35	97.2	80.48	24.42	72.09	88.86
Week 32 (Day 225)	>= 2	36	67.9	34	94.4	78.43	24.11	70.02	86.84
Week 36 (Day 253)	>= 2	36	67.9	34	94.4	80.39	25.45	71.51	89.27
Week 40 (Day 281)	>= 2	35	66.0	32	91.4	83.33	24.32	74.57	92.10
Week 44 (Day 309)	>= 2	32	60.4	31	96.9	82.26	24.70	73.20	91.32
Week 48 (Day 337)	>= 2	31	58.5	17	54.8	87.25	26.04	73.87	100.64
Week 52 (Day 365)	>= 2	22	41.5	2	9.1	91.67	11.79	-14.22	197.55
Week 56 (Day 393)	>= 2	21	39.6	8	38.1	85.42	24.30	65.11	105.73
Week 60 (Day 421)	>= 2	18	34.0	1	5.6	100.00	NE	NE	NE
Week 64 (Day 449)	>= 2	18	34.0	5	27.8	96.67	7.45	87.41	105.92
Week 68 (Day 477)	>= 2	16	30.2	1	6.3	66.67	NE	NE	NE
Week 72 (Day 505)	>= 2	16	30.2	3	18.8	94.44	9.62	70.54	118.35
Week 76 (Day 533)	>= 2	14	26.4	2	14.3	66.67	0.00	NE	NE
Week 80 (Day 561)	>= 2	14	26.4	4	28.6	83.33	19.25	52.71	113.96
Week 84 (Day 589)	>= 2	9	17.0	1	11.1	66.67	NE	NE	NE
Week 88 (Day 617)	>= 2	6	11.3	2	33.3	100.00	0.00	NE	NE
Week 92 (Day 645)	>= 2	2	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 2	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 2	53	100.0	53	100.0	75.16	30.42	66.77	83.54
End of Study (LOCF)	>= 2	53	100.0	53	100.0	74.84	30.42	66.46	83.23

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
¹ in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
² mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TP_QSC30RF_SG.xls
27OCT2021 7:31

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Role functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	49	45.4	36.3	54.8
	Cycle 12 (LOCF)	n/a	108	95.6	30	27.8	20.2	36.9
	End of Study (LOCF)	n/a	108	95.6	28	25.9	18.6	34.9
Sex	All visits	Female	67	59.3	28	41.8	30.7	53.7
		Male	41	36.3	21	51.2	36.5	65.7
	Cycle 12 (LOCF)	Female	67	59.3	16	23.9	15.3	35.3
		Male	41	36.3	14	34.1	21.6	49.5
	End of Study (LOCF)	Female	67	59.3	15	22.4	14.1	33.7
		Male	41	36.3	13	31.7	19.6	47.0
Age	All visits	< 65	73	64.6	29	39.7	29.3	51.2
		>= 65	35	31.0	20	57.1	40.9	72.0
	Cycle 12 (LOCF)	< 65	73	64.6	19	26.0	17.3	37.1
		>= 65	35	31.0	11	31.4	18.6	48.0
	End of Study (LOCF)	< 65	73	64.6	16	21.9	14.0	32.7
		>= 65	35	31.0	12	34.3	20.8	50.8
ECOG performance status	All visits	0	31	27.4	17	54.8	37.8	70.8
		1	76	67.3	31	40.8	30.4	52.0
		Missing	1	0.9	1	100.0	20.7	100.0
	Cycle 12 (LOCF)	0	31	27.4	11	35.5	21.1	53.1
		1	76	67.3	18	23.7	15.5	34.4
		Missing	1	0.9	1	100.0	20.7	100.0
	End of Study (LOCF)	0	31	27.4	12	38.7	23.7	56.2
		1	76	67.3	15	19.7	12.3	30.0
		Missing	1	0.9	1	100.0	20.7	100.0
Geographic region	All visits	USA	22	19.5	7	31.8	16.4	52.7
		Europe (EU)	29	25.7	16	55.2	37.5	71.6
		Asia (AS)	57	50.4	26	45.6	33.4	58.4
	Cycle 12 (LOCF)	USA	22	19.5	3	13.6	4.7	33.3
		Europe (EU)	29	25.7	10	34.5	19.9	52.7
		Asia (AS)	57	50.4	17	29.8	19.5	42.7
	End of Study (LOCF)	USA	22	19.5	2	9.1	2.5	27.8
		Europe (EU)	29	25.7	9	31.0	17.3	49.2
		Asia (AS)	57	50.4	17	29.8	19.5	42.7
Race/ethnicity	All visits	Asian	58	51.3	26	44.8	32.7	57.5
		Non-Asian	44	38.9	21	47.7	33.8	62.1
		Unknown	6	5.3	2	33.3	9.7	70.0
	Cycle 12 (LOCF)	Asian	58	51.3	17	29.3	19.2	42.0

		Non-Asian	44	38.9	13	29.5	18.2	44.2
		Unknown	6	5.3	0	0.0	0.0	39.0
	End of Study (LOCF)	Asian	58	51.3	17	29.3	19.2	42.0
		Non-Asian	44	38.9	11	25.0	14.6	39.4
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	26	45.6	33.4	58.4
		>= 2	51	45.1	23	45.1	32.3	58.6
	Cycle 12 (LOCF)	1	57	50.4	18	31.6	21.0	44.5
		>= 2	51	45.1	12	23.5	14.0	36.8
	End of Study (LOCF)	1	57	50.4	17	29.8	19.5	42.7
		>= 2	51	45.1	11	21.6	12.5	34.6

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30RF_W10_SG.xls
15OCT2021 13:38

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Role functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

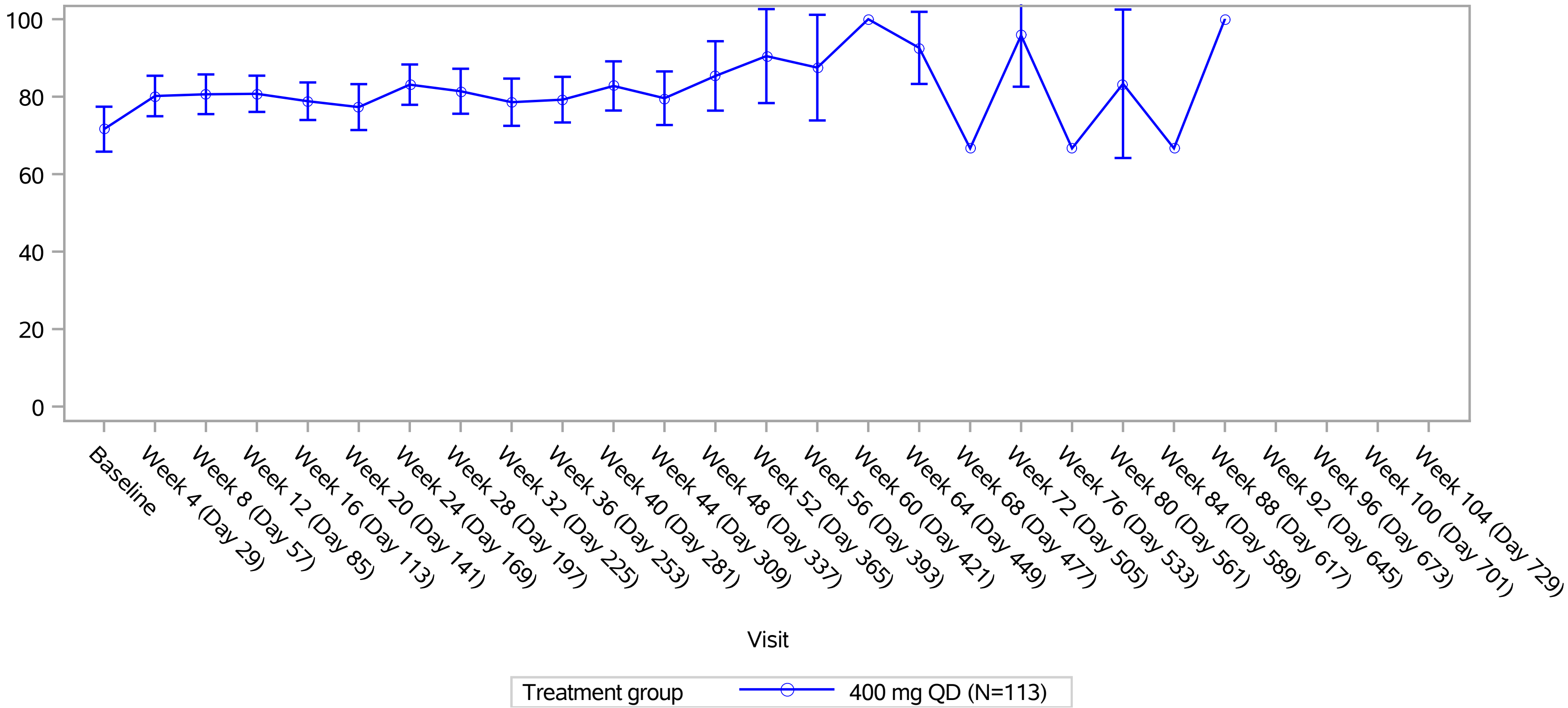
			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	49	45.4	36.3	54.8
	Cycle 12 (LOCF)	n/a	108	95.6	30	27.8	20.2	36.9
	End of Study (LOCF)	n/a	108	95.6	28	25.9	18.6	34.9
Sex	All visits	Female	67	59.3	28	41.8	30.7	53.7
		Male	41	36.3	21	51.2	36.5	65.7
	Cycle 12 (LOCF)	Female	67	59.3	16	23.9	15.3	35.3
		Male	41	36.3	14	34.1	21.6	49.5
	End of Study (LOCF)	Female	67	59.3	15	22.4	14.1	33.7
		Male	41	36.3	13	31.7	19.6	47.0
Age	All visits	< 65	73	64.6	29	39.7	29.3	51.2
		>= 65	35	31.0	20	57.1	40.9	72.0
	Cycle 12 (LOCF)	< 65	73	64.6	19	26.0	17.3	37.1
		>= 65	35	31.0	11	31.4	18.6	48.0
	End of Study (LOCF)	< 65	73	64.6	16	21.9	14.0	32.7
		>= 65	35	31.0	12	34.3	20.8	50.8
ECOG performance status	All visits	0	31	27.4	17	54.8	37.8	70.8
		1	76	67.3	31	40.8	30.4	52.0
		Missing	1	0.9	1	100.0	20.7	100.0
	Cycle 12 (LOCF)	0	31	27.4	11	35.5	21.1	53.1
		1	76	67.3	18	23.7	15.5	34.4
		Missing	1	0.9	1	100.0	20.7	100.0
	End of Study (LOCF)	0	31	27.4	12	38.7	23.7	56.2
		1	76	67.3	15	19.7	12.3	30.0
		Missing	1	0.9	1	100.0	20.7	100.0
Geographic region	All visits	USA	22	19.5	7	31.8	16.4	52.7
		Europe (EU)	29	25.7	16	55.2	37.5	71.6
		Asia (AS)	57	50.4	26	45.6	33.4	58.4
	Cycle 12 (LOCF)	USA	22	19.5	3	13.6	4.7	33.3
		Europe (EU)	29	25.7	10	34.5	19.9	52.7
		Asia (AS)	57	50.4	17	29.8	19.5	42.7
	End of Study (LOCF)	USA	22	19.5	2	9.1	2.5	27.8
		Europe (EU)	29	25.7	9	31.0	17.3	49.2
		Asia (AS)	57	50.4	17	29.8	19.5	42.7
Race/ethnicity	All visits	Asian	58	51.3	26	44.8	32.7	57.5
		Non-Asian	44	38.9	21	47.7	33.8	62.1
		Unknown	6	5.3	2	33.3	9.7	70.0
	Cycle 12 (LOCF)	Asian	58	51.3	17	29.3	19.2	42.0

		Non-Asian	44	38.9	13	29.5	18.2	44.2
		Unknown	6	5.3	0	0.0	0.0	39.0
	End of Study (LOCF)	Asian	58	51.3	17	29.3	19.2	42.0
		Non-Asian	44	38.9	11	25.0	14.6	39.4
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	26	45.6	33.4	58.4
		>= 2	51	45.1	23	45.1	32.3	58.6
	Cycle 12 (LOCF)	1	57	50.4	18	31.6	21.0	44.5
		>= 2	51	45.1	12	23.5	14.0	36.8
	End of Study (LOCF)	1	57	50.4	17	29.8	19.5	42.7
		>= 2	51	45.1	11	21.6	12.5	34.6

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30RF_W15_SG.xls
15OCT2021 13:27

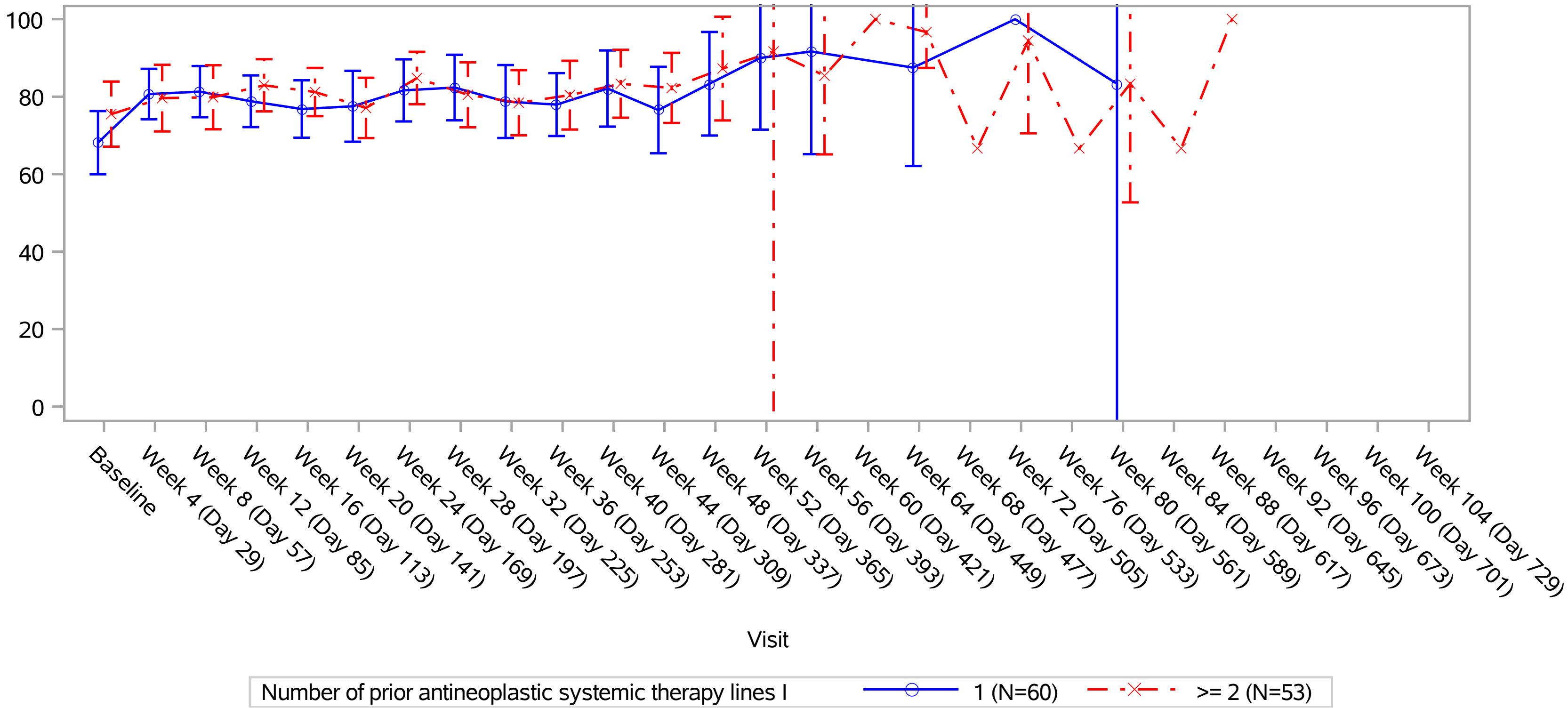
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Role functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30RF.pdf
15OCT2021 17:20

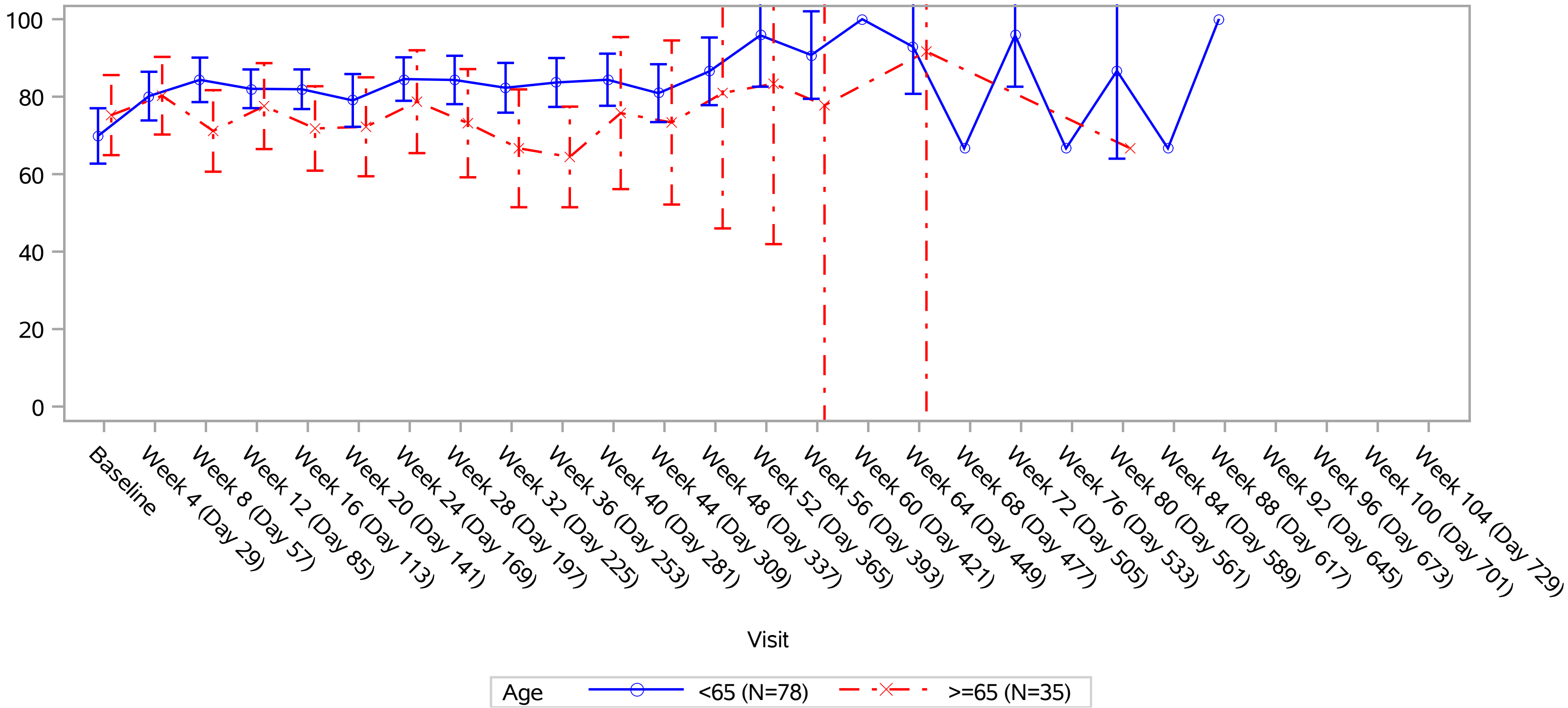
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Role functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30RF_PRTHL1.pdf
15OCT2021 20:12

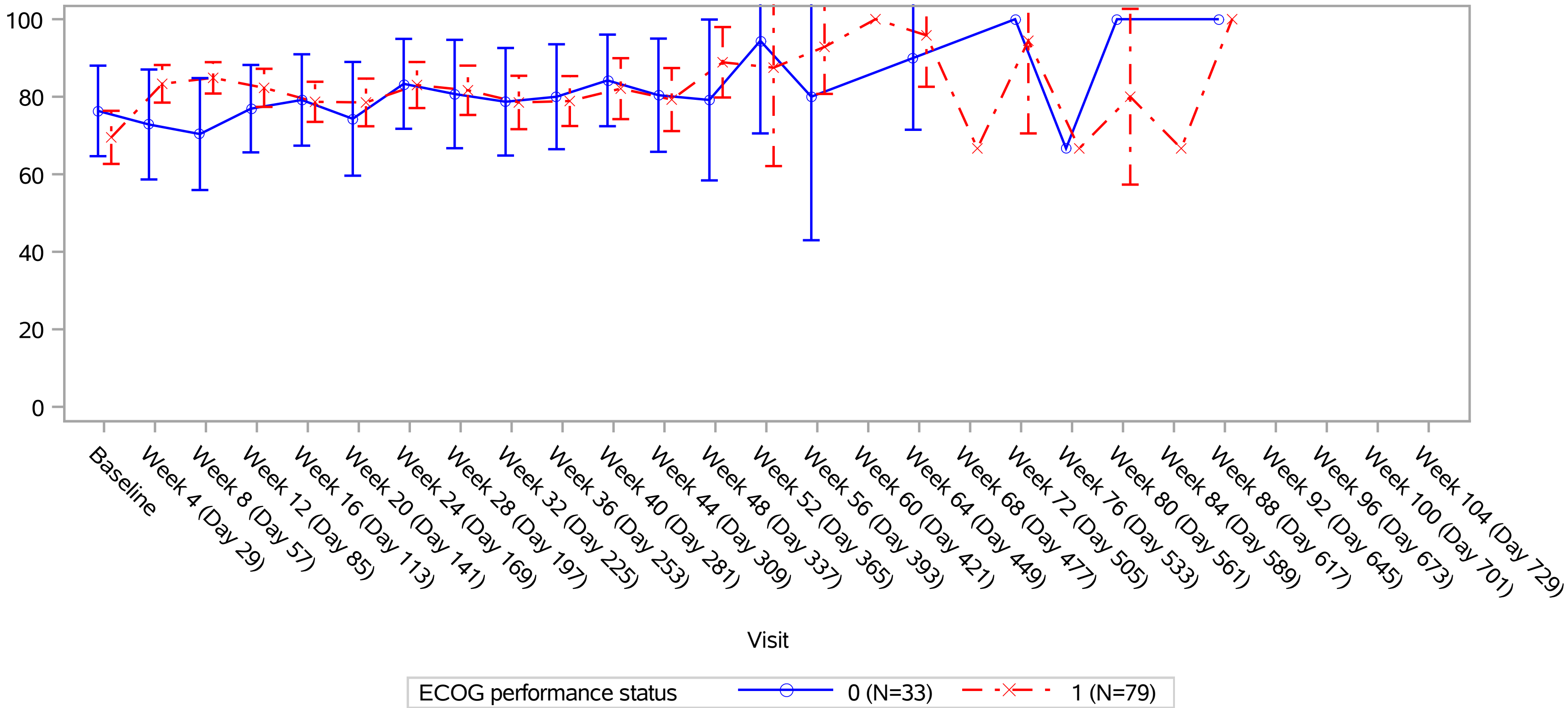
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Role functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30RF_SGAGE65.pdf
15OCT2021 17:49

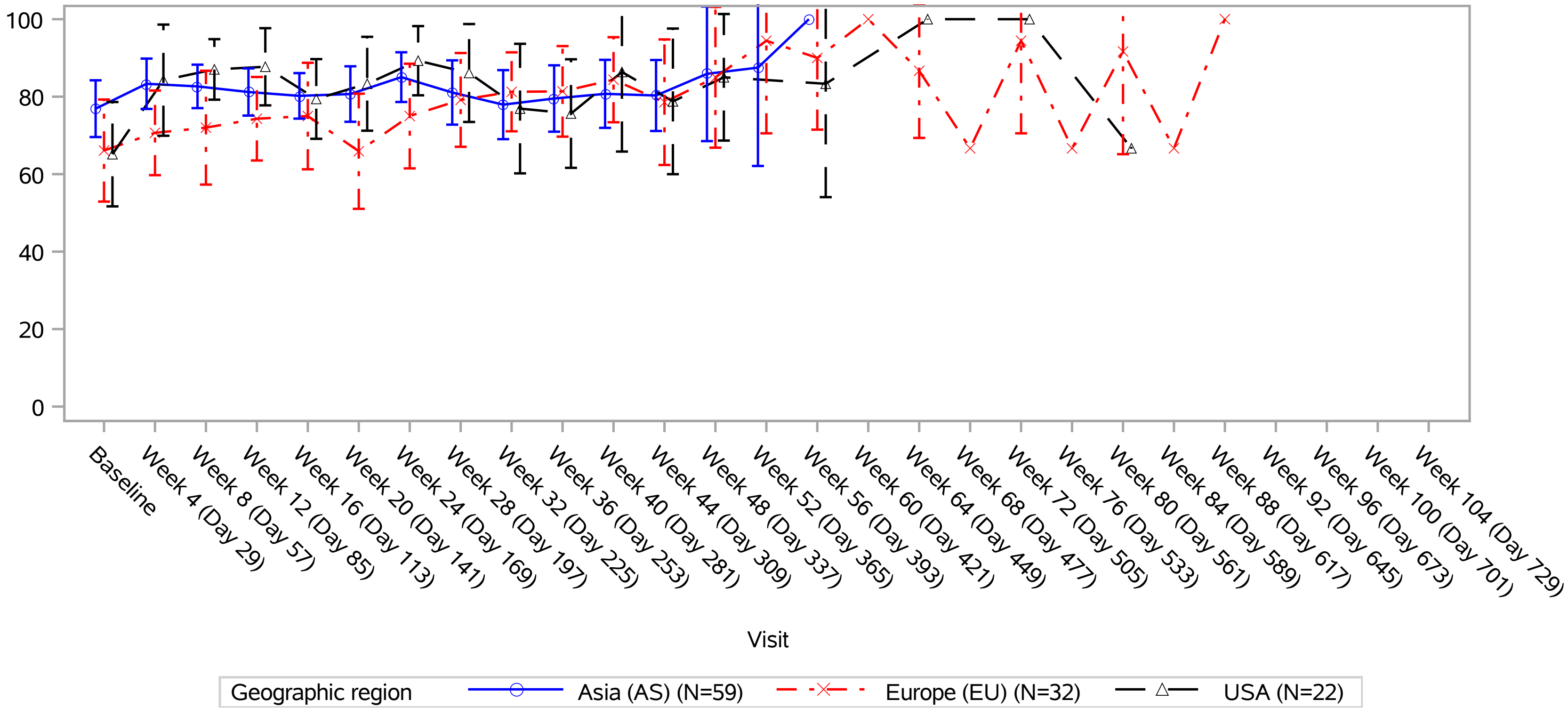
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Role functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30RF_SGECOG.pdf
15OCT2021 18:20

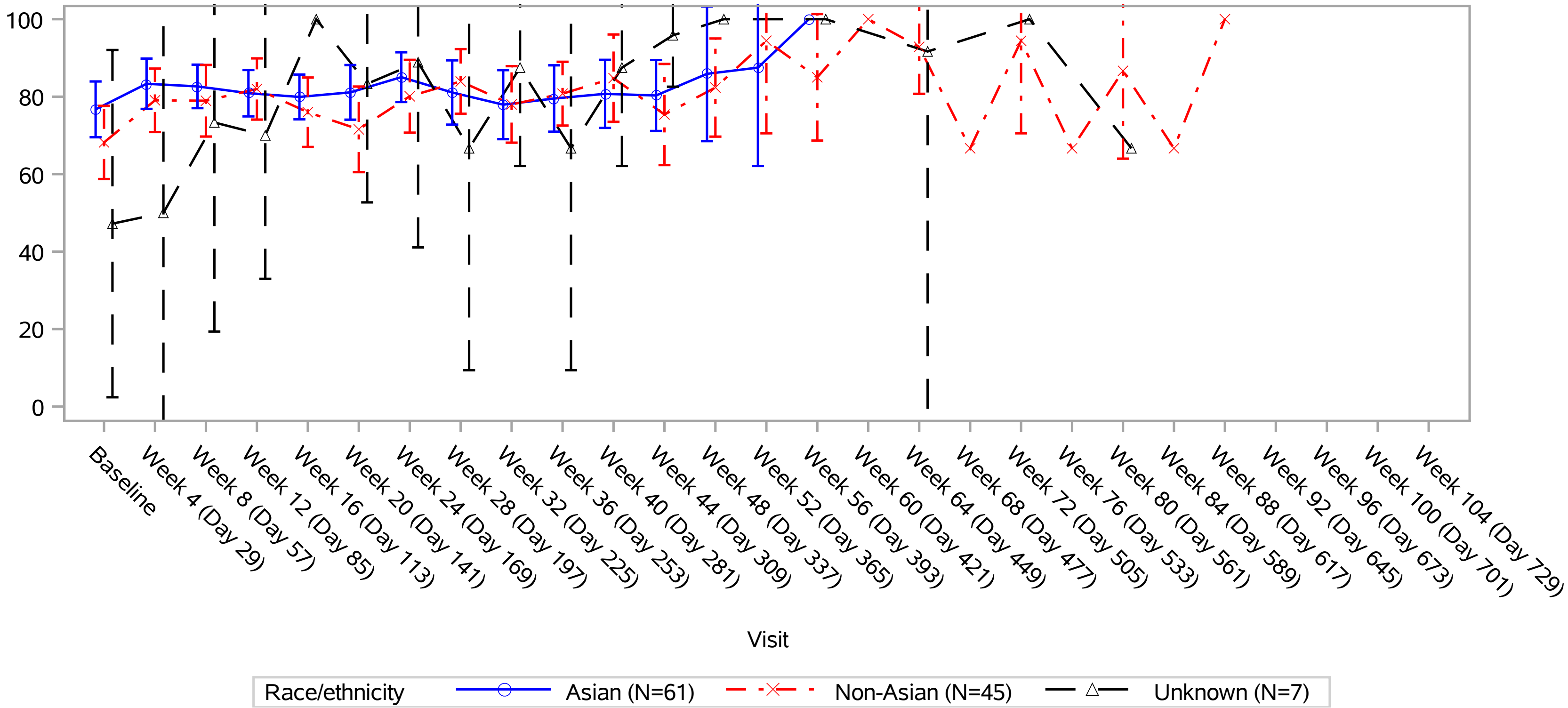
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Role functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30RF_SGGEO.pdf
15OCT2021 18:50

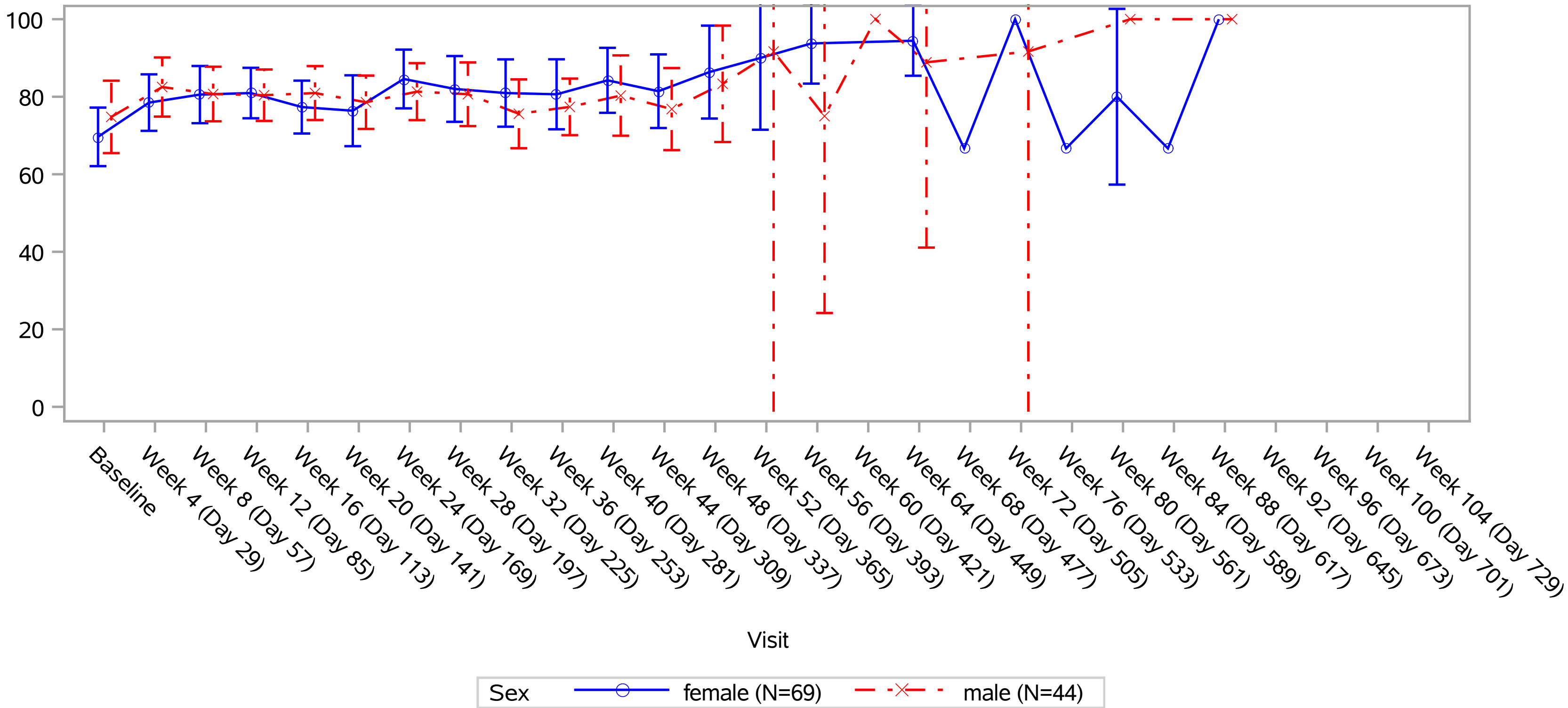
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Role functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30RF_SGRE.pdf
15OCT2021 19:21

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Role functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30RF_SGSEX.pdf
15OCT2021 19:51

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Social functioning
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=113)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	113	100.0	108	95.6	74.38	26.71	69.29	79.48
Week 4 (Day 29)	n/a	113	100.0	95	84.1	80.35	23.19	75.63	85.07
Week 8 (Day 57)	n/a	101	89.4	92	91.1	81.52	21.03	77.17	85.88
Week 12 (Day 85)	n/a	97	85.8	90	92.8	81.48	21.99	76.88	86.09
Week 16 (Day 113)	n/a	95	84.1	84	88.4	80.75	21.41	76.11	85.40
Week 20 (Day 141)	n/a	89	78.8	82	92.1	79.07	26.43	73.26	84.87
Week 24 (Day 169)	n/a	81	71.7	73	90.1	80.82	22.85	75.49	86.15
Week 28 (Day 197)	n/a	74	65.5	69	93.2	81.64	20.64	76.68	86.60
Week 32 (Day 225)	n/a	71	62.8	63	88.7	79.89	23.22	74.05	85.74
Week 36 (Day 253)	n/a	71	62.8	65	91.5	80.51	19.45	75.69	85.33
Week 40 (Day 281)	n/a	67	59.3	59	88.1	82.49	21.54	76.87	88.10
Week 44 (Day 309)	n/a	64	56.6	58	90.6	80.17	26.02	73.33	87.01
Week 48 (Day 337)	n/a	58	51.3	33	56.9	83.33	23.94	74.85	91.82
Week 52 (Day 365)	n/a	45	39.8	7	15.6	88.10	15.85	73.43	102.76
Week 56 (Day 393)	n/a	37	32.7	12	32.4	86.11	17.16	75.21	97.02
Week 60 (Day 421)	n/a	32	28.3	1	3.1	100.00	NE	NE	NE
Week 64 (Day 449)	n/a	31	27.4	9	29.0	94.44	8.33	88.04	100.85
Week 68 (Day 477)	n/a	28	24.8	1	3.6	66.67	NE	NE	NE
Week 72 (Day 505)	n/a	28	24.8	4	14.3	100.00	0.00	NE	NE
Week 76 (Day 533)	n/a	25	22.1	2	8.0	75.00	11.79	-30.89	180.89
Week 80 (Day 561)	n/a	25	22.1	6	24.0	88.89	27.22	60.33	117.45
Week 84 (Day 589)	n/a	18	15.9	1	5.6	100.00	NE	NE	NE
Week 88 (Day 617)	n/a	14	12.4	2	14.3	100.00	0.00	NE	NE
Week 92 (Day 645)	n/a	7	6.2	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	5.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	2.7	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	113	100.0	111	98.2	76.73	25.85	71.86	81.59
End of Study (LOCF)	n/a	113	100.0	111	98.2	76.58	25.16	71.84	81.31
Sex									
Baseline	Female	69	100.0	67	97.1	75.62	26.64	69.12	82.12
Week 4 (Day 29)	Female	69	100.0	55	79.7	82.12	23.32	75.82	88.43
Week 8 (Day 57)	Female	63	91.3	54	85.7	82.41	22.76	76.20	88.62
Week 12 (Day 85)	Female	60	87.0	56	93.3	80.36	23.38	74.10	86.62
Week 16 (Day 113)	Female	58	84.1	49	84.5	79.93	23.32	73.23	86.63
Week 20 (Day 141)	Female	53	76.8	47	88.7	77.30	30.38	68.38	86.23
Week 24 (Day 169)	Female	47	68.1	40	85.1	81.67	24.11	73.96	89.38
Week 28 (Day 197)	Female	42	60.9	38	90.5	81.14	22.65	73.70	88.59
Week 32 (Day 225)	Female	42	60.9	35	83.3	81.43	24.18	73.12	89.73
Week 36 (Day 253)	Female	42	60.9	37	88.1	82.43	21.14	75.39	89.48
Week 40 (Day 281)	Female	41	59.4	37	90.2	84.23	22.55	76.72	91.75
Week 44 (Day 309)	Female	41	59.4	35	85.4	82.86	26.96	73.60	92.12
Week 48 (Day 337)	Female	37	53.6	22	59.5	85.61	23.74	75.08	96.13
Week 52 (Day 365)	Female	29	42.0	5	17.2	90.00	14.91	71.49	108.51
Week 56 (Day 393)	Female	24	34.8	8	33.3	87.50	17.25	73.08	101.92
Week 60 (Day 421)	Female	22	31.9	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Female	22	31.9	6	27.3	94.44	8.61	85.41	103.48
Week 68 (Day 477)	Female	20	29.0	1	5.0	66.67	NE	NE	NE
Week 72 (Day 505)	Female	20	29.0	2	10.0	100.00	0.00	NE	NE
Week 76 (Day 533)	Female	18	26.1	2	11.1	75.00	11.79	-30.89	180.89
Week 80 (Day 561)	Female	18	26.1	5	27.8	86.67	29.81	49.65	123.69
Week 84 (Day 589)	Female	12	17.4	1	8.3	100.00	NE	NE	NE
Week 88 (Day 617)	Female	9	13.0	1	11.1	100.00	NE	NE	NE
Week 92 (Day 645)	Female	6	8.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	7.2	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	2.9	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	1.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	69	100.0	68	98.6	78.43	27.02	71.89	84.97
End of Study (LOCF)	Female	69	100.0	68	98.6	78.92	26.80	72.43	85.41
Baseline	Male	44	100.0	41	93.2	72.36	27.03	63.83	80.89
Week 4 (Day 29)	Male	44	100.0	40	90.9	77.92	23.08	70.54	85.30
Week 8 (Day 57)	Male	38	86.4	38	100.0	80.26	18.52	74.17	86.35
Week 12 (Day 85)	Male	37	84.1	34	91.9	83.33	19.68	76.47	90.20
Week 16 (Day 113)	Male	37	84.1	35	94.6	81.90	18.69	75.49	88.32
Week 20 (Day 141)	Male	36	81.8	35	97.2	81.43	20.12	74.52	88.34
Week 24 (Day 169)	Male	34	77.3	33	97.1	79.80	21.55	72.16	87.44
Week 28 (Day 197)	Male	32	72.7	31	96.9	82.26	18.22	75.57	88.94
Week 32 (Day 225)	Male	29	65.9	28	96.6	77.98	22.25	69.35	86.60
Week 36 (Day 253)	Male	29	65.9	28	96.6	77.98	17.00	71.38	84.57
Week 40 (Day 281)	Male	26	59.1	22	84.6	79.55	19.88	70.73	88.36
Week 44 (Day 309)	Male	23	52.3	23	100.0	76.09	24.53	65.48	86.69
Week 48 (Day 337)	Male	21	47.7	11	52.4	78.79	24.82	62.11	95.46
Week 52 (Day 365)	Male	16	36.4	2	12.5	83.33	23.57	-128.44	295.10
Week 56 (Day 393)	Male	13	29.5	4	30.8	83.33	19.25	52.71	113.96
Week 60 (Day 421)	Male	10	22.7	1	10.0	100.00	NE	NE	NE
Week 64 (Day 449)	Male	9	20.5	3	33.3	94.44	9.62	70.54	118.35
Week 68 (Day 477)	Male	8	18.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	8	18.2	2	25.0	100.00	0.00	NE	NE
Week 76 (Day 533)	Male	7	15.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	7	15.9	1	14.3	100.00	NE	NE	NE
Week 84 (Day 589)	Male	6	13.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	5	11.4	1	20.0	100.00	NE	NE	NE
Week 92 (Day 645)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	44	100.0	43	97.7	74.03	23.93	66.67	81.40
End of Study (LOCF)	Male	44	100.0	43	97.7	72.87	22.13	66.06	79.68
Age									

Baseline	< 65	78	100.0	73	93.6	74.20	25.92	68.15	80.25
Week 4 (Day 29)	< 65	78	100.0	68	87.2	79.90	23.32	74.26	85.55
Week 8 (Day 57)	< 65	73	93.6	66	90.4	83.84	17.29	79.59	88.09
Week 12 (Day 85)	< 65	71	91.0	64	90.1	83.07	18.90	78.35	87.79
Week 16 (Day 113)	< 65	69	88.5	58	84.1	84.48	16.48	80.15	88.82
Week 20 (Day 141)	< 65	65	83.3	61	93.8	80.05	25.43	73.54	86.57
Week 24 (Day 169)	< 65	59	75.6	55	93.2	80.00	21.61	74.16	85.84
Week 28 (Day 197)	< 65	55	70.5	51	92.7	81.37	21.51	75.32	87.42
Week 32 (Day 225)	< 65	53	67.9	48	90.6	81.94	22.50	75.41	88.48
Week 36 (Day 253)	< 65	53	67.9	50	94.3	81.33	20.10	75.62	87.05
Week 40 (Day 281)	< 65	52	66.7	48	92.3	83.68	20.77	77.65	89.71
Week 44 (Day 309)	< 65	52	66.7	48	92.3	80.56	25.11	73.26	87.85
Week 48 (Day 337)	< 65	47	60.3	26	55.3	83.97	20.27	75.79	92.16
Week 52 (Day 365)	< 65	36	46.2	4	11.1	95.83	8.33	82.57	109.09
Week 56 (Day 393)	< 65	30	38.5	9	30.0	88.89	18.63	74.57	103.21
Week 60 (Day 421)	< 65	25	32.1	1	4.0	100.00	NE	NE	NE
Week 64 (Day 449)	< 65	24	30.8	7	29.2	95.24	8.13	87.72	102.76
Week 68 (Day 477)	< 65	22	28.2	1	4.5	66.67	NE	NE	NE
Week 72 (Day 505)	< 65	22	28.2	4	18.2	100.00	0.00	NE	NE
Week 76 (Day 533)	< 65	21	26.9	2	9.5	75.00	11.79	-30.89	180.89
Week 80 (Day 561)	< 65	21	26.9	5	23.8	86.67	29.81	49.65	123.69
Week 84 (Day 589)	< 65	15	19.2	1	6.7	100.00	NE	NE	NE
Week 88 (Day 617)	< 65	12	15.4	2	16.7	100.00	0.00	NE	NE
Week 92 (Day 645)	< 65	6	7.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	6.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	78	100.0	76	97.4	78.29	24.65	72.66	83.92
End of Study (LOCF)	< 65	78	100.0	76	97.4	78.73	23.82	73.28	84.17
Baseline	>= 65	35	100.0	35	100.0	74.76	28.69	64.91	84.62
Week 4 (Day 29)	>= 65	35	100.0	27	77.1	81.48	23.27	72.28	90.69
Week 8 (Day 57)	>= 65	28	80.0	26	92.9	75.64	27.98	64.34	86.94
Week 12 (Day 85)	>= 65	26	74.3	26	100.0	77.56	28.26	66.15	88.98

Week 16 (Day 113)	>= 65	26	74.3	26	100.0	72.44	28.26	61.02	83.85
Week 20 (Day 141)	>= 65	24	68.6	21	87.5	76.19	29.61	62.71	89.67
Week 24 (Day 169)	>= 65	22	62.9	18	81.8	83.33	26.81	70.00	96.67
Week 28 (Day 197)	>= 65	19	54.3	18	94.7	82.41	18.50	73.21	91.61
Week 32 (Day 225)	>= 65	18	51.4	15	83.3	73.33	25.04	59.47	87.20
Week 36 (Day 253)	>= 65	18	51.4	15	83.3	77.78	17.44	68.12	87.44
Week 40 (Day 281)	>= 65	15	42.9	11	73.3	77.27	25.03	60.46	94.08
Week 44 (Day 309)	>= 65	12	34.3	10	83.3	78.33	31.48	55.82	100.85
Week 48 (Day 337)	>= 65	11	31.4	7	63.6	80.95	36.55	47.15	114.76
Week 52 (Day 365)	>= 65	9	25.7	3	33.3	77.78	19.25	29.97	125.59
Week 56 (Day 393)	>= 65	7	20.0	3	42.9	77.78	9.62	53.87	101.68
Week 60 (Day 421)	>= 65	7	20.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	7	20.0	2	28.6	91.67	11.79	-14.22	197.55
Week 68 (Day 477)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	4	11.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	4	11.4	1	25.0	100.00	NE	NE	NE
Week 84 (Day 589)	>= 65	3	8.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	5.7	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	35	100.0	35	100.0	73.33	28.35	63.59	83.07
End of Study (LOCF)	>= 65	35	100.0	35	100.0	71.90	27.64	62.41	81.40
ECOG performance status									
Baseline	0	33	100.0	31	93.9	76.88	26.06	67.32	86.44
Week 4 (Day 29)	0	33	100.0	27	81.8	72.84	31.40	60.42	85.26
Week 8 (Day 57)	0	30	90.9	27	90.0	78.40	28.43	67.15	89.64
Week 12 (Day 85)	0	29	87.9	26	89.7	79.49	27.21	68.50	90.48
Week 16 (Day 113)	0	28	84.8	24	85.7	77.78	26.31	66.67	88.89
Week 20 (Day 141)	0	26	78.8	23	88.5	80.43	31.24	66.92	93.94
Week 24 (Day 169)	0	24	72.7	20	83.3	80.00	25.71	67.97	92.03
Week 28 (Day 197)	0	21	63.6	19	90.5	78.07	24.88	66.08	90.06

Week 32 (Day 225)	0	21	63.6	18	85.7	80.56	26.35	67.45	93.66
Week 36 (Day 253)	0	21	63.6	20	95.2	82.50	20.57	72.87	92.13
Week 40 (Day 281)	0	21	63.6	19	90.5	87.72	23.47	76.41	99.03
Week 44 (Day 309)	0	21	63.6	17	81.0	79.41	28.58	64.72	94.11
Week 48 (Day 337)	0	19	57.6	12	63.2	79.17	31.88	58.91	99.42
Week 52 (Day 365)	0	18	54.5	3	16.7	83.33	16.67	41.93	124.74
Week 56 (Day 393)	0	16	48.5	5	31.3	90.00	14.91	71.49	108.51
Week 60 (Day 421)	0	16	48.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	0	16	48.5	5	31.3	93.33	9.13	82.00	104.67
Week 68 (Day 477)	0	14	42.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	0	14	42.4	1	7.1	100.00	NE	NE	NE
Week 76 (Day 533)	0	12	36.4	1	8.3	83.33	NE	NE	NE
Week 80 (Day 561)	0	12	36.4	1	8.3	100.00	NE	NE	NE
Week 84 (Day 589)	0	10	30.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	9	27.3	1	11.1	100.00	NE	NE	NE
Week 92 (Day 645)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	9.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	3.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	33	100.0	33	100.0	75.25	30.37	64.48	86.02
End of Study (LOCF)	0	33	100.0	33	100.0	74.24	29.49	63.79	84.70
Baseline	1	79	100.0	76	96.2	73.03	27.08	66.84	79.21
Week 4 (Day 29)	1	79	100.0	67	84.8	83.58	18.46	79.08	88.09
Week 8 (Day 57)	1	70	88.6	65	92.9	82.82	17.17	78.57	87.08
Week 12 (Day 85)	1	68	86.1	64	94.1	82.29	19.67	77.38	87.21
Week 16 (Day 113)	1	67	84.8	60	89.6	81.94	19.23	76.98	86.91
Week 20 (Day 141)	1	63	79.7	59	93.7	78.53	24.58	72.13	84.94
Week 24 (Day 169)	1	57	72.2	53	93.0	81.13	21.94	75.09	87.18
Week 28 (Day 197)	1	53	67.1	50	94.3	83.00	18.90	77.63	88.37
Week 32 (Day 225)	1	50	63.3	45	90.0	79.63	22.16	72.97	86.29
Week 36 (Day 253)	1	50	63.3	45	90.0	79.63	19.10	73.89	85.37
Week 40 (Day 281)	1	46	58.2	40	87.0	80.00	20.39	73.48	86.52

Week 44 (Day 309)	1	43	54.4	41	95.3	80.49	25.25	72.52	88.46
Week 48 (Day 337)	1	39	49.4	21	53.8	85.71	18.47	77.31	94.12
Week 52 (Day 365)	1	27	34.2	4	14.8	91.67	16.67	65.15	118.19
Week 56 (Day 393)	1	21	26.6	7	33.3	83.33	19.25	65.53	101.13
Week 60 (Day 421)	1	16	20.3	1	6.3	100.00	NE	NE	NE
Week 64 (Day 449)	1	15	19.0	4	26.7	95.83	8.33	82.57	109.09
Week 68 (Day 477)	1	14	17.7	1	7.1	66.67	NE	NE	NE
Week 72 (Day 505)	1	14	17.7	3	21.4	100.00	0.00	NE	NE
Week 76 (Day 533)	1	13	16.5	1	7.7	66.67	NE	NE	NE
Week 80 (Day 561)	1	13	16.5	5	38.5	86.67	29.81	49.65	123.69
Week 84 (Day 589)	1	8	10.1	1	12.5	100.00	NE	NE	NE
Week 88 (Day 617)	1	5	6.3	1	20.0	100.00	NE	NE	NE
Week 92 (Day 645)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	2.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	79	100.0	77	97.5	77.49	24.00	72.04	82.94
End of Study (LOCF)	1	79	100.0	77	97.5	77.71	23.35	72.40	83.01
Baseline	Missing	1	100.0	1	100.0	100.00	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	66.67	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	66.67	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	66.67	NE	NE	NE
Geographic region									
Baseline	USA	22	100.0	22	100.0	83.33	19.25	74.80	91.87
Week 4 (Day 29)	USA	22	100.0	18	81.8	86.11	25.08	73.64	98.58
Week 8 (Day 57)	USA	20	90.9	18	90.0	88.89	16.17	80.85	96.93
Week 12 (Day 85)	USA	20	90.9	19	95.0	89.47	19.41	80.12	98.83
Week 16 (Day 113)	USA	19	86.4	16	84.2	87.50	14.27	79.89	95.11
Week 20 (Day 141)	USA	19	86.4	17	89.5	84.31	20.81	73.61	95.01
Week 24 (Day 169)	USA	16	72.7	14	87.5	90.48	15.63	81.45	99.50
Week 28 (Day 197)	USA	15	68.2	12	80.0	90.28	15.01	80.74	99.81
Week 32 (Day 225)	USA	15	68.2	13	86.7	79.49	23.72	65.15	93.82
Week 36 (Day 253)	USA	15	68.2	13	86.7	79.49	22.72	65.76	93.22
Week 40 (Day 281)	USA	14	63.6	11	78.6	90.91	21.56	76.43	105.39

Week 44 (Day 309)	USA	13	59.1	11	84.6	84.85	26.30	67.18	102.52
Week 48 (Day 337)	USA	13	59.1	10	76.9	85.00	21.44	69.66	100.34
Week 52 (Day 365)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	USA	12	54.5	6	50.0	83.33	21.08	61.21	105.46
Week 60 (Day 421)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	11	50.0	4	36.4	100.00	0.00	NE	NE
Week 68 (Day 477)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	10	45.5	1	10.0	100.00	NE	NE	NE
Week 76 (Day 533)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	10	45.5	2	20.0	66.67	47.14	-356.87	490.21
Week 84 (Day 589)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	13.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	4.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	22	100.0	22	100.0	84.09	23.84	73.52	94.66
End of Study (LOCF)	USA	22	100.0	22	100.0	82.58	23.84	72.01	93.14
Baseline	Europe (EU)	32	100.0	29	90.6	65.52	29.19	54.42	76.62
Week 4 (Day 29)	Europe (EU)	32	100.0	25	78.1	76.00	25.04	65.67	86.33
Week 8 (Day 57)	Europe (EU)	29	90.6	25	86.2	80.00	24.06	70.07	89.93
Week 12 (Day 85)	Europe (EU)	26	81.3	24	92.3	77.78	25.38	67.06	88.49
Week 16 (Day 113)	Europe (EU)	25	78.1	20	80.0	80.00	21.36	70.00	90.00
Week 20 (Day 141)	Europe (EU)	23	71.9	21	91.3	68.25	35.71	52.00	84.51
Week 24 (Day 169)	Europe (EU)	21	65.6	20	95.2	72.50	27.19	59.78	85.22
Week 28 (Day 197)	Europe (EU)	20	62.5	20	100.0	76.67	23.20	65.81	87.52
Week 32 (Day 225)	Europe (EU)	18	56.3	16	88.9	78.13	22.54	66.11	90.14
Week 36 (Day 253)	Europe (EU)	18	56.3	17	94.4	80.39	21.44	69.37	91.41
Week 40 (Day 281)	Europe (EU)	17	53.1	16	94.1	82.29	23.15	69.96	94.63
Week 44 (Day 309)	Europe (EU)	17	53.1	14	82.4	78.57	28.06	62.37	94.77

Week 48 (Day 337)	Europe (EU)	14	43.8	10	71.4	85.00	16.57	73.14	96.86
Week 52 (Day 365)	Europe (EU)	13	40.6	3	23.1	83.33	16.67	41.93	124.74
Week 56 (Day 393)	Europe (EU)	11	34.4	5	45.5	93.33	9.13	82.00	104.67
Week 60 (Day 421)	Europe (EU)	11	34.4	1	9.1	100.00	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	11	34.4	5	45.5	90.00	9.13	78.67	101.33
Week 68 (Day 477)	Europe (EU)	10	31.3	1	10.0	66.67	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	10	31.3	3	30.0	100.00	0.00	NE	NE
Week 76 (Day 533)	Europe (EU)	8	25.0	2	25.0	75.00	11.79	-30.89	180.89
Week 80 (Day 561)	Europe (EU)	8	25.0	4	50.0	100.00	0.00	NE	NE
Week 84 (Day 589)	Europe (EU)	6	18.8	1	16.7	100.00	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	9.4	2	66.7	100.00	0.00	NE	NE
Cycle 12 (LOCF)	Europe (EU)	32	100.0	31	96.9	73.12	27.11	63.18	83.06
End of Study (LOCF)	Europe (EU)	32	100.0	31	96.9	75.27	25.77	65.81	84.72
Baseline	Asia (AS)	59	100.0	57	96.6	75.44	26.93	68.29	82.58
Week 4 (Day 29)	Asia (AS)	59	100.0	52	88.1	80.45	21.57	74.44	86.45
Week 8 (Day 57)	Asia (AS)	52	88.1	49	94.2	79.59	20.77	73.63	85.56
Week 12 (Day 85)	Asia (AS)	51	86.4	47	92.2	80.14	20.75	74.05	86.23
Week 16 (Day 113)	Asia (AS)	51	86.4	48	94.1	78.82	23.25	72.07	85.57
Week 20 (Day 141)	Asia (AS)	47	79.7	44	93.6	82.20	21.98	75.51	88.88
Week 24 (Day 169)	Asia (AS)	44	74.6	39	88.6	81.62	21.56	74.63	88.61
Week 28 (Day 197)	Asia (AS)	39	66.1	37	94.9	81.53	20.33	74.75	88.31
Week 32 (Day 225)	Asia (AS)	38	64.4	34	89.5	80.88	23.97	72.52	89.25
Week 36 (Day 253)	Asia (AS)	38	64.4	35	92.1	80.95	17.69	74.88	87.03
Week 40 (Day 281)	Asia (AS)	36	61.0	32	88.9	79.69	20.62	72.25	87.12
Week 44 (Day 309)	Asia (AS)	34	57.6	33	97.1	79.29	25.70	70.18	88.40
Week 48 (Day 337)	Asia (AS)	31	52.5	13	41.9	80.77	31.07	62.00	99.54
Week 52 (Day 365)	Asia (AS)	20	33.9	4	20.0	91.67	16.67	65.15	118.19
Week 56 (Day 393)	Asia (AS)	14	23.7	1	7.1	66.67	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	10.2	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	8.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	3.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	59	100.0	58	98.3	75.86	25.78	69.08	82.64
End of Study (LOCF)	Asia (AS)	59	100.0	58	98.3	75.00	25.41	68.32	81.68
Race/ethnicity									
Baseline	Asian	61	100.0	58	95.1	75.29	26.72	68.26	82.31
Week 4 (Day 29)	Asian	61	100.0	52	85.2	80.45	21.57	74.44	86.45
Week 8 (Day 57)	Asian	53	86.9	49	92.5	79.59	20.77	73.63	85.56
Week 12 (Day 85)	Asian	52	85.2	48	92.3	79.86	20.62	73.87	85.85
Week 16 (Day 113)	Asian	52	85.2	48	92.3	78.82	23.25	72.07	85.57
Week 20 (Day 141)	Asian	48	78.7	45	93.8	81.11	22.92	74.23	88.00
Week 24 (Day 169)	Asian	44	72.1	39	88.6	81.62	21.56	74.63	88.61
Week 28 (Day 197)	Asian	39	63.9	37	94.9	81.53	20.33	74.75	88.31
Week 32 (Day 225)	Asian	38	62.3	34	89.5	80.88	23.97	72.52	89.25
Week 36 (Day 253)	Asian	38	62.3	35	92.1	80.95	17.69	74.88	87.03
Week 40 (Day 281)	Asian	36	59.0	32	88.9	79.69	20.62	72.25	87.12
Week 44 (Day 309)	Asian	34	55.7	33	97.1	79.29	25.70	70.18	88.40
Week 48 (Day 337)	Asian	31	50.8	13	41.9	80.77	31.07	62.00	99.54
Week 52 (Day 365)	Asian	20	32.8	4	20.0	91.67	16.67	65.15	118.19
Week 56 (Day 393)	Asian	14	23.0	1	7.1	66.67	NE	NE	NE
Week 60 (Day 421)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	9.8	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	8.2	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	3.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	61	100.0	59	96.7	75.14	26.15	68.33	81.96
End of Study (LOCF)	Asian	61	100.0	59	96.7	74.29	25.77	67.58	81.01
Baseline	Non-Asian	45	100.0	44	97.8	74.62	25.54	66.86	82.39
Week 4 (Day 29)	Non-Asian	45	100.0	39	86.7	82.48	21.27	75.58	89.37
Week 8 (Day 57)	Non-Asian	42	93.3	38	90.5	84.65	21.36	77.63	91.67
Week 12 (Day 85)	Non-Asian	39	86.7	37	94.9	84.23	23.88	76.27	92.20
Week 16 (Day 113)	Non-Asian	37	82.2	34	91.9	82.35	18.78	75.80	88.90
Week 20 (Day 141)	Non-Asian	36	80.0	33	91.7	75.25	31.49	64.09	86.42
Week 24 (Day 169)	Non-Asian	32	71.1	31	96.9	80.11	25.25	70.85	89.37
Week 28 (Day 197)	Non-Asian	30	66.7	28	93.3	84.52	18.10	77.50	91.54
Week 32 (Day 225)	Non-Asian	28	62.2	25	89.3	79.33	23.21	69.75	88.92
Week 36 (Day 253)	Non-Asian	28	62.2	26	92.9	82.05	20.51	73.77	90.33
Week 40 (Day 281)	Non-Asian	26	57.8	23	88.5	84.78	23.52	74.61	94.95
Week 44 (Day 309)	Non-Asian	25	55.6	21	84.0	79.37	28.82	66.25	92.48
Week 48 (Day 337)	Non-Asian	23	51.1	17	73.9	85.29	19.44	75.30	95.29
Week 52 (Day 365)	Non-Asian	21	46.7	3	14.3	83.33	16.67	41.93	124.74
Week 56 (Day 393)	Non-Asian	19	42.2	10	52.6	86.67	17.21	74.35	98.98
Week 60 (Day 421)	Non-Asian	19	42.2	1	5.3	100.00	NE	NE	NE
Week 64 (Day 449)	Non-Asian	18	40.0	7	38.9	92.86	8.91	84.62	101.10
Week 68 (Day 477)	Non-Asian	17	37.8	1	5.9	66.67	NE	NE	NE
Week 72 (Day 505)	Non-Asian	17	37.8	3	17.6	100.00	0.00	NE	NE
Week 76 (Day 533)	Non-Asian	15	33.3	2	13.3	75.00	11.79	-30.89	180.89
Week 80 (Day 561)	Non-Asian	15	33.3	5	33.3	86.67	29.81	49.65	123.69
Week 84 (Day 589)	Non-Asian	10	22.2	1	10.0	100.00	NE	NE	NE
Week 88 (Day 617)	Non-Asian	7	15.6	2	28.6	100.00	0.00	NE	NE
Week 92 (Day 645)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	45	100.0	45	100.0	77.04	26.42	69.10	84.97

End of Study (LOCF)	Non-Asian	45	100.0	45	100.0	77.41	24.91	69.92	84.89
Baseline	Unknown	7	100.0	6	85.7	63.89	37.14	24.91	102.87
Week 4 (Day 29)	Unknown	7	100.0	4	57.1	58.33	50.00	-21.23	137.89
Week 8 (Day 57)	Unknown	6	85.7	5	83.3	76.67	22.36	48.90	104.43
Week 12 (Day 85)	Unknown	6	85.7	5	83.3	76.67	22.36	48.90	104.43
Week 16 (Day 113)	Unknown	6	85.7	2	33.3	100.00	0.00	NE	NE
Week 20 (Day 141)	Unknown	5	71.4	4	80.0	87.50	15.96	62.11	112.89
Week 24 (Day 169)	Unknown	5	71.4	3	60.0	77.78	19.25	29.97	125.59
Week 28 (Day 197)	Unknown	5	71.4	4	80.0	62.50	34.36	7.83	117.17
Week 32 (Day 225)	Unknown	5	71.4	4	80.0	75.00	21.52	40.76	109.24
Week 36 (Day 253)	Unknown	5	71.4	4	80.0	66.67	27.22	23.36	109.97
Week 40 (Day 281)	Unknown	5	71.4	4	80.0	91.67	16.67	65.15	118.19
Week 44 (Day 309)	Unknown	5	71.4	4	80.0	91.67	9.62	76.36	106.98
Week 48 (Day 337)	Unknown	4	57.1	3	75.0	83.33	16.67	41.93	124.74
Week 52 (Day 365)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	4	57.1	1	25.0	100.00	NE	NE	NE
Week 60 (Day 421)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	4	57.1	2	50.0	100.00	0.00	NE	NE
Week 68 (Day 477)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	3	42.9	1	33.3	100.00	NE	NE	NE
Week 76 (Day 533)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	3	42.9	1	33.3	100.00	NE	NE	NE
Week 84 (Day 589)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	14.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	7	100.0	7	100.0	88.10	18.54	70.94	105.25
End of Study (LOCF)	Unknown	7	100.0	7	100.0	90.48	18.90	73.00	107.95
Number of prior antineoplastic systemic therapy lines I									
Baseline	1	60	100.0	57	95.0	76.61	25.17	69.93	83.29

Week 4 (Day 29)	1	60	100.0	50	83.3	83.33	20.76	77.43	89.23
Week 8 (Day 57)	1	54	90.0	49	90.7	81.63	20.48	75.75	87.52
Week 12 (Day 85)	1	52	86.7	48	92.3	80.56	23.65	73.69	87.42
Week 16 (Day 113)	1	51	85.0	45	88.2	82.96	19.30	77.17	88.76
Week 20 (Day 141)	1	48	80.0	42	87.5	78.97	28.53	70.08	87.86
Week 24 (Day 169)	1	43	71.7	39	90.7	79.91	25.13	71.77	88.06
Week 28 (Day 197)	1	38	63.3	34	89.5	81.37	22.39	73.56	89.18
Week 32 (Day 225)	1	35	58.3	29	82.9	78.16	24.44	68.86	87.46
Week 36 (Day 253)	1	35	58.3	31	88.6	80.11	19.45	72.97	87.24
Week 40 (Day 281)	1	32	53.3	27	84.4	82.10	23.54	72.79	91.41
Week 44 (Day 309)	1	32	53.3	27	84.4	79.01	27.96	67.95	90.07
Week 48 (Day 337)	1	27	45.0	16	59.3	82.29	23.15	69.96	94.63
Week 52 (Day 365)	1	23	38.3	5	21.7	90.00	14.91	71.49	108.51
Week 56 (Day 393)	1	16	26.7	4	25.0	91.67	9.62	76.36	106.98
Week 60 (Day 421)	1	14	23.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	13	21.7	4	30.8	91.67	9.62	76.36	106.98
Week 68 (Day 477)	1	12	20.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	12	20.0	1	8.3	100.00	NE	NE	NE
Week 76 (Day 533)	1	11	18.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	11	18.3	2	18.2	100.00	0.00	NE	NE
Week 84 (Day 589)	1	9	15.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	1	8	13.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	1	3	5.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	1	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	60	100.0	58	96.7	77.30	26.62	70.30	84.30
End of Study (LOCF)	1	60	100.0	58	96.7	77.01	25.14	70.40	83.62
Baseline	>= 2	53	100.0	51	96.2	71.90	28.38	63.91	79.88
Week 4 (Day 29)	>= 2	53	100.0	45	84.9	77.04	25.45	69.39	84.68
Week 8 (Day 57)	>= 2	47	88.7	43	91.5	81.40	21.89	74.66	88.13
Week 12 (Day 85)	>= 2	45	84.9	42	93.3	82.54	20.15	76.26	88.82
Week 16 (Day 113)	>= 2	44	83.0	39	88.6	78.21	23.62	70.55	85.86

Week 20 (Day 141)	>= 2	41	77.4	40	97.6	79.17	24.39	71.37	86.97
Week 24 (Day 169)	>= 2	38	71.7	34	89.5	81.86	20.25	74.80	88.93
Week 28 (Day 197)	>= 2	36	67.9	35	97.2	81.90	19.12	75.34	88.47
Week 32 (Day 225)	>= 2	36	67.9	34	94.4	81.37	22.39	73.56	89.18
Week 36 (Day 253)	>= 2	36	67.9	34	94.4	80.88	19.73	74.00	87.77
Week 40 (Day 281)	>= 2	35	66.0	32	91.4	82.81	20.07	75.58	90.05
Week 44 (Day 309)	>= 2	32	60.4	31	96.9	81.18	24.62	72.15	90.21
Week 48 (Day 337)	>= 2	31	58.5	17	54.8	84.31	25.32	71.29	97.33
Week 52 (Day 365)	>= 2	22	41.5	2	9.1	83.33	23.57	-128.44	295.10
Week 56 (Day 393)	>= 2	21	39.6	8	38.1	83.33	19.92	66.68	99.99
Week 60 (Day 421)	>= 2	18	34.0	1	5.6	100.00	NE	NE	NE
Week 64 (Day 449)	>= 2	18	34.0	5	27.8	96.67	7.45	87.41	105.92
Week 68 (Day 477)	>= 2	16	30.2	1	6.3	66.67	NE	NE	NE
Week 72 (Day 505)	>= 2	16	30.2	3	18.8	100.00	0.00	NE	NE
Week 76 (Day 533)	>= 2	14	26.4	2	14.3	75.00	11.79	-30.89	180.89
Week 80 (Day 561)	>= 2	14	26.4	4	28.6	83.33	33.33	30.29	136.37
Week 84 (Day 589)	>= 2	9	17.0	1	11.1	100.00	NE	NE	NE
Week 88 (Day 617)	>= 2	6	11.3	2	33.3	100.00	0.00	NE	NE
Week 92 (Day 645)	>= 2	2	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 2	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 2	53	100.0	53	100.0	76.10	25.21	69.15	83.05
End of Study (LOCF)	>= 2	53	100.0	53	100.0	76.10	25.43	69.09	83.11

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TP_QSC30SF_SG.xls
27OCT2021 7:31

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Social functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	42	38.9	30.2	48.3
	Cycle 12 (LOCF)	n/a	108	95.6	27	25.0	17.8	33.9
	End of Study (LOCF)	n/a	108	95.6	28	25.9	18.6	34.9
Sex	All visits	Female	67	59.3	24	35.8	25.4	47.8
		Male	41	36.3	18	43.9	29.9	59.0
	Cycle 12 (LOCF)	Female	67	59.3	15	22.4	14.1	33.7
		Male	41	36.3	12	29.3	17.6	44.5
	End of Study (LOCF)	Female	67	59.3	15	22.4	14.1	33.7
		Male	41	36.3	13	31.7	19.6	47.0
Age	All visits	< 65	73	64.6	25	34.2	24.4	45.7
		>= 65	35	31.0	17	48.6	33.0	64.4
	Cycle 12 (LOCF)	< 65	73	64.6	17	23.3	15.1	34.2
		>= 65	35	31.0	10	28.6	16.3	45.1
	End of Study (LOCF)	< 65	73	64.6	17	23.3	15.1	34.2
		>= 65	35	31.0	11	31.4	18.6	48.0
ECOG performance status	All visits	0	31	27.4	15	48.4	32.0	65.2
		1	76	67.3	26	34.2	24.5	45.4
		Missing	1	0.9	1	100.0	20.7	100.0
	Cycle 12 (LOCF)	0	31	27.4	10	32.3	18.6	49.9
		1	76	67.3	16	21.1	13.4	31.5
		Missing	1	0.9	1	100.0	20.7	100.0
	End of Study (LOCF)	0	31	27.4	11	35.5	21.1	53.1
		1	76	67.3	16	21.1	13.4	31.5
		Missing	1	0.9	1	100.0	20.7	100.0
Geographic region	All visits	USA	22	19.5	8	36.4	19.7	57.0
		Europe (EU)	29	25.7	11	37.9	22.7	56.0
		Asia (AS)	57	50.4	23	40.4	28.6	53.3
	Cycle 12 (LOCF)	USA	22	19.5	4	18.2	7.3	38.5
		Europe (EU)	29	25.7	7	24.1	12.2	42.1
		Asia (AS)	57	50.4	16	28.1	18.1	40.8
	End of Study (LOCF)	USA	22	19.5	5	22.7	10.1	43.4
		Europe (EU)	29	25.7	6	20.7	9.8	38.4
		Asia (AS)	57	50.4	17	29.8	19.5	42.7
Race/ethnicity	All visits	Asian	58	51.3	24	41.4	29.6	54.2
		Non-Asian	44	38.9	16	36.4	23.8	51.1
		Unknown	6	5.3	2	33.3	9.7	70.0
	Cycle 12 (LOCF)	Asian	58	51.3	17	29.3	19.2	42.0

		Non-Asian	44	38.9	10	22.7	12.8	37.0
		Unknown	6	5.3	0	0.0	0.0	39.0
	End of Study (LOCF)	Asian	58	51.3	18	31.0	20.6	43.8
		Non-Asian	44	38.9	10	22.7	12.8	37.0
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	25	43.9	31.8	56.7
		>= 2	51	45.1	17	33.3	22.0	47.0
	Cycle 12 (LOCF)	1	57	50.4	16	28.1	18.1	40.8
		>= 2	51	45.1	11	21.6	12.5	34.6
	End of Study (LOCF)	1	57	50.4	17	29.8	19.5	42.7
		>= 2	51	45.1	11	21.6	12.5	34.6

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30SF_W10_SG.xls
15OCT2021 13:38

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Social functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

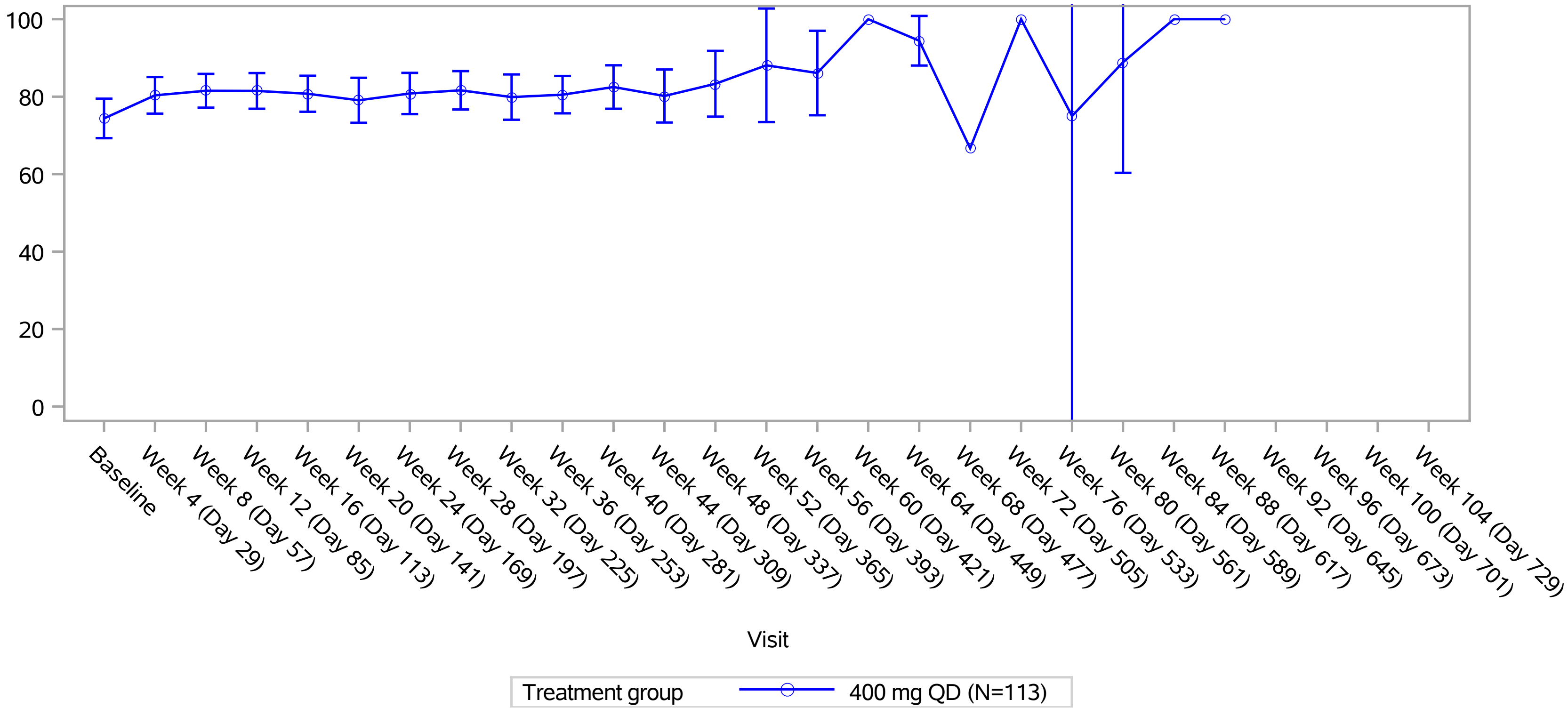
			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	42	38.9	30.2	48.3
	Cycle 12 (LOCF)	n/a	108	95.6	27	25.0	17.8	33.9
	End of Study (LOCF)	n/a	108	95.6	28	25.9	18.6	34.9
Sex	All visits	Female	67	59.3	24	35.8	25.4	47.8
		Male	41	36.3	18	43.9	29.9	59.0
	Cycle 12 (LOCF)	Female	67	59.3	15	22.4	14.1	33.7
		Male	41	36.3	12	29.3	17.6	44.5
	End of Study (LOCF)	Female	67	59.3	15	22.4	14.1	33.7
		Male	41	36.3	13	31.7	19.6	47.0
Age	All visits	< 65	73	64.6	25	34.2	24.4	45.7
		>= 65	35	31.0	17	48.6	33.0	64.4
	Cycle 12 (LOCF)	< 65	73	64.6	17	23.3	15.1	34.2
		>= 65	35	31.0	10	28.6	16.3	45.1
	End of Study (LOCF)	< 65	73	64.6	17	23.3	15.1	34.2
		>= 65	35	31.0	11	31.4	18.6	48.0
ECOG performance status	All visits	0	31	27.4	15	48.4	32.0	65.2
		1	76	67.3	26	34.2	24.5	45.4
		Missing	1	0.9	1	100.0	20.7	100.0
	Cycle 12 (LOCF)	0	31	27.4	10	32.3	18.6	49.9
		1	76	67.3	16	21.1	13.4	31.5
		Missing	1	0.9	1	100.0	20.7	100.0
	End of Study (LOCF)	0	31	27.4	11	35.5	21.1	53.1
		1	76	67.3	16	21.1	13.4	31.5
		Missing	1	0.9	1	100.0	20.7	100.0
Geographic region	All visits	USA	22	19.5	8	36.4	19.7	57.0
		Europe (EU)	29	25.7	11	37.9	22.7	56.0
		Asia (AS)	57	50.4	23	40.4	28.6	53.3
	Cycle 12 (LOCF)	USA	22	19.5	4	18.2	7.3	38.5
		Europe (EU)	29	25.7	7	24.1	12.2	42.1
		Asia (AS)	57	50.4	16	28.1	18.1	40.8
	End of Study (LOCF)	USA	22	19.5	5	22.7	10.1	43.4
		Europe (EU)	29	25.7	6	20.7	9.8	38.4
		Asia (AS)	57	50.4	17	29.8	19.5	42.7
Race/ethnicity	All visits	Asian	58	51.3	24	41.4	29.6	54.2
		Non-Asian	44	38.9	16	36.4	23.8	51.1
		Unknown	6	5.3	2	33.3	9.7	70.0
	Cycle 12 (LOCF)	Asian	58	51.3	17	29.3	19.2	42.0

		Non-Asian	44	38.9	10	22.7	12.8	37.0
		Unknown	6	5.3	0	0.0	0.0	39.0
	End of Study (LOCF)	Asian	58	51.3	18	31.0	20.6	43.8
		Non-Asian	44	38.9	10	22.7	12.8	37.0
		Unknown	6	5.3	0	0.0	0.0	39.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	25	43.9	31.8	56.7
		>= 2	51	45.1	17	33.3	22.0	47.0
	Cycle 12 (LOCF)	1	57	50.4	16	28.1	18.1	40.8
		>= 2	51	45.1	11	21.6	12.5	34.6
	End of Study (LOCF)	1	57	50.4	17	29.8	19.5	42.7
		>= 2	51	45.1	11	21.6	12.5	34.6

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30SF_W15_SG.xls
15OCT2021 13:28

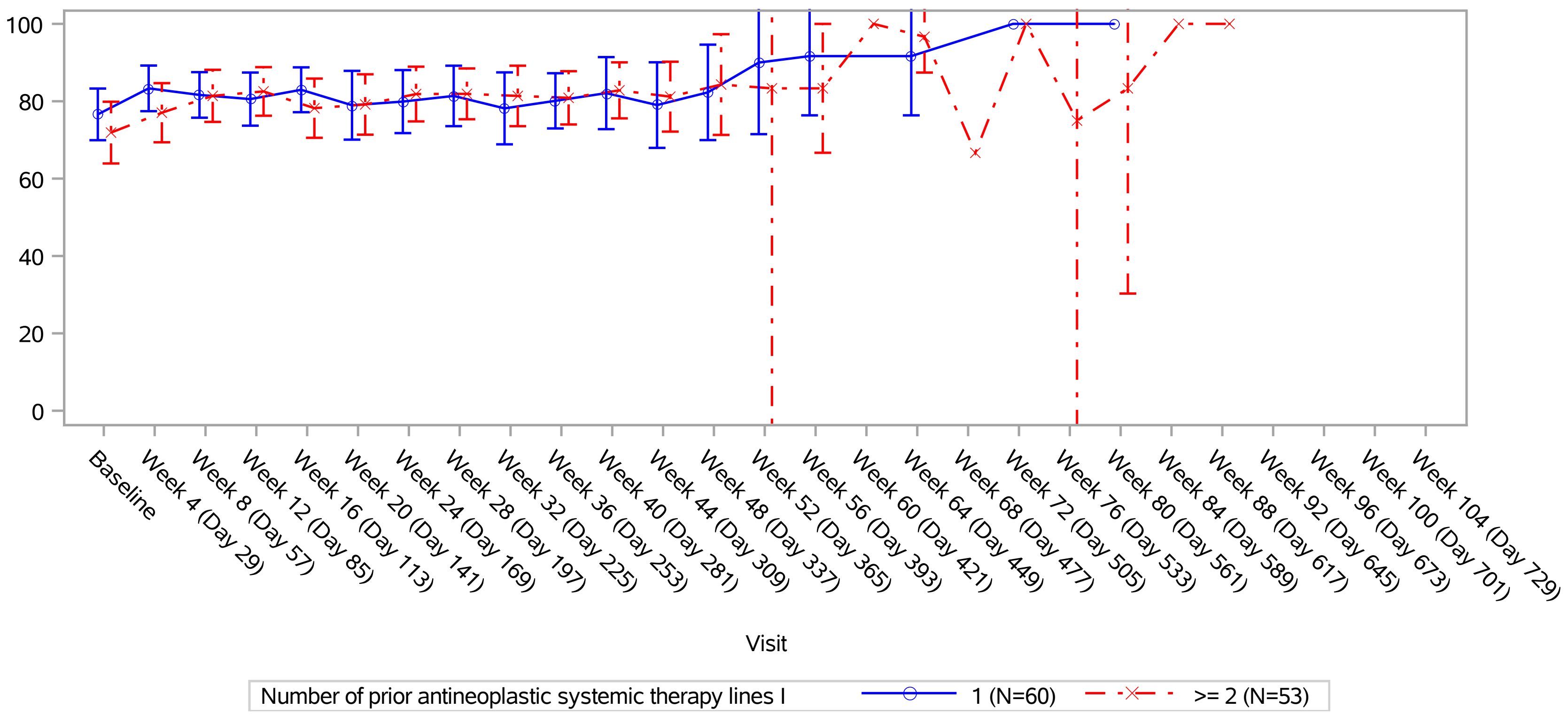
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Social functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30SF.pdf
15OCT2021 17:20

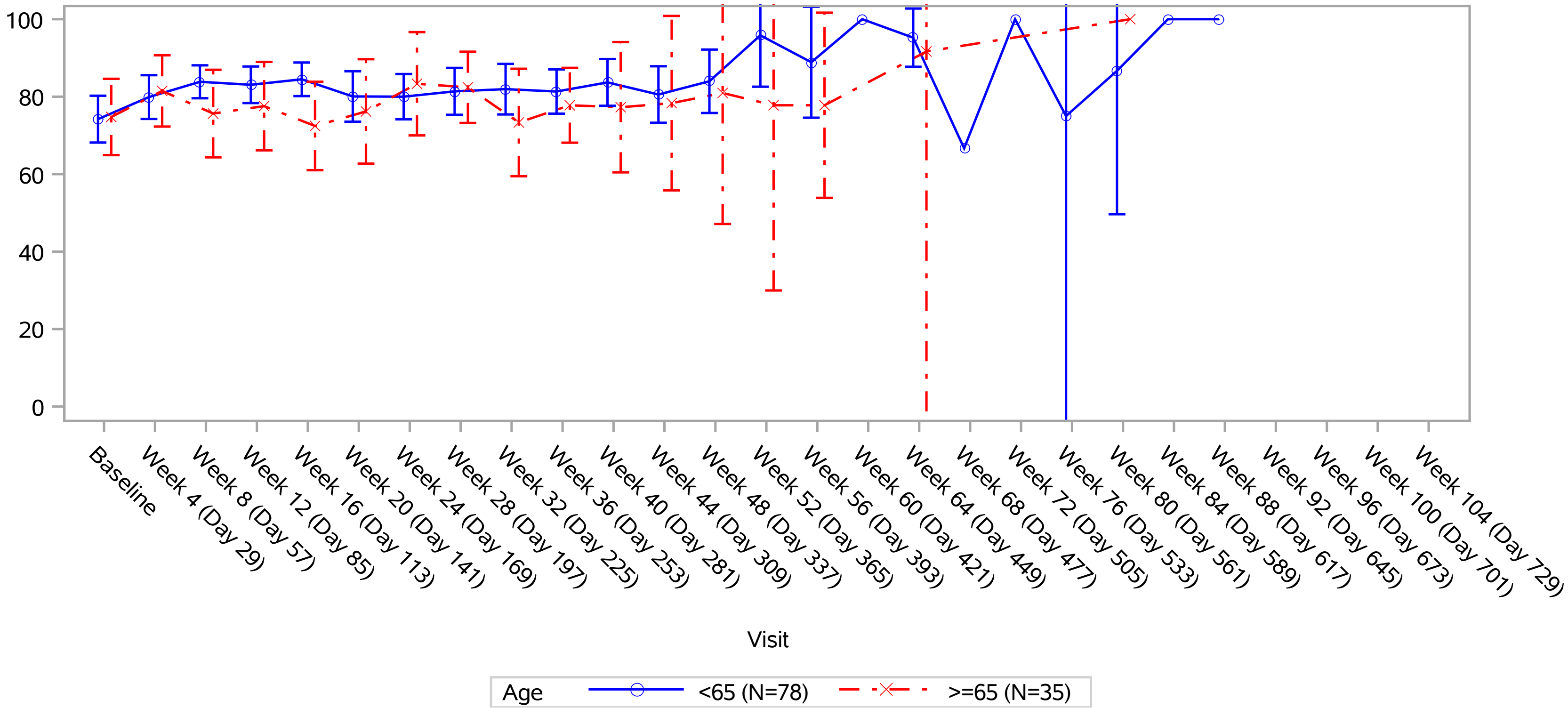
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Social functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30SF_PRTHL1.pdf
15OCT2021 20:12

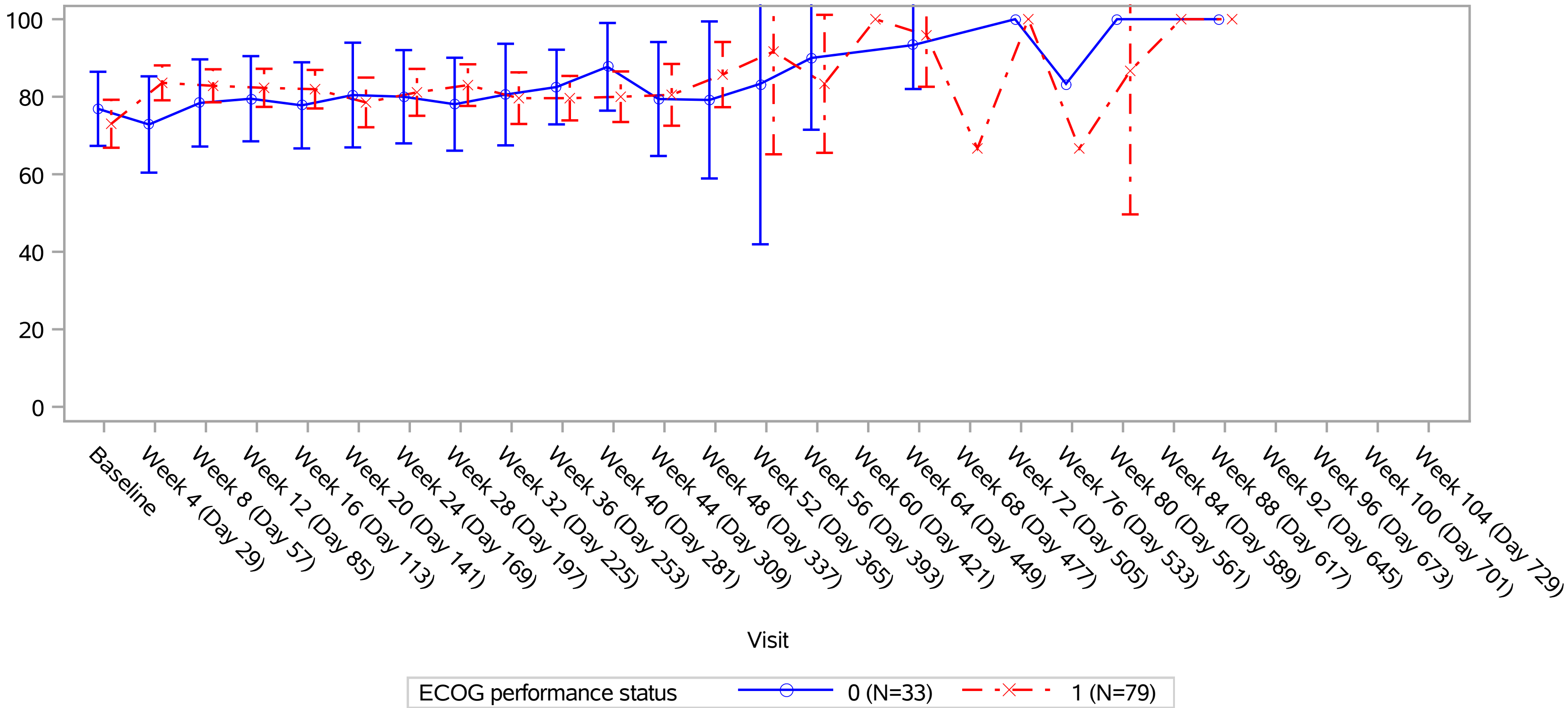
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Social functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30SF_SGAGE65.pdf
15OCT2021 17:49

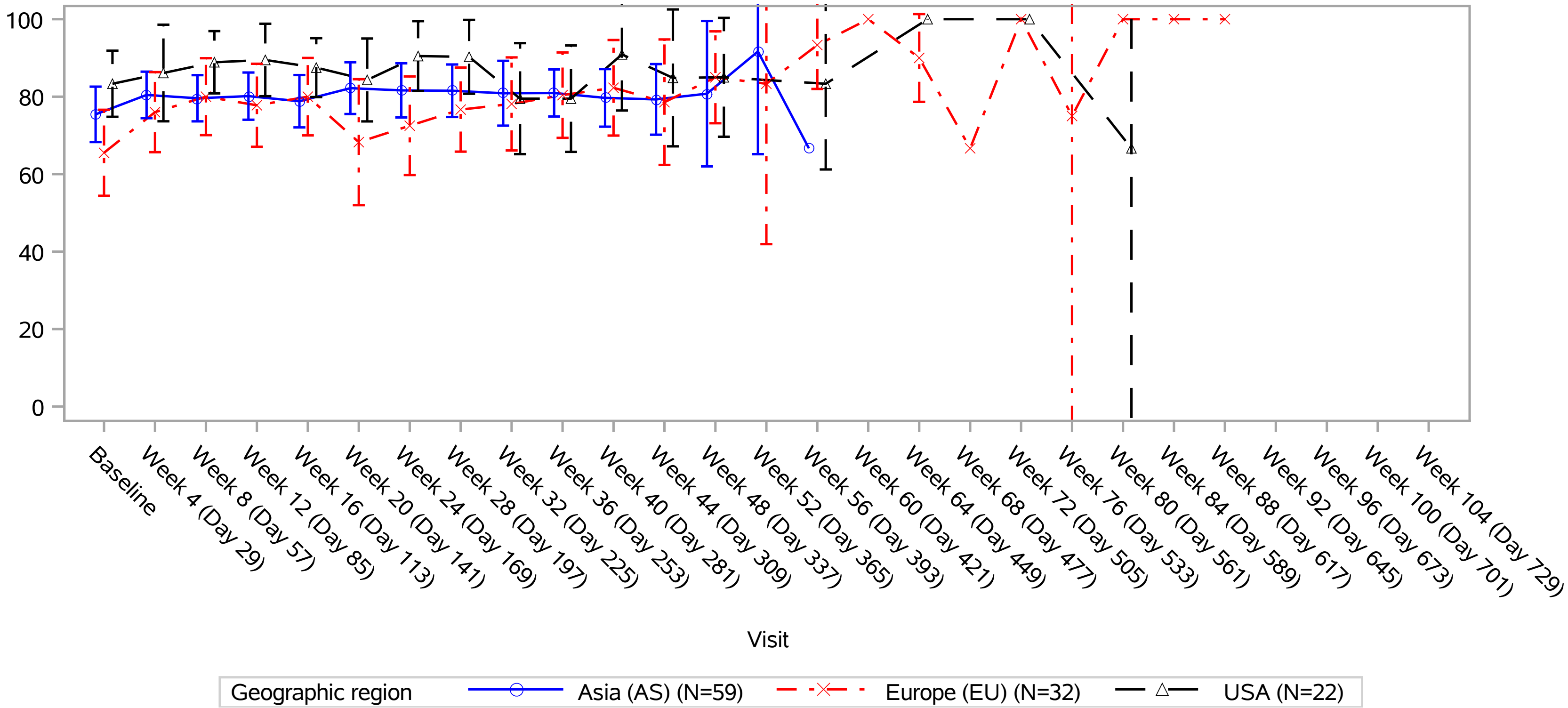
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Social functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30SF_SGECOG.pdf
15OCT2021 18:20

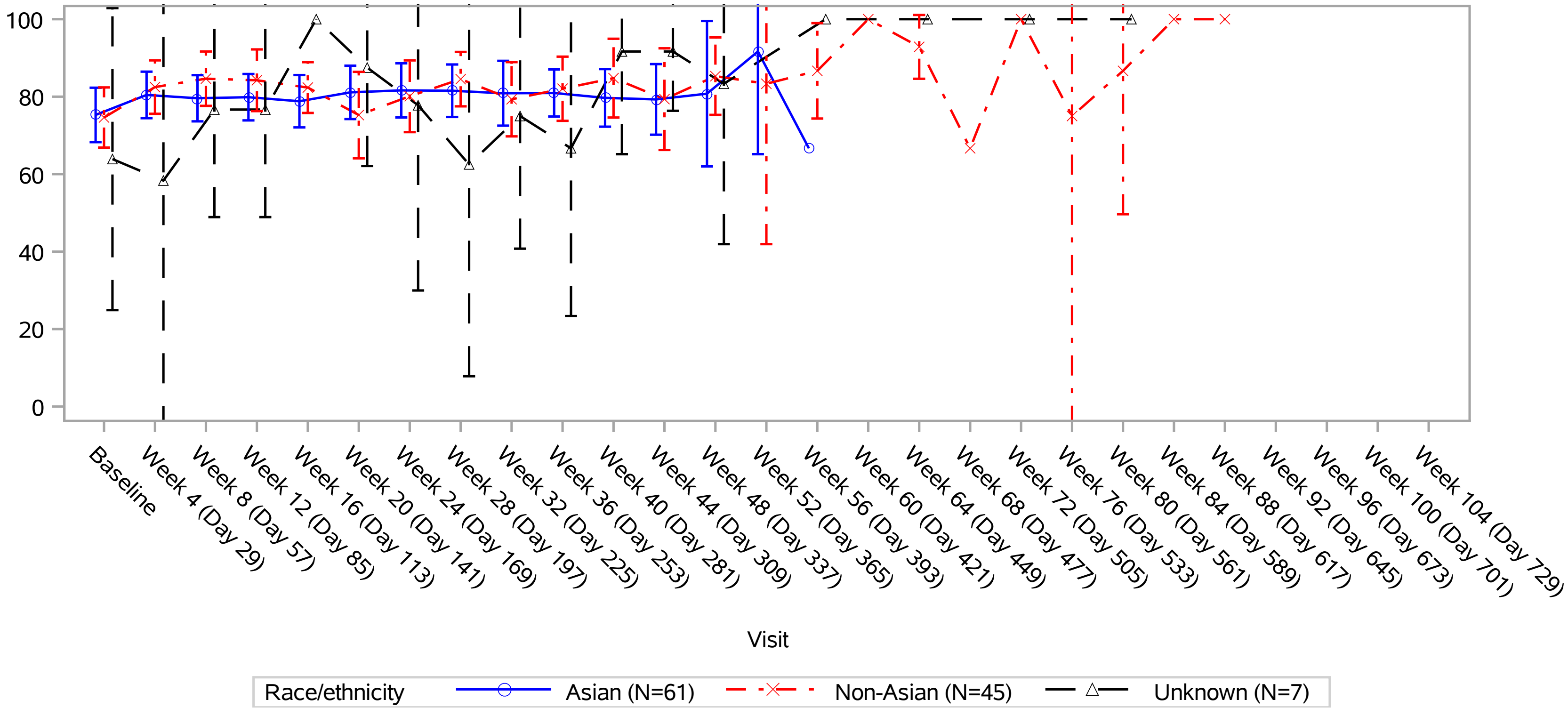
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Social functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30SF_SGGEO.pdf
15OCT2021 18:51

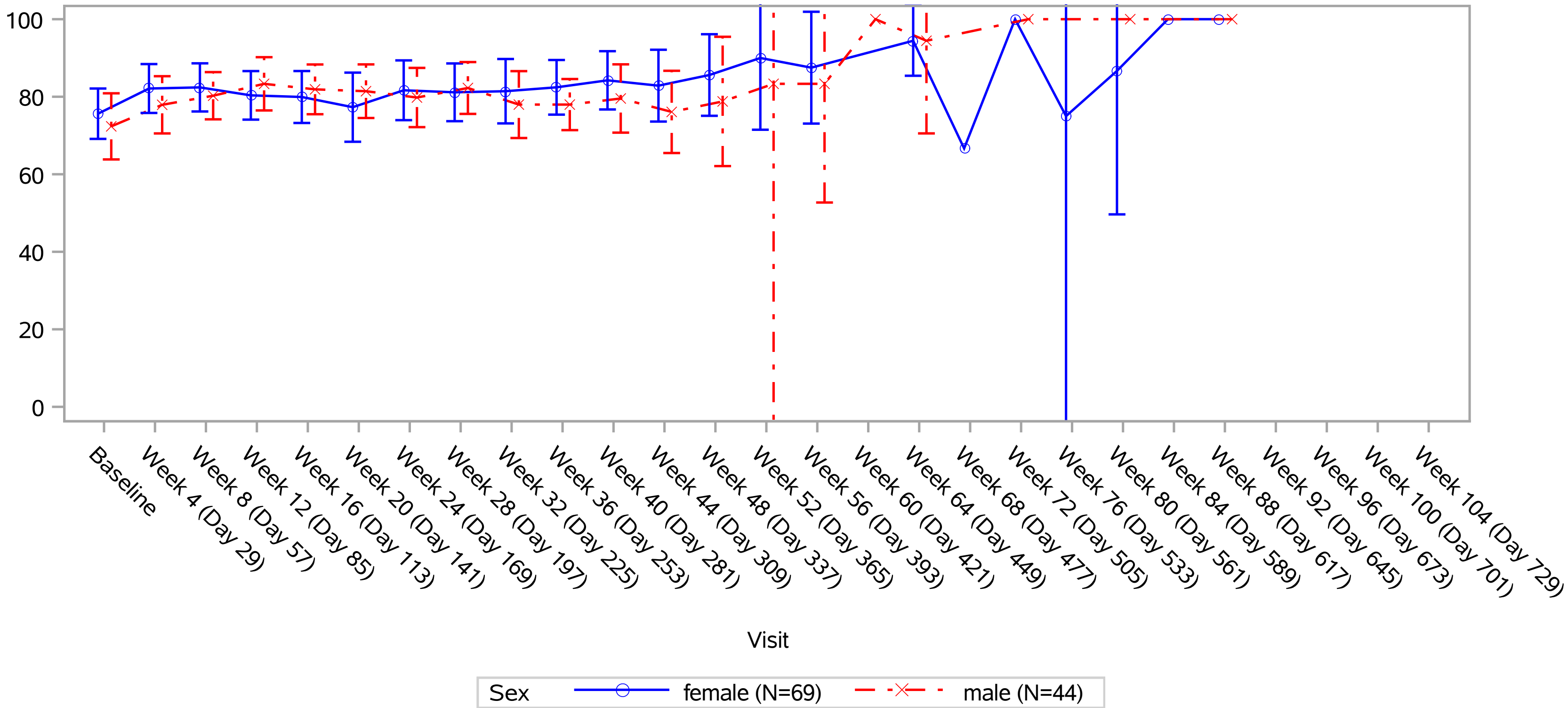
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Social functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30SF_SGRE.pdf
15OCT2021 19:21

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Social functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30SF_SGSEX.pdf
15OCT2021 19:52

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Insomnia
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=113)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	113	100.0	108	95.6	27.16	30.28	21.38	32.94
Week 4 (Day 29)	n/a	113	100.0	93	82.3	18.28	26.70	12.78	23.78
Week 8 (Day 57)	n/a	101	89.4	92	91.1	13.77	21.05	9.41	18.13
Week 12 (Day 85)	n/a	97	85.8	90	92.8	14.44	21.23	10.00	18.89
Week 16 (Day 113)	n/a	95	84.1	85	89.5	12.94	24.18	7.73	18.16
Week 20 (Day 141)	n/a	89	78.8	83	93.3	15.66	27.22	9.72	21.61
Week 24 (Day 169)	n/a	81	71.7	73	90.1	15.53	27.26	9.16	21.89
Week 28 (Day 197)	n/a	74	65.5	69	93.2	14.01	24.53	8.12	19.90
Week 32 (Day 225)	n/a	71	62.8	63	88.7	14.81	25.94	8.28	21.35
Week 36 (Day 253)	n/a	71	62.8	64	90.1	13.02	24.21	6.97	19.07
Week 40 (Day 281)	n/a	67	59.3	59	88.1	15.25	27.90	7.98	22.53
Week 44 (Day 309)	n/a	64	56.6	58	90.6	16.09	31.37	7.84	24.34
Week 48 (Day 337)	n/a	58	51.3	33	56.9	17.17	26.51	7.77	26.57
Week 52 (Day 365)	n/a	45	39.8	7	15.6	19.05	26.23	-5.21	43.30
Week 56 (Day 393)	n/a	37	32.7	12	32.4	19.44	33.21	-1.65	40.54
Week 60 (Day 421)	n/a	32	28.3	1	3.1	0.00	NE	NE	NE
Week 64 (Day 449)	n/a	31	27.4	9	29.0	3.70	11.11	-4.84	12.24
Week 68 (Day 477)	n/a	28	24.8	1	3.6	0.00	NE	NE	NE
Week 72 (Day 505)	n/a	28	24.8	4	14.3	0.00	0.00	NE	NE
Week 76 (Day 533)	n/a	25	22.1	2	8.0	0.00	0.00	NE	NE
Week 80 (Day 561)	n/a	25	22.1	6	24.0	11.11	17.21	-6.95	29.18
Week 84 (Day 589)	n/a	18	15.9	1	5.6	33.33	NE	NE	NE
Week 88 (Day 617)	n/a	14	12.4	2	14.3	0.00	0.00	NE	NE
Week 92 (Day 645)	n/a	7	6.2	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	5.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	2.7	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	113	100.0	111	98.2	20.12	31.23	14.25	25.99
End of Study (LOCF)	n/a	113	100.0	111	98.2	21.62	30.70	15.85	27.40
Sex									
Baseline	Female	69	100.0	67	97.1	31.34	30.08	24.01	38.68
Week 4 (Day 29)	Female	69	100.0	55	79.7	21.82	30.24	13.64	29.99
Week 8 (Day 57)	Female	63	91.3	54	85.7	16.05	23.11	9.74	22.36
Week 12 (Day 85)	Female	60	87.0	56	93.3	16.07	22.91	9.94	22.21
Week 16 (Day 113)	Female	58	84.1	50	86.2	16.00	24.50	9.04	22.96
Week 20 (Day 141)	Female	53	76.8	48	90.6	19.44	29.84	10.78	28.11
Week 24 (Day 169)	Female	47	68.1	40	85.1	18.33	29.19	9.00	27.67
Week 28 (Day 197)	Female	42	60.9	38	90.5	15.79	27.66	6.70	24.88
Week 32 (Day 225)	Female	42	60.9	35	83.3	17.14	28.44	7.37	26.91
Week 36 (Day 253)	Female	42	60.9	37	88.1	13.51	27.73	4.27	22.76
Week 40 (Day 281)	Female	41	59.4	37	90.2	18.02	30.02	8.01	28.03
Week 44 (Day 309)	Female	41	59.4	35	85.4	13.33	29.37	3.24	23.42
Week 48 (Day 337)	Female	37	53.6	22	59.5	19.70	28.47	7.07	32.32
Week 52 (Day 365)	Female	29	42.0	5	17.2	20.00	29.81	-17.02	57.02
Week 56 (Day 393)	Female	24	34.8	8	33.3	25.00	38.83	-7.46	57.46
Week 60 (Day 421)	Female	22	31.9	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Female	22	31.9	6	27.3	5.56	13.61	-8.73	19.84
Week 68 (Day 477)	Female	20	29.0	1	5.0	0.00	NE	NE	NE
Week 72 (Day 505)	Female	20	29.0	2	10.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Female	18	26.1	2	11.1	0.00	0.00	NE	NE
Week 80 (Day 561)	Female	18	26.1	5	27.8	13.33	18.26	-9.34	36.00
Week 84 (Day 589)	Female	12	17.4	1	8.3	33.33	NE	NE	NE
Week 88 (Day 617)	Female	9	13.0	1	11.1	0.00	NE	NE	NE
Week 92 (Day 645)	Female	6	8.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	7.2	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	2.9	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	1.4	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	69	100.0	68	98.6	22.55	32.80	14.61	30.49
End of Study (LOCF)	Female	69	100.0	68	98.6	26.47	33.86	18.28	34.67
Baseline	Male	44	100.0	41	93.2	20.33	29.70	10.95	29.70
Week 4 (Day 29)	Male	44	100.0	38	86.4	13.16	19.82	6.64	19.67
Week 8 (Day 57)	Male	38	86.4	38	100.0	10.53	17.51	4.77	16.28
Week 12 (Day 85)	Male	37	84.1	34	91.9	11.76	18.13	5.44	18.09
Week 16 (Day 113)	Male	37	84.1	35	94.6	8.57	23.35	0.55	16.59
Week 20 (Day 141)	Male	36	81.8	35	97.2	10.48	22.54	2.73	18.22
Week 24 (Day 169)	Male	34	77.3	33	97.1	12.12	24.75	3.35	20.90
Week 28 (Day 197)	Male	32	72.7	31	96.9	11.83	20.27	4.39	19.26
Week 32 (Day 225)	Male	29	65.9	28	96.6	11.90	22.62	3.14	20.67
Week 36 (Day 253)	Male	29	65.9	27	93.1	12.35	18.83	4.90	19.79
Week 40 (Day 281)	Male	26	59.1	22	84.6	10.61	23.87	0.02	21.19
Week 44 (Day 309)	Male	23	52.3	23	100.0	20.29	34.44	5.40	35.18
Week 48 (Day 337)	Male	21	47.7	11	52.4	12.12	22.47	-2.98	27.22
Week 52 (Day 365)	Male	16	36.4	2	12.5	16.67	23.57	-195.10	228.44
Week 56 (Day 393)	Male	13	29.5	4	30.8	8.33	16.67	-18.19	34.85
Week 60 (Day 421)	Male	10	22.7	1	10.0	0.00	NE	NE	NE
Week 64 (Day 449)	Male	9	20.5	3	33.3	0.00	0.00	NE	NE
Week 68 (Day 477)	Male	8	18.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	8	18.2	2	25.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Male	7	15.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	7	15.9	1	14.3	0.00	NE	NE	NE
Week 84 (Day 589)	Male	6	13.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	5	11.4	1	20.0	0.00	NE	NE	NE
Week 92 (Day 645)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	44	100.0	43	97.7	16.28	28.52	7.50	25.06
End of Study (LOCF)	Male	44	100.0	43	97.7	13.95	23.27	6.79	21.11
Age									

Baseline	< 65	78	100.0	73	93.6	26.94	31.26	19.65	34.23
Week 4 (Day 29)	< 65	78	100.0	66	84.6	19.70	28.63	12.66	26.74
Week 8 (Day 57)	< 65	73	93.6	66	90.4	12.12	20.78	7.01	17.23
Week 12 (Day 85)	< 65	71	91.0	64	90.1	11.98	19.12	7.20	16.76
Week 16 (Day 113)	< 65	69	88.5	59	85.5	10.73	21.83	5.04	16.42
Week 20 (Day 141)	< 65	65	83.3	62	95.4	16.67	29.41	9.20	24.14
Week 24 (Day 169)	< 65	59	75.6	55	93.2	13.94	26.21	6.85	21.02
Week 28 (Day 197)	< 65	55	70.5	51	92.7	14.38	25.17	7.30	21.46
Week 32 (Day 225)	< 65	53	67.9	48	90.6	13.89	27.36	5.94	21.83
Week 36 (Day 253)	< 65	53	67.9	50	94.3	13.33	26.08	5.92	20.75
Week 40 (Day 281)	< 65	52	66.7	48	92.3	14.58	28.27	6.37	22.79
Week 44 (Day 309)	< 65	52	66.7	48	92.3	15.97	31.50	6.82	25.12
Week 48 (Day 337)	< 65	47	60.3	26	55.3	12.82	21.24	4.24	21.40
Week 52 (Day 365)	< 65	36	46.2	4	11.1	16.67	33.33	-36.37	69.71
Week 56 (Day 393)	< 65	30	38.5	9	30.0	14.81	33.79	-11.16	40.79
Week 60 (Day 421)	< 65	25	32.1	1	4.0	0.00	NE	NE	NE
Week 64 (Day 449)	< 65	24	30.8	7	29.2	0.00	0.00	NE	NE
Week 68 (Day 477)	< 65	22	28.2	1	4.5	0.00	NE	NE	NE
Week 72 (Day 505)	< 65	22	28.2	4	18.2	0.00	0.00	NE	NE
Week 76 (Day 533)	< 65	21	26.9	2	9.5	0.00	0.00	NE	NE
Week 80 (Day 561)	< 65	21	26.9	5	23.8	13.33	18.26	-9.34	36.00
Week 84 (Day 589)	< 65	15	19.2	1	6.7	33.33	NE	NE	NE
Week 88 (Day 617)	< 65	12	15.4	2	16.7	0.00	0.00	NE	NE
Week 92 (Day 645)	< 65	6	7.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	6.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	78	100.0	76	97.4	19.74	32.28	12.36	27.11
End of Study (LOCF)	< 65	78	100.0	76	97.4	21.49	31.60	14.27	28.71
Baseline	>= 65	35	100.0	35	100.0	27.62	28.57	17.81	37.43
Week 4 (Day 29)	>= 65	35	100.0	27	77.1	14.81	21.35	6.37	23.26
Week 8 (Day 57)	>= 65	28	80.0	26	92.9	17.95	21.56	9.24	26.66
Week 12 (Day 85)	>= 65	26	74.3	26	100.0	20.51	25.08	10.38	30.64

Week 16 (Day 113)	>= 65	26	74.3	26	100.0	17.95	28.64	6.38	29.52
Week 20 (Day 141)	>= 65	24	68.6	21	87.5	12.70	19.65	3.75	21.64
Week 24 (Day 169)	>= 65	22	62.9	18	81.8	20.37	30.55	5.18	35.56
Week 28 (Day 197)	>= 65	19	54.3	18	94.7	12.96	23.26	1.40	24.53
Week 32 (Day 225)	>= 65	18	51.4	15	83.3	17.78	21.33	5.96	29.59
Week 36 (Day 253)	>= 65	18	51.4	14	77.8	11.90	16.57	2.33	21.47
Week 40 (Day 281)	>= 65	15	42.9	11	73.3	18.18	27.34	-0.19	36.55
Week 44 (Day 309)	>= 65	12	34.3	10	83.3	16.67	32.39	-6.51	39.84
Week 48 (Day 337)	>= 65	11	31.4	7	63.6	33.33	38.49	-2.26	68.93
Week 52 (Day 365)	>= 65	9	25.7	3	33.3	22.22	19.25	-25.59	70.03
Week 56 (Day 393)	>= 65	7	20.0	3	42.9	33.33	33.33	-49.47	116.14
Week 60 (Day 421)	>= 65	7	20.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	7	20.0	2	28.6	16.67	23.57	-195.10	228.44
Week 68 (Day 477)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	6	17.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	4	11.4	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	4	11.4	1	25.0	0.00	NE	NE	NE
Week 84 (Day 589)	>= 65	3	8.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	5.7	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	2.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	35	100.0	35	100.0	20.95	29.25	10.91	31.00
End of Study (LOCF)	>= 65	35	100.0	35	100.0	21.90	29.09	11.91	31.90
ECOG performance status									
Baseline	0	33	100.0	31	93.9	23.66	30.05	12.63	34.68
Week 4 (Day 29)	0	33	100.0	26	78.8	26.92	34.02	13.18	40.66
Week 8 (Day 57)	0	30	90.9	27	90.0	19.75	23.13	10.60	28.90
Week 12 (Day 85)	0	29	87.9	26	89.7	12.82	19.04	5.13	20.51
Week 16 (Day 113)	0	28	84.8	24	85.7	19.44	32.48	5.73	33.16
Week 20 (Day 141)	0	26	78.8	24	92.3	19.44	29.35	7.05	31.84
Week 24 (Day 169)	0	24	72.7	20	83.3	21.67	32.94	6.25	37.08
Week 28 (Day 197)	0	21	63.6	19	90.5	15.79	28.04	2.27	29.30

Week 32 (Day 225)	0	21	63.6	18	85.7	12.96	23.26	1.40	24.53
Week 36 (Day 253)	0	21	63.6	19	90.5	8.77	18.73	-0.26	17.80
Week 40 (Day 281)	0	21	63.6	19	90.5	15.79	23.22	4.60	26.98
Week 44 (Day 309)	0	21	63.6	17	81.0	23.53	38.67	3.65	43.41
Week 48 (Day 337)	0	19	57.6	12	63.2	19.44	33.21	-1.65	40.54
Week 52 (Day 365)	0	18	54.5	3	16.7	33.33	33.33	-49.47	116.14
Week 56 (Day 393)	0	16	48.5	5	31.3	20.00	29.81	-17.02	57.02
Week 60 (Day 421)	0	16	48.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	0	16	48.5	5	31.3	6.67	14.91	-11.84	25.18
Week 68 (Day 477)	0	14	42.4	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	0	14	42.4	1	7.1	0.00	NE	NE	NE
Week 76 (Day 533)	0	12	36.4	1	8.3	0.00	NE	NE	NE
Week 80 (Day 561)	0	12	36.4	1	8.3	0.00	NE	NE	NE
Week 84 (Day 589)	0	10	30.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	9	27.3	1	11.1	0.00	NE	NE	NE
Week 92 (Day 645)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	12.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	9.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	3.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	33	100.0	33	100.0	24.24	34.63	11.96	36.52
End of Study (LOCF)	0	33	100.0	33	100.0	25.25	35.39	12.71	37.80
Baseline	1	79	100.0	76	96.2	28.51	30.65	21.51	35.51
Week 4 (Day 29)	1	79	100.0	66	83.5	15.15	22.78	9.55	20.75
Week 8 (Day 57)	1	70	88.6	65	92.9	11.28	19.79	6.38	16.19
Week 12 (Day 85)	1	68	86.1	64	94.1	15.10	22.17	9.57	20.64
Week 16 (Day 113)	1	67	84.8	61	91.0	10.38	19.76	5.32	15.44
Week 20 (Day 141)	1	63	79.7	59	93.7	14.12	26.41	7.24	21.01
Week 24 (Day 169)	1	57	72.2	53	93.0	13.21	24.75	6.38	20.03
Week 28 (Day 197)	1	53	67.1	50	94.3	13.33	23.33	6.70	19.96
Week 32 (Day 225)	1	50	63.3	45	90.0	15.56	27.15	7.40	23.71
Week 36 (Day 253)	1	50	63.3	45	90.0	14.81	26.17	6.95	22.68
Week 40 (Day 281)	1	46	58.2	40	87.0	15.00	30.15	5.36	24.64

Week 44 (Day 309)	1	43	54.4	41	95.3	13.01	27.77	4.24	21.77
Week 48 (Day 337)	1	39	49.4	21	53.8	15.87	22.65	5.56	26.19
Week 52 (Day 365)	1	27	34.2	4	14.8	8.33	16.67	-18.19	34.85
Week 56 (Day 393)	1	21	26.6	7	33.3	19.05	37.80	-15.91	54.00
Week 60 (Day 421)	1	16	20.3	1	6.3	0.00	NE	NE	NE
Week 64 (Day 449)	1	15	19.0	4	26.7	0.00	0.00	NE	NE
Week 68 (Day 477)	1	14	17.7	1	7.1	0.00	NE	NE	NE
Week 72 (Day 505)	1	14	17.7	3	21.4	0.00	0.00	NE	NE
Week 76 (Day 533)	1	13	16.5	1	7.7	0.00	NE	NE	NE
Week 80 (Day 561)	1	13	16.5	5	38.5	13.33	18.26	-9.34	36.00
Week 84 (Day 589)	1	8	10.1	1	12.5	33.33	NE	NE	NE
Week 88 (Day 617)	1	5	6.3	1	20.0	0.00	NE	NE	NE
Week 92 (Day 645)	1	3	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	2.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	79	100.0	77	97.5	18.61	29.86	11.84	25.39
End of Study (LOCF)	1	79	100.0	77	97.5	20.35	28.69	13.83	26.86
Baseline	Missing	1	100.0	1	100.0	33.33	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Geographic region									
Baseline	USA	22	100.0	22	100.0	37.88	29.63	24.74	51.02
Week 4 (Day 29)	USA	22	100.0	17	77.3	17.65	26.66	3.94	31.35
Week 8 (Day 57)	USA	20	90.9	18	90.0	24.07	25.06	11.61	36.54
Week 12 (Day 85)	USA	20	90.9	19	95.0	24.56	26.86	11.62	37.51
Week 16 (Day 113)	USA	19	86.4	17	89.5	19.61	23.74	7.40	31.82
Week 20 (Day 141)	USA	19	86.4	17	89.5	17.65	23.91	5.35	29.94
Week 24 (Day 169)	USA	16	72.7	14	87.5	19.05	25.20	4.50	33.60
Week 28 (Day 197)	USA	15	68.2	12	80.0	13.89	22.29	-0.27	28.05
Week 32 (Day 225)	USA	15	68.2	13	86.7	23.08	36.98	0.73	45.42
Week 36 (Day 253)	USA	15	68.2	12	80.0	19.44	33.21	-1.65	40.54
Week 40 (Day 281)	USA	14	63.6	11	78.6	24.24	39.70	-2.43	50.91

Week 44 (Day 309)	USA	13	59.1	11	84.6	24.24	39.70	-2.43	50.91
Week 48 (Day 337)	USA	13	59.1	10	76.9	20.00	28.11	-0.11	40.11
Week 52 (Day 365)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	USA	12	54.5	6	50.0	27.78	38.97	-13.12	68.67
Week 60 (Day 421)	USA	12	54.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	11	50.0	4	36.4	0.00	0.00	NE	NE
Week 68 (Day 477)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	10	45.5	1	10.0	0.00	NE	NE	NE
Week 76 (Day 533)	USA	10	45.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	10	45.5	2	20.0	16.67	23.57	-195.10	228.44
Week 84 (Day 589)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	6	27.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	22.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	13.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	4.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	22	100.0	22	100.0	24.24	32.82	9.69	38.80
End of Study (LOCF)	USA	22	100.0	22	100.0	19.70	24.47	8.85	30.55
Baseline	Europe (EU)	32	100.0	29	90.6	24.14	28.03	13.48	34.80
Week 4 (Day 29)	Europe (EU)	32	100.0	24	75.0	26.39	32.57	12.64	40.14
Week 8 (Day 57)	Europe (EU)	29	90.6	25	86.2	20.00	25.46	9.49	30.51
Week 12 (Day 85)	Europe (EU)	26	81.3	24	92.3	11.11	16.05	4.33	17.89
Week 16 (Day 113)	Europe (EU)	25	78.1	20	80.0	16.67	29.62	2.81	30.53
Week 20 (Day 141)	Europe (EU)	23	71.9	22	95.7	16.67	28.64	3.97	29.36
Week 24 (Day 169)	Europe (EU)	21	65.6	20	95.2	21.67	32.94	6.25	37.08
Week 28 (Day 197)	Europe (EU)	20	62.5	20	100.0	20.00	31.34	5.33	34.67
Week 32 (Day 225)	Europe (EU)	18	56.3	16	88.9	10.42	20.07	-0.28	21.11
Week 36 (Day 253)	Europe (EU)	18	56.3	17	94.4	13.73	29.01	-1.19	28.64
Week 40 (Day 281)	Europe (EU)	17	53.1	16	94.1	16.67	29.81	0.78	32.55
Week 44 (Day 309)	Europe (EU)	17	53.1	14	82.4	14.29	36.31	-6.68	35.25

Week 48 (Day 337)	Europe (EU)	14	43.8	10	71.4	20.00	23.31	3.33	36.67
Week 52 (Day 365)	Europe (EU)	13	40.6	3	23.1	33.33	33.33	-49.47	116.14
Week 56 (Day 393)	Europe (EU)	11	34.4	5	45.5	13.33	29.81	-23.69	50.35
Week 60 (Day 421)	Europe (EU)	11	34.4	1	9.1	0.00	NE	NE	NE
Week 64 (Day 449)	Europe (EU)	11	34.4	5	45.5	6.67	14.91	-11.84	25.18
Week 68 (Day 477)	Europe (EU)	10	31.3	1	10.0	0.00	NE	NE	NE
Week 72 (Day 505)	Europe (EU)	10	31.3	3	30.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Europe (EU)	8	25.0	2	25.0	0.00	0.00	NE	NE
Week 80 (Day 561)	Europe (EU)	8	25.0	4	50.0	8.33	16.67	-18.19	34.85
Week 84 (Day 589)	Europe (EU)	6	18.8	1	16.7	33.33	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	9.4	2	66.7	0.00	0.00	NE	NE
Cycle 12 (LOCF)	Europe (EU)	32	100.0	31	96.9	22.58	33.76	10.20	34.96
End of Study (LOCF)	Europe (EU)	32	100.0	31	96.9	29.03	33.05	16.91	41.15
Baseline	Asia (AS)	59	100.0	57	96.6	24.56	31.20	16.28	32.84
Week 4 (Day 29)	Asia (AS)	59	100.0	52	88.1	14.74	23.26	8.27	21.22
Week 8 (Day 57)	Asia (AS)	52	88.1	49	94.2	6.80	13.57	2.90	10.70
Week 12 (Day 85)	Asia (AS)	51	86.4	47	92.2	12.06	20.17	6.13	17.98
Week 16 (Day 113)	Asia (AS)	51	86.4	48	94.1	9.03	21.46	2.80	15.26
Week 20 (Day 141)	Asia (AS)	47	79.7	44	93.6	14.39	28.21	5.82	22.97
Week 24 (Day 169)	Asia (AS)	44	74.6	39	88.6	11.11	24.58	3.14	19.08
Week 28 (Day 197)	Asia (AS)	39	66.1	37	94.9	10.81	20.87	3.85	17.77
Week 32 (Day 225)	Asia (AS)	38	64.4	34	89.5	13.73	23.38	5.57	21.88
Week 36 (Day 253)	Asia (AS)	38	64.4	35	92.1	10.48	17.66	4.41	16.54
Week 40 (Day 281)	Asia (AS)	36	61.0	32	88.9	11.46	21.77	3.61	19.31
Week 44 (Day 309)	Asia (AS)	34	57.6	33	97.1	14.14	26.39	4.78	23.50
Week 48 (Day 337)	Asia (AS)	31	52.5	13	41.9	12.82	28.99	-4.70	30.34
Week 52 (Day 365)	Asia (AS)	20	33.9	4	20.0	8.33	16.67	-18.19	34.85
Week 56 (Day 393)	Asia (AS)	14	23.7	1	7.1	0.00	NE	NE	NE
Week 60 (Day 421)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	9	15.3	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	8	13.6	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	7	11.9	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	10.2	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	8.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	3.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	59	100.0	58	98.3	17.24	29.45	9.50	24.98
End of Study (LOCF)	Asia (AS)	59	100.0	58	98.3	18.39	31.33	10.15	26.63
Race/ethnicity									
Baseline	Asian	61	100.0	58	95.1	24.71	30.94	16.58	32.85
Week 4 (Day 29)	Asian	61	100.0	52	85.2	14.74	23.26	8.27	21.22
Week 8 (Day 57)	Asian	53	86.9	49	92.5	6.80	13.57	2.90	10.70
Week 12 (Day 85)	Asian	52	85.2	48	92.3	12.50	20.19	6.64	18.36
Week 16 (Day 113)	Asian	52	85.2	49	94.2	9.52	21.52	3.34	15.70
Week 20 (Day 141)	Asian	48	78.7	45	93.8	15.56	28.95	6.86	24.25
Week 24 (Day 169)	Asian	44	72.1	39	88.6	11.11	24.58	3.14	19.08
Week 28 (Day 197)	Asian	39	63.9	37	94.9	10.81	20.87	3.85	17.77
Week 32 (Day 225)	Asian	38	62.3	34	89.5	13.73	23.38	5.57	21.88
Week 36 (Day 253)	Asian	38	62.3	35	92.1	10.48	17.66	4.41	16.54
Week 40 (Day 281)	Asian	36	59.0	32	88.9	11.46	21.77	3.61	19.31
Week 44 (Day 309)	Asian	34	55.7	33	97.1	14.14	26.39	4.78	23.50
Week 48 (Day 337)	Asian	31	50.8	13	41.9	12.82	28.99	-4.70	30.34
Week 52 (Day 365)	Asian	20	32.8	4	20.0	8.33	16.67	-18.19	34.85
Week 56 (Day 393)	Asian	14	23.0	1	7.1	0.00	NE	NE	NE
Week 60 (Day 421)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	9	14.8	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	8	13.1	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	7	11.5	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	9.8	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	8.2	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	3.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	61	100.0	59	96.7	18.08	29.89	10.29	25.87
End of Study (LOCF)	Asian	61	100.0	59	96.7	19.21	31.69	10.95	27.47
Baseline	Non-Asian	45	100.0	44	97.8	31.06	29.99	21.94	40.18
Week 4 (Day 29)	Non-Asian	45	100.0	37	82.2	18.92	25.51	10.41	27.42
Week 8 (Day 57)	Non-Asian	42	93.3	38	90.5	21.93	24.84	13.76	30.10
Week 12 (Day 85)	Non-Asian	39	86.7	37	94.9	17.12	23.07	9.43	24.81
Week 16 (Day 113)	Non-Asian	37	82.2	34	91.9	16.67	26.27	7.50	25.83
Week 20 (Day 141)	Non-Asian	36	80.0	34	94.4	15.69	24.94	6.98	24.39
Week 24 (Day 169)	Non-Asian	32	71.1	31	96.9	22.58	30.29	11.47	33.69
Week 28 (Day 197)	Non-Asian	30	66.7	28	93.3	15.48	24.82	5.85	25.10
Week 32 (Day 225)	Non-Asian	28	62.2	25	89.3	16.00	29.06	4.00	28.00
Week 36 (Day 253)	Non-Asian	28	62.2	25	89.3	16.00	30.61	3.36	28.64
Week 40 (Day 281)	Non-Asian	26	57.8	23	88.5	18.84	34.56	3.89	33.79
Week 44 (Day 309)	Non-Asian	25	55.6	21	84.0	17.46	35.93	1.10	33.82
Week 48 (Day 337)	Non-Asian	23	51.1	17	73.9	21.57	26.20	8.10	35.04
Week 52 (Day 365)	Non-Asian	21	46.7	3	14.3	33.33	33.33	-49.47	116.14
Week 56 (Day 393)	Non-Asian	19	42.2	10	52.6	23.33	35.31	-1.93	48.59
Week 60 (Day 421)	Non-Asian	19	42.2	1	5.3	0.00	NE	NE	NE
Week 64 (Day 449)	Non-Asian	18	40.0	7	38.9	4.76	12.60	-6.89	16.41
Week 68 (Day 477)	Non-Asian	17	37.8	1	5.9	0.00	NE	NE	NE
Week 72 (Day 505)	Non-Asian	17	37.8	3	17.6	0.00	0.00	NE	NE
Week 76 (Day 533)	Non-Asian	15	33.3	2	13.3	0.00	0.00	NE	NE
Week 80 (Day 561)	Non-Asian	15	33.3	5	33.3	6.67	14.91	-11.84	25.18
Week 84 (Day 589)	Non-Asian	10	22.2	1	10.0	33.33	NE	NE	NE
Week 88 (Day 617)	Non-Asian	7	15.6	2	28.6	0.00	0.00	NE	NE
Week 92 (Day 645)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	6.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	2.2	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	45	100.0	45	100.0	22.96	32.43	13.22	32.71

End of Study (LOCF)	Non-Asian	45	100.0	45	100.0	24.44	28.78	15.80	33.09
Baseline	Unknown	7	100.0	6	85.7	22.22	27.22	-6.34	50.78
Week 4 (Day 29)	Unknown	7	100.0	4	57.1	58.33	50.00	-21.23	137.89
Week 8 (Day 57)	Unknown	6	85.7	5	83.3	20.00	29.81	-17.02	57.02
Week 12 (Day 85)	Unknown	6	85.7	5	83.3	13.33	18.26	-9.34	36.00
Week 16 (Day 113)	Unknown	6	85.7	2	33.3	33.33	47.14	-390.21	456.87
Week 20 (Day 141)	Unknown	5	71.4	4	80.0	16.67	33.33	-36.37	69.71
Week 24 (Day 169)	Unknown	5	71.4	3	60.0	0.00	0.00	NE	NE
Week 28 (Day 197)	Unknown	5	71.4	4	80.0	33.33	47.14	-41.68	108.34
Week 32 (Day 225)	Unknown	5	71.4	4	80.0	16.67	33.33	-36.37	69.71
Week 36 (Day 253)	Unknown	5	71.4	4	80.0	16.67	33.33	-36.37	69.71
Week 40 (Day 281)	Unknown	5	71.4	4	80.0	25.00	31.91	-25.78	75.78
Week 44 (Day 309)	Unknown	5	71.4	4	80.0	25.00	50.00	-54.56	104.56
Week 48 (Day 337)	Unknown	4	57.1	3	75.0	11.11	19.25	-36.70	58.92
Week 52 (Day 365)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	4	57.1	1	25.0	0.00	NE	NE	NE
Week 60 (Day 421)	Unknown	4	57.1	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	4	57.1	2	50.0	0.00	0.00	NE	NE
Week 68 (Day 477)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	3	42.9	1	33.3	0.00	NE	NE	NE
Week 76 (Day 533)	Unknown	3	42.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	3	42.9	1	33.3	33.33	NE	NE	NE
Week 84 (Day 589)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	28.6	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	14.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	7	100.0	7	100.0	19.05	37.80	-15.91	54.00
End of Study (LOCF)	Unknown	7	100.0	7	100.0	23.81	37.09	-10.49	58.11
Number of prior antineoplastic systemic therapy lines I									
Baseline	1	60	100.0	57	95.0	26.32	29.37	18.52	34.11

Week 4 (Day 29)	1	60	100.0	48	80.0	15.28	25.69	7.82	22.74
Week 8 (Day 57)	1	54	90.0	49	90.7	14.97	22.63	8.47	21.47
Week 12 (Day 85)	1	52	86.7	48	92.3	14.58	21.64	8.30	20.87
Week 16 (Day 113)	1	51	85.0	46	90.2	14.49	25.97	6.78	22.20
Week 20 (Day 141)	1	48	80.0	43	89.6	15.50	25.56	7.64	23.37
Week 24 (Day 169)	1	43	71.7	39	90.7	15.38	27.41	6.50	24.27
Week 28 (Day 197)	1	38	63.3	34	89.5	12.75	27.23	3.24	22.25
Week 32 (Day 225)	1	35	58.3	29	82.9	12.64	24.26	3.42	21.87
Week 36 (Day 253)	1	35	58.3	31	88.6	13.98	25.49	4.63	23.33
Week 40 (Day 281)	1	32	53.3	27	84.4	14.81	31.12	2.50	27.13
Week 44 (Day 309)	1	32	53.3	27	84.4	13.58	32.37	0.78	26.39
Week 48 (Day 337)	1	27	45.0	16	59.3	16.67	24.34	3.70	29.64
Week 52 (Day 365)	1	23	38.3	5	21.7	20.00	29.81	-17.02	57.02
Week 56 (Day 393)	1	16	26.7	4	25.0	16.67	33.33	-36.37	69.71
Week 60 (Day 421)	1	14	23.3	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	1	13	21.7	4	30.8	8.33	16.67	-18.19	34.85
Week 68 (Day 477)	1	12	20.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	1	12	20.0	1	8.3	0.00	NE	NE	NE
Week 76 (Day 533)	1	11	18.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	1	11	18.3	2	18.2	0.00	0.00	NE	NE
Week 84 (Day 589)	1	9	15.0	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	1	8	13.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	5	8.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	1	3	5.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	1	1	1.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	60	100.0	58	96.7	17.24	30.10	9.33	25.16
End of Study (LOCF)	1	60	100.0	58	96.7	18.39	29.40	10.66	26.12
Baseline	>= 2	53	100.0	51	96.2	28.10	31.53	19.24	36.97
Week 4 (Day 29)	>= 2	53	100.0	45	84.9	21.48	27.67	13.17	29.79
Week 8 (Day 57)	>= 2	47	88.7	43	91.5	12.40	19.28	6.47	18.34
Week 12 (Day 85)	>= 2	45	84.9	42	93.3	14.29	21.01	7.74	20.83
Week 16 (Day 113)	>= 2	44	83.0	39	88.6	11.11	22.08	3.96	18.27

Week 20 (Day 141)	>= 2	41	77.4	40	97.6	15.83	29.22	6.49	25.18
Week 24 (Day 169)	>= 2	38	71.7	34	89.5	15.69	27.51	6.09	25.28
Week 28 (Day 197)	>= 2	36	67.9	35	97.2	15.24	21.91	7.71	22.76
Week 32 (Day 225)	>= 2	36	67.9	34	94.4	16.67	27.52	7.06	26.27
Week 36 (Day 253)	>= 2	36	67.9	33	91.7	12.12	23.30	3.86	20.38
Week 40 (Day 281)	>= 2	35	66.0	32	91.4	15.62	25.38	6.48	24.77
Week 44 (Day 309)	>= 2	32	60.4	31	96.9	18.28	30.84	6.97	29.59
Week 48 (Day 337)	>= 2	31	58.5	17	54.8	17.65	29.15	2.66	32.63
Week 52 (Day 365)	>= 2	22	41.5	2	9.1	16.67	23.57	-195.10	228.44
Week 56 (Day 393)	>= 2	21	39.6	8	38.1	20.83	35.36	-8.72	50.39
Week 60 (Day 421)	>= 2	18	34.0	1	5.6	0.00	NE	NE	NE
Week 64 (Day 449)	>= 2	18	34.0	5	27.8	0.00	0.00	NE	NE
Week 68 (Day 477)	>= 2	16	30.2	1	6.3	0.00	NE	NE	NE
Week 72 (Day 505)	>= 2	16	30.2	3	18.8	0.00	0.00	NE	NE
Week 76 (Day 533)	>= 2	14	26.4	2	14.3	0.00	0.00	NE	NE
Week 80 (Day 561)	>= 2	14	26.4	4	28.6	16.67	19.25	-13.96	47.29
Week 84 (Day 589)	>= 2	9	17.0	1	11.1	33.33	NE	NE	NE
Week 88 (Day 617)	>= 2	6	11.3	2	33.3	0.00	0.00	NE	NE
Week 92 (Day 645)	>= 2	2	3.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 2	1	1.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 2	53	100.0	53	100.0	23.27	32.41	14.34	32.20
End of Study (LOCF)	>= 2	53	100.0	53	100.0	25.16	31.96	16.35	33.97

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
¹ in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
² mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TP_QSC30SL_SG.xls
27OCT2021 7:32

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Insomnia
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	39	36.1	27.7	45.5
	Cycle 12 (LOCF)	n/a	108	95.6	20	18.5	12.3	26.9
	End of Study (LOCF)	n/a	108	95.6	22	20.4	13.9	28.9
Sex	All visits	Female	67	59.3	23	34.3	24.1	46.3
		Male	41	36.3	16	39.0	25.7	54.3
	Cycle 12 (LOCF)	Female	67	59.3	13	19.4	11.7	30.4
		Male	41	36.3	7	17.1	8.5	31.3
	End of Study (LOCF)	Female	67	59.3	17	25.4	16.5	36.9
		Male	41	36.3	5	12.2	5.3	25.5
Age	All visits	< 65	73	64.6	27	37.0	26.8	48.5
		>= 65	35	31.0	12	34.3	20.8	50.8
	Cycle 12 (LOCF)	< 65	73	64.6	14	19.2	11.8	29.7
		>= 65	35	31.0	6	17.1	8.1	32.7
	End of Study (LOCF)	< 65	73	64.6	16	21.9	14.0	32.7
		>= 65	35	31.0	6	17.1	8.1	32.7
ECOG performance status	All visits	0	31	27.4	11	35.5	21.1	53.1
		1	76	67.3	28	36.8	26.9	48.1
		Missing	1	0.9	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	31	27.4	7	22.6	11.4	39.8
		1	76	67.3	13	17.1	10.3	27.1
		Missing	1	0.9	0	0.0	0.0	79.3
	End of Study (LOCF)	0	31	27.4	7	22.6	11.4	39.8
		1	76	67.3	15	19.7	12.3	30.0
		Missing	1	0.9	0	0.0	0.0	79.3
Geographic region	All visits	USA	22	19.5	7	31.8	16.4	52.7
		Europe (EU)	29	25.7	12	41.4	25.5	59.3
		Asia (AS)	57	50.4	20	35.1	24.0	48.1
	Cycle 12 (LOCF)	USA	22	19.5	4	18.2	7.3	38.5
		Europe (EU)	29	25.7	6	20.7	9.8	38.4
		Asia (AS)	57	50.4	10	17.5	9.8	29.4
	End of Study (LOCF)	USA	22	19.5	2	9.1	2.5	27.8
		Europe (EU)	29	25.7	10	34.5	19.9	52.7
		Asia (AS)	57	50.4	10	17.5	9.8	29.4
Race/ethnicity	All visits	Asian	58	51.3	21	36.2	25.1	49.1
		Non-Asian	44	38.9	15	34.1	21.9	48.9
		Unknown	6	5.3	3	50.0	18.8	81.2
	Cycle 12 (LOCF)	Asian	58	51.3	11	19.0	10.9	30.9

		Non-Asian	44	38.9	8	18.2	9.5	32.0
		Unknown	6	5.3	1	16.7	3.0	56.4
	End of Study (LOCF)	Asian	58	51.3	11	19.0	10.9	30.9
		Non-Asian	44	38.9	9	20.5	11.2	34.5
		Unknown	6	5.3	2	33.3	9.7	70.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	19	33.3	22.5	46.3
		>= 2	51	45.1	20	39.2	27.0	52.9
	Cycle 12 (LOCF)	1	57	50.4	8	14.0	7.3	25.3
		>= 2	51	45.1	12	23.5	14.0	36.8
	End of Study (LOCF)	1	57	50.4	9	15.8	8.5	27.4
		>= 2	51	45.1	13	25.5	15.5	38.9

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30SL_W10_SG.xls
15OCT2021 13:39

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Insomnia
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

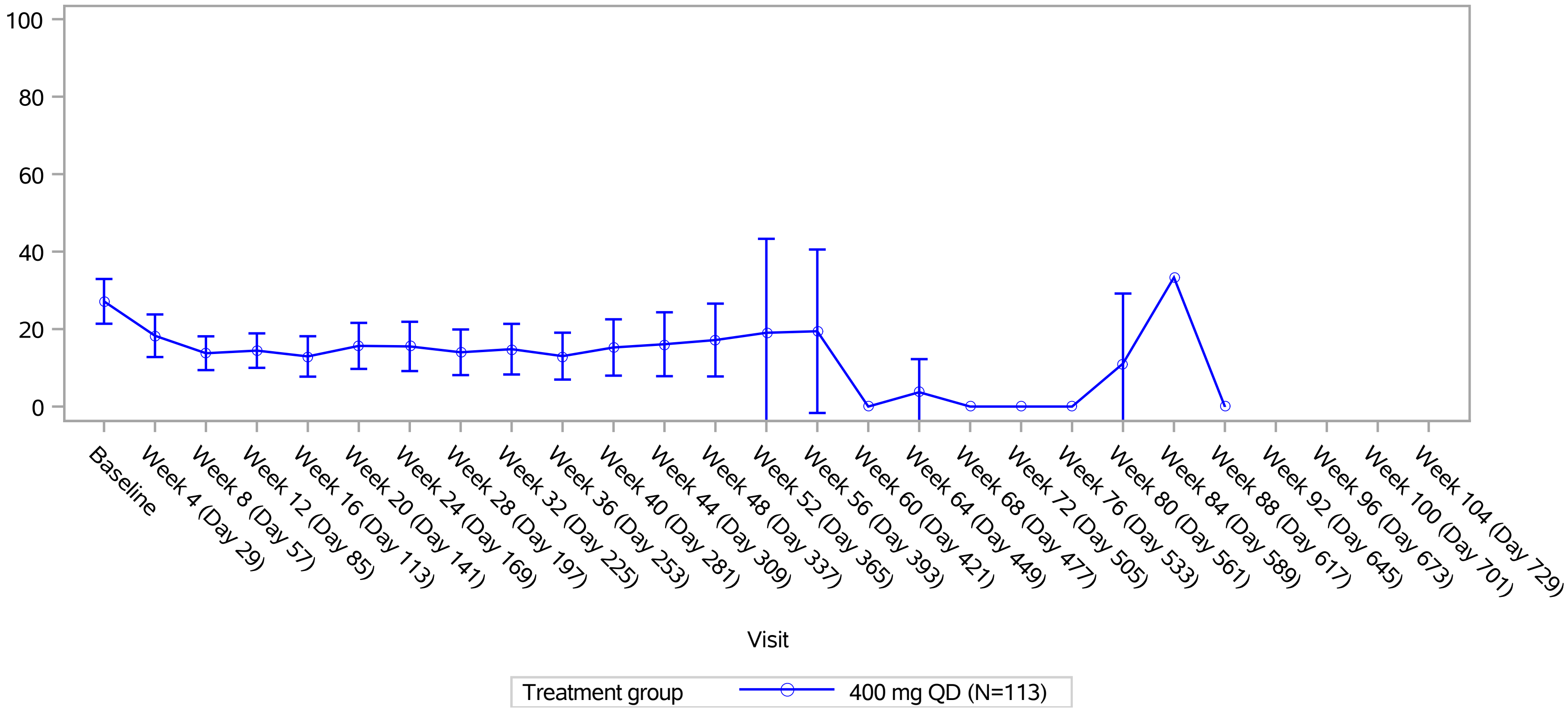
			400 mg QD (N=113)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	108	95.6	39	36.1	27.7	45.5
	Cycle 12 (LOCF)	n/a	108	95.6	20	18.5	12.3	26.9
	End of Study (LOCF)	n/a	108	95.6	22	20.4	13.9	28.9
Sex	All visits	Female	67	59.3	23	34.3	24.1	46.3
		Male	41	36.3	16	39.0	25.7	54.3
	Cycle 12 (LOCF)	Female	67	59.3	13	19.4	11.7	30.4
		Male	41	36.3	7	17.1	8.5	31.3
	End of Study (LOCF)	Female	67	59.3	17	25.4	16.5	36.9
		Male	41	36.3	5	12.2	5.3	25.5
Age	All visits	< 65	73	64.6	27	37.0	26.8	48.5
		>= 65	35	31.0	12	34.3	20.8	50.8
	Cycle 12 (LOCF)	< 65	73	64.6	14	19.2	11.8	29.7
		>= 65	35	31.0	6	17.1	8.1	32.7
	End of Study (LOCF)	< 65	73	64.6	16	21.9	14.0	32.7
		>= 65	35	31.0	6	17.1	8.1	32.7
ECOG performance status	All visits	0	31	27.4	11	35.5	21.1	53.1
		1	76	67.3	28	36.8	26.9	48.1
		Missing	1	0.9	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	31	27.4	7	22.6	11.4	39.8
		1	76	67.3	13	17.1	10.3	27.1
		Missing	1	0.9	0	0.0	0.0	79.3
	End of Study (LOCF)	0	31	27.4	7	22.6	11.4	39.8
		1	76	67.3	15	19.7	12.3	30.0
		Missing	1	0.9	0	0.0	0.0	79.3
Geographic region	All visits	USA	22	19.5	7	31.8	16.4	52.7
		Europe (EU)	29	25.7	12	41.4	25.5	59.3
		Asia (AS)	57	50.4	20	35.1	24.0	48.1
	Cycle 12 (LOCF)	USA	22	19.5	4	18.2	7.3	38.5
		Europe (EU)	29	25.7	6	20.7	9.8	38.4
		Asia (AS)	57	50.4	10	17.5	9.8	29.4
	End of Study (LOCF)	USA	22	19.5	2	9.1	2.5	27.8
		Europe (EU)	29	25.7	10	34.5	19.9	52.7
		Asia (AS)	57	50.4	10	17.5	9.8	29.4
Race/ethnicity	All visits	Asian	58	51.3	21	36.2	25.1	49.1
		Non-Asian	44	38.9	15	34.1	21.9	48.9
		Unknown	6	5.3	3	50.0	18.8	81.2
	Cycle 12 (LOCF)	Asian	58	51.3	11	19.0	10.9	30.9

		Non-Asian	44	38.9	8	18.2	9.5	32.0
		Unknown	6	5.3	1	16.7	3.0	56.4
	End of Study (LOCF)	Asian	58	51.3	11	19.0	10.9	30.9
		Non-Asian	44	38.9	9	20.5	11.2	34.5
		Unknown	6	5.3	2	33.3	9.7	70.0
Number of prior antineoplastic systemic therapy lines I	All visits	1	57	50.4	19	33.3	22.5	46.3
		>= 2	51	45.1	20	39.2	27.0	52.9
	Cycle 12 (LOCF)	1	57	50.4	8	14.0	7.3	25.3
		>= 2	51	45.1	12	23.5	14.0	36.8
	End of Study (LOCF)	1	57	50.4	9	15.8	8.5	27.4
		>= 2	51	45.1	13	25.5	15.5	38.9

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TP_QSC30SL_W15_SG.xls
15OCT2021 13:29

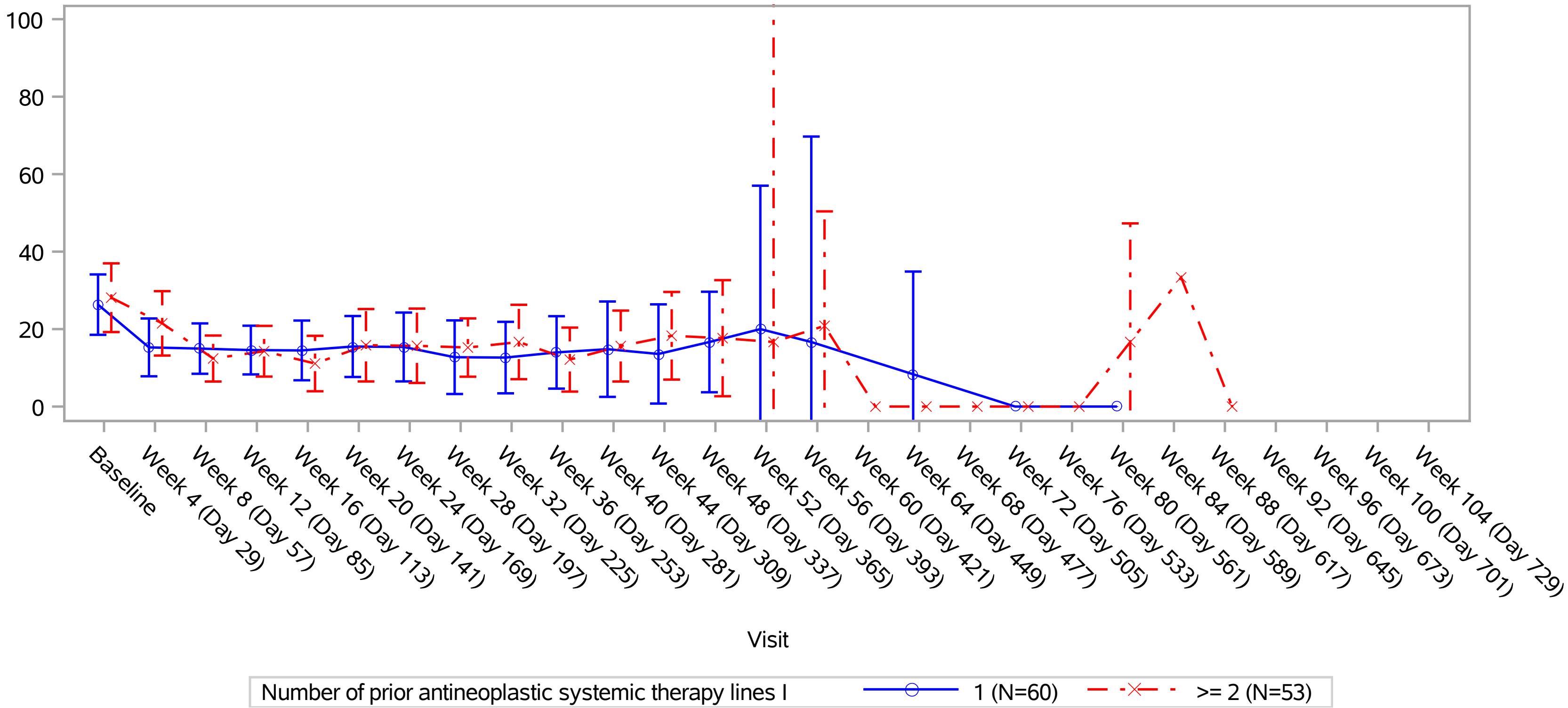
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Insomnia
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30SL.pdf
15OCT2021 17:21

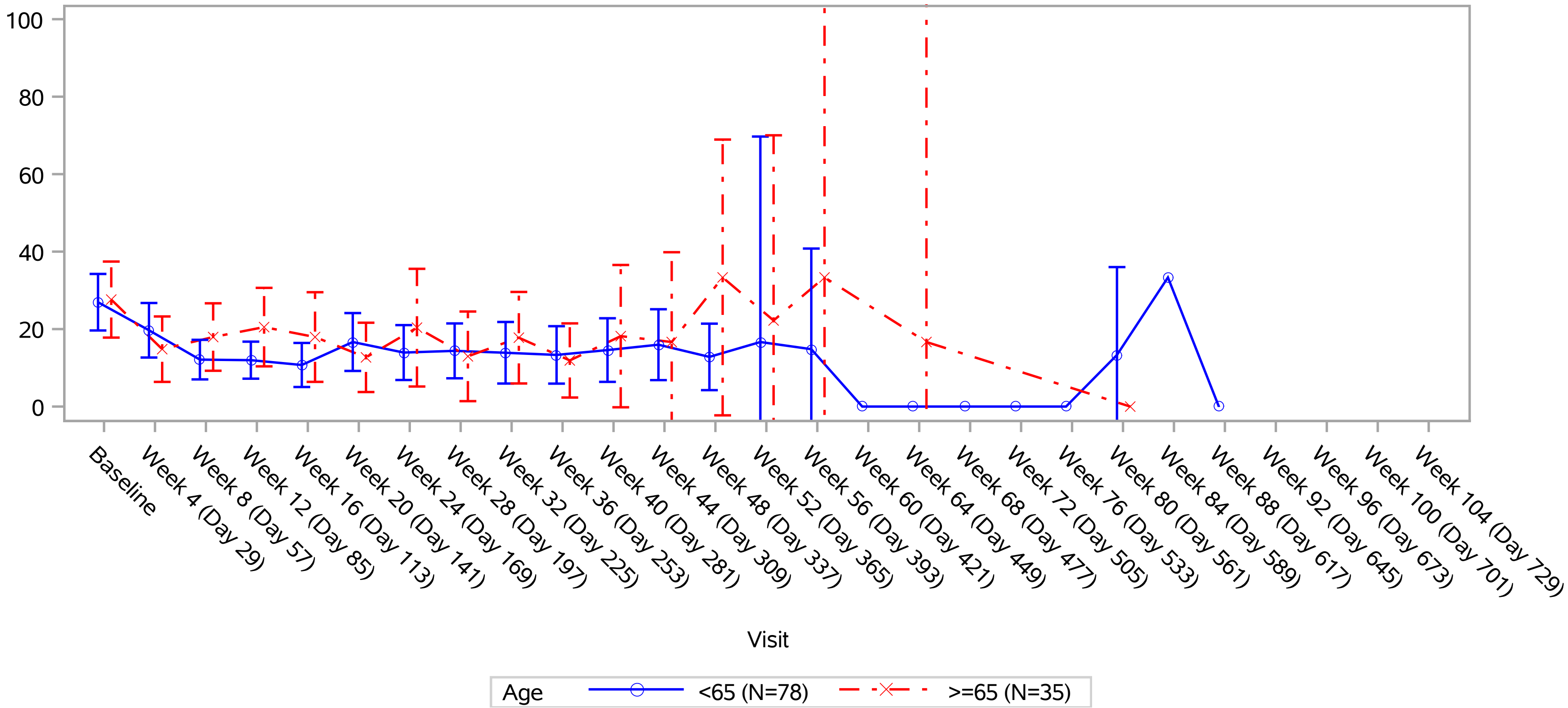
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Insomnia
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30SL_PRTHL1.pdf
15OCT2021 20:13

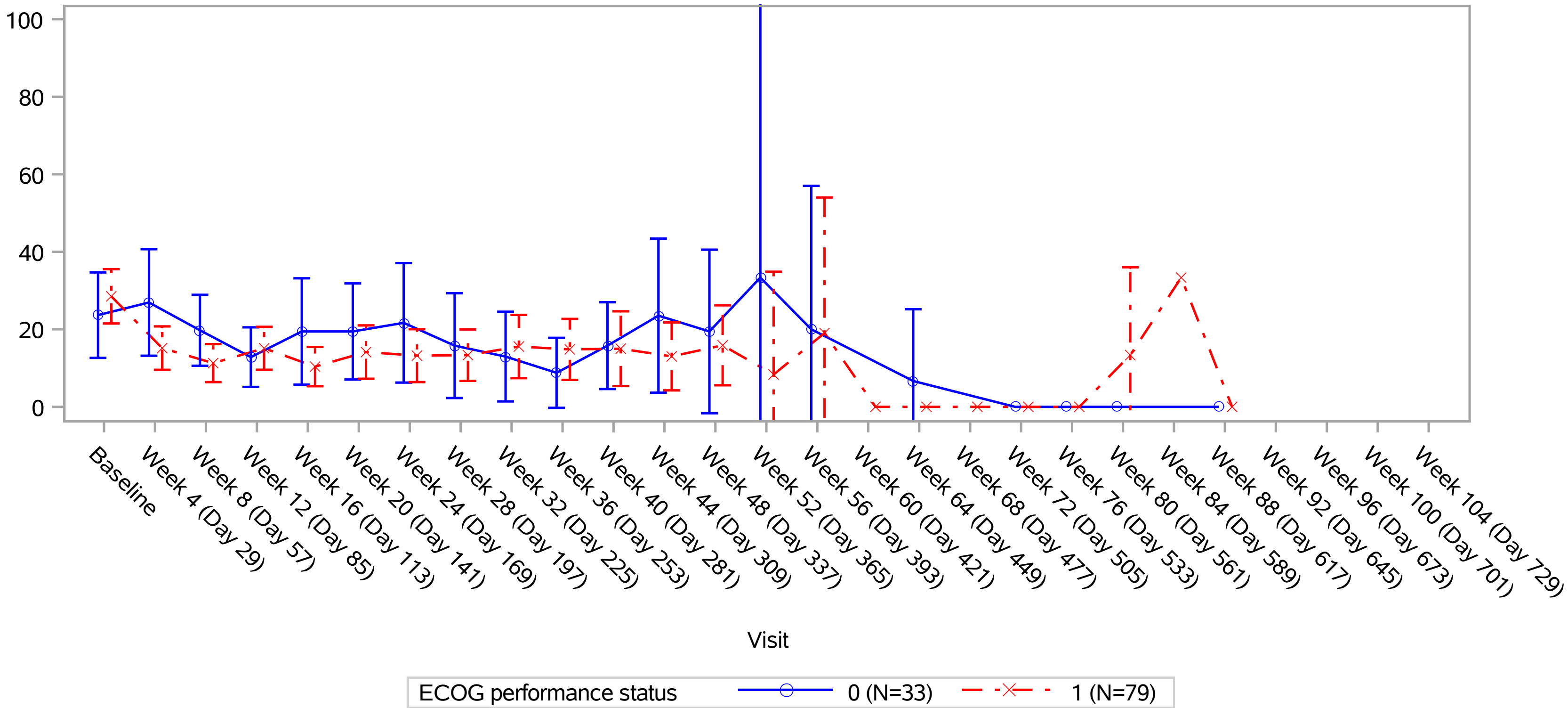
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Insomnia
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30SL_SGAGE65.pdf
15OCT2021 17:50

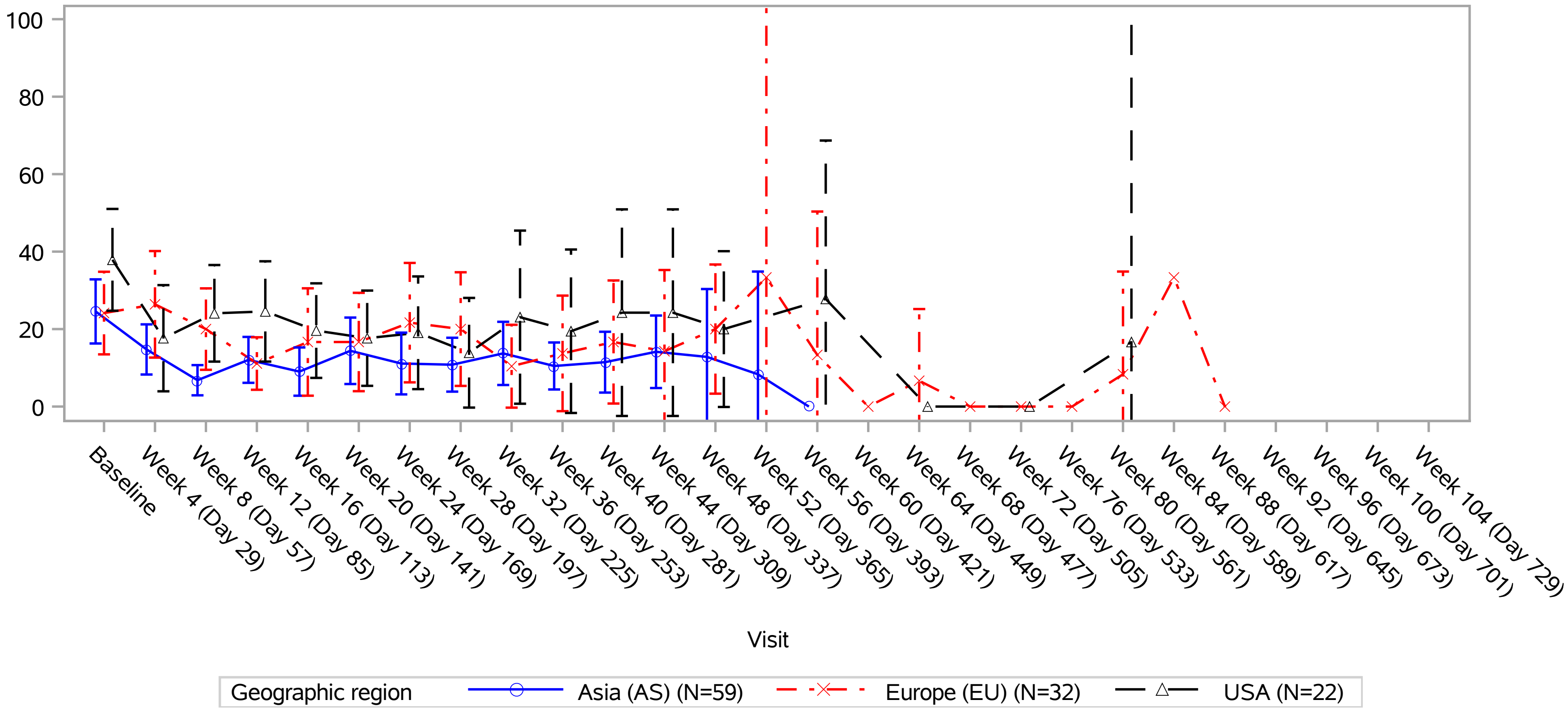
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Insomnia
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30SL_SGECOG.pdf
15OCT2021 18:21

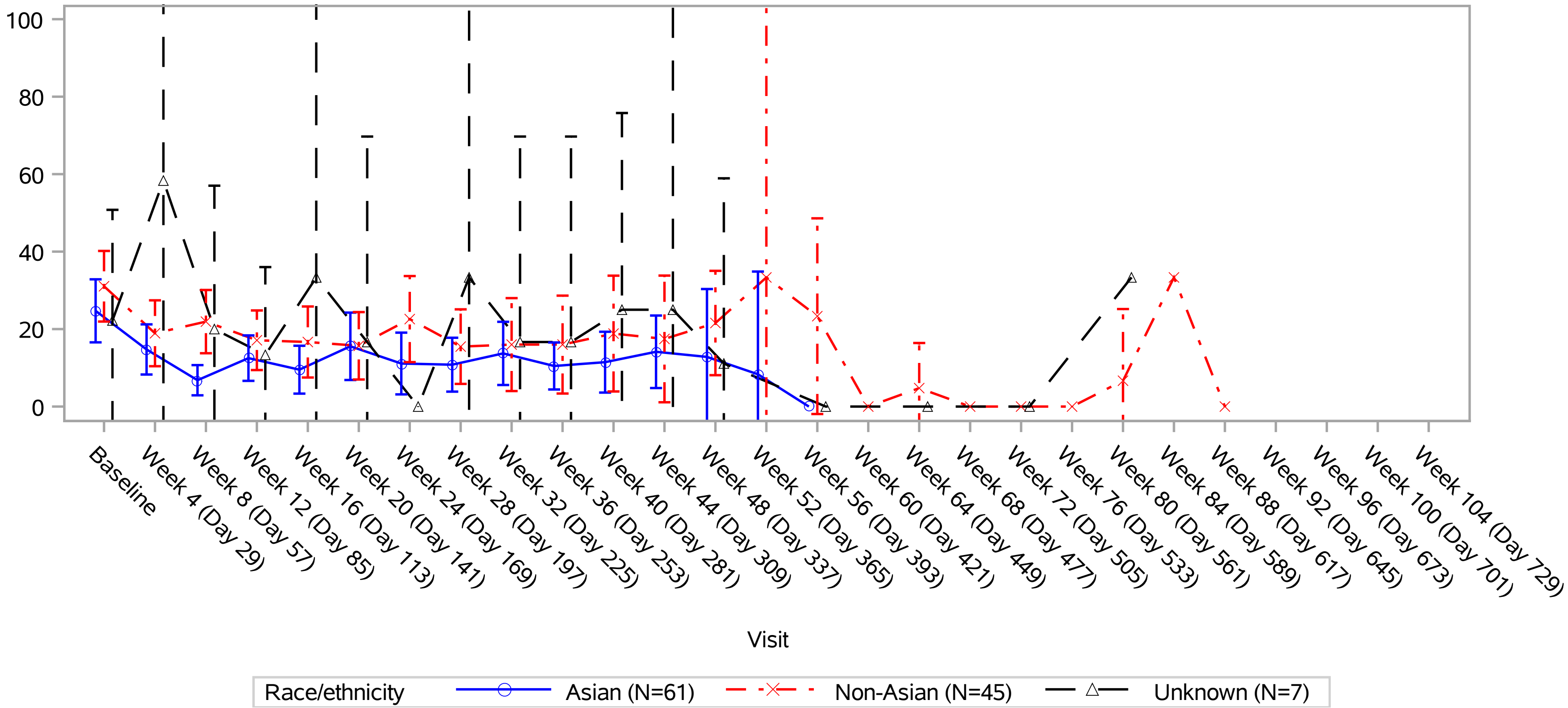
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Insomnia
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30SL_SGGEO.pdf
15OCT2021 18:52

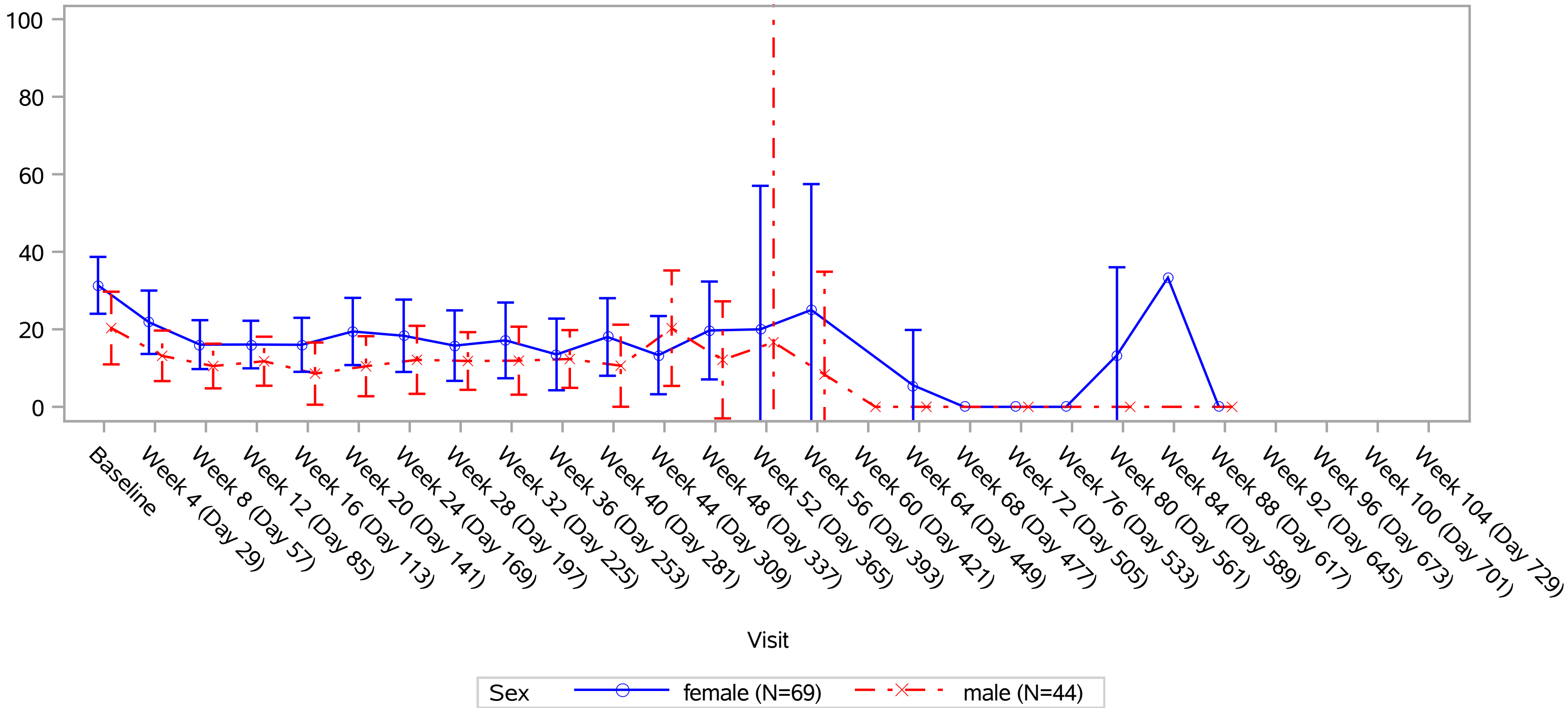
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Insomnia
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30SL_SGRE.pdf
15OCT2021 19:22

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Pre-Treated Patients, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Insomnia
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TP_QSC30SL_SGSEX.pdf
15OCT2021 19:53

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Appetite Loss
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=221)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	221	100.0	212	95.9	20.75	29.37	16.78	24.73
Week 4 (Day 29)	n/a	221	100.0	190	86.0	11.58	20.73	8.61	14.55
Week 8 (Day 57)	n/a	193	87.3	171	88.6	11.70	23.56	8.14	15.25
Week 12 (Day 85)	n/a	176	79.6	161	91.5	7.87	17.29	5.18	10.56
Week 16 (Day 113)	n/a	164	74.2	143	87.2	8.86	16.29	6.17	11.55
Week 20 (Day 141)	n/a	148	67.0	138	93.2	10.39	22.35	6.62	14.15
Week 24 (Day 169)	n/a	137	62.0	122	89.1	8.47	18.95	5.07	11.87
Week 28 (Day 197)	n/a	129	58.4	120	93.0	7.78	20.15	4.14	11.42
Week 32 (Day 225)	n/a	119	53.8	104	87.4	7.69	19.83	3.84	11.55
Week 36 (Day 253)	n/a	112	50.7	95	84.8	8.42	18.17	4.72	12.12
Week 40 (Day 281)	n/a	104	47.1	91	87.5	7.33	17.07	3.77	10.88
Week 44 (Day 309)	n/a	95	43.0	84	88.4	9.52	20.42	5.09	13.95
Week 48 (Day 337)	n/a	81	36.7	45	55.6	5.19	15.82	0.43	9.94
Week 52 (Day 365)	n/a	64	29.0	11	17.2	6.06	13.48	-3.00	15.12
Week 56 (Day 393)	n/a	54	24.4	18	33.3	3.70	10.78	-1.66	9.06
Week 60 (Day 421)	n/a	43	19.5	2	4.7	0.00	0.00	NE	NE
Week 64 (Day 449)	n/a	41	18.6	12	29.3	0.00	0.00	NE	NE
Week 68 (Day 477)	n/a	34	15.4	2	5.9	0.00	0.00	NE	NE
Week 72 (Day 505)	n/a	34	15.4	5	14.7	0.00	0.00	NE	NE
Week 76 (Day 533)	n/a	31	14.0	3	9.7	0.00	0.00	NE	NE
Week 80 (Day 561)	n/a	30	13.6	6	20.0	16.67	40.82	-26.18	59.51
Week 84 (Day 589)	n/a	19	8.6	1	5.3	0.00	NE	NE	NE
Week 88 (Day 617)	n/a	15	6.8	2	13.3	0.00	0.00	NE	NE
Week 92 (Day 645)	n/a	8	3.6	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	2.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	1.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	221	100.0	219	99.1	14.00	25.28	10.64	17.37
End of Study (LOCF)	n/a	221	100.0	219	99.1	13.39	25.00	10.06	16.72
Sex									
Baseline	Female	128	100.0	123	96.1	23.04	30.81	17.53	28.54
Week 4 (Day 29)	Female	128	100.0	105	82.0	13.33	19.94	9.48	17.19
Week 8 (Day 57)	Female	112	87.5	98	87.5	15.99	27.17	10.54	21.43
Week 12 (Day 85)	Female	104	81.3	95	91.3	10.18	20.09	6.08	14.27
Week 16 (Day 113)	Female	96	75.0	81	84.4	11.52	17.61	7.63	15.42
Week 20 (Day 141)	Female	86	67.2	80	93.0	13.33	24.65	7.85	18.82
Week 24 (Day 169)	Female	78	60.9	67	85.9	10.45	20.28	5.50	15.39
Week 28 (Day 197)	Female	72	56.3	65	90.3	10.77	22.90	5.09	16.44
Week 32 (Day 225)	Female	69	53.9	58	84.1	8.62	20.29	3.29	13.96
Week 36 (Day 253)	Female	64	50.0	52	81.3	7.69	19.38	2.30	13.09
Week 40 (Day 281)	Female	59	46.1	53	89.8	6.92	16.48	2.37	11.46
Week 44 (Day 309)	Female	56	43.8	47	83.9	12.06	22.44	5.47	18.65
Week 48 (Day 337)	Female	48	37.5	26	54.2	6.41	18.90	-1.22	14.04
Week 52 (Day 365)	Female	38	29.7	6	15.8	11.11	17.21	-6.95	29.18
Week 56 (Day 393)	Female	31	24.2	9	29.0	7.41	14.70	-3.89	18.71
Week 60 (Day 421)	Female	27	21.1	1	3.7	0.00	NE	NE	NE
Week 64 (Day 449)	Female	26	20.3	8	30.8	0.00	0.00	NE	NE
Week 68 (Day 477)	Female	23	18.0	2	8.7	0.00	0.00	NE	NE
Week 72 (Day 505)	Female	23	18.0	3	13.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Female	21	16.4	3	14.3	0.00	0.00	NE	NE
Week 80 (Day 561)	Female	20	15.6	5	25.0	20.00	44.72	-35.53	75.53
Week 84 (Day 589)	Female	12	9.4	1	8.3	0.00	NE	NE	NE
Week 88 (Day 617)	Female	9	7.0	1	11.1	0.00	NE	NE	NE
Week 92 (Day 645)	Female	6	4.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	3.9	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	1.6	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	0.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	128	100.0	127	99.2	16.80	27.82	11.91	21.68
End of Study (LOCF)	Female	128	100.0	127	99.2	16.01	27.81	11.13	20.89
Baseline	Male	93	100.0	89	95.7	17.60	27.10	11.89	23.31
Week 4 (Day 29)	Male	93	100.0	85	91.4	9.41	21.59	4.76	14.07
Week 8 (Day 57)	Male	81	87.1	73	90.1	5.94	16.05	2.19	9.68
Week 12 (Day 85)	Male	72	77.4	66	91.7	4.55	11.53	1.71	7.38
Week 16 (Day 113)	Male	68	73.1	62	91.2	5.38	13.76	1.88	8.87
Week 20 (Day 141)	Male	62	66.7	58	93.5	6.32	18.16	1.55	11.10
Week 24 (Day 169)	Male	59	63.4	55	93.2	6.06	17.08	1.44	10.68
Week 28 (Day 197)	Male	57	61.3	55	96.5	4.24	15.78	-0.02	8.51
Week 32 (Day 225)	Male	50	53.8	46	92.0	6.52	19.40	0.76	12.28
Week 36 (Day 253)	Male	48	51.6	43	89.6	9.30	16.79	4.14	14.47
Week 40 (Day 281)	Male	45	48.4	38	84.4	7.89	18.07	1.96	13.83
Week 44 (Day 309)	Male	39	41.9	37	94.9	6.31	17.28	0.54	12.07
Week 48 (Day 337)	Male	33	35.5	19	57.6	3.51	10.51	-1.56	8.57
Week 52 (Day 365)	Male	26	28.0	5	19.2	0.00	0.00	NE	NE
Week 56 (Day 393)	Male	23	24.7	9	39.1	0.00	0.00	NE	NE
Week 60 (Day 421)	Male	16	17.2	1	6.3	0.00	NE	NE	NE
Week 64 (Day 449)	Male	15	16.1	4	26.7	0.00	0.00	NE	NE
Week 68 (Day 477)	Male	11	11.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	11	11.8	2	18.2	0.00	0.00	NE	NE
Week 76 (Day 533)	Male	10	10.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	10	10.8	1	10.0	0.00	NE	NE	NE
Week 84 (Day 589)	Male	7	7.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	6	6.5	1	16.7	0.00	NE	NE	NE
Week 92 (Day 645)	Male	2	2.2	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	93	100.0	92	98.9	10.14	20.81	5.83	14.46
End of Study (LOCF)	Male	93	100.0	92	98.9	9.78	20.10	5.62	13.94
Age									

Baseline	< 65	141	100.0	133	94.3	20.55	29.22	15.54	25.56
Week 4 (Day 29)	< 65	141	100.0	123	87.2	9.49	17.86	6.30	12.67
Week 8 (Day 57)	< 65	127	90.1	113	89.0	7.96	18.51	4.51	11.42
Week 12 (Day 85)	< 65	118	83.7	106	89.8	5.97	15.80	2.93	9.02
Week 16 (Day 113)	< 65	108	76.6	93	86.1	7.89	15.07	4.78	10.99
Week 20 (Day 141)	< 65	100	70.9	97	97.0	10.65	22.33	6.15	15.15
Week 24 (Day 169)	< 65	93	66.0	86	92.5	7.75	17.47	4.01	11.50
Week 28 (Day 197)	< 65	88	62.4	83	94.3	6.02	16.58	2.40	9.64
Week 32 (Day 225)	< 65	83	58.9	73	88.0	5.02	14.35	1.67	8.37
Week 36 (Day 253)	< 65	78	55.3	70	89.7	4.76	13.05	1.65	7.87
Week 40 (Day 281)	< 65	75	53.2	69	92.0	4.83	13.13	1.68	7.99
Week 44 (Day 309)	< 65	71	50.4	65	91.5	8.72	18.89	4.04	13.40
Week 48 (Day 337)	< 65	61	43.3	33	54.1	5.05	14.72	-0.17	10.27
Week 52 (Day 365)	< 65	48	34.0	6	12.5	5.56	13.61	-8.73	19.84
Week 56 (Day 393)	< 65	41	29.1	11	26.8	6.06	13.48	-3.00	15.12
Week 60 (Day 421)	< 65	33	23.4	2	6.1	0.00	0.00	NE	NE
Week 64 (Day 449)	< 65	31	22.0	10	32.3	0.00	0.00	NE	NE
Week 68 (Day 477)	< 65	26	18.4	2	7.7	0.00	0.00	NE	NE
Week 72 (Day 505)	< 65	26	18.4	5	19.2	0.00	0.00	NE	NE
Week 76 (Day 533)	< 65	25	17.7	3	12.0	0.00	0.00	NE	NE
Week 80 (Day 561)	< 65	24	17.0	5	20.8	20.00	44.72	-35.53	75.53
Week 84 (Day 589)	< 65	16	11.3	1	6.3	0.00	NE	NE	NE
Week 88 (Day 617)	< 65	13	9.2	2	15.4	0.00	0.00	NE	NE
Week 92 (Day 645)	< 65	7	5.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	3.5	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	2.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	0.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	141	100.0	139	98.6	12.71	24.54	8.59	16.83
End of Study (LOCF)	< 65	141	100.0	139	98.6	11.99	24.41	7.90	16.08
Baseline	>= 65	80	100.0	79	98.8	21.10	29.80	14.42	27.77
Week 4 (Day 29)	>= 65	80	100.0	67	83.8	15.42	24.84	9.36	21.48
Week 8 (Day 57)	>= 65	66	82.5	58	87.9	18.97	30.02	11.07	26.86
Week 12 (Day 85)	>= 65	58	72.5	55	94.8	11.52	19.48	6.25	16.78

Week 16 (Day 113)	>= 65	56	70.0	50	89.3	10.67	18.37	5.45	15.89
Week 20 (Day 141)	>= 65	48	60.0	41	85.4	9.76	22.66	2.60	16.91
Week 24 (Day 169)	>= 65	44	55.0	36	81.8	10.19	22.28	2.65	17.72
Week 28 (Day 197)	>= 65	41	51.3	37	90.2	11.71	26.31	2.94	20.48
Week 32 (Day 225)	>= 65	36	45.0	31	86.1	13.98	28.25	3.62	24.34
Week 36 (Day 253)	>= 65	34	42.5	25	73.5	18.67	25.60	8.10	29.24
Week 40 (Day 281)	>= 65	29	36.3	22	75.9	15.15	24.62	4.24	26.07
Week 44 (Day 309)	>= 65	24	30.0	19	79.2	12.28	25.36	0.06	24.51
Week 48 (Day 337)	>= 65	20	25.0	12	60.0	5.56	19.25	-6.67	17.78
Week 52 (Day 365)	>= 65	16	20.0	5	31.3	6.67	14.91	-11.84	25.18
Week 56 (Day 393)	>= 65	13	16.3	7	53.8	0.00	0.00	NE	NE
Week 60 (Day 421)	>= 65	10	12.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	10	12.5	2	20.0	0.00	0.00	NE	NE
Week 68 (Day 477)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	6	7.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	6	7.5	1	16.7	0.00	NE	NE	NE
Week 84 (Day 589)	>= 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	2.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	80	100.0	80	100.0	16.25	26.52	10.35	22.15
End of Study (LOCF)	>= 65	80	100.0	80	100.0	15.83	25.97	10.05	21.61
ECOG performance status									
Baseline	0	63	100.0	60	95.2	18.89	32.11	10.60	27.18
Week 4 (Day 29)	0	63	100.0	56	88.9	14.29	26.10	7.30	21.27
Week 8 (Day 57)	0	58	92.1	52	89.7	15.38	30.58	6.87	23.90
Week 12 (Day 85)	0	55	87.3	50	90.9	10.67	21.76	4.48	16.85
Week 16 (Day 113)	0	54	85.7	45	83.3	7.41	14.01	3.20	11.62
Week 20 (Day 141)	0	52	82.5	48	92.3	10.42	21.91	4.05	16.78
Week 24 (Day 169)	0	49	77.8	43	87.8	3.88	13.03	-0.13	7.89
Week 28 (Day 197)	0	46	73.0	42	91.3	8.73	24.48	1.10	16.36

Week 32 (Day 225)	0	41	65.1	34	82.9	3.92	17.91	-2.33	10.17
Week 36 (Day 253)	0	39	61.9	31	79.5	4.30	14.25	-0.93	9.53
Week 40 (Day 281)	0	37	58.7	30	81.1	5.56	15.37	-0.18	11.30
Week 44 (Day 309)	0	36	57.1	29	80.6	9.20	19.71	1.70	16.69
Week 48 (Day 337)	0	28	44.4	18	64.3	9.26	22.30	-1.83	20.35
Week 52 (Day 365)	0	27	42.9	6	22.2	5.56	13.61	-8.73	19.84
Week 56 (Day 393)	0	24	38.1	8	33.3	0.00	0.00	NE	NE
Week 60 (Day 421)	0	21	33.3	1	4.8	0.00	NE	NE	NE
Week 64 (Day 449)	0	21	33.3	7	33.3	0.00	0.00	NE	NE
Week 68 (Day 477)	0	17	27.0	1	5.9	0.00	NE	NE	NE
Week 72 (Day 505)	0	17	27.0	2	11.8	0.00	0.00	NE	NE
Week 76 (Day 533)	0	15	23.8	2	13.3	0.00	0.00	NE	NE
Week 80 (Day 561)	0	14	22.2	1	7.1	0.00	NE	NE	NE
Week 84 (Day 589)	0	11	17.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	10	15.9	1	10.0	0.00	NE	NE	NE
Week 92 (Day 645)	0	5	7.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	6.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	4.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	63	100.0	63	100.0	18.52	32.12	10.43	26.61
End of Study (LOCF)	0	63	100.0	63	100.0	16.40	31.61	8.44	24.36
Baseline	1	157	100.0	151	96.2	21.63	28.34	17.08	26.19
Week 4 (Day 29)	1	157	100.0	133	84.7	10.53	18.06	7.43	13.62
Week 8 (Day 57)	1	134	85.4	119	88.8	10.08	19.67	6.51	13.66
Week 12 (Day 85)	1	121	77.1	111	91.7	6.61	14.78	3.83	9.39
Week 16 (Day 113)	1	110	70.1	98	89.1	9.52	17.26	6.06	12.98
Week 20 (Day 141)	1	96	61.1	90	93.8	10.37	22.70	5.62	15.13
Week 24 (Day 169)	1	88	56.1	79	89.8	10.97	21.16	6.23	15.71
Week 28 (Day 197)	1	83	52.9	78	94.0	7.26	17.53	3.31	11.22
Week 32 (Day 225)	1	78	49.7	70	89.7	9.52	20.57	4.62	14.43
Week 36 (Day 253)	1	73	46.5	64	87.7	10.42	19.59	5.52	15.31
Week 40 (Day 281)	1	67	42.7	61	91.0	8.20	17.90	3.61	12.78

Week 44 (Day 309)	1	59	37.6	55	93.2	9.70	20.96	4.03	15.36
Week 48 (Day 337)	1	53	33.8	27	50.9	2.47	8.90	-1.05	5.99
Week 52 (Day 365)	1	37	23.6	5	13.5	6.67	14.91	-11.84	25.18
Week 56 (Day 393)	1	30	19.1	10	33.3	6.67	14.05	-3.39	16.72
Week 60 (Day 421)	1	22	14.0	1	4.5	0.00	NE	NE	NE
Week 64 (Day 449)	1	20	12.7	5	25.0	0.00	0.00	NE	NE
Week 68 (Day 477)	1	17	10.8	1	5.9	0.00	NE	NE	NE
Week 72 (Day 505)	1	17	10.8	3	17.6	0.00	0.00	NE	NE
Week 76 (Day 533)	1	16	10.2	1	6.3	0.00	NE	NE	NE
Week 80 (Day 561)	1	16	10.2	5	31.3	20.00	44.72	-35.53	75.53
Week 84 (Day 589)	1	8	5.1	1	12.5	0.00	NE	NE	NE
Week 88 (Day 617)	1	5	3.2	1	20.0	0.00	NE	NE	NE
Week 92 (Day 645)	1	3	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	157	100.0	155	98.7	12.26	21.83	8.79	15.72
End of Study (LOCF)	1	157	100.0	155	98.7	12.26	21.83	8.79	15.72
Baseline	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Geographic region									
Baseline	USA	43	100.0	41	95.3	17.89	29.90	8.45	27.33
Week 4 (Day 29)	USA	43	100.0	37	86.0	6.31	13.24	1.89	10.72
Week 8 (Day 57)	USA	41	95.3	37	90.2	9.01	15.01	4.01	14.01
Week 12 (Day 85)	USA	41	95.3	38	92.7	8.77	16.77	3.26	14.29
Week 16 (Day 113)	USA	40	93.0	33	82.5	7.07	13.84	2.16	11.98
Week 20 (Day 141)	USA	39	90.7	35	89.7	10.48	25.27	1.80	19.16
Week 24 (Day 169)	USA	36	83.7	33	91.7	6.06	19.46	-0.84	12.96
Week 28 (Day 197)	USA	35	81.4	31	88.6	4.30	18.74	-2.57	11.18
Week 32 (Day 225)	USA	32	74.4	28	87.5	8.33	23.35	-0.72	17.39
Week 36 (Day 253)	USA	32	74.4	24	75.0	2.78	13.61	-2.97	8.52
Week 40 (Day 281)	USA	29	67.4	23	79.3	10.14	21.17	0.99	19.30

Week 44 (Day 309)	USA	26	60.5	21	80.8	12.70	22.30	2.55	22.85
Week 48 (Day 337)	USA	21	48.8	15	71.4	2.22	8.61	-2.54	6.99
Week 52 (Day 365)	USA	18	41.9	1	5.6	0.00	NE	NE	NE
Week 56 (Day 393)	USA	18	41.9	9	50.0	7.41	14.70	-3.89	18.71
Week 60 (Day 421)	USA	17	39.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	15	34.9	5	33.3	0.00	0.00	NE	NE
Week 68 (Day 477)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	12	27.9	1	8.3	0.00	NE	NE	NE
Week 76 (Day 533)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	12	27.9	2	16.7	50.00	70.71	-585.31	685.31
Week 84 (Day 589)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	6	14.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	11.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	7.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	43	100.0	43	100.0	7.75	17.57	2.34	13.16
End of Study (LOCF)	USA	43	100.0	43	100.0	7.75	20.36	1.49	14.02
Baseline	Europe (EU)	74	100.0	69	93.2	18.84	26.49	12.48	25.21
Week 4 (Day 29)	Europe (EU)	74	100.0	64	86.5	14.06	23.61	8.16	19.96
Week 8 (Day 57)	Europe (EU)	65	87.8	55	84.6	14.55	28.52	6.84	22.26
Week 12 (Day 85)	Europe (EU)	57	77.0	49	86.0	9.52	21.52	3.34	15.70
Week 16 (Day 113)	Europe (EU)	55	74.3	44	80.0	9.85	16.98	4.69	15.01
Week 20 (Day 141)	Europe (EU)	49	66.2	46	93.9	11.59	22.46	4.92	18.26
Week 24 (Day 169)	Europe (EU)	47	63.5	42	89.4	9.52	18.46	3.77	15.28
Week 28 (Day 197)	Europe (EU)	45	60.8	43	95.6	10.85	23.82	3.52	18.18
Week 32 (Day 225)	Europe (EU)	39	52.7	35	89.7	4.76	11.83	0.70	8.83
Week 36 (Day 253)	Europe (EU)	34	45.9	30	88.2	4.44	14.47	-0.96	9.85
Week 40 (Day 281)	Europe (EU)	31	41.9	30	96.8	2.22	8.46	-0.94	5.38
Week 44 (Day 309)	Europe (EU)	28	37.8	24	85.7	8.33	20.26	-0.22	16.89

Week 48 (Day 337)	Europe (EU)	22	29.7	16	72.7	6.25	18.13	-3.41	15.91
Week 52 (Day 365)	Europe (EU)	19	25.7	6	31.6	5.56	13.61	-8.73	19.84
Week 56 (Day 393)	Europe (EU)	17	23.0	7	41.2	0.00	0.00	NE	NE
Week 60 (Day 421)	Europe (EU)	15	20.3	2	13.3	0.00	0.00	NE	NE
Week 64 (Day 449)	Europe (EU)	15	20.3	7	46.7	0.00	0.00	NE	NE
Week 68 (Day 477)	Europe (EU)	13	17.6	2	15.4	0.00	0.00	NE	NE
Week 72 (Day 505)	Europe (EU)	13	17.6	4	30.8	0.00	0.00	NE	NE
Week 76 (Day 533)	Europe (EU)	11	14.9	3	27.3	0.00	0.00	NE	NE
Week 80 (Day 561)	Europe (EU)	10	13.5	4	40.0	0.00	0.00	NE	NE
Week 84 (Day 589)	Europe (EU)	6	8.1	1	16.7	0.00	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	4.1	2	66.7	0.00	0.00	NE	NE
Cycle 12 (LOCF)	Europe (EU)	74	100.0	73	98.6	17.35	26.71	11.12	23.58
End of Study (LOCF)	Europe (EU)	74	100.0	73	98.6	15.98	25.53	10.03	21.94
Baseline	Asia (AS)	104	100.0	102	98.1	23.20	31.04	17.11	29.30
Week 4 (Day 29)	Asia (AS)	104	100.0	89	85.6	11.99	20.87	7.59	16.38
Week 8 (Day 57)	Asia (AS)	87	83.7	79	90.8	10.97	23.09	5.80	16.14
Week 12 (Day 85)	Asia (AS)	78	75.0	74	94.9	6.31	14.26	3.00	9.61
Week 16 (Day 113)	Asia (AS)	69	66.3	66	95.7	9.09	17.09	4.89	13.29
Week 20 (Day 141)	Asia (AS)	60	57.7	57	95.0	9.36	20.66	3.88	14.84
Week 24 (Day 169)	Asia (AS)	54	51.9	47	87.0	9.22	19.29	3.56	14.88
Week 28 (Day 197)	Asia (AS)	49	47.1	46	93.9	7.25	17.09	2.17	12.32
Week 32 (Day 225)	Asia (AS)	48	46.2	41	85.4	9.76	22.66	2.60	16.91
Week 36 (Day 253)	Asia (AS)	46	44.2	41	89.1	14.63	21.15	7.96	21.31
Week 40 (Day 281)	Asia (AS)	44	42.3	38	86.4	9.65	18.84	3.46	15.84
Week 44 (Day 309)	Asia (AS)	41	39.4	39	95.1	8.55	19.82	2.12	14.97
Week 48 (Day 337)	Asia (AS)	38	36.5	14	36.8	7.14	19.30	-4.00	18.29
Week 52 (Day 365)	Asia (AS)	27	26.0	4	14.8	8.33	16.67	-18.19	34.85
Week 56 (Day 393)	Asia (AS)	19	18.3	2	10.5	0.00	0.00	NE	NE
Week 60 (Day 421)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	5.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	104	100.0	103	99.0	14.24	26.65	9.03	19.45
End of Study (LOCF)	Asia (AS)	104	100.0	103	99.0	13.92	26.21	8.79	19.04
Race/ethnicity									
Baseline	Asian	109	100.0	106	97.2	23.58	31.53	17.51	29.66
Week 4 (Day 29)	Asian	109	100.0	92	84.4	11.96	20.72	7.67	16.25
Week 8 (Day 57)	Asian	91	83.5	80	87.9	11.25	23.08	6.11	16.39
Week 12 (Day 85)	Asian	82	75.2	78	95.1	6.84	14.57	3.55	10.12
Week 16 (Day 113)	Asian	73	67.0	70	95.9	9.05	16.95	5.01	13.09
Week 20 (Day 141)	Asian	64	58.7	60	93.8	11.11	23.50	5.04	17.18
Week 24 (Day 169)	Asian	57	52.3	50	87.7	10.67	22.78	4.19	17.14
Week 28 (Day 197)	Asian	52	47.7	49	94.2	8.84	21.27	2.73	14.95
Week 32 (Day 225)	Asian	50	45.9	43	86.0	11.63	26.11	3.59	19.66
Week 36 (Day 253)	Asian	48	44.0	43	89.6	15.50	22.24	8.66	22.35
Week 40 (Day 281)	Asian	46	42.2	40	87.0	10.83	20.52	4.27	17.39
Week 44 (Day 309)	Asian	43	39.4	41	95.3	9.76	21.40	3.00	16.51
Week 48 (Day 337)	Asian	40	36.7	15	37.5	6.67	18.69	-3.68	17.02
Week 52 (Day 365)	Asian	29	26.6	5	17.2	6.67	14.91	-11.84	25.18
Week 56 (Day 393)	Asian	21	19.3	3	14.3	0.00	0.00	NE	NE
Week 60 (Day 421)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	5.5	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	4.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	1.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	109	100.0	107	98.2	14.64	26.77	9.51	19.77
End of Study (LOCF)	Asian	109	100.0	107	98.2	14.33	26.35	9.28	19.38
Baseline	Non-Asian	99	100.0	96	97.0	17.71	26.47	12.35	23.07
Week 4 (Day 29)	Non-Asian	99	100.0	88	88.9	10.61	19.28	6.52	14.69
Week 8 (Day 57)	Non-Asian	91	91.9	82	90.1	13.41	25.04	7.91	18.92
Week 12 (Day 85)	Non-Asian	83	83.8	74	89.2	8.56	19.16	4.12	13.00
Week 16 (Day 113)	Non-Asian	80	80.8	68	85.0	9.31	16.13	5.41	13.22
Week 20 (Day 141)	Non-Asian	74	74.7	69	93.2	11.11	22.63	5.68	16.55
Week 24 (Day 169)	Non-Asian	70	70.7	65	92.9	7.69	16.42	3.62	11.76
Week 28 (Day 197)	Non-Asian	67	67.7	63	94.0	6.35	16.78	2.12	10.58
Week 32 (Day 225)	Non-Asian	60	60.6	53	88.3	5.66	14.23	1.74	9.58
Week 36 (Day 253)	Non-Asian	55	55.6	46	83.6	0.72	4.91	-0.73	2.18
Week 40 (Day 281)	Non-Asian	49	49.5	44	89.8	4.55	13.62	0.40	8.69
Week 44 (Day 309)	Non-Asian	43	43.4	35	81.4	9.52	20.72	2.40	16.64
Week 48 (Day 337)	Non-Asian	35	35.4	26	74.3	5.13	15.47	-1.12	11.38
Week 52 (Day 365)	Non-Asian	29	29.3	6	20.7	5.56	13.61	-8.73	19.84
Week 56 (Day 393)	Non-Asian	27	27.3	14	51.9	4.76	12.10	-2.23	11.75
Week 60 (Day 421)	Non-Asian	26	26.3	2	7.7	0.00	0.00	NE	NE
Week 64 (Day 449)	Non-Asian	24	24.2	9	37.5	0.00	0.00	NE	NE
Week 68 (Day 477)	Non-Asian	20	20.2	2	10.0	0.00	0.00	NE	NE
Week 72 (Day 505)	Non-Asian	20	20.2	3	15.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Non-Asian	18	18.2	3	16.7	0.00	0.00	NE	NE
Week 80 (Day 561)	Non-Asian	17	17.2	5	29.4	20.00	44.72	-35.53	75.53
Week 84 (Day 589)	Non-Asian	11	11.1	1	9.1	0.00	NE	NE	NE
Week 88 (Day 617)	Non-Asian	8	8.1	2	25.0	0.00	0.00	NE	NE
Week 92 (Day 645)	Non-Asian	4	4.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	3.0	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	99	100.0	99	100.0	14.14	24.79	9.20	19.08

End of Study (LOCF)	Non-Asian	99	100.0	99	100.0	13.47	24.71	8.54	18.40
Baseline	Unknown	13	100.0	10	76.9	20.00	32.20	-3.04	43.04
Week 4 (Day 29)	Unknown	13	100.0	10	76.9	16.67	32.39	-6.51	39.84
Week 8 (Day 57)	Unknown	11	84.6	9	81.8	0.00	0.00	NE	NE
Week 12 (Day 85)	Unknown	11	84.6	9	81.8	11.11	23.57	-7.01	29.23
Week 16 (Day 113)	Unknown	11	84.6	5	45.5	0.00	0.00	NE	NE
Week 20 (Day 141)	Unknown	10	76.9	9	90.0	0.00	0.00	NE	NE
Week 24 (Day 169)	Unknown	10	76.9	7	70.0	0.00	0.00	NE	NE
Week 28 (Day 197)	Unknown	10	76.9	8	80.0	12.50	35.36	-17.06	42.06
Week 32 (Day 225)	Unknown	9	69.2	8	88.9	0.00	0.00	NE	NE
Week 36 (Day 253)	Unknown	9	69.2	6	66.7	16.67	27.89	-12.60	45.93
Week 40 (Day 281)	Unknown	9	69.2	7	77.8	4.76	12.60	-6.89	16.41
Week 44 (Day 309)	Unknown	9	69.2	8	88.9	8.33	15.43	-4.57	21.23
Week 48 (Day 337)	Unknown	6	46.2	4	66.7	0.00	0.00	NE	NE
Week 52 (Day 365)	Unknown	6	46.2	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	6	46.2	1	16.7	0.00	NE	NE	NE
Week 60 (Day 421)	Unknown	5	38.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	5	38.5	3	60.0	0.00	0.00	NE	NE
Week 68 (Day 477)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	4	30.8	2	50.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	4	30.8	1	25.0	0.00	NE	NE	NE
Week 84 (Day 589)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	7.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	13	100.0	13	100.0	7.69	14.62	-1.14	16.53
End of Study (LOCF)	Unknown	13	100.0	13	100.0	5.13	12.52	-2.44	12.69

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TO_QSC30AP_SG.xls
27OCT2021 7:11

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Appetite Loss
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	64	30.2	24.4	36.7
	Cycle 12 (LOCF)	n/a	212	95.9	27	12.7	8.9	17.9
	End of Study (LOCF)	n/a	212	95.9	24	11.3	7.7	16.3
Sex	All visits	Female	123	55.7	42	34.1	26.4	42.9
		Male	89	40.3	22	24.7	16.9	34.6
	Cycle 12 (LOCF)	Female	123	55.7	17	13.8	8.8	21.0
		Male	89	40.3	10	11.2	6.2	19.5
	End of Study (LOCF)	Female	123	55.7	14	11.4	6.9	18.2
		Male	89	40.3	10	11.2	6.2	19.5
Age	All visits	< 65	133	60.2	38	28.6	21.6	36.8
		>= 65	79	35.7	26	32.9	23.6	43.9
	Cycle 12 (LOCF)	< 65	133	60.2	15	11.3	7.0	17.8
		>= 65	79	35.7	12	15.2	8.9	24.7
	End of Study (LOCF)	< 65	133	60.2	12	9.0	5.2	15.1
		>= 65	79	35.7	12	15.2	8.9	24.7
ECOG performance status	All visits	0	60	27.1	23	38.3	27.1	51.0
		1	151	68.3	41	27.2	20.7	34.7
		Missing	1	0.5	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	60	27.1	11	18.3	10.6	29.9
		1	151	68.3	16	10.6	6.6	16.5
		Missing	1	0.5	0	0.0	0.0	79.3
	End of Study (LOCF)	0	60	27.1	9	15.0	8.1	26.1
		1	151	68.3	15	9.9	6.1	15.7
		Missing	1	0.5	0	0.0	0.0	79.3
Geographic region	All visits	USA	41	18.6	9	22.0	12.0	36.7
		Europe (EU)	69	31.2	26	37.7	27.2	49.5
		Asia (AS)	102	46.2	29	28.4	20.6	37.8
	Cycle 12 (LOCF)	USA	41	18.6	2	4.9	1.3	16.1
		Europe (EU)	69	31.2	13	18.8	11.4	29.6
		Asia (AS)	102	46.2	12	11.8	6.9	19.4
	End of Study (LOCF)	USA	41	18.6	1	2.4	0.4	12.6
		Europe (EU)	69	31.2	11	15.9	9.1	26.3
		Asia (AS)	102	46.2	12	11.8	6.9	19.4
Race/ethnicity	All visits	Asian	106	48.0	30	28.3	20.6	37.5
		Non-Asian	96	43.4	32	33.3	24.7	43.2
		Unknown	10	4.5	2	20.0	5.7	51.0
	Cycle 12 (LOCF)	Asian	106	48.0	12	11.3	6.6	18.8

		Non-Asian	96	43.4	14	14.6	8.9	23.0
		Unknown	10	4.5	1	10.0	1.8	40.4
	End of Study (LOCF)	Asian	106	48.0	12	11.3	6.6	18.8
		Non-Asian	96	43.4	11	11.5	6.5	19.4
		Unknown	10	4.5	1	10.0	1.8	40.4

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30AP_W10_SG.xls
15OCT2021 12:49

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Appetite Loss
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

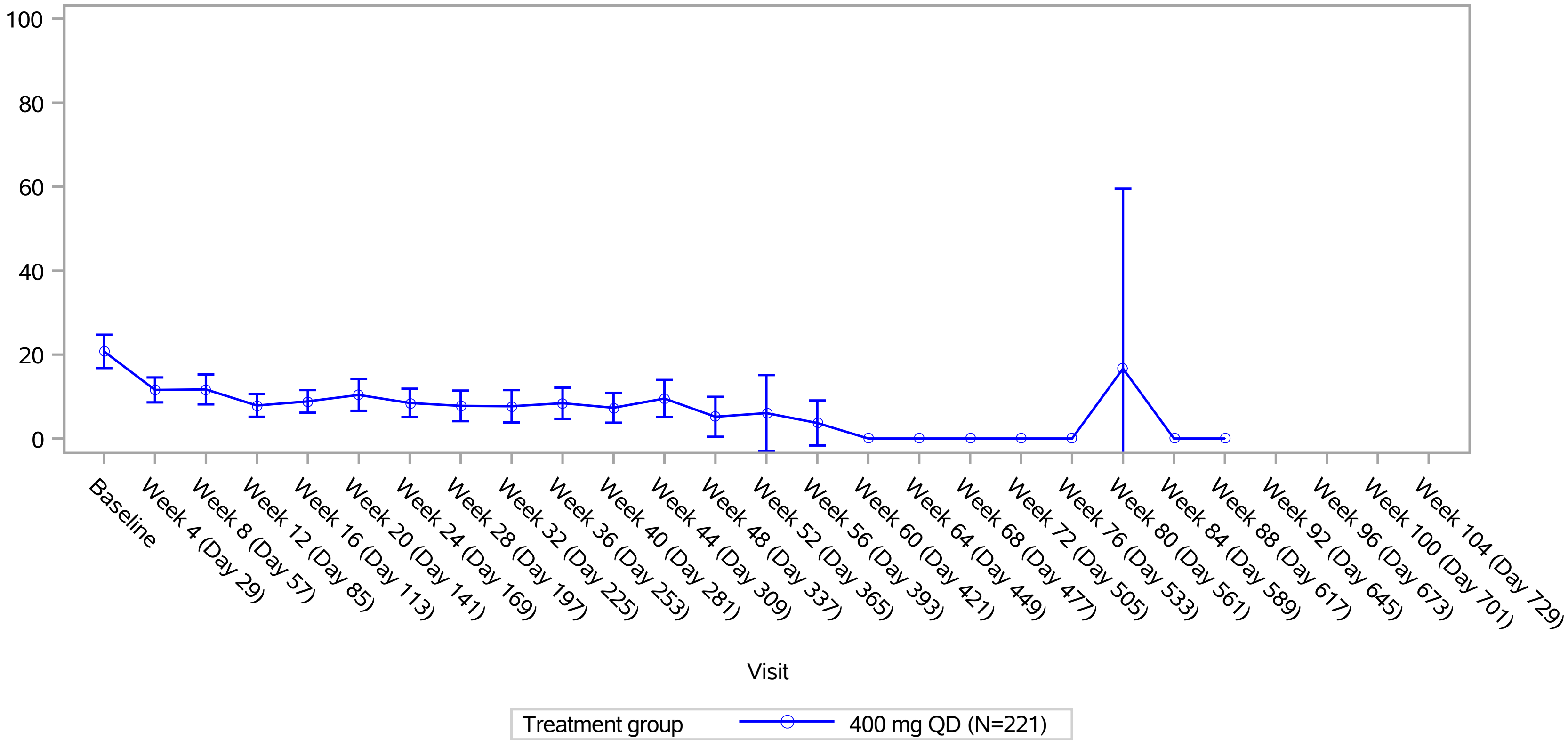
			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	64	30.2	24.4	36.7
	Cycle 12 (LOCF)	n/a	212	95.9	27	12.7	8.9	17.9
	End of Study (LOCF)	n/a	212	95.9	24	11.3	7.7	16.3
Sex	All visits	Female	123	55.7	42	34.1	26.4	42.9
		Male	89	40.3	22	24.7	16.9	34.6
	Cycle 12 (LOCF)	Female	123	55.7	17	13.8	8.8	21.0
		Male	89	40.3	10	11.2	6.2	19.5
	End of Study (LOCF)	Female	123	55.7	14	11.4	6.9	18.2
		Male	89	40.3	10	11.2	6.2	19.5
Age	All visits	< 65	133	60.2	38	28.6	21.6	36.8
		>= 65	79	35.7	26	32.9	23.6	43.9
	Cycle 12 (LOCF)	< 65	133	60.2	15	11.3	7.0	17.8
		>= 65	79	35.7	12	15.2	8.9	24.7
	End of Study (LOCF)	< 65	133	60.2	12	9.0	5.2	15.1
		>= 65	79	35.7	12	15.2	8.9	24.7
ECOG performance status	All visits	0	60	27.1	23	38.3	27.1	51.0
		1	151	68.3	41	27.2	20.7	34.7
		Missing	1	0.5	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	60	27.1	11	18.3	10.6	29.9
		1	151	68.3	16	10.6	6.6	16.5
		Missing	1	0.5	0	0.0	0.0	79.3
	End of Study (LOCF)	0	60	27.1	9	15.0	8.1	26.1
		1	151	68.3	15	9.9	6.1	15.7
		Missing	1	0.5	0	0.0	0.0	79.3
Geographic region	All visits	USA	41	18.6	9	22.0	12.0	36.7
		Europe (EU)	69	31.2	26	37.7	27.2	49.5
		Asia (AS)	102	46.2	29	28.4	20.6	37.8
	Cycle 12 (LOCF)	USA	41	18.6	2	4.9	1.3	16.1
		Europe (EU)	69	31.2	13	18.8	11.4	29.6
		Asia (AS)	102	46.2	12	11.8	6.9	19.4
	End of Study (LOCF)	USA	41	18.6	1	2.4	0.4	12.6
		Europe (EU)	69	31.2	11	15.9	9.1	26.3
		Asia (AS)	102	46.2	12	11.8	6.9	19.4
Race/ethnicity	All visits	Asian	106	48.0	30	28.3	20.6	37.5
		Non-Asian	96	43.4	32	33.3	24.7	43.2
		Unknown	10	4.5	2	20.0	5.7	51.0
	Cycle 12 (LOCF)	Asian	106	48.0	12	11.3	6.6	18.8

		Non-Asian	96	43.4	14	14.6	8.9	23.0
		Unknown	10	4.5	1	10.0	1.8	40.4
	End of Study (LOCF)	Asian	106	48.0	12	11.3	6.6	18.8
		Non-Asian	96	43.4	11	11.5	6.5	19.4
		Unknown	10	4.5	1	10.0	1.8	40.4

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30AP_W15_SG.xls
15OCT2021 12:39

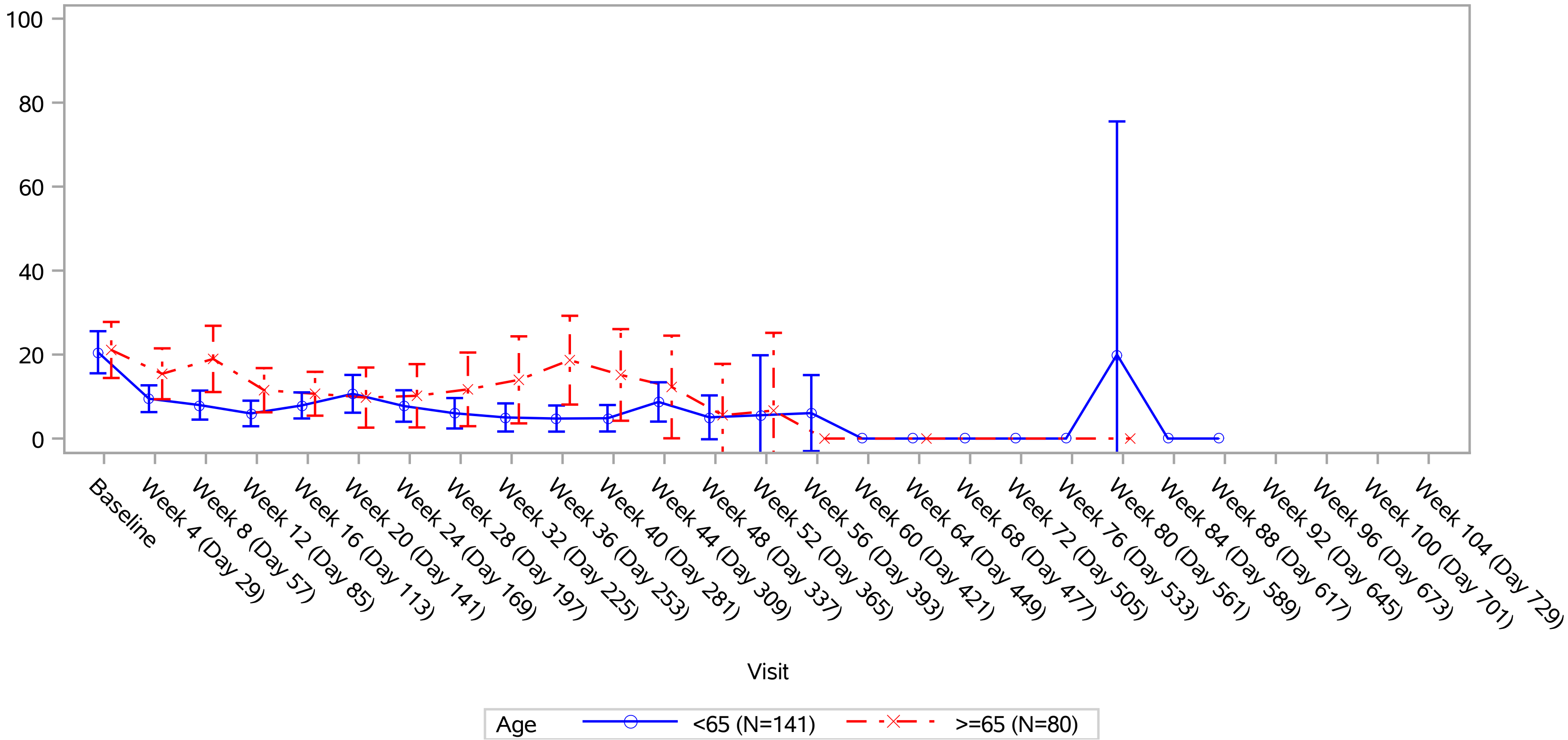
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Appetite Loss
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30AP.pdf
15OCT2021 17:02

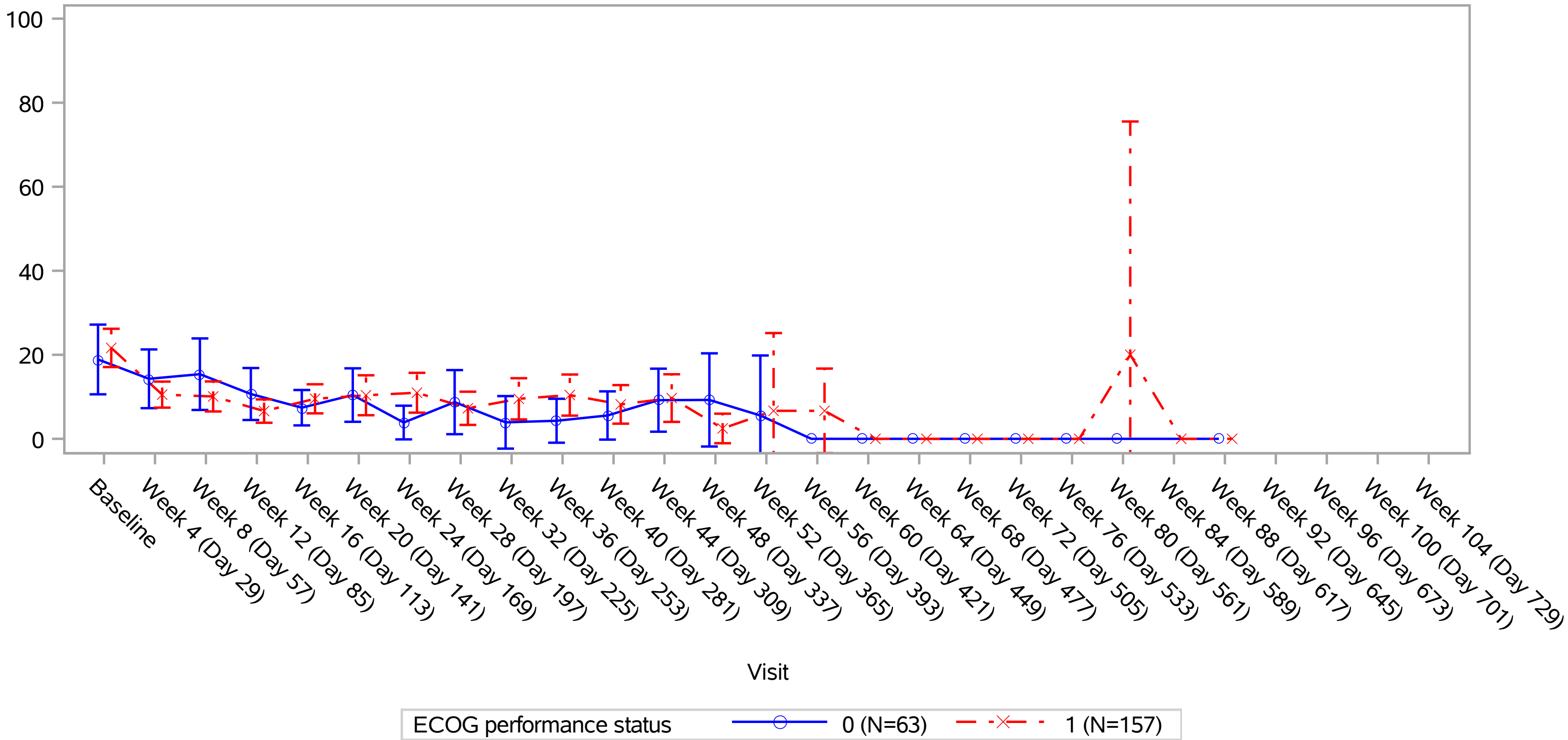
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Appetite Loss
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30AP_SGAGE65.pdf
15OCT2021 17:31

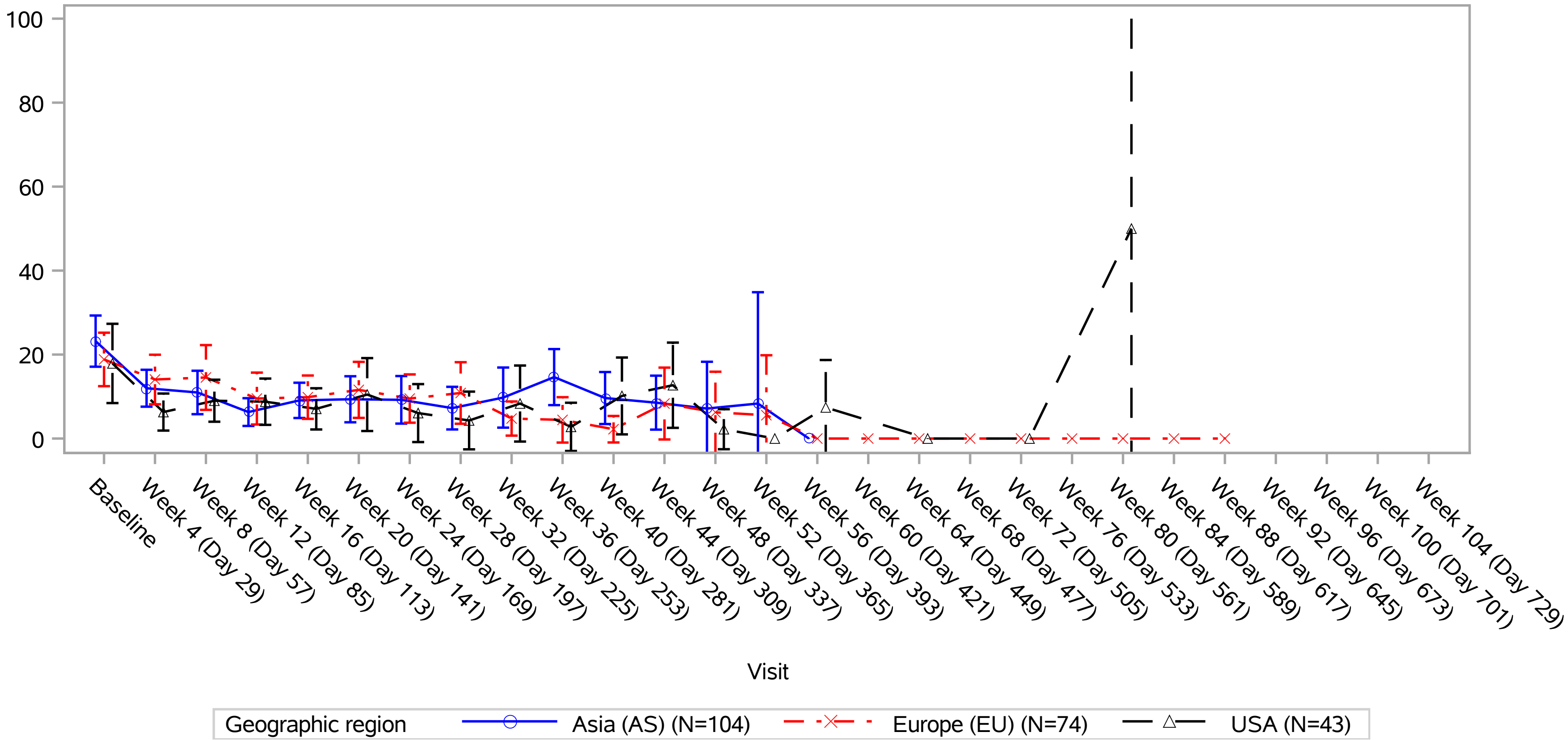
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Appetite Loss
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30AP_SGECOG.pdf
15OCT2021 18:01

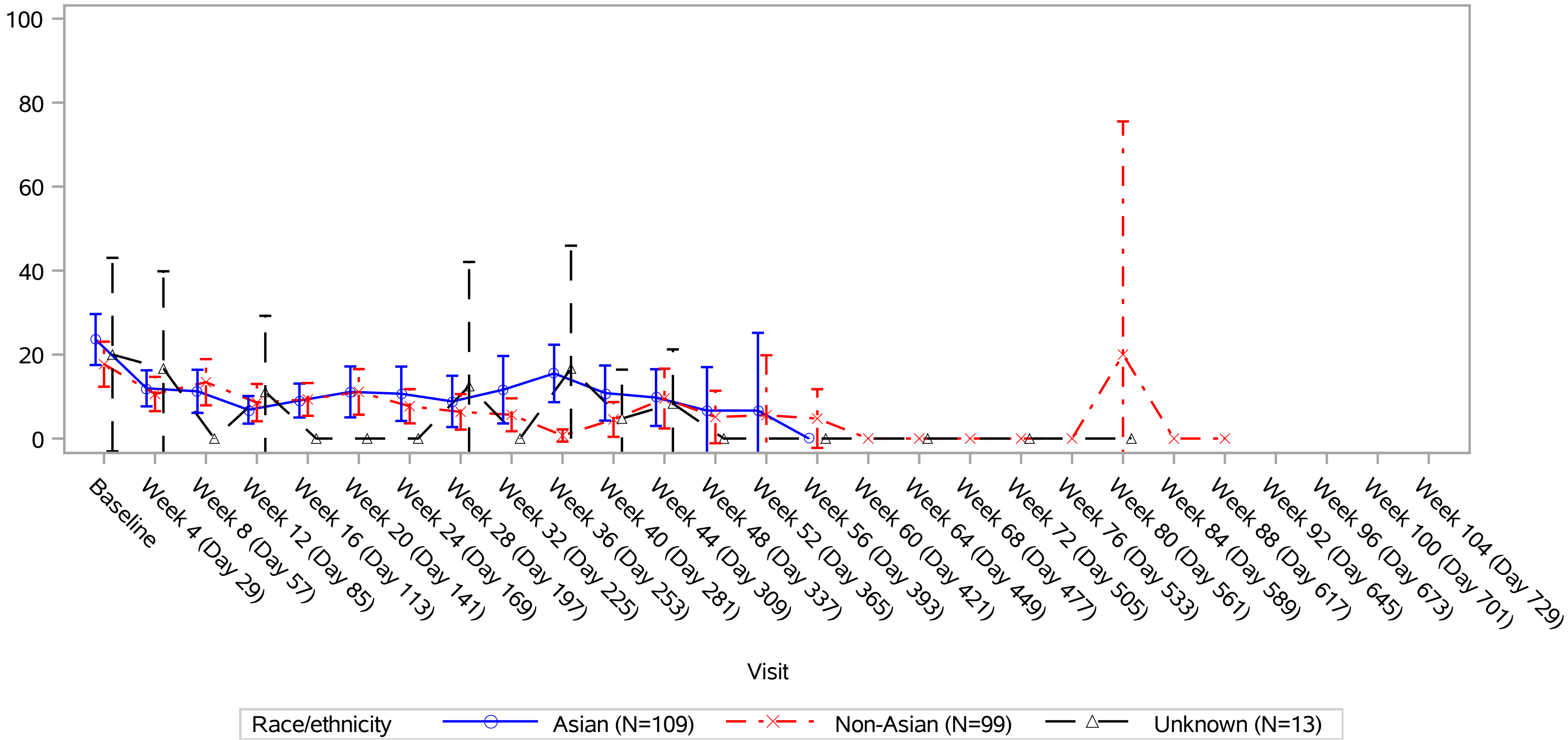
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Appetite Loss
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30AP_SGGEO.pdf
15OCT2021 18:32

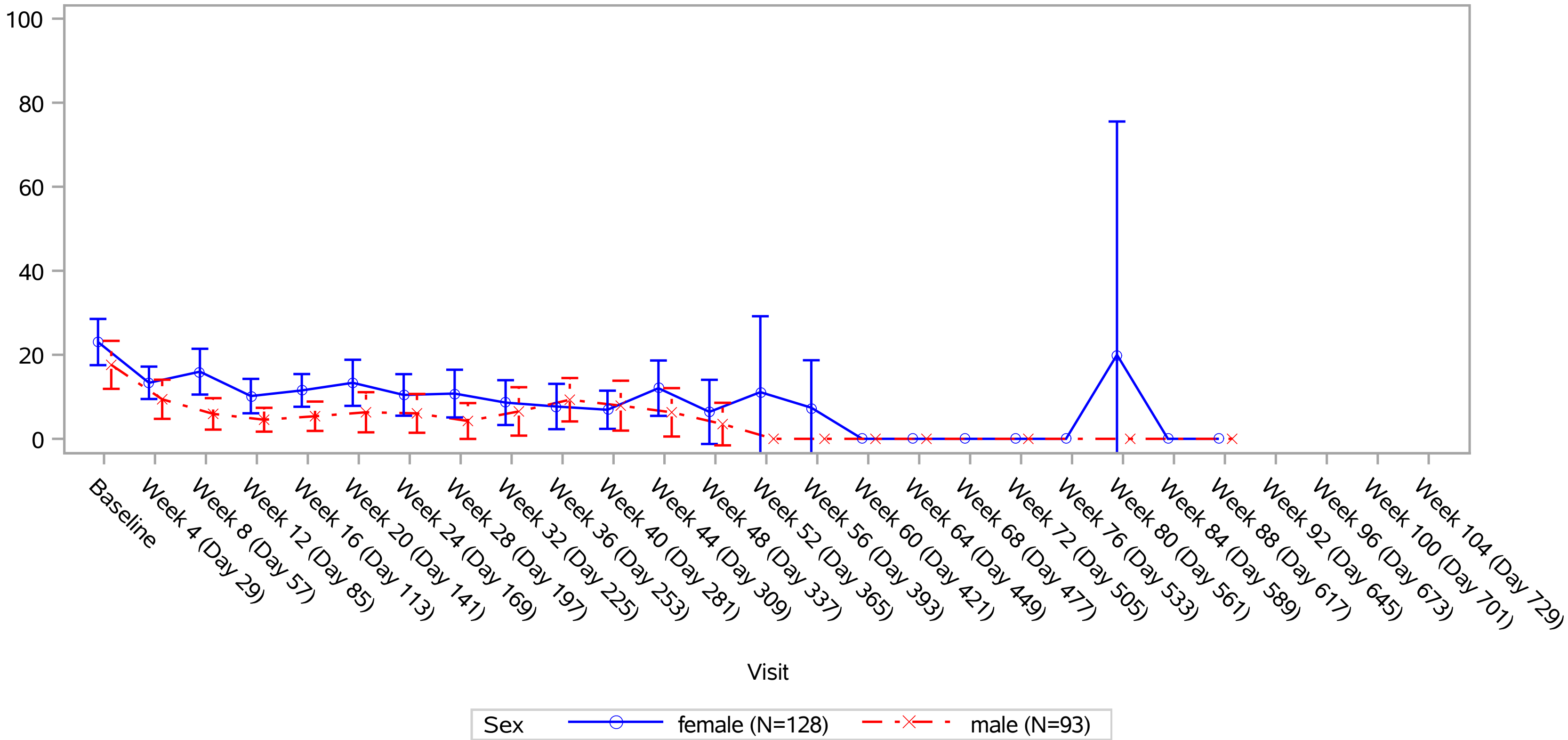
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Appetite Loss
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30AP_SGRE.pdf
15OCT2021 19:02

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Appetite Loss
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30AP_SGSEX.pdf
15OCT2021 19:33

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Cognitive functioning
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=221)							
		Patients				Statistics			
Name Visit	Level	in study¹	%	with value¹	%	mean²	SD	CI LL	CI UL
All									
Baseline	n/a	221	100.0	212	95.9	87.74	19.10	85.15	90.32
Week 4 (Day 29)	n/a	221	100.0	191	86.4	90.14	17.61	87.63	92.65
Week 8 (Day 57)	n/a	193	87.3	171	88.6	91.23	15.48	88.89	93.56
Week 12 (Day 85)	n/a	176	79.6	160	90.9	89.90	14.61	87.61	92.18
Week 16 (Day 113)	n/a	164	74.2	143	87.2	88.58	15.63	85.99	91.16
Week 20 (Day 141)	n/a	148	67.0	138	93.2	89.73	16.77	86.91	92.56
Week 24 (Day 169)	n/a	137	62.0	122	89.1	90.44	14.52	87.83	93.04
Week 28 (Day 197)	n/a	129	58.4	120	93.0	89.58	16.03	86.69	92.48
Week 32 (Day 225)	n/a	119	53.8	104	87.4	89.10	18.25	85.55	92.65
Week 36 (Day 253)	n/a	112	50.7	95	84.8	87.89	19.67	83.89	91.90
Week 40 (Day 281)	n/a	104	47.1	91	87.5	88.10	19.76	83.98	92.21
Week 44 (Day 309)	n/a	95	43.0	84	88.4	86.71	21.61	82.02	91.40
Week 48 (Day 337)	n/a	81	36.7	45	55.6	85.93	21.60	79.44	92.42
Week 52 (Day 365)	n/a	64	29.0	11	17.2	96.97	6.74	92.44	101.50
Week 56 (Day 393)	n/a	54	24.4	18	33.3	86.11	18.30	77.01	95.21
Week 60 (Day 421)	n/a	43	19.5	2	4.7	100.00	0.00	NE	NE
Week 64 (Day 449)	n/a	41	18.6	12	29.3	90.28	13.22	81.88	98.67
Week 68 (Day 477)	n/a	34	15.4	2	5.9	91.67	11.79	-14.22	197.55
Week 72 (Day 505)	n/a	34	15.4	5	14.7	100.00	0.00	NE	NE
Week 76 (Day 533)	n/a	31	14.0	3	9.7	100.00	0.00	NE	NE
Week 80 (Day 561)	n/a	30	13.6	6	20.0	75.00	31.18	42.28	107.72
Week 84 (Day 589)	n/a	19	8.6	1	5.3	100.00	NE	NE	NE
Week 88 (Day 617)	n/a	15	6.8	2	13.3	100.00	0.00	NE	NE
Week 92 (Day 645)	n/a	8	3.6	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	2.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	1.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	221	100.0	219	99.1	87.14	19.04	84.60	89.67
End of Study (LOCF)	n/a	221	100.0	219	99.1	87.14	18.22	84.71	89.57
Sex									
Baseline	Female	128	100.0	123	96.1	86.18	21.52	82.34	90.02
Week 4 (Day 29)	Female	128	100.0	106	82.8	91.35	16.46	88.18	94.52
Week 8 (Day 57)	Female	112	87.5	98	87.5	90.14	16.89	86.75	93.52
Week 12 (Day 85)	Female	104	81.3	94	90.4	89.01	15.37	85.86	92.16
Week 16 (Day 113)	Female	96	75.0	81	84.4	87.65	15.54	84.22	91.09
Week 20 (Day 141)	Female	86	67.2	80	93.0	90.21	18.12	86.18	94.24
Week 24 (Day 169)	Female	78	60.9	67	85.9	90.55	14.86	86.92	94.17
Week 28 (Day 197)	Female	72	56.3	65	90.3	87.95	17.56	83.60	92.30
Week 32 (Day 225)	Female	69	53.9	58	84.1	87.64	18.88	82.68	92.61
Week 36 (Day 253)	Female	64	50.0	52	81.3	85.58	21.90	79.48	91.67
Week 40 (Day 281)	Female	59	46.1	53	89.8	86.79	20.24	81.21	92.37
Week 44 (Day 309)	Female	56	43.8	47	83.9	85.82	22.78	79.13	92.50
Week 48 (Day 337)	Female	48	37.5	26	54.2	85.90	22.95	76.63	95.17
Week 52 (Day 365)	Female	38	29.7	6	15.8	97.22	6.80	90.08	104.36
Week 56 (Day 393)	Female	31	24.2	9	29.0	87.04	23.24	69.17	104.90
Week 60 (Day 421)	Female	27	21.1	1	3.7	100.00	NE	NE	NE
Week 64 (Day 449)	Female	26	20.3	8	30.8	93.75	8.63	86.54	100.96
Week 68 (Day 477)	Female	23	18.0	2	8.7	91.67	11.79	-14.22	197.55
Week 72 (Day 505)	Female	23	18.0	3	13.0	100.00	0.00	NE	NE
Week 76 (Day 533)	Female	21	16.4	3	14.3	100.00	0.00	NE	NE
Week 80 (Day 561)	Female	20	15.6	5	25.0	70.00	32.06	30.19	109.81
Week 84 (Day 589)	Female	12	9.4	1	8.3	100.00	NE	NE	NE
Week 88 (Day 617)	Female	9	7.0	1	11.1	100.00	NE	NE	NE
Week 92 (Day 645)	Female	6	4.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	3.9	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	1.6	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	0.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	128	100.0	127	99.2	86.35	19.41	82.94	89.76
End of Study (LOCF)	Female	128	100.0	127	99.2	86.48	19.10	83.13	89.84
Baseline	Male	93	100.0	89	95.7	89.89	15.00	86.73	93.05
Week 4 (Day 29)	Male	93	100.0	85	91.4	88.63	18.94	84.54	92.71
Week 8 (Day 57)	Male	81	87.1	73	90.1	92.69	13.32	89.59	95.80
Week 12 (Day 85)	Male	72	77.4	66	91.7	91.16	13.47	87.85	94.47
Week 16 (Day 113)	Male	68	73.1	62	91.2	89.78	15.78	85.78	93.79
Week 20 (Day 141)	Male	62	66.7	58	93.5	89.08	14.83	85.18	92.98
Week 24 (Day 169)	Male	59	63.4	55	93.2	90.30	14.23	86.46	94.15
Week 28 (Day 197)	Male	57	61.3	55	96.5	91.52	13.93	87.75	95.28
Week 32 (Day 225)	Male	50	53.8	46	92.0	90.94	17.46	85.76	96.13
Week 36 (Day 253)	Male	48	51.6	43	89.6	90.70	16.39	85.65	95.74
Week 40 (Day 281)	Male	45	48.4	38	84.4	89.91	19.20	83.60	96.22
Week 44 (Day 309)	Male	39	41.9	37	94.9	87.84	20.28	81.08	94.60
Week 48 (Day 337)	Male	33	35.5	19	57.6	85.96	20.23	76.21	95.72
Week 52 (Day 365)	Male	26	28.0	5	19.2	96.67	7.45	87.41	105.92
Week 56 (Day 393)	Male	23	24.7	9	39.1	85.19	13.03	75.17	95.20
Week 60 (Day 421)	Male	16	17.2	1	6.3	100.00	NE	NE	NE
Week 64 (Day 449)	Male	15	16.1	4	26.7	83.33	19.25	52.71	113.96
Week 68 (Day 477)	Male	11	11.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	11	11.8	2	18.2	100.00	0.00	NE	NE
Week 76 (Day 533)	Male	10	10.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	10	10.8	1	10.0	100.00	NE	NE	NE
Week 84 (Day 589)	Male	7	7.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	6	6.5	1	16.7	100.00	NE	NE	NE
Week 92 (Day 645)	Male	2	2.2	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	93	100.0	92	98.9	88.22	18.58	84.38	92.07
End of Study (LOCF)	Male	93	100.0	92	98.9	88.04	17.00	84.52	91.56
Age									

Baseline	< 65	141	100.0	133	94.3	88.72	18.07	85.62	91.82
Week 4 (Day 29)	< 65	141	100.0	123	87.2	91.87	16.58	88.91	94.83
Week 8 (Day 57)	< 65	127	90.1	113	89.0	92.33	13.74	89.77	94.89
Week 12 (Day 85)	< 65	118	83.7	105	89.0	92.06	13.09	89.53	94.60
Week 16 (Day 113)	< 65	108	76.6	93	86.1	90.32	15.01	87.23	93.41
Week 20 (Day 141)	< 65	100	70.9	97	97.0	90.55	15.76	87.37	93.73
Week 24 (Day 169)	< 65	93	66.0	86	92.5	91.28	14.17	88.24	94.32
Week 28 (Day 197)	< 65	88	62.4	83	94.3	90.76	14.55	87.59	93.94
Week 32 (Day 225)	< 65	83	58.9	73	88.0	91.32	17.37	87.27	95.38
Week 36 (Day 253)	< 65	78	55.3	70	89.7	90.00	17.81	85.75	94.25
Week 40 (Day 281)	< 65	75	53.2	69	92.0	89.61	19.20	85.00	94.22
Week 44 (Day 309)	< 65	71	50.4	65	91.5	89.23	20.50	84.15	94.31
Week 48 (Day 337)	< 65	61	43.3	33	54.1	88.89	18.48	82.34	95.44
Week 52 (Day 365)	< 65	48	34.0	6	12.5	97.22	6.80	90.08	104.36
Week 56 (Day 393)	< 65	41	29.1	11	26.8	83.33	21.08	69.17	97.50
Week 60 (Day 421)	< 65	33	23.4	2	6.1	100.00	0.00	NE	NE
Week 64 (Day 449)	< 65	31	22.0	10	32.3	90.00	14.05	79.95	100.05
Week 68 (Day 477)	< 65	26	18.4	2	7.7	91.67	11.79	-14.22	197.55
Week 72 (Day 505)	< 65	26	18.4	5	19.2	100.00	0.00	NE	NE
Week 76 (Day 533)	< 65	25	17.7	3	12.0	100.00	0.00	NE	NE
Week 80 (Day 561)	< 65	24	17.0	5	20.8	73.33	34.56	30.42	116.25
Week 84 (Day 589)	< 65	16	11.3	1	6.3	100.00	NE	NE	NE
Week 88 (Day 617)	< 65	13	9.2	2	15.4	100.00	0.00	NE	NE
Week 92 (Day 645)	< 65	7	5.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	3.5	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	2.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	0.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	141	100.0	139	98.6	89.21	18.26	86.15	92.27
End of Study (LOCF)	< 65	141	100.0	139	98.6	89.33	16.91	86.49	92.16
Baseline	>= 65	80	100.0	79	98.8	86.08	20.75	81.43	90.72
Week 4 (Day 29)	>= 65	80	100.0	68	85.0	87.01	19.07	82.39	91.63
Week 8 (Day 57)	>= 65	66	82.5	58	87.9	89.08	18.35	84.26	93.91
Week 12 (Day 85)	>= 65	58	72.5	55	94.8	85.76	16.49	81.30	90.21

Week 16 (Day 113)	>= 65	56	70.0	50	89.3	85.33	16.37	80.68	89.99
Week 20 (Day 141)	>= 65	48	60.0	41	85.4	87.80	19.01	81.80	93.81
Week 24 (Day 169)	>= 65	44	55.0	36	81.8	88.43	15.34	83.24	93.62
Week 28 (Day 197)	>= 65	41	51.3	37	90.2	86.94	18.90	80.64	93.24
Week 32 (Day 225)	>= 65	36	45.0	31	86.1	83.87	19.48	76.73	91.01
Week 36 (Day 253)	>= 65	34	42.5	25	73.5	82.00	23.53	72.29	91.71
Week 40 (Day 281)	>= 65	29	36.3	22	75.9	83.33	21.21	73.93	92.74
Week 44 (Day 309)	>= 65	24	30.0	19	79.2	78.07	23.60	66.69	89.45
Week 48 (Day 337)	>= 65	20	25.0	12	60.0	77.78	27.83	60.10	95.46
Week 52 (Day 365)	>= 65	16	20.0	5	31.3	96.67	7.45	87.41	105.92
Week 56 (Day 393)	>= 65	13	16.3	7	53.8	90.48	13.11	78.35	102.60
Week 60 (Day 421)	>= 65	10	12.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	10	12.5	2	20.0	91.67	11.79	-14.22	197.55
Week 68 (Day 477)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	6	7.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	6	7.5	1	16.7	83.33	NE	NE	NE
Week 84 (Day 589)	>= 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	2.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	80	100.0	80	100.0	83.54	19.93	79.11	87.98
End of Study (LOCF)	>= 65	80	100.0	80	100.0	83.33	19.84	78.92	87.75
ECOG performance status									
Baseline	0	63	100.0	60	95.2	87.50	22.05	81.80	93.20
Week 4 (Day 29)	0	63	100.0	56	88.9	90.77	19.83	85.46	96.08
Week 8 (Day 57)	0	58	92.1	52	89.7	91.03	16.98	86.30	95.75
Week 12 (Day 85)	0	55	87.3	49	89.1	90.82	16.69	86.02	95.61
Week 16 (Day 113)	0	54	85.7	45	83.3	91.11	14.91	86.63	95.59
Week 20 (Day 141)	0	52	82.5	48	92.3	90.28	19.40	84.65	95.91
Week 24 (Day 169)	0	49	77.8	43	87.8	91.86	14.72	87.33	96.39
Week 28 (Day 197)	0	46	73.0	42	91.3	91.67	16.15	86.63	96.70

Week 32 (Day 225)	0	41	65.1	34	82.9	92.16	17.03	86.21	98.10
Week 36 (Day 253)	0	39	61.9	31	79.5	90.32	21.42	82.47	98.18
Week 40 (Day 281)	0	37	58.7	30	81.1	88.89	21.14	80.99	96.78
Week 44 (Day 309)	0	36	57.1	29	80.6	86.21	24.43	76.92	95.50
Week 48 (Day 337)	0	28	44.4	18	64.3	87.04	26.54	73.84	100.24
Week 52 (Day 365)	0	27	42.9	6	22.2	97.22	6.80	90.08	104.36
Week 56 (Day 393)	0	24	38.1	8	33.3	87.50	14.77	75.15	99.85
Week 60 (Day 421)	0	21	33.3	1	4.8	100.00	NE	NE	NE
Week 64 (Day 449)	0	21	33.3	7	33.3	90.48	16.27	75.43	105.52
Week 68 (Day 477)	0	17	27.0	1	5.9	100.00	NE	NE	NE
Week 72 (Day 505)	0	17	27.0	2	11.8	100.00	0.00	NE	NE
Week 76 (Day 533)	0	15	23.8	2	13.3	100.00	0.00	NE	NE
Week 80 (Day 561)	0	14	22.2	1	7.1	83.33	NE	NE	NE
Week 84 (Day 589)	0	11	17.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	10	15.9	1	10.0	100.00	NE	NE	NE
Week 92 (Day 645)	0	5	7.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	6.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	4.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	63	100.0	63	100.0	87.57	22.19	81.98	93.16
End of Study (LOCF)	0	63	100.0	63	100.0	87.83	21.00	82.54	93.12
Baseline	1	157	100.0	151	96.2	87.75	17.92	84.87	90.63
Week 4 (Day 29)	1	157	100.0	134	85.4	89.80	16.72	86.94	92.66
Week 8 (Day 57)	1	134	85.4	119	88.8	91.32	14.85	88.62	94.01
Week 12 (Day 85)	1	121	77.1	111	91.7	89.49	13.66	86.92	92.06
Week 16 (Day 113)	1	110	70.1	98	89.1	87.41	15.89	84.23	90.60
Week 20 (Day 141)	1	96	61.1	90	93.8	89.44	15.29	86.24	92.65
Week 24 (Day 169)	1	88	56.1	79	89.8	89.66	14.45	86.43	92.90
Week 28 (Day 197)	1	83	52.9	78	94.0	88.46	15.96	84.86	92.06
Week 32 (Day 225)	1	78	49.7	70	89.7	87.62	18.75	83.15	92.09
Week 36 (Day 253)	1	73	46.5	64	87.7	86.72	18.82	82.02	91.42
Week 40 (Day 281)	1	67	42.7	61	91.0	87.70	19.22	82.78	92.63

Week 44 (Day 309)	1	59	37.6	55	93.2	86.97	20.21	81.51	92.43
Week 48 (Day 337)	1	53	33.8	27	50.9	85.19	18.10	78.02	92.35
Week 52 (Day 365)	1	37	23.6	5	13.5	96.67	7.45	87.41	105.92
Week 56 (Day 393)	1	30	19.1	10	33.3	85.00	21.44	69.66	100.34
Week 60 (Day 421)	1	22	14.0	1	4.5	100.00	NE	NE	NE
Week 64 (Day 449)	1	20	12.7	5	25.0	90.00	9.13	78.67	101.33
Week 68 (Day 477)	1	17	10.8	1	5.9	83.33	NE	NE	NE
Week 72 (Day 505)	1	17	10.8	3	17.6	100.00	0.00	NE	NE
Week 76 (Day 533)	1	16	10.2	1	6.3	100.00	NE	NE	NE
Week 80 (Day 561)	1	16	10.2	5	31.3	73.33	34.56	30.42	116.25
Week 84 (Day 589)	1	8	5.1	1	12.5	100.00	NE	NE	NE
Week 88 (Day 617)	1	5	3.2	1	20.0	100.00	NE	NE	NE
Week 92 (Day 645)	1	3	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	157	100.0	155	98.7	86.88	17.71	84.07	89.69
End of Study (LOCF)	1	157	100.0	155	98.7	86.77	17.06	84.07	89.48
Baseline	Missing	1	100.0	1	100.0	100.00	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	100.00	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	100.00	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	100.00	NE	NE	NE
Geographic region									
Baseline	USA	43	100.0	41	95.3	91.87	11.86	88.13	95.61
Week 4 (Day 29)	USA	43	100.0	38	88.4	88.16	18.55	82.06	94.25
Week 8 (Day 57)	USA	41	95.3	37	90.2	90.09	13.87	85.47	94.71
Week 12 (Day 85)	USA	41	95.3	37	90.2	88.74	13.64	84.19	93.29
Week 16 (Day 113)	USA	40	93.0	33	82.5	86.87	16.01	81.19	92.54
Week 20 (Day 141)	USA	39	90.7	35	89.7	90.00	16.27	84.41	95.59
Week 24 (Day 169)	USA	36	83.7	33	91.7	90.40	14.45	85.28	95.53
Week 28 (Day 197)	USA	35	81.4	31	88.6	90.32	16.54	84.26	96.39
Week 32 (Day 225)	USA	32	74.4	28	87.5	86.31	23.59	77.16	95.46
Week 36 (Day 253)	USA	32	74.4	24	75.0	84.72	21.93	75.46	93.98
Week 40 (Day 281)	USA	29	67.4	23	79.3	87.68	21.45	78.41	96.96

Week 44 (Day 309)	USA	26	60.5	21	80.8	84.92	24.67	73.69	96.15
Week 48 (Day 337)	USA	21	48.8	15	71.4	85.56	22.60	73.04	98.07
Week 52 (Day 365)	USA	18	41.9	1	5.6	100.00	NE	NE	NE
Week 56 (Day 393)	USA	18	41.9	9	50.0	85.19	22.74	67.71	102.66
Week 60 (Day 421)	USA	17	39.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	15	34.9	5	33.3	93.33	9.13	82.00	104.67
Week 68 (Day 477)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	12	27.9	1	8.3	100.00	NE	NE	NE
Week 76 (Day 533)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	12	27.9	2	16.7	50.00	47.14	-373.54	473.54
Week 84 (Day 589)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	6	14.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	11.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	7.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	43	100.0	43	100.0	87.21	20.20	80.99	93.42
End of Study (LOCF)	USA	43	100.0	43	100.0	86.82	19.44	80.84	92.80
Baseline	Europe (EU)	74	100.0	69	93.2	84.54	20.87	79.53	89.55
Week 4 (Day 29)	Europe (EU)	74	100.0	64	86.5	90.89	17.80	86.44	95.33
Week 8 (Day 57)	Europe (EU)	65	87.8	55	84.6	90.61	15.30	86.47	94.74
Week 12 (Day 85)	Europe (EU)	57	77.0	49	86.0	89.46	15.85	84.90	94.01
Week 16 (Day 113)	Europe (EU)	55	74.3	44	80.0	87.88	16.22	82.95	92.81
Week 20 (Day 141)	Europe (EU)	49	66.2	46	93.9	89.49	16.61	84.56	94.43
Week 24 (Day 169)	Europe (EU)	47	63.5	42	89.4	89.68	16.44	84.56	94.81
Week 28 (Day 197)	Europe (EU)	45	60.8	43	95.6	88.37	14.79	83.82	92.92
Week 32 (Day 225)	Europe (EU)	39	52.7	35	89.7	93.81	10.76	90.11	97.51
Week 36 (Day 253)	Europe (EU)	34	45.9	30	88.2	90.56	17.33	84.08	97.03
Week 40 (Day 281)	Europe (EU)	31	41.9	30	96.8	88.33	20.60	80.64	96.03
Week 44 (Day 309)	Europe (EU)	28	37.8	24	85.7	88.19	21.69	79.04	97.35

Week 48 (Day 337)	Europe (EU)	22	29.7	16	72.7	88.54	16.91	79.53	97.55
Week 52 (Day 365)	Europe (EU)	19	25.7	6	31.6	97.22	6.80	90.08	104.36
Week 56 (Day 393)	Europe (EU)	17	23.0	7	41.2	88.10	15.85	73.43	102.76
Week 60 (Day 421)	Europe (EU)	15	20.3	2	13.3	100.00	0.00	NE	NE
Week 64 (Day 449)	Europe (EU)	15	20.3	7	46.7	88.10	15.85	73.43	102.76
Week 68 (Day 477)	Europe (EU)	13	17.6	2	15.4	91.67	11.79	-14.22	197.55
Week 72 (Day 505)	Europe (EU)	13	17.6	4	30.8	100.00	0.00	NE	NE
Week 76 (Day 533)	Europe (EU)	11	14.9	3	27.3	100.00	0.00	NE	NE
Week 80 (Day 561)	Europe (EU)	10	13.5	4	40.0	87.50	15.96	62.11	112.89
Week 84 (Day 589)	Europe (EU)	6	8.1	1	16.7	100.00	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	4.1	2	66.7	100.00	0.00	NE	NE
Cycle 12 (LOCF)	Europe (EU)	74	100.0	73	98.6	86.76	19.44	82.22	91.29
End of Study (LOCF)	Europe (EU)	74	100.0	73	98.6	86.99	17.40	82.93	91.05
Baseline	Asia (AS)	104	100.0	102	98.1	88.24	19.98	84.31	92.16
Week 4 (Day 29)	Asia (AS)	104	100.0	89	85.6	90.45	17.20	86.83	94.07
Week 8 (Day 57)	Asia (AS)	87	83.7	79	90.8	92.19	16.42	88.52	95.87
Week 12 (Day 85)	Asia (AS)	78	75.0	74	94.9	90.77	14.37	87.44	94.10
Week 16 (Day 113)	Asia (AS)	69	66.3	66	95.7	89.90	15.16	86.17	93.63
Week 20 (Day 141)	Asia (AS)	60	57.7	57	95.0	89.77	17.47	85.13	94.40
Week 24 (Day 169)	Asia (AS)	54	51.9	47	87.0	91.13	12.93	87.34	94.93
Week 28 (Day 197)	Asia (AS)	49	47.1	46	93.9	90.22	17.06	85.15	95.28
Week 32 (Day 225)	Asia (AS)	48	46.2	41	85.4	86.99	18.82	81.05	92.93
Week 36 (Day 253)	Asia (AS)	46	44.2	41	89.1	87.80	20.08	81.47	94.14
Week 40 (Day 281)	Asia (AS)	44	42.3	38	86.4	88.16	18.55	82.06	94.25
Week 44 (Day 309)	Asia (AS)	41	39.4	39	95.1	86.75	20.30	80.17	93.33
Week 48 (Day 337)	Asia (AS)	38	36.5	14	36.8	83.33	26.15	68.24	98.43
Week 52 (Day 365)	Asia (AS)	27	26.0	4	14.8	95.83	8.33	82.57	109.09
Week 56 (Day 393)	Asia (AS)	19	18.3	2	10.5	83.33	0.00	NE	NE
Week 60 (Day 421)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	5.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	104	100.0	103	99.0	87.38	18.45	83.77	90.98
End of Study (LOCF)	Asia (AS)	104	100.0	103	99.0	87.38	18.45	83.77	90.98
Race/ethnicity									
Baseline	Asian	109	100.0	106	97.2	88.36	19.68	84.58	92.15
Week 4 (Day 29)	Asian	109	100.0	92	84.4	90.58	16.99	87.06	94.10
Week 8 (Day 57)	Asian	91	83.5	80	87.9	91.87	16.56	88.19	95.56
Week 12 (Day 85)	Asian	82	75.2	78	95.1	90.38	14.34	87.15	93.62
Week 16 (Day 113)	Asian	73	67.0	70	95.9	89.76	15.09	86.16	93.36
Week 20 (Day 141)	Asian	64	58.7	60	93.8	88.89	18.07	84.22	93.56
Week 24 (Day 169)	Asian	57	52.3	50	87.7	91.00	13.13	87.27	94.73
Week 28 (Day 197)	Asian	52	47.7	49	94.2	89.80	17.62	84.74	94.86
Week 32 (Day 225)	Asian	50	45.9	43	86.0	87.21	18.49	81.52	92.90
Week 36 (Day 253)	Asian	48	44.0	43	89.6	87.60	19.95	81.46	93.74
Week 40 (Day 281)	Asian	46	42.2	40	87.0	87.92	18.49	82.00	93.83
Week 44 (Day 309)	Asian	43	39.4	41	95.3	86.59	20.15	80.23	92.94
Week 48 (Day 337)	Asian	40	36.7	15	37.5	84.44	25.56	70.29	98.60
Week 52 (Day 365)	Asian	29	26.6	5	17.2	96.67	7.45	87.41	105.92
Week 56 (Day 393)	Asian	21	19.3	3	14.3	88.89	9.62	64.99	112.79
Week 60 (Day 421)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	5.5	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	4.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	1.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	109	100.0	107	98.2	87.07	18.64	83.50	90.64
End of Study (LOCF)	Asian	109	100.0	107	98.2	87.07	18.64	83.50	90.64
Baseline	Non-Asian	99	100.0	96	97.0	87.85	18.33	84.13	91.56
Week 4 (Day 29)	Non-Asian	99	100.0	89	89.9	91.01	17.78	87.27	94.76
Week 8 (Day 57)	Non-Asian	91	91.9	82	90.1	91.06	14.63	87.84	94.27
Week 12 (Day 85)	Non-Asian	83	83.8	73	88.0	91.10	14.19	87.79	94.41
Week 16 (Day 113)	Non-Asian	80	80.8	68	85.0	87.50	16.38	83.53	91.47
Week 20 (Day 141)	Non-Asian	74	74.7	69	93.2	90.58	16.29	86.67	94.49
Week 24 (Day 169)	Non-Asian	70	70.7	65	92.9	90.77	15.60	86.90	94.63
Week 28 (Day 197)	Non-Asian	67	67.7	63	94.0	90.21	14.86	86.47	93.95
Week 32 (Day 225)	Non-Asian	60	60.6	53	88.3	90.88	18.65	85.74	96.02
Week 36 (Day 253)	Non-Asian	55	55.6	46	83.6	89.86	17.74	84.59	95.12
Week 40 (Day 281)	Non-Asian	49	49.5	44	89.8	89.02	21.25	82.56	95.48
Week 44 (Day 309)	Non-Asian	43	43.4	35	81.4	89.05	22.12	81.45	96.65
Week 48 (Day 337)	Non-Asian	35	35.4	26	74.3	86.54	20.56	78.23	94.84
Week 52 (Day 365)	Non-Asian	29	29.3	6	20.7	97.22	6.80	90.08	104.36
Week 56 (Day 393)	Non-Asian	27	27.3	14	51.9	86.90	19.81	75.47	98.34
Week 60 (Day 421)	Non-Asian	26	26.3	2	7.7	100.00	0.00	NE	NE
Week 64 (Day 449)	Non-Asian	24	24.2	9	37.5	88.89	14.43	77.79	99.98
Week 68 (Day 477)	Non-Asian	20	20.2	2	10.0	91.67	11.79	-14.22	197.55
Week 72 (Day 505)	Non-Asian	20	20.2	3	15.0	100.00	0.00	NE	NE
Week 76 (Day 533)	Non-Asian	18	18.2	3	16.7	100.00	0.00	NE	NE
Week 80 (Day 561)	Non-Asian	17	17.2	5	29.4	76.67	34.56	33.75	119.58
Week 84 (Day 589)	Non-Asian	11	11.1	1	9.1	100.00	NE	NE	NE
Week 88 (Day 617)	Non-Asian	8	8.1	2	25.0	100.00	0.00	NE	NE
Week 92 (Day 645)	Non-Asian	4	4.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	3.0	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	99	100.0	99	100.0	87.88	19.02	84.09	91.67

End of Study (LOCF)	Non-Asian	99	100.0	99	100.0	87.54	17.87	83.98	91.11
Baseline	Unknown	13	100.0	10	76.9	80.00	20.49	65.34	94.66
Week 4 (Day 29)	Unknown	13	100.0	10	76.9	78.33	19.33	64.51	92.16
Week 8 (Day 57)	Unknown	11	84.6	9	81.8	87.04	13.89	76.36	97.71
Week 12 (Day 85)	Unknown	11	84.6	9	81.8	75.93	14.70	64.63	87.22
Week 16 (Day 113)	Unknown	11	84.6	5	45.5	86.67	13.94	69.35	103.98
Week 20 (Day 141)	Unknown	10	76.9	9	90.0	88.89	11.79	79.83	97.95
Week 24 (Day 169)	Unknown	10	76.9	7	70.0	83.33	13.61	70.75	95.92
Week 28 (Day 197)	Unknown	10	76.9	8	80.0	83.33	15.43	70.43	96.23
Week 32 (Day 225)	Unknown	9	69.2	8	88.9	87.50	14.77	75.15	99.85
Week 36 (Day 253)	Unknown	9	69.2	6	66.7	75.00	29.34	44.20	105.80
Week 40 (Day 281)	Unknown	9	69.2	7	77.8	83.33	19.25	65.53	101.13
Week 44 (Day 309)	Unknown	9	69.2	8	88.9	77.08	26.63	54.82	99.35
Week 48 (Day 337)	Unknown	6	46.2	4	66.7	87.50	15.96	62.11	112.89
Week 52 (Day 365)	Unknown	6	46.2	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	6	46.2	1	16.7	66.67	NE	NE	NE
Week 60 (Day 421)	Unknown	5	38.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	5	38.5	3	60.0	94.44	9.62	70.54	118.35
Week 68 (Day 477)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	4	30.8	2	50.0	100.00	0.00	NE	NE
Week 76 (Day 533)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	4	30.8	1	25.0	66.67	NE	NE	NE
Week 84 (Day 589)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	7.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	13	100.0	13	100.0	82.05	23.04	68.13	95.97
End of Study (LOCF)	Unknown	13	100.0	13	100.0	84.62	18.59	73.38	95.85

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TO_QSC30CF_SG.xls
27OCT2021 7:11

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Cognitive functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	88	41.5	35.1	48.2
	Cycle 12 (LOCF)	n/a	212	95.9	41	19.3	14.6	25.2
	End of Study (LOCF)	n/a	212	95.9	44	20.8	15.8	26.7
Sex	All visits	Female	123	55.7	47	38.2	30.1	47.0
		Male	89	40.3	41	46.1	36.1	56.4
	Cycle 12 (LOCF)	Female	123	55.7	20	16.3	10.8	23.8
		Male	89	40.3	21	23.6	16.0	33.4
	End of Study (LOCF)	Female	123	55.7	22	17.9	12.1	25.6
		Male	89	40.3	22	24.7	16.9	34.6
Age	All visits	< 65	133	60.2	49	36.8	29.1	45.3
		>= 65	79	35.7	39	49.4	38.6	60.2
	Cycle 12 (LOCF)	< 65	133	60.2	20	15.0	10.0	22.1
		>= 65	79	35.7	21	26.6	18.1	37.2
	End of Study (LOCF)	< 65	133	60.2	23	17.3	11.8	24.6
		>= 65	79	35.7	21	26.6	18.1	37.2
ECOG performance status	All visits	0	60	27.1	26	43.3	31.6	55.9
		1	151	68.3	62	41.1	33.5	49.0
		Missing	1	0.5	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	60	27.1	10	16.7	9.3	28.0
		1	151	68.3	31	20.5	14.9	27.7
		Missing	1	0.5	0	0.0	0.0	79.3
	End of Study (LOCF)	0	60	27.1	13	21.7	13.1	33.6
		1	151	68.3	31	20.5	14.9	27.7
		Missing	1	0.5	0	0.0	0.0	79.3
Geographic region	All visits	USA	41	18.6	22	53.7	38.7	67.9
		Europe (EU)	69	31.2	29	42.0	31.1	53.8
		Asia (AS)	102	46.2	37	36.3	27.6	45.9
	Cycle 12 (LOCF)	USA	41	18.6	12	29.3	17.6	44.5
		Europe (EU)	69	31.2	10	14.5	8.1	24.7
		Asia (AS)	102	46.2	19	18.6	12.3	27.3
	End of Study (LOCF)	USA	41	18.6	12	29.3	17.6	44.5
		Europe (EU)	69	31.2	13	18.8	11.4	29.6
		Asia (AS)	102	46.2	19	18.6	12.3	27.3
Race/ethnicity	All visits	Asian	106	48.0	40	37.7	29.1	47.2
		Non-Asian	96	43.4	45	46.9	37.2	56.8
		Unknown	10	4.5	3	30.0	10.8	60.3
	Cycle 12 (LOCF)	Asian	106	48.0	21	19.8	13.3	28.4

		Non-Asian	96	43.4	18	18.8	12.2	27.7
		Unknown	10	4.5	2	20.0	5.7	51.0
	End of Study (LOCF)	Asian	106	48.0	21	19.8	13.3	28.4
		Non-Asian	96	43.4	21	21.9	14.8	31.1
		Unknown	10	4.5	2	20.0	5.7	51.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30CF_W10_SG.xls
15OCT2021 12:50

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Cognitive functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

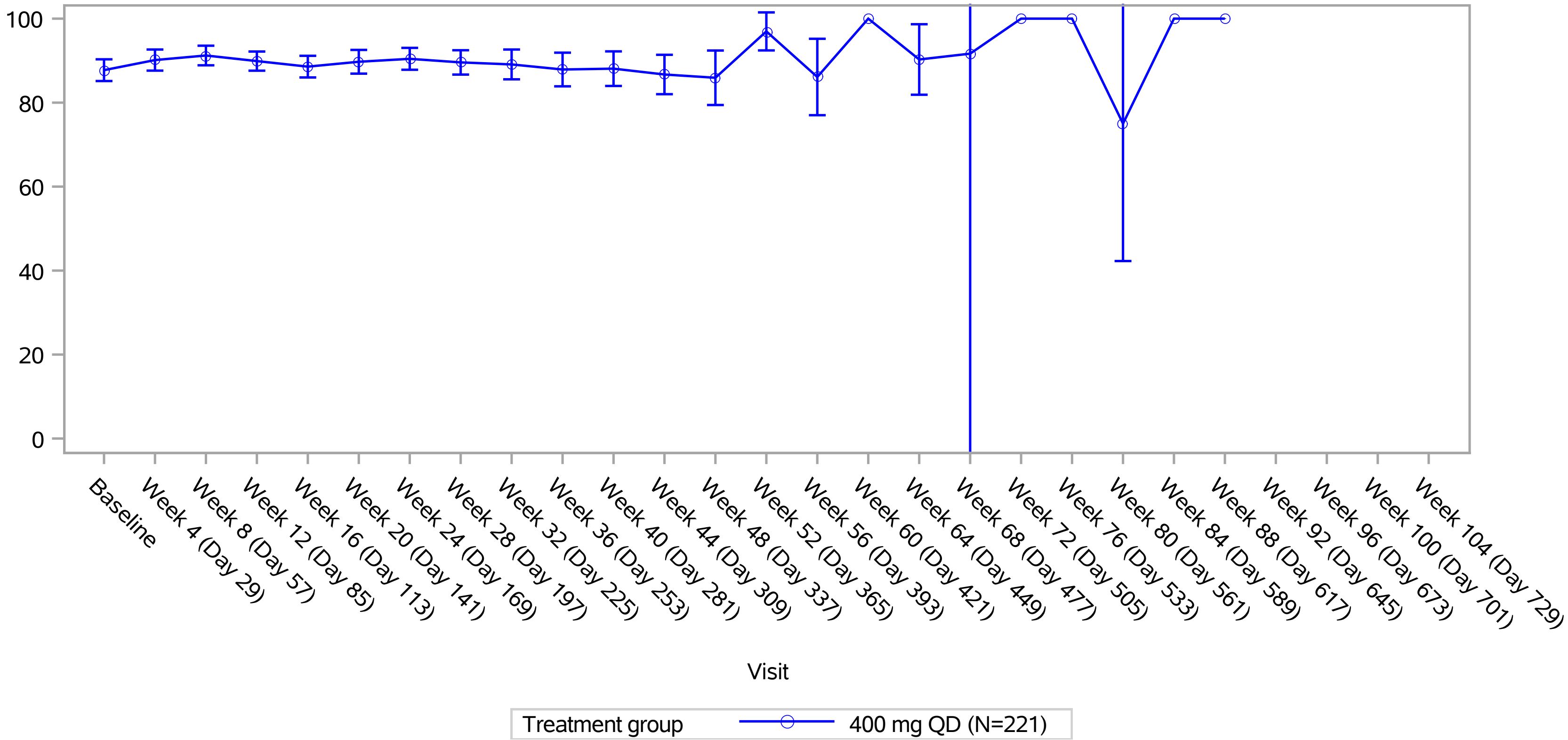
			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	88	41.5	35.1	48.2
	Cycle 12 (LOCF)	n/a	212	95.9	41	19.3	14.6	25.2
	End of Study (LOCF)	n/a	212	95.9	44	20.8	15.8	26.7
Sex	All visits	Female	123	55.7	47	38.2	30.1	47.0
		Male	89	40.3	41	46.1	36.1	56.4
	Cycle 12 (LOCF)	Female	123	55.7	20	16.3	10.8	23.8
		Male	89	40.3	21	23.6	16.0	33.4
	End of Study (LOCF)	Female	123	55.7	22	17.9	12.1	25.6
		Male	89	40.3	22	24.7	16.9	34.6
Age	All visits	< 65	133	60.2	49	36.8	29.1	45.3
		>= 65	79	35.7	39	49.4	38.6	60.2
	Cycle 12 (LOCF)	< 65	133	60.2	20	15.0	10.0	22.1
		>= 65	79	35.7	21	26.6	18.1	37.2
	End of Study (LOCF)	< 65	133	60.2	23	17.3	11.8	24.6
		>= 65	79	35.7	21	26.6	18.1	37.2
ECOG performance status	All visits	0	60	27.1	26	43.3	31.6	55.9
		1	151	68.3	62	41.1	33.5	49.0
		Missing	1	0.5	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	60	27.1	10	16.7	9.3	28.0
		1	151	68.3	31	20.5	14.9	27.7
		Missing	1	0.5	0	0.0	0.0	79.3
	End of Study (LOCF)	0	60	27.1	13	21.7	13.1	33.6
		1	151	68.3	31	20.5	14.9	27.7
		Missing	1	0.5	0	0.0	0.0	79.3
Geographic region	All visits	USA	41	18.6	22	53.7	38.7	67.9
		Europe (EU)	69	31.2	29	42.0	31.1	53.8
		Asia (AS)	102	46.2	37	36.3	27.6	45.9
	Cycle 12 (LOCF)	USA	41	18.6	12	29.3	17.6	44.5
		Europe (EU)	69	31.2	10	14.5	8.1	24.7
		Asia (AS)	102	46.2	19	18.6	12.3	27.3
	End of Study (LOCF)	USA	41	18.6	12	29.3	17.6	44.5
		Europe (EU)	69	31.2	13	18.8	11.4	29.6
		Asia (AS)	102	46.2	19	18.6	12.3	27.3
Race/ethnicity	All visits	Asian	106	48.0	40	37.7	29.1	47.2
		Non-Asian	96	43.4	45	46.9	37.2	56.8
		Unknown	10	4.5	3	30.0	10.8	60.3
	Cycle 12 (LOCF)	Asian	106	48.0	21	19.8	13.3	28.4

		Non-Asian	96	43.4	18	18.8	12.2	27.7
		Unknown	10	4.5	2	20.0	5.7	51.0
	End of Study (LOCF)	Asian	106	48.0	21	19.8	13.3	28.4
		Non-Asian	96	43.4	21	21.9	14.8	31.1
		Unknown	10	4.5	2	20.0	5.7	51.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30CF_W15_SG.xls
15OCT2021 12:40

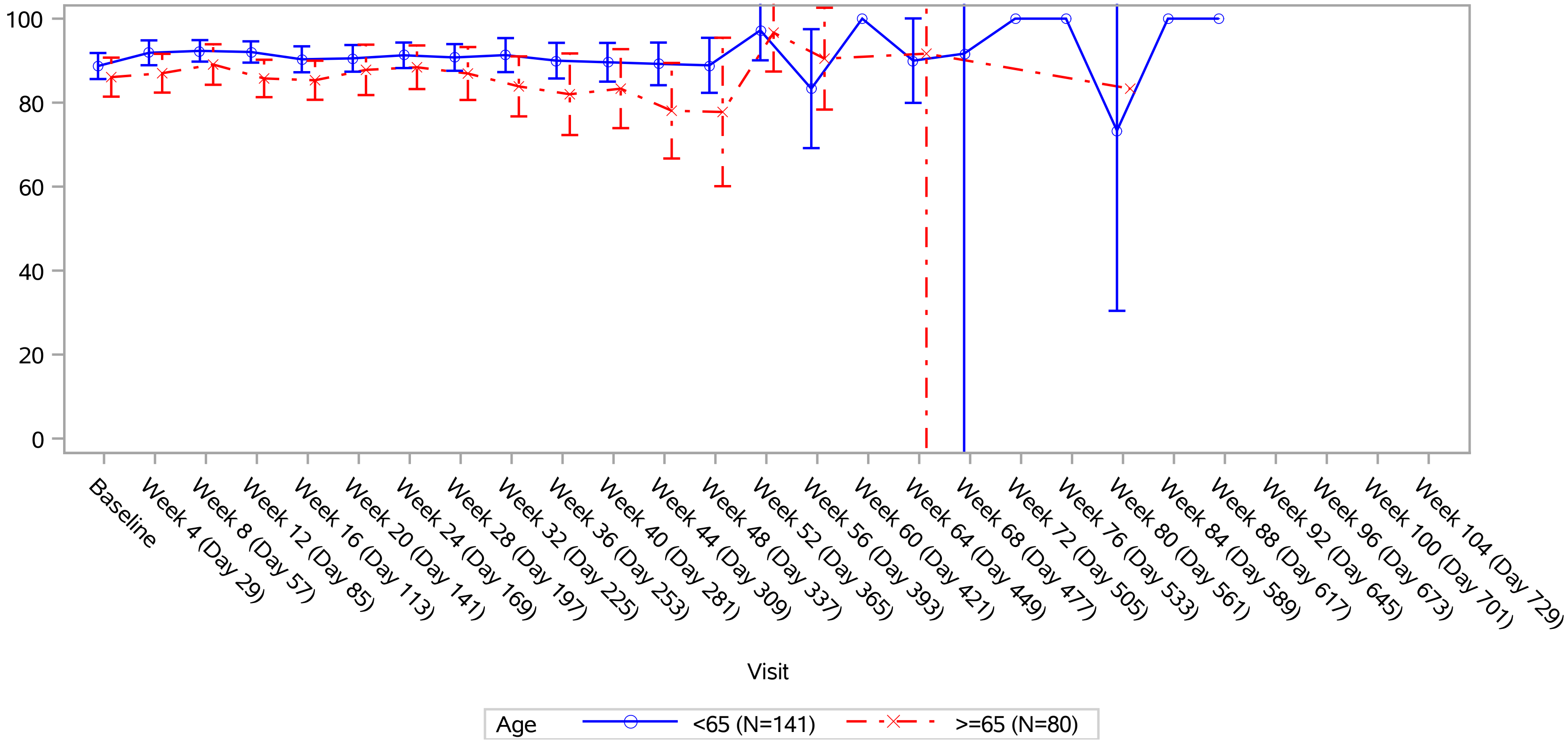
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Cognitive functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30CF.pdf
15OCT2021 17:03

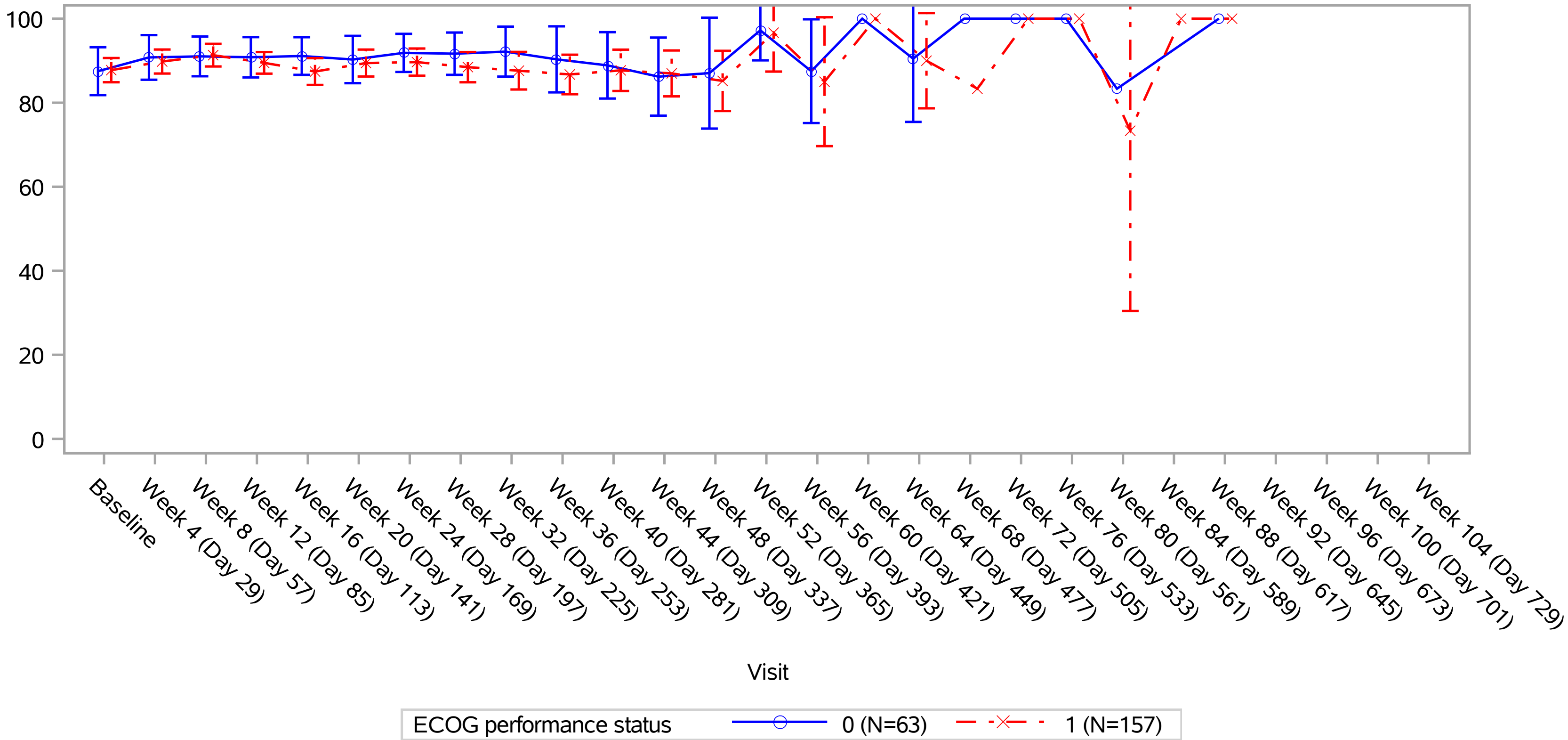
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Cognitive functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30CF_SGAGE65.pdf
15OCT2021 17:32

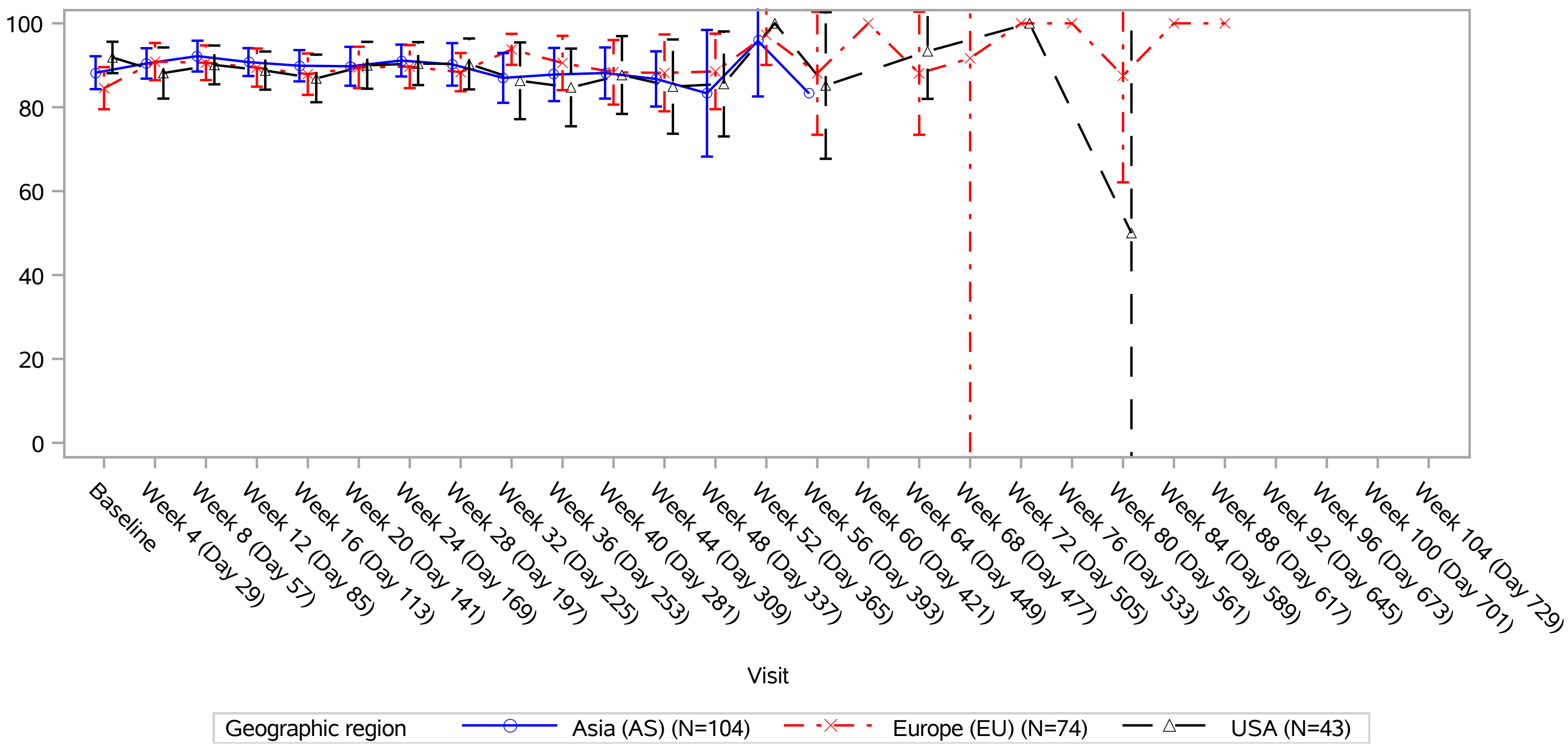
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Cognitive functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30CF_SGECOG.pdf
15OCT2021 18:01

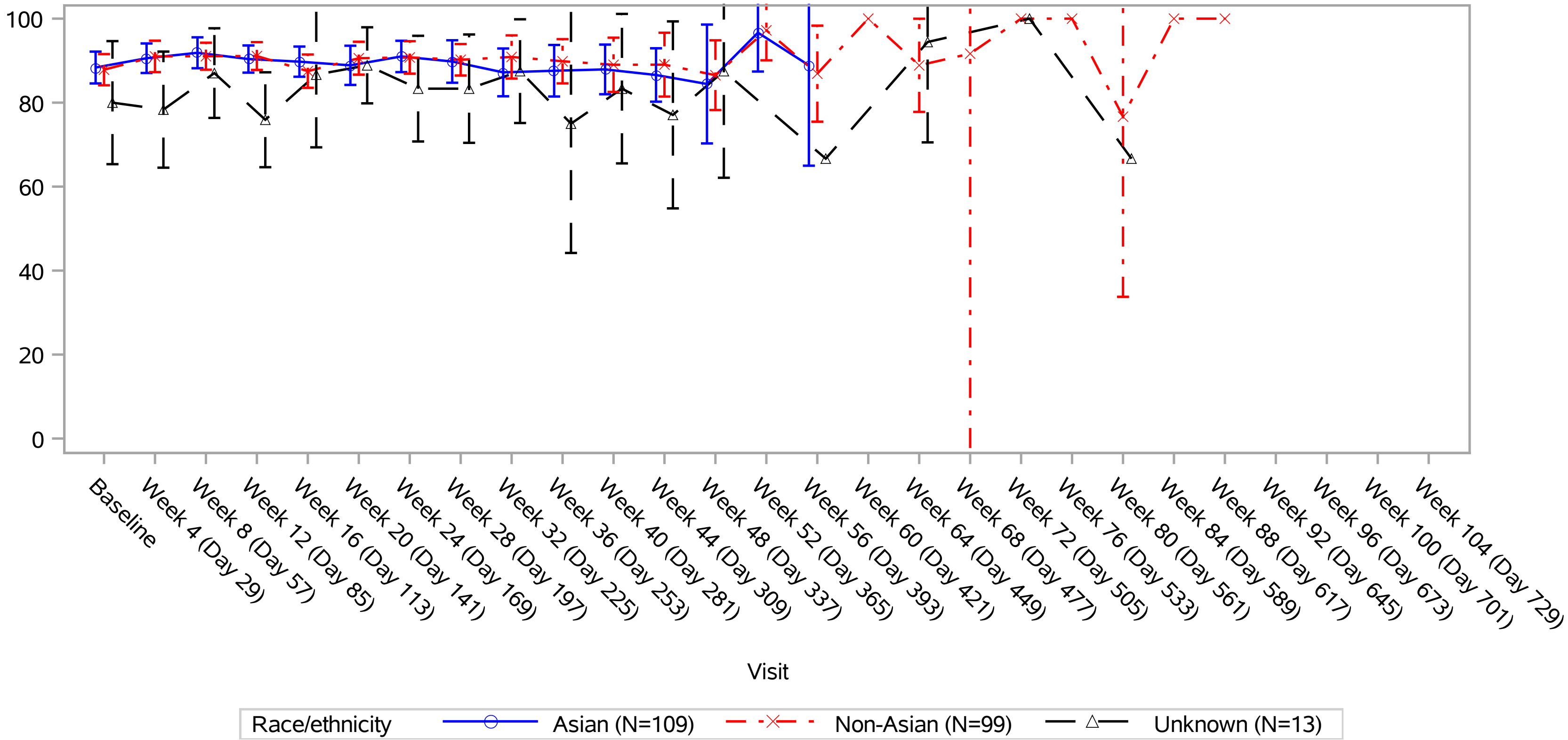
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Cognitive functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30CF_SGGEO.pdf
15OCT2021 18:32

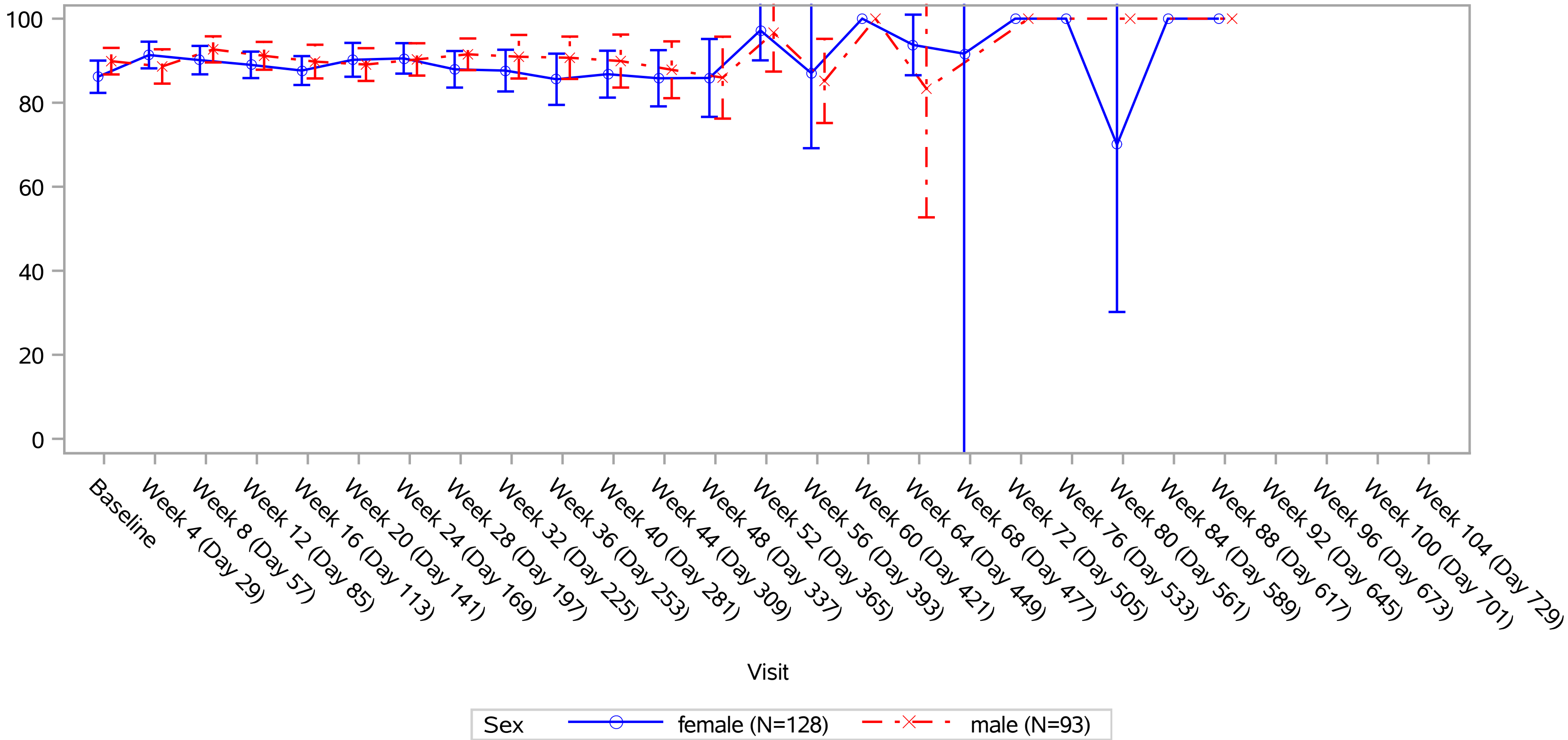
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Cognitive functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30CF_SGRE.pdf
15OCT2021 19:03

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Cognitive functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30CF_SGSEX.pdf
15OCT2021 19:33

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Constipation
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=221)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	221	100.0	212	95.9	12.74	23.18	9.60	15.87
Week 4 (Day 29)	n/a	221	100.0	191	86.4	25.13	29.76	20.88	29.38
Week 8 (Day 57)	n/a	193	87.3	171	88.6	19.30	26.28	15.33	23.27
Week 12 (Day 85)	n/a	176	79.6	161	91.5	19.46	25.43	15.50	23.42
Week 16 (Day 113)	n/a	164	74.2	143	87.2	20.75	25.58	16.52	24.97
Week 20 (Day 141)	n/a	148	67.0	138	93.2	19.08	25.12	14.85	23.31
Week 24 (Day 169)	n/a	137	62.0	122	89.1	16.39	24.34	12.03	20.76
Week 28 (Day 197)	n/a	129	58.4	120	93.0	18.61	26.57	13.81	23.41
Week 32 (Day 225)	n/a	119	53.8	104	87.4	16.35	24.58	11.57	21.13
Week 36 (Day 253)	n/a	112	50.7	95	84.8	18.95	26.48	13.55	24.34
Week 40 (Day 281)	n/a	104	47.1	91	87.5	17.95	27.80	12.16	23.74
Week 44 (Day 309)	n/a	95	43.0	84	88.4	19.44	31.14	12.69	26.20
Week 48 (Day 337)	n/a	81	36.7	45	55.6	14.81	27.11	6.67	22.96
Week 52 (Day 365)	n/a	64	29.0	11	17.2	15.15	17.41	3.46	26.85
Week 56 (Day 393)	n/a	54	24.4	18	33.3	25.93	31.43	10.30	41.55
Week 60 (Day 421)	n/a	43	19.5	2	4.7	16.67	23.57	-195.10	228.44
Week 64 (Day 449)	n/a	41	18.6	12	29.3	25.00	32.18	4.56	45.44
Week 68 (Day 477)	n/a	34	15.4	2	5.9	33.33	0.00	NE	NE
Week 72 (Day 505)	n/a	34	15.4	5	14.7	20.00	29.81	-17.02	57.02
Week 76 (Day 533)	n/a	31	14.0	3	9.7	0.00	0.00	NE	NE
Week 80 (Day 561)	n/a	30	13.6	6	20.0	5.56	13.61	-8.73	19.84
Week 84 (Day 589)	n/a	19	8.6	1	5.3	0.00	NE	NE	NE
Week 88 (Day 617)	n/a	15	6.8	2	13.3	0.00	0.00	NE	NE
Week 92 (Day 645)	n/a	8	3.6	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	2.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	1.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	221	100.0	219	99.1	18.87	28.00	15.14	22.60
End of Study (LOCF)	n/a	221	100.0	219	99.1	17.96	26.56	14.42	21.50
Sex									
Baseline	Female	128	100.0	123	96.1	14.36	25.99	9.72	19.00
Week 4 (Day 29)	Female	128	100.0	106	82.8	30.82	31.44	24.76	36.87
Week 8 (Day 57)	Female	112	87.5	98	87.5	22.11	29.48	16.20	28.02
Week 12 (Day 85)	Female	104	81.3	95	91.3	22.46	28.53	16.64	28.27
Week 16 (Day 113)	Female	96	75.0	81	84.4	23.46	29.08	17.03	29.89
Week 20 (Day 141)	Female	86	67.2	80	93.0	22.92	29.34	16.39	29.45
Week 24 (Day 169)	Female	78	60.9	67	85.9	17.41	27.44	10.72	24.11
Week 28 (Day 197)	Female	72	56.3	65	90.3	20.00	28.75	12.88	27.12
Week 32 (Day 225)	Female	69	53.9	58	84.1	18.97	28.00	11.60	26.33
Week 36 (Day 253)	Female	64	50.0	52	81.3	21.15	29.54	12.93	29.38
Week 40 (Day 281)	Female	59	46.1	53	89.8	20.13	32.25	11.24	29.02
Week 44 (Day 309)	Female	56	43.8	47	83.9	21.28	35.05	10.99	31.57
Week 48 (Day 337)	Female	48	37.5	26	54.2	17.95	31.60	5.19	30.71
Week 52 (Day 365)	Female	38	29.7	6	15.8	16.67	18.26	-2.49	35.83
Week 56 (Day 393)	Female	31	24.2	9	29.0	25.93	36.43	-2.08	53.93
Week 60 (Day 421)	Female	27	21.1	1	3.7	33.33	NE	NE	NE
Week 64 (Day 449)	Female	26	20.3	8	30.8	33.33	35.63	3.54	63.12
Week 68 (Day 477)	Female	23	18.0	2	8.7	33.33	0.00	NE	NE
Week 72 (Day 505)	Female	23	18.0	3	13.0	33.33	33.33	-49.47	116.14
Week 76 (Day 533)	Female	21	16.4	3	14.3	0.00	0.00	NE	NE
Week 80 (Day 561)	Female	20	15.6	5	25.0	6.67	14.91	-11.84	25.18
Week 84 (Day 589)	Female	12	9.4	1	8.3	0.00	NE	NE	NE
Week 88 (Day 617)	Female	9	7.0	1	11.1	0.00	NE	NE	NE
Week 92 (Day 645)	Female	6	4.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	3.9	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	1.6	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	0.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	128	100.0	127	99.2	19.69	30.96	14.25	25.12
End of Study (LOCF)	Female	128	100.0	127	99.2	18.64	28.68	13.60	23.67
Baseline	Male	93	100.0	89	95.7	10.49	18.53	6.58	14.39
Week 4 (Day 29)	Male	93	100.0	85	91.4	18.04	26.00	12.43	23.65
Week 8 (Day 57)	Male	81	87.1	73	90.1	15.53	20.85	10.66	20.39
Week 12 (Day 85)	Male	72	77.4	66	91.7	15.15	19.55	10.35	19.96
Week 16 (Day 113)	Male	68	73.1	62	91.2	17.20	19.78	12.18	22.23
Week 20 (Day 141)	Male	62	66.7	58	93.5	13.79	16.56	9.44	18.15
Week 24 (Day 169)	Male	59	63.4	55	93.2	15.15	20.10	9.72	20.59
Week 28 (Day 197)	Male	57	61.3	55	96.5	16.97	23.89	10.51	23.43
Week 32 (Day 225)	Male	50	53.8	46	92.0	13.04	19.22	7.34	18.75
Week 36 (Day 253)	Male	48	51.6	43	89.6	16.28	22.27	9.43	23.13
Week 40 (Day 281)	Male	45	48.4	38	84.4	14.91	20.06	8.32	21.50
Week 44 (Day 309)	Male	39	41.9	37	94.9	17.12	25.61	8.58	25.65
Week 48 (Day 337)	Male	33	35.5	19	57.6	10.53	19.41	1.17	19.88
Week 52 (Day 365)	Male	26	28.0	5	19.2	13.33	18.26	-9.34	36.00
Week 56 (Day 393)	Male	23	24.7	9	39.1	25.93	27.78	4.57	47.28
Week 60 (Day 421)	Male	16	17.2	1	6.3	0.00	NE	NE	NE
Week 64 (Day 449)	Male	15	16.1	4	26.7	8.33	16.67	-18.19	34.85
Week 68 (Day 477)	Male	11	11.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	11	11.8	2	18.2	0.00	0.00	NE	NE
Week 76 (Day 533)	Male	10	10.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	10	10.8	1	10.0	0.00	NE	NE	NE
Week 84 (Day 589)	Male	7	7.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	6	6.5	1	16.7	0.00	NE	NE	NE
Week 92 (Day 645)	Male	2	2.2	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	93	100.0	92	98.9	17.75	23.41	12.90	22.60
End of Study (LOCF)	Male	93	100.0	92	98.9	17.03	23.44	12.18	21.88
Age									

Baseline	< 65	141	100.0	133	94.3	12.78	24.52	8.58	16.99
Week 4 (Day 29)	< 65	141	100.0	123	87.2	25.75	29.82	20.42	31.07
Week 8 (Day 57)	< 65	127	90.1	113	89.0	21.53	28.14	16.29	26.78
Week 12 (Day 85)	< 65	118	83.7	106	89.8	18.24	24.83	13.46	23.02
Week 16 (Day 113)	< 65	108	76.6	93	86.1	17.92	23.86	13.01	22.83
Week 20 (Day 141)	< 65	100	70.9	97	97.0	17.53	25.04	12.48	22.57
Week 24 (Day 169)	< 65	93	66.0	86	92.5	17.05	25.94	11.49	22.62
Week 28 (Day 197)	< 65	88	62.4	83	94.3	19.28	26.09	13.58	24.97
Week 32 (Day 225)	< 65	83	58.9	73	88.0	14.16	23.52	8.67	19.64
Week 36 (Day 253)	< 65	78	55.3	70	89.7	17.14	25.22	11.13	23.16
Week 40 (Day 281)	< 65	75	53.2	69	92.0	16.43	27.78	9.75	23.10
Week 44 (Day 309)	< 65	71	50.4	65	91.5	17.44	30.11	9.98	24.90
Week 48 (Day 337)	< 65	61	43.3	33	54.1	12.12	24.75	3.35	20.90
Week 52 (Day 365)	< 65	48	34.0	6	12.5	11.11	17.21	-6.95	29.18
Week 56 (Day 393)	< 65	41	29.1	11	26.8	24.24	33.63	1.65	46.84
Week 60 (Day 421)	< 65	33	23.4	2	6.1	16.67	23.57	-195.10	228.44
Week 64 (Day 449)	< 65	31	22.0	10	32.3	26.67	34.43	2.04	51.29
Week 68 (Day 477)	< 65	26	18.4	2	7.7	33.33	0.00	NE	NE
Week 72 (Day 505)	< 65	26	18.4	5	19.2	20.00	29.81	-17.02	57.02
Week 76 (Day 533)	< 65	25	17.7	3	12.0	0.00	0.00	NE	NE
Week 80 (Day 561)	< 65	24	17.0	5	20.8	6.67	14.91	-11.84	25.18
Week 84 (Day 589)	< 65	16	11.3	1	6.3	0.00	NE	NE	NE
Week 88 (Day 617)	< 65	13	9.2	2	15.4	0.00	0.00	NE	NE
Week 92 (Day 645)	< 65	7	5.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	3.5	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	2.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	0.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	141	100.0	139	98.6	17.99	28.17	13.26	22.71
End of Study (LOCF)	< 65	141	100.0	139	98.6	15.83	25.48	11.55	20.10
Baseline	>= 65	80	100.0	79	98.8	12.66	20.88	7.98	17.34
Week 4 (Day 29)	>= 65	80	100.0	68	85.0	24.02	29.84	16.80	31.24
Week 8 (Day 57)	>= 65	66	82.5	58	87.9	14.94	21.78	9.21	20.67
Week 12 (Day 85)	>= 65	58	72.5	55	94.8	21.82	26.62	14.62	29.01

Week 16 (Day 113)	>= 65	56	70.0	50	89.3	26.00	28.00	18.04	33.96
Week 20 (Day 141)	>= 65	48	60.0	41	85.4	22.76	25.21	14.81	30.72
Week 24 (Day 169)	>= 65	44	55.0	36	81.8	14.81	20.23	7.97	21.66
Week 28 (Day 197)	>= 65	41	51.3	37	90.2	17.12	27.91	7.81	26.42
Week 32 (Day 225)	>= 65	36	45.0	31	86.1	21.51	26.59	11.75	31.26
Week 36 (Day 253)	>= 65	34	42.5	25	73.5	24.00	29.69	11.74	36.26
Week 40 (Day 281)	>= 65	29	36.3	22	75.9	22.73	27.96	10.33	35.12
Week 44 (Day 309)	>= 65	24	30.0	19	79.2	26.32	34.39	9.74	42.89
Week 48 (Day 337)	>= 65	20	25.0	12	60.0	22.22	32.82	1.37	43.08
Week 52 (Day 365)	>= 65	16	20.0	5	31.3	20.00	18.26	-2.67	42.67
Week 56 (Day 393)	>= 65	13	16.3	7	53.8	28.57	29.99	0.83	56.31
Week 60 (Day 421)	>= 65	10	12.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	10	12.5	2	20.0	16.67	23.57	-195.10	228.44
Week 68 (Day 477)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	6	7.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	6	7.5	1	16.7	0.00	NE	NE	NE
Week 84 (Day 589)	>= 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	2.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	80	100.0	80	100.0	20.42	27.81	14.23	26.61
End of Study (LOCF)	>= 65	80	100.0	80	100.0	21.67	28.11	15.41	27.92
ECOG performance status									
Baseline	0	63	100.0	60	95.2	10.56	24.16	4.32	16.80
Week 4 (Day 29)	0	63	100.0	56	88.9	30.95	32.32	22.30	39.61
Week 8 (Day 57)	0	58	92.1	52	89.7	23.08	29.92	14.75	31.41
Week 12 (Day 85)	0	55	87.3	50	90.9	19.33	26.16	11.90	26.77
Week 16 (Day 113)	0	54	85.7	45	83.3	20.74	28.68	12.12	29.36
Week 20 (Day 141)	0	52	82.5	48	92.3	15.97	24.78	8.78	23.17
Week 24 (Day 169)	0	49	77.8	43	87.8	12.40	20.60	6.06	18.74
Week 28 (Day 197)	0	46	73.0	42	91.3	13.49	23.35	6.22	20.77

Week 32 (Day 225)	0	41	65.1	34	82.9	12.75	24.64	4.15	21.34
Week 36 (Day 253)	0	39	61.9	31	79.5	13.98	22.40	5.76	22.20
Week 40 (Day 281)	0	37	58.7	30	81.1	14.44	28.61	3.76	25.13
Week 44 (Day 309)	0	36	57.1	29	80.6	12.64	28.75	1.71	23.58
Week 48 (Day 337)	0	28	44.4	18	64.3	11.11	25.57	-1.60	23.82
Week 52 (Day 365)	0	27	42.9	6	22.2	16.67	18.26	-2.49	35.83
Week 56 (Day 393)	0	24	38.1	8	33.3	20.83	24.80	0.10	41.57
Week 60 (Day 421)	0	21	33.3	1	4.8	33.33	NE	NE	NE
Week 64 (Day 449)	0	21	33.3	7	33.3	19.05	17.82	2.57	35.53
Week 68 (Day 477)	0	17	27.0	1	5.9	33.33	NE	NE	NE
Week 72 (Day 505)	0	17	27.0	2	11.8	16.67	23.57	-195.10	228.44
Week 76 (Day 533)	0	15	23.8	2	13.3	0.00	0.00	NE	NE
Week 80 (Day 561)	0	14	22.2	1	7.1	0.00	NE	NE	NE
Week 84 (Day 589)	0	11	17.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	10	15.9	1	10.0	0.00	NE	NE	NE
Week 92 (Day 645)	0	5	7.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	6.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	4.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	63	100.0	63	100.0	17.46	29.85	9.94	24.98
End of Study (LOCF)	0	63	100.0	63	100.0	15.87	26.00	9.33	22.42
Baseline	1	157	100.0	151	96.2	13.69	22.86	10.01	17.36
Week 4 (Day 29)	1	157	100.0	134	85.4	22.64	28.50	17.77	27.51
Week 8 (Day 57)	1	134	85.4	119	88.8	17.65	24.48	13.20	22.09
Week 12 (Day 85)	1	121	77.1	111	91.7	19.52	25.21	14.78	24.26
Week 16 (Day 113)	1	110	70.1	98	89.1	20.75	24.18	15.90	25.60
Week 20 (Day 141)	1	96	61.1	90	93.8	20.74	25.27	15.45	26.03
Week 24 (Day 169)	1	88	56.1	79	89.8	18.57	26.01	12.74	24.39
Week 28 (Day 197)	1	83	52.9	78	94.0	21.37	27.90	15.08	27.66
Week 32 (Day 225)	1	78	49.7	70	89.7	18.10	24.53	12.25	23.94
Week 36 (Day 253)	1	73	46.5	64	87.7	21.35	28.09	14.34	28.37
Week 40 (Day 281)	1	67	42.7	61	91.0	19.67	27.47	12.64	26.71

Week 44 (Day 309)	1	59	37.6	55	93.2	23.03	31.99	14.38	31.68
Week 48 (Day 337)	1	53	33.8	27	50.9	17.28	28.30	6.09	28.48
Week 52 (Day 365)	1	37	23.6	5	13.5	13.33	18.26	-9.34	36.00
Week 56 (Day 393)	1	30	19.1	10	33.3	30.00	36.68	3.76	56.24
Week 60 (Day 421)	1	22	14.0	1	4.5	0.00	NE	NE	NE
Week 64 (Day 449)	1	20	12.7	5	25.0	33.33	47.14	-25.20	91.87
Week 68 (Day 477)	1	17	10.8	1	5.9	33.33	NE	NE	NE
Week 72 (Day 505)	1	17	10.8	3	17.6	22.22	38.49	-73.39	117.84
Week 76 (Day 533)	1	16	10.2	1	6.3	0.00	NE	NE	NE
Week 80 (Day 561)	1	16	10.2	5	31.3	6.67	14.91	-11.84	25.18
Week 84 (Day 589)	1	8	5.1	1	12.5	0.00	NE	NE	NE
Week 88 (Day 617)	1	5	3.2	1	20.0	0.00	NE	NE	NE
Week 92 (Day 645)	1	3	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	157	100.0	155	98.7	19.35	27.36	15.01	23.70
End of Study (LOCF)	1	157	100.0	155	98.7	18.71	26.88	14.44	22.98
Baseline	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	33.33	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	33.33	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	33.33	NE	NE	NE
Geographic region									
Baseline	USA	43	100.0	41	95.3	13.01	16.46	7.81	18.20
Week 4 (Day 29)	USA	43	100.0	38	88.4	26.32	31.15	16.08	36.56
Week 8 (Day 57)	USA	41	95.3	37	90.2	20.72	25.28	12.29	29.15
Week 12 (Day 85)	USA	41	95.3	38	92.7	21.05	26.19	12.44	29.66
Week 16 (Day 113)	USA	40	93.0	33	82.5	18.18	23.70	9.78	26.59
Week 20 (Day 141)	USA	39	90.7	35	89.7	11.43	21.30	4.11	18.75
Week 24 (Day 169)	USA	36	83.7	33	91.7	16.16	23.75	7.74	24.58
Week 28 (Day 197)	USA	35	81.4	31	88.6	19.35	25.49	10.00	28.71
Week 32 (Day 225)	USA	32	74.4	28	87.5	16.67	26.45	6.41	26.92
Week 36 (Day 253)	USA	32	74.4	24	75.0	23.61	28.62	11.52	35.70
Week 40 (Day 281)	USA	29	67.4	23	79.3	14.49	26.26	3.14	25.85

Week 44 (Day 309)	USA	26	60.5	21	80.8	15.87	29.10	2.63	29.12
Week 48 (Day 337)	USA	21	48.8	15	71.4	8.89	26.63	-5.86	23.63
Week 52 (Day 365)	USA	18	41.9	1	5.6	0.00	NE	NE	NE
Week 56 (Day 393)	USA	18	41.9	9	50.0	29.63	35.14	2.62	56.64
Week 60 (Day 421)	USA	17	39.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	15	34.9	5	33.3	26.67	43.46	-27.30	80.63
Week 68 (Day 477)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	12	27.9	1	8.3	0.00	NE	NE	NE
Week 76 (Day 533)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	12	27.9	2	16.7	0.00	0.00	NE	NE
Week 84 (Day 589)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	6	14.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	11.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	7.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	43	100.0	43	100.0	16.28	27.58	7.79	24.77
End of Study (LOCF)	USA	43	100.0	43	100.0	16.28	27.58	7.79	24.77
Baseline	Europe (EU)	74	100.0	69	93.2	12.56	23.64	6.88	18.24
Week 4 (Day 29)	Europe (EU)	74	100.0	64	86.5	32.81	32.80	24.62	41.00
Week 8 (Day 57)	Europe (EU)	65	87.8	55	84.6	23.03	27.12	15.70	30.36
Week 12 (Day 85)	Europe (EU)	57	77.0	49	86.0	23.81	28.05	15.75	31.87
Week 16 (Day 113)	Europe (EU)	55	74.3	44	80.0	27.27	28.09	18.73	35.81
Week 20 (Day 141)	Europe (EU)	49	66.2	46	93.9	26.09	26.21	18.30	33.87
Week 24 (Day 169)	Europe (EU)	47	63.5	42	89.4	17.46	24.68	9.77	25.15
Week 28 (Day 197)	Europe (EU)	45	60.8	43	95.6	17.83	24.50	10.29	25.37
Week 32 (Day 225)	Europe (EU)	39	52.7	35	89.7	17.14	21.95	9.60	24.68
Week 36 (Day 253)	Europe (EU)	34	45.9	30	88.2	23.33	27.89	12.92	33.75
Week 40 (Day 281)	Europe (EU)	31	41.9	30	96.8	24.44	30.24	13.15	35.74
Week 44 (Day 309)	Europe (EU)	28	37.8	24	85.7	22.22	33.57	8.05	36.40

Week 48 (Day 337)	Europe (EU)	22	29.7	16	72.7	22.92	26.44	8.83	37.01
Week 52 (Day 365)	Europe (EU)	19	25.7	6	31.6	22.22	17.21	4.16	40.29
Week 56 (Day 393)	Europe (EU)	17	23.0	7	41.2	23.81	31.71	-5.51	53.13
Week 60 (Day 421)	Europe (EU)	15	20.3	2	13.3	16.67	23.57	-195.10	228.44
Week 64 (Day 449)	Europe (EU)	15	20.3	7	46.7	23.81	25.20	0.51	47.11
Week 68 (Day 477)	Europe (EU)	13	17.6	2	15.4	33.33	0.00	NE	NE
Week 72 (Day 505)	Europe (EU)	13	17.6	4	30.8	25.00	31.91	-25.78	75.78
Week 76 (Day 533)	Europe (EU)	11	14.9	3	27.3	0.00	0.00	NE	NE
Week 80 (Day 561)	Europe (EU)	10	13.5	4	40.0	8.33	16.67	-18.19	34.85
Week 84 (Day 589)	Europe (EU)	6	8.1	1	16.7	0.00	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	4.1	2	66.7	0.00	0.00	NE	NE
Cycle 12 (LOCF)	Europe (EU)	74	100.0	73	98.6	23.29	29.75	16.35	30.23
End of Study (LOCF)	Europe (EU)	74	100.0	73	98.6	22.37	26.68	16.15	28.60
Baseline	Asia (AS)	104	100.0	102	98.1	12.75	25.28	7.78	17.71
Week 4 (Day 29)	Asia (AS)	104	100.0	89	85.6	19.10	25.57	13.72	24.49
Week 8 (Day 57)	Asia (AS)	87	83.7	79	90.8	16.03	26.07	10.19	21.87
Week 12 (Day 85)	Asia (AS)	78	75.0	74	94.9	15.77	22.90	10.46	21.07
Week 16 (Day 113)	Asia (AS)	69	66.3	66	95.7	17.68	24.26	11.71	23.64
Week 20 (Day 141)	Asia (AS)	60	57.7	57	95.0	18.13	25.25	11.43	24.83
Week 24 (Day 169)	Asia (AS)	54	51.9	47	87.0	15.60	24.92	8.29	22.92
Week 28 (Day 197)	Asia (AS)	49	47.1	46	93.9	18.84	29.52	10.07	27.61
Week 32 (Day 225)	Asia (AS)	48	46.2	41	85.4	15.45	25.92	7.26	23.63
Week 36 (Day 253)	Asia (AS)	46	44.2	41	89.1	13.01	23.43	5.61	20.40
Week 40 (Day 281)	Asia (AS)	44	42.3	38	86.4	14.91	26.51	6.20	23.62
Week 44 (Day 309)	Asia (AS)	41	39.4	39	95.1	19.66	31.27	9.52	29.79
Week 48 (Day 337)	Asia (AS)	38	36.5	14	36.8	11.90	28.06	-4.30	28.11
Week 52 (Day 365)	Asia (AS)	27	26.0	4	14.8	8.33	16.67	-18.19	34.85
Week 56 (Day 393)	Asia (AS)	19	18.3	2	10.5	16.67	23.57	-195.10	228.44
Week 60 (Day 421)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	5.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	104	100.0	103	99.0	16.83	26.76	11.60	22.06
End of Study (LOCF)	Asia (AS)	104	100.0	103	99.0	15.53	25.91	10.47	20.60
Race/ethnicity									
Baseline	Asian	109	100.0	106	97.2	12.89	25.02	8.08	17.71
Week 4 (Day 29)	Asian	109	100.0	92	84.4	18.48	25.37	13.22	23.73
Week 8 (Day 57)	Asian	91	83.5	80	87.9	15.83	25.97	10.05	21.61
Week 12 (Day 85)	Asian	82	75.2	78	95.1	14.96	22.57	9.87	20.05
Week 16 (Day 113)	Asian	73	67.0	70	95.9	17.14	23.90	11.44	22.84
Week 20 (Day 141)	Asian	64	58.7	60	93.8	17.78	24.90	11.34	24.21
Week 24 (Day 169)	Asian	57	52.3	50	87.7	15.33	24.48	8.38	22.29
Week 28 (Day 197)	Asian	52	47.7	49	94.2	18.37	28.92	10.06	26.67
Week 32 (Day 225)	Asian	50	45.9	43	86.0	14.73	25.51	6.88	22.58
Week 36 (Day 253)	Asian	48	44.0	43	89.6	12.40	23.03	5.32	19.49
Week 40 (Day 281)	Asian	46	42.2	40	87.0	14.17	26.03	5.84	22.49
Week 44 (Day 309)	Asian	43	39.4	41	95.3	18.70	30.78	8.99	28.41
Week 48 (Day 337)	Asian	40	36.7	15	37.5	11.11	27.22	-3.96	26.18
Week 52 (Day 365)	Asian	29	26.6	5	17.2	6.67	14.91	-11.84	25.18
Week 56 (Day 393)	Asian	21	19.3	3	14.3	11.11	19.25	-36.70	58.92
Week 60 (Day 421)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	5.5	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	4.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	1.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	109	100.0	107	98.2	16.51	26.45	11.44	21.58
End of Study (LOCF)	Asian	109	100.0	107	98.2	15.26	25.61	10.36	20.17
Baseline	Non-Asian	99	100.0	96	97.0	12.85	21.83	8.42	17.27
Week 4 (Day 29)	Non-Asian	99	100.0	89	89.9	29.21	31.31	22.62	35.81
Week 8 (Day 57)	Non-Asian	91	91.9	82	90.1	21.54	25.32	15.98	27.11
Week 12 (Day 85)	Non-Asian	83	83.8	74	89.2	23.42	26.88	17.20	29.65
Week 16 (Day 113)	Non-Asian	80	80.8	68	85.0	23.53	27.05	16.98	30.08
Week 20 (Day 141)	Non-Asian	74	74.7	69	93.2	19.81	25.13	13.77	25.84
Week 24 (Day 169)	Non-Asian	70	70.7	65	92.9	16.92	25.09	10.71	23.14
Week 28 (Day 197)	Non-Asian	67	67.7	63	94.0	19.05	25.90	12.53	25.57
Week 32 (Day 225)	Non-Asian	60	60.6	53	88.3	16.35	24.13	9.70	23.00
Week 36 (Day 253)	Non-Asian	55	55.6	46	83.6	23.91	28.69	15.39	32.43
Week 40 (Day 281)	Non-Asian	49	49.5	44	89.8	19.70	29.04	10.87	28.53
Week 44 (Day 309)	Non-Asian	43	43.4	35	81.4	18.10	30.62	7.58	28.61
Week 48 (Day 337)	Non-Asian	35	35.4	26	74.3	17.95	28.64	6.38	29.52
Week 52 (Day 365)	Non-Asian	29	29.3	6	20.7	22.22	17.21	4.16	40.29
Week 56 (Day 393)	Non-Asian	27	27.3	14	51.9	30.95	33.24	11.76	50.15
Week 60 (Day 421)	Non-Asian	26	26.3	2	7.7	16.67	23.57	-195.10	228.44
Week 64 (Day 449)	Non-Asian	24	24.2	9	37.5	29.63	35.14	2.62	56.64
Week 68 (Day 477)	Non-Asian	20	20.2	2	10.0	33.33	0.00	NE	NE
Week 72 (Day 505)	Non-Asian	20	20.2	3	15.0	22.22	38.49	-73.39	117.84
Week 76 (Day 533)	Non-Asian	18	18.2	3	16.7	0.00	0.00	NE	NE
Week 80 (Day 561)	Non-Asian	17	17.2	5	29.4	6.67	14.91	-11.84	25.18
Week 84 (Day 589)	Non-Asian	11	11.1	1	9.1	0.00	NE	NE	NE
Week 88 (Day 617)	Non-Asian	8	8.1	2	25.0	0.00	0.00	NE	NE
Week 92 (Day 645)	Non-Asian	4	4.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	3.0	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	99	100.0	99	100.0	20.20	29.28	14.36	26.04

End of Study (LOCF)	Non-Asian	99	100.0	99	100.0	20.54	28.05	14.94	26.13
Baseline	Unknown	13	100.0	10	76.9	10.00	16.10	-1.52	21.52
Week 4 (Day 29)	Unknown	13	100.0	10	76.9	50.00	36.00	24.24	75.76
Week 8 (Day 57)	Unknown	11	84.6	9	81.8	29.63	35.14	2.62	56.64
Week 12 (Day 85)	Unknown	11	84.6	9	81.8	25.93	32.39	1.03	50.83
Week 16 (Day 113)	Unknown	11	84.6	5	45.5	33.33	23.57	4.07	62.60
Week 20 (Day 141)	Unknown	10	76.9	9	90.0	22.22	28.87	0.03	44.41
Week 24 (Day 169)	Unknown	10	76.9	7	70.0	19.05	17.82	2.57	35.53
Week 28 (Day 197)	Unknown	10	76.9	8	80.0	16.67	17.82	1.77	31.56
Week 32 (Day 225)	Unknown	9	69.2	8	88.9	25.00	23.57	5.29	44.71
Week 36 (Day 253)	Unknown	9	69.2	6	66.7	27.78	25.09	1.44	54.11
Week 40 (Day 281)	Unknown	9	69.2	7	77.8	28.57	29.99	0.83	56.31
Week 44 (Day 309)	Unknown	9	69.2	8	88.9	29.17	37.53	-2.21	60.55
Week 48 (Day 337)	Unknown	6	46.2	4	66.7	8.33	16.67	-18.19	34.85
Week 52 (Day 365)	Unknown	6	46.2	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	6	46.2	1	16.7	0.00	NE	NE	NE
Week 60 (Day 421)	Unknown	5	38.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	5	38.5	3	60.0	11.11	19.25	-36.70	58.92
Week 68 (Day 477)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	4	30.8	2	50.0	16.67	23.57	-195.10	228.44
Week 76 (Day 533)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	4	30.8	1	25.0	0.00	NE	NE	NE
Week 84 (Day 589)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	7.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	13	100.0	13	100.0	28.21	29.96	10.10	46.31
End of Study (LOCF)	Unknown	13	100.0	13	100.0	20.51	21.68	7.41	33.61

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TO_QSC30CO_SG.xls
27OCT2021 7:12

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Constipation
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	112	52.8	46.1	59.4
	Cycle 12 (LOCF)	n/a	212	95.9	53	25.0	19.7	31.2
	End of Study (LOCF)	n/a	212	95.9	51	24.1	18.8	30.2
Sex	All visits	Female	123	55.7	69	56.1	47.3	64.6
		Male	89	40.3	43	48.3	38.2	58.5
	Cycle 12 (LOCF)	Female	123	55.7	28	22.8	16.2	30.9
		Male	89	40.3	25	28.1	19.8	38.2
	End of Study (LOCF)	Female	123	55.7	27	22.0	15.5	30.1
		Male	89	40.3	24	27.0	18.8	37.0
Age	All visits	< 65	133	60.2	70	52.6	44.2	60.9
		>= 65	79	35.7	42	53.2	42.3	63.8
	Cycle 12 (LOCF)	< 65	133	60.2	31	23.3	16.9	31.2
		>= 65	79	35.7	22	27.8	19.2	38.6
	End of Study (LOCF)	< 65	133	60.2	29	21.8	15.6	29.6
		>= 65	79	35.7	22	27.8	19.2	38.6
ECOG performance status	All visits	0	60	27.1	40	66.7	54.1	77.3
		1	151	68.3	71	47.0	39.2	55.0
		Missing	1	0.5	1	100.0	20.7	100.0
	Cycle 12 (LOCF)	0	60	27.1	13	21.7	13.1	33.6
		1	151	68.3	39	25.8	19.5	33.3
		Missing	1	0.5	1	100.0	20.7	100.0
	End of Study (LOCF)	0	60	27.1	13	21.7	13.1	33.6
		1	151	68.3	37	24.5	18.3	31.9
		Missing	1	0.5	1	100.0	20.7	100.0
Geographic region	All visits	USA	41	18.6	27	65.9	50.5	78.4
		Europe (EU)	69	31.2	43	62.3	50.5	72.8
		Asia (AS)	102	46.2	42	41.2	32.1	50.9
	Cycle 12 (LOCF)	USA	41	18.6	8	19.5	10.2	34.0
		Europe (EU)	69	31.2	24	34.8	24.6	46.6
		Asia (AS)	102	46.2	21	20.6	13.9	29.4
	End of Study (LOCF)	USA	41	18.6	8	19.5	10.2	34.0
		Europe (EU)	69	31.2	24	34.8	24.6	46.6
		Asia (AS)	102	46.2	19	18.6	12.3	27.3
Race/ethnicity	All visits	Asian	106	48.0	42	39.6	30.8	49.1
		Non-Asian	96	43.4	64	66.7	56.8	75.3
		Unknown	10	4.5	6	60.0	31.3	83.2
	Cycle 12 (LOCF)	Asian	106	48.0	21	19.8	13.3	28.4

		Non-Asian	96	43.4	28	29.2	21.0	38.9
		Unknown	10	4.5	4	40.0	16.8	68.7
	End of Study (LOCF)	Asian	106	48.0	19	17.9	11.8	26.3
		Non-Asian	96	43.4	29	30.2	21.9	40.0
		Unknown	10	4.5	3	30.0	10.8	60.3

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30CO_W10_SG.xls
15OCT2021 12:50

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Constipation
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

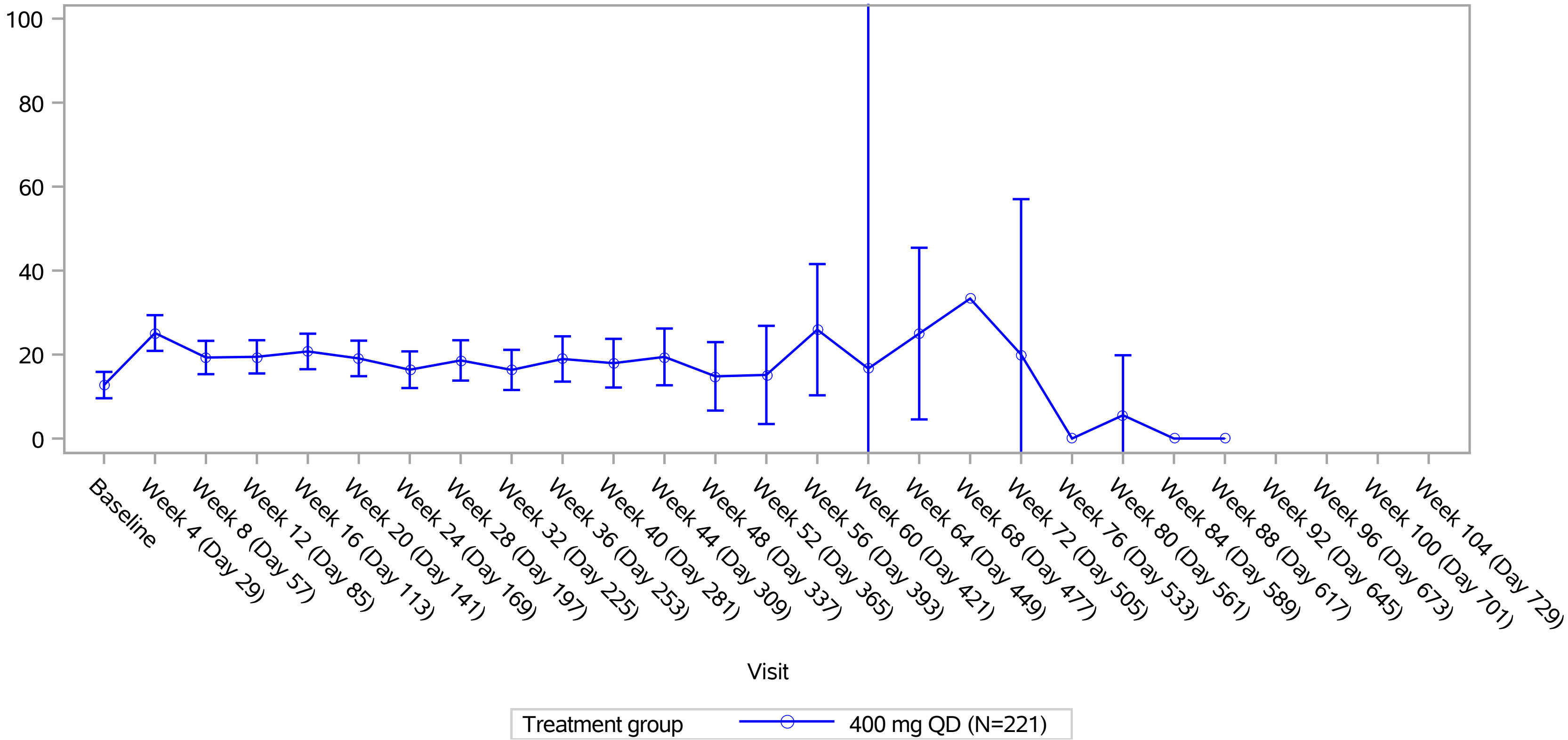
			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	112	52.8	46.1	59.4
	Cycle 12 (LOCF)	n/a	212	95.9	53	25.0	19.7	31.2
	End of Study (LOCF)	n/a	212	95.9	51	24.1	18.8	30.2
Sex	All visits	Female	123	55.7	69	56.1	47.3	64.6
		Male	89	40.3	43	48.3	38.2	58.5
	Cycle 12 (LOCF)	Female	123	55.7	28	22.8	16.2	30.9
		Male	89	40.3	25	28.1	19.8	38.2
	End of Study (LOCF)	Female	123	55.7	27	22.0	15.5	30.1
		Male	89	40.3	24	27.0	18.8	37.0
Age	All visits	< 65	133	60.2	70	52.6	44.2	60.9
		>= 65	79	35.7	42	53.2	42.3	63.8
	Cycle 12 (LOCF)	< 65	133	60.2	31	23.3	16.9	31.2
		>= 65	79	35.7	22	27.8	19.2	38.6
	End of Study (LOCF)	< 65	133	60.2	29	21.8	15.6	29.6
		>= 65	79	35.7	22	27.8	19.2	38.6
ECOG performance status	All visits	0	60	27.1	40	66.7	54.1	77.3
		1	151	68.3	71	47.0	39.2	55.0
		Missing	1	0.5	1	100.0	20.7	100.0
	Cycle 12 (LOCF)	0	60	27.1	13	21.7	13.1	33.6
		1	151	68.3	39	25.8	19.5	33.3
		Missing	1	0.5	1	100.0	20.7	100.0
	End of Study (LOCF)	0	60	27.1	13	21.7	13.1	33.6
		1	151	68.3	37	24.5	18.3	31.9
		Missing	1	0.5	1	100.0	20.7	100.0
Geographic region	All visits	USA	41	18.6	27	65.9	50.5	78.4
		Europe (EU)	69	31.2	43	62.3	50.5	72.8
		Asia (AS)	102	46.2	42	41.2	32.1	50.9
	Cycle 12 (LOCF)	USA	41	18.6	8	19.5	10.2	34.0
		Europe (EU)	69	31.2	24	34.8	24.6	46.6
		Asia (AS)	102	46.2	21	20.6	13.9	29.4
	End of Study (LOCF)	USA	41	18.6	8	19.5	10.2	34.0
		Europe (EU)	69	31.2	24	34.8	24.6	46.6
		Asia (AS)	102	46.2	19	18.6	12.3	27.3
Race/ethnicity	All visits	Asian	106	48.0	42	39.6	30.8	49.1
		Non-Asian	96	43.4	64	66.7	56.8	75.3
		Unknown	10	4.5	6	60.0	31.3	83.2
	Cycle 12 (LOCF)	Asian	106	48.0	21	19.8	13.3	28.4

		Non-Asian	96	43.4	28	29.2	21.0	38.9
		Unknown	10	4.5	4	40.0	16.8	68.7
	End of Study (LOCF)	Asian	106	48.0	19	17.9	11.8	26.3
		Non-Asian	96	43.4	29	30.2	21.9	40.0
		Unknown	10	4.5	3	30.0	10.8	60.3

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30CO_W15_SG.xls
15OCT2021 12:40

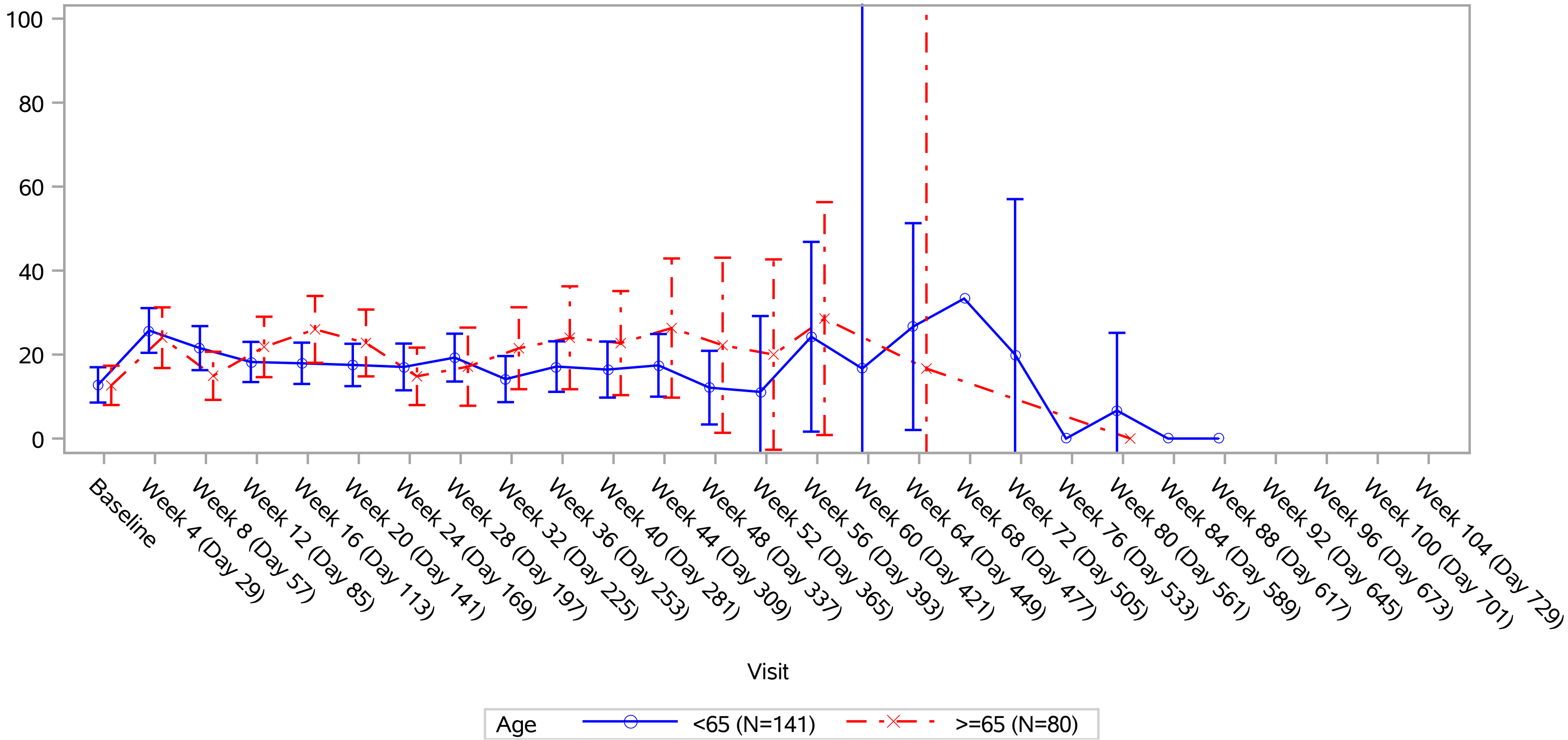
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Constipation
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30CO.pdf
15OCT2021 17:03

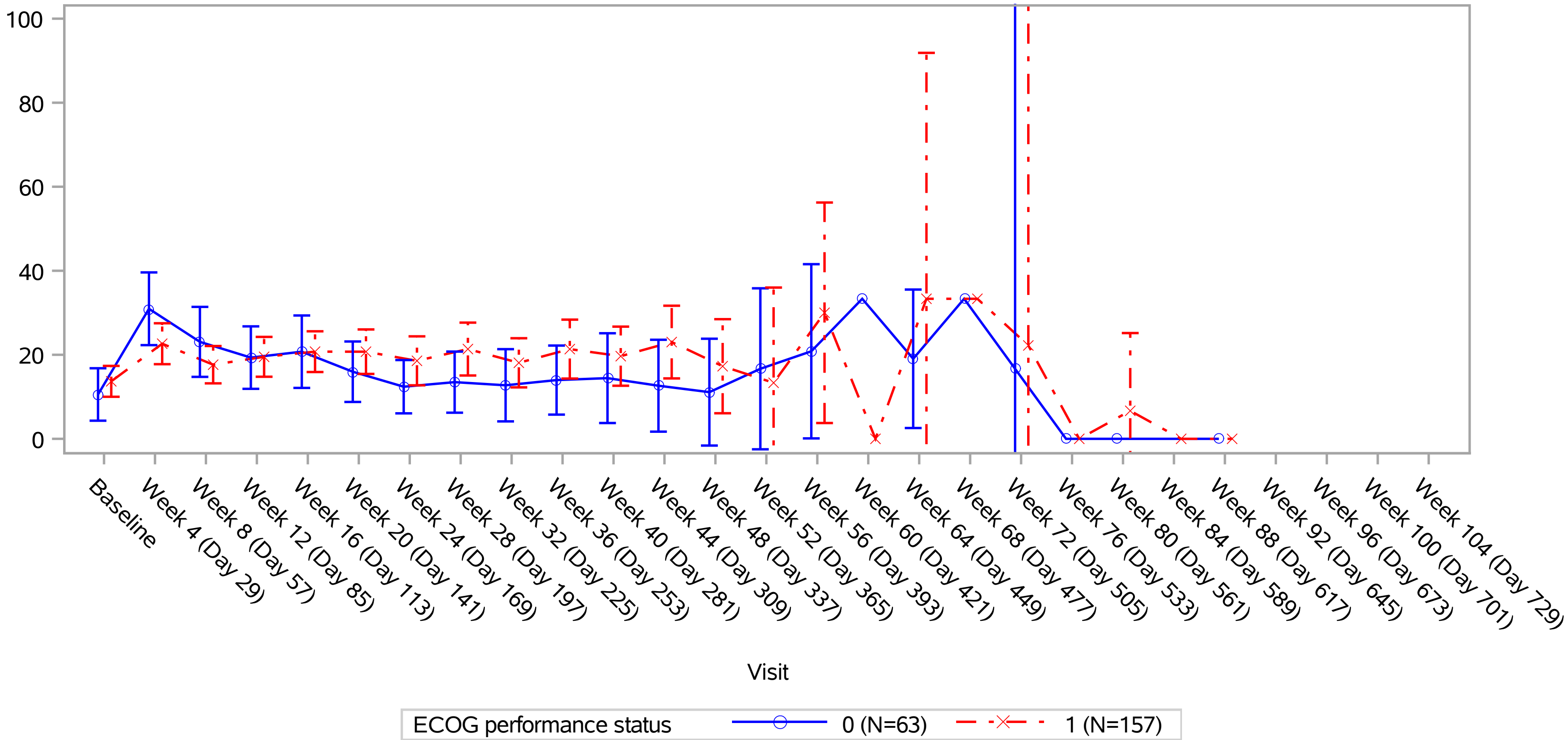
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Constipation
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30CO_SGAGE65.pdf
15OCT2021 17:33

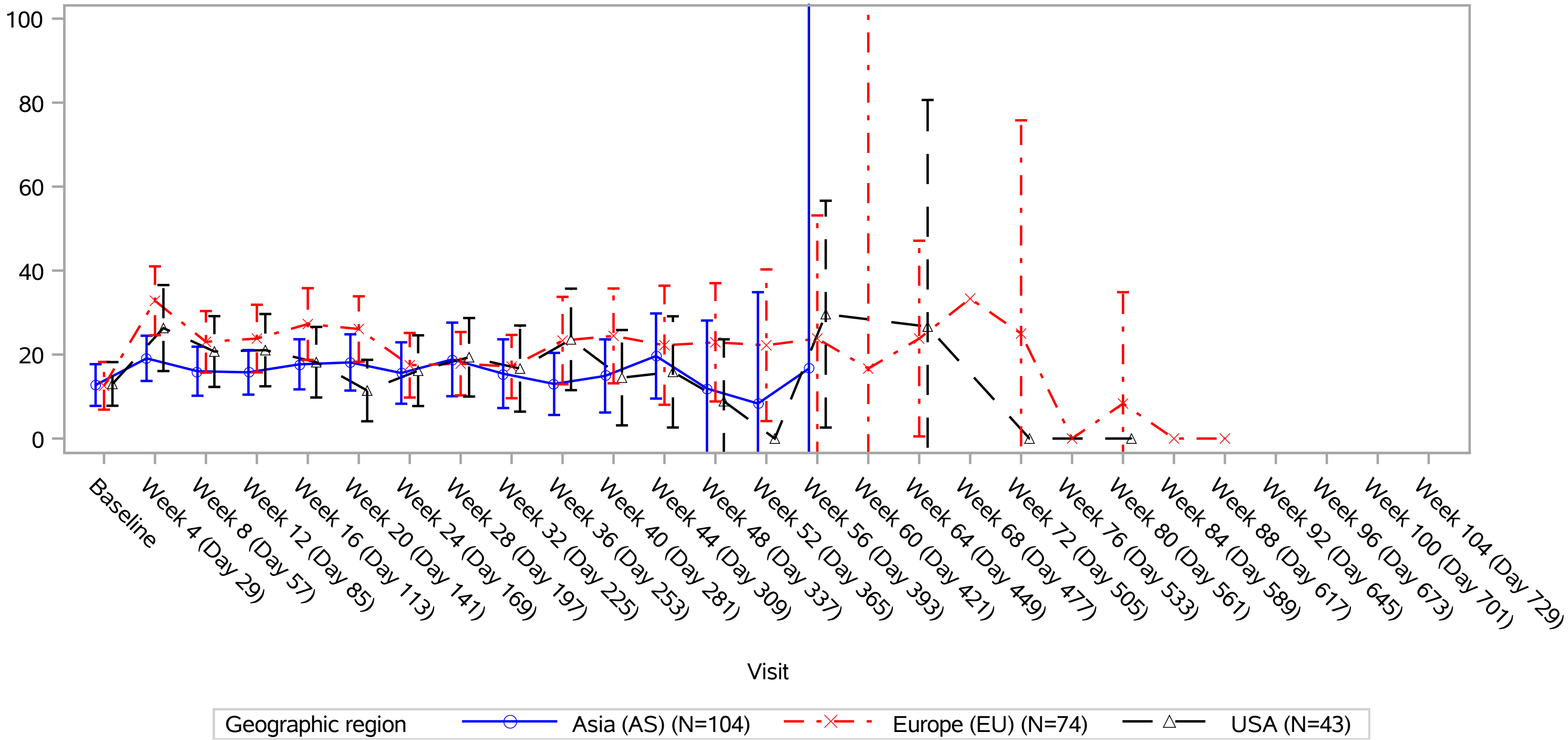
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Constipation
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30CO_SGECOG.pdf
15OCT2021 18:02

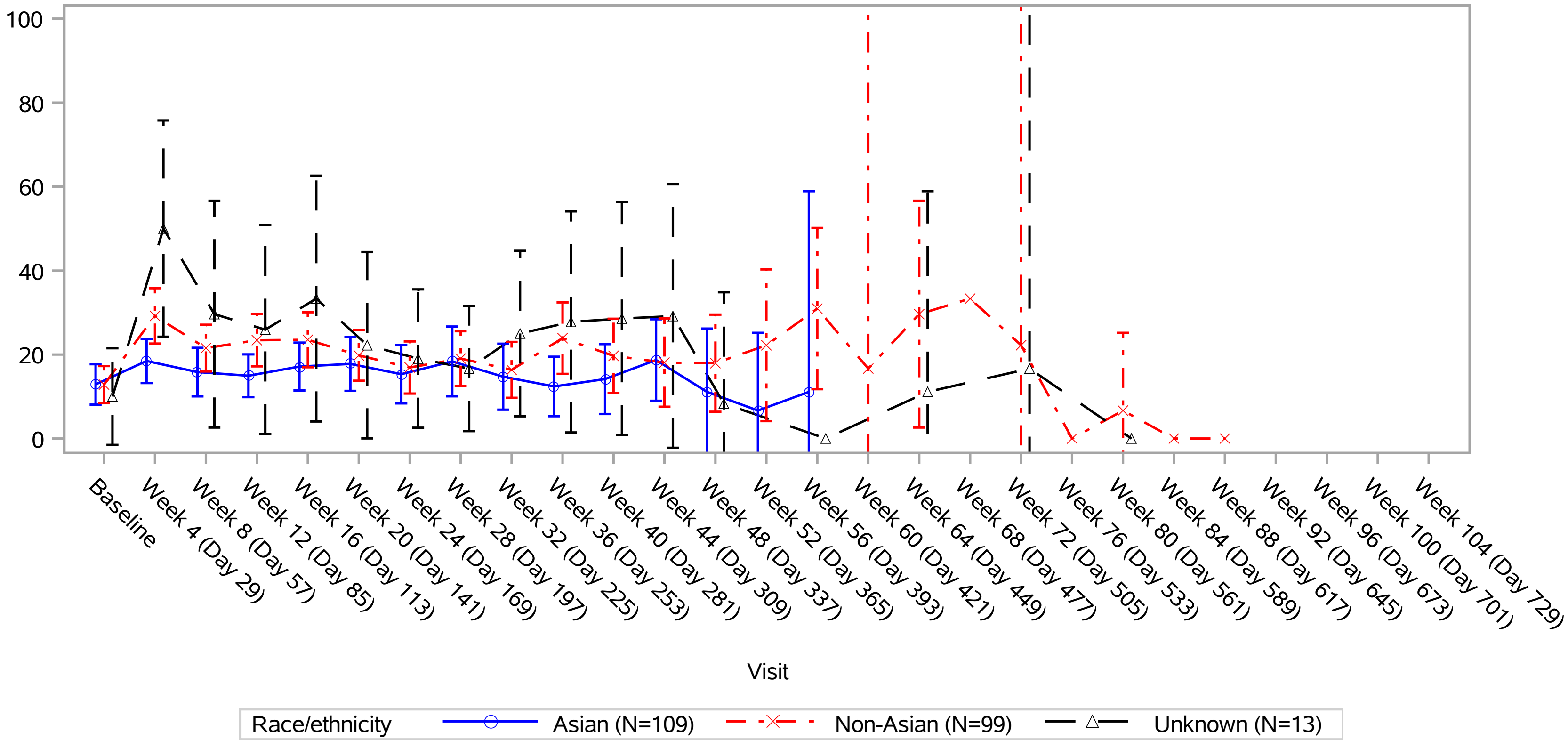
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Constipation
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30CO_SGGEO.pdf
15OCT2021 18:33

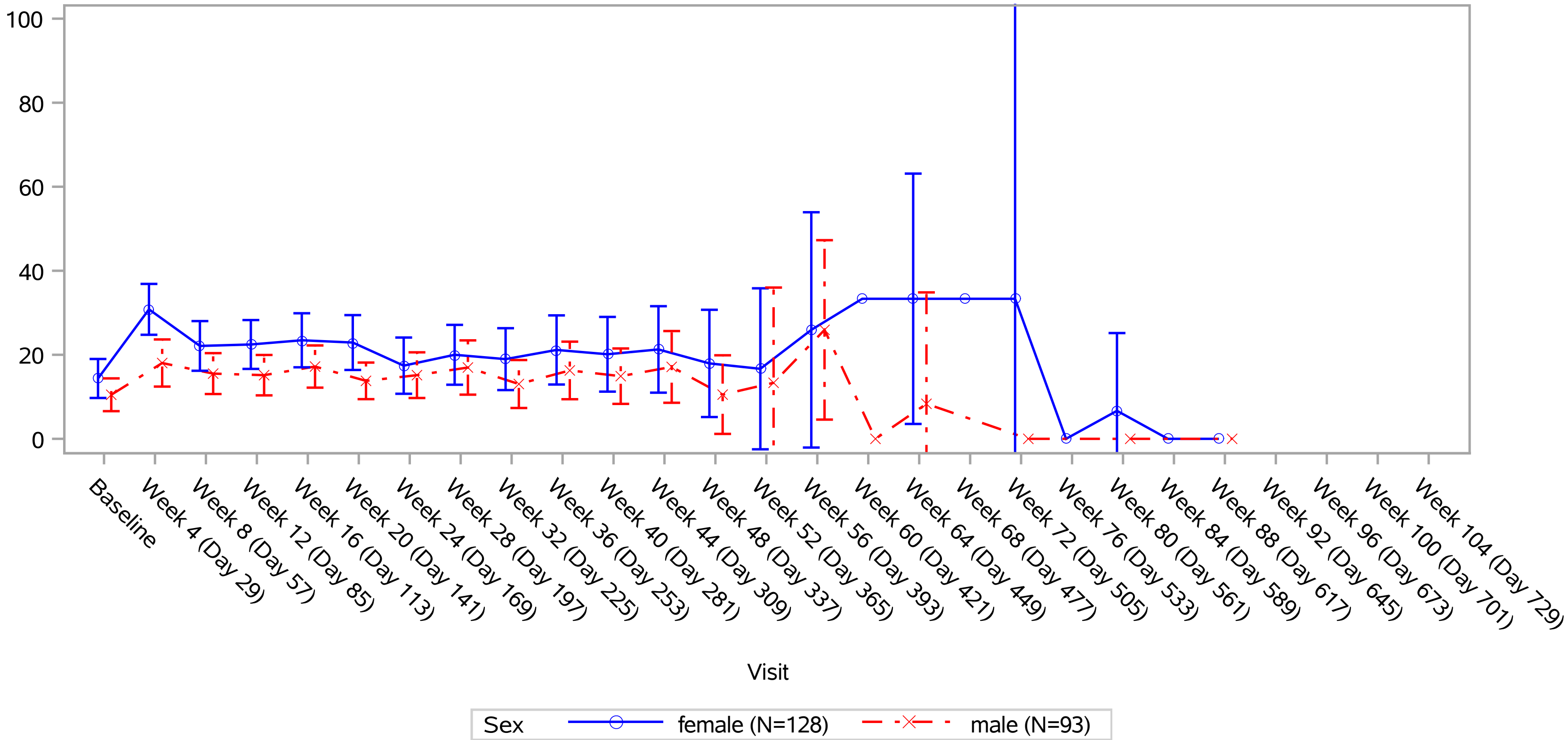
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Constipation
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30CO_SGRE.pdf
15OCT2021 19:04

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Constipation
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30CO_SGSEX.pdf
15OCT2021 19:34

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Diarrhoea
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=221)							
		Patients				Statistics			
Name Visit	Level	in study¹	%	with value¹	%	mean²	SD	CI LL	CI UL
All									
Baseline	n/a	221	100.0	212	95.9	4.56	12.78	2.83	6.29
Week 4 (Day 29)	n/a	221	100.0	191	86.4	5.93	14.90	3.81	8.06
Week 8 (Day 57)	n/a	193	87.3	171	88.6	7.02	17.04	4.45	9.59
Week 12 (Day 85)	n/a	176	79.6	160	90.9	6.67	17.05	4.00	9.33
Week 16 (Day 113)	n/a	164	74.2	143	87.2	5.83	14.43	3.44	8.21
Week 20 (Day 141)	n/a	148	67.0	138	93.2	5.07	14.47	2.64	7.51
Week 24 (Day 169)	n/a	137	62.0	122	89.1	6.28	16.22	3.38	9.19
Week 28 (Day 197)	n/a	129	58.4	120	93.0	7.78	19.20	4.31	11.25
Week 32 (Day 225)	n/a	119	53.8	104	87.4	6.73	18.80	3.07	10.39
Week 36 (Day 253)	n/a	112	50.7	95	84.8	5.61	15.87	2.38	8.85
Week 40 (Day 281)	n/a	104	47.1	90	86.5	5.93	15.46	2.69	9.16
Week 44 (Day 309)	n/a	95	43.0	84	88.4	7.14	17.22	3.41	10.88
Week 48 (Day 337)	n/a	81	36.7	45	55.6	3.70	10.59	0.52	6.89
Week 52 (Day 365)	n/a	64	29.0	11	17.2	6.06	13.48	-3.00	15.12
Week 56 (Day 393)	n/a	54	24.4	18	33.3	0.00	0.00	NE	NE
Week 60 (Day 421)	n/a	43	19.5	2	4.7	0.00	0.00	NE	NE
Week 64 (Day 449)	n/a	41	18.6	12	29.3	5.56	12.97	-2.69	13.80
Week 68 (Day 477)	n/a	34	15.4	2	5.9	0.00	0.00	NE	NE
Week 72 (Day 505)	n/a	34	15.4	5	14.7	0.00	0.00	NE	NE
Week 76 (Day 533)	n/a	31	14.0	3	9.7	0.00	0.00	NE	NE
Week 80 (Day 561)	n/a	30	13.6	6	20.0	0.00	0.00	NE	NE
Week 84 (Day 589)	n/a	19	8.6	1	5.3	0.00	NE	NE	NE
Week 88 (Day 617)	n/a	15	6.8	2	13.3	0.00	0.00	NE	NE
Week 92 (Day 645)	n/a	8	3.6	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	2.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	1.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	221	100.0	219	99.1	8.52	19.38	5.94	11.10
End of Study (LOCF)	n/a	221	100.0	219	99.1	8.22	19.25	5.66	10.78
Sex									
Baseline	Female	128	100.0	123	96.1	5.42	13.07	3.09	7.75
Week 4 (Day 29)	Female	128	100.0	106	82.8	6.29	13.89	3.61	8.96
Week 8 (Day 57)	Female	112	87.5	98	87.5	9.52	19.73	5.57	13.48
Week 12 (Day 85)	Female	104	81.3	94	90.4	6.03	13.79	3.20	8.85
Week 16 (Day 113)	Female	96	75.0	81	84.4	7.82	16.89	4.08	11.55
Week 20 (Day 141)	Female	86	67.2	80	93.0	5.42	15.41	1.99	8.85
Week 24 (Day 169)	Female	78	60.9	67	85.9	8.46	19.54	3.69	13.22
Week 28 (Day 197)	Female	72	56.3	65	90.3	7.18	19.09	2.45	11.91
Week 32 (Day 225)	Female	69	53.9	58	84.1	6.32	17.05	1.84	10.81
Week 36 (Day 253)	Female	64	50.0	52	81.3	5.13	13.82	1.28	8.98
Week 40 (Day 281)	Female	59	46.1	52	88.1	5.13	12.14	1.75	8.51
Week 44 (Day 309)	Female	56	43.8	47	83.9	8.51	20.23	2.57	14.45
Week 48 (Day 337)	Female	48	37.5	26	54.2	5.13	12.26	0.17	10.08
Week 52 (Day 365)	Female	38	29.7	6	15.8	5.56	13.61	-8.73	19.84
Week 56 (Day 393)	Female	31	24.2	9	29.0	0.00	0.00	NE	NE
Week 60 (Day 421)	Female	27	21.1	1	3.7	0.00	NE	NE	NE
Week 64 (Day 449)	Female	26	20.3	8	30.8	8.33	15.43	-4.57	21.23
Week 68 (Day 477)	Female	23	18.0	2	8.7	0.00	0.00	NE	NE
Week 72 (Day 505)	Female	23	18.0	3	13.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Female	21	16.4	3	14.3	0.00	0.00	NE	NE
Week 80 (Day 561)	Female	20	15.6	5	25.0	0.00	0.00	NE	NE
Week 84 (Day 589)	Female	12	9.4	1	8.3	0.00	NE	NE	NE
Week 88 (Day 617)	Female	9	7.0	1	11.1	0.00	NE	NE	NE
Week 92 (Day 645)	Female	6	4.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	3.9	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	1.6	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	0.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	128	100.0	127	99.2	9.97	20.71	6.34	13.61
End of Study (LOCF)	Female	128	100.0	127	99.2	9.71	20.62	6.09	13.33
Baseline	Male	93	100.0	89	95.7	3.37	12.36	0.77	5.97
Week 4 (Day 29)	Male	93	100.0	85	91.4	5.49	16.14	2.01	8.97
Week 8 (Day 57)	Male	81	87.1	73	90.1	3.65	11.87	0.88	6.42
Week 12 (Day 85)	Male	72	77.4	66	91.7	7.58	20.92	2.43	12.72
Week 16 (Day 113)	Male	68	73.1	62	91.2	3.23	9.94	0.70	5.75
Week 20 (Day 141)	Male	62	66.7	58	93.5	4.60	13.17	1.14	8.06
Week 24 (Day 169)	Male	59	63.4	55	93.2	3.64	10.49	0.80	6.47
Week 28 (Day 197)	Male	57	61.3	55	96.5	8.48	19.48	3.22	13.75
Week 32 (Day 225)	Male	50	53.8	46	92.0	7.25	20.98	1.02	13.48
Week 36 (Day 253)	Male	48	51.6	43	89.6	6.20	18.19	0.60	11.80
Week 40 (Day 281)	Male	45	48.4	38	84.4	7.02	19.23	0.70	13.34
Week 44 (Day 309)	Male	39	41.9	37	94.9	5.41	12.46	1.25	9.56
Week 48 (Day 337)	Male	33	35.5	19	57.6	1.75	7.65	-1.93	5.44
Week 52 (Day 365)	Male	26	28.0	5	19.2	6.67	14.91	-11.84	25.18
Week 56 (Day 393)	Male	23	24.7	9	39.1	0.00	0.00	NE	NE
Week 60 (Day 421)	Male	16	17.2	1	6.3	0.00	NE	NE	NE
Week 64 (Day 449)	Male	15	16.1	4	26.7	0.00	0.00	NE	NE
Week 68 (Day 477)	Male	11	11.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	11	11.8	2	18.2	0.00	0.00	NE	NE
Week 76 (Day 533)	Male	10	10.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	10	10.8	1	10.0	0.00	NE	NE	NE
Week 84 (Day 589)	Male	7	7.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	6	6.5	1	16.7	0.00	NE	NE	NE
Week 92 (Day 645)	Male	2	2.2	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	93	100.0	92	98.9	6.52	17.29	2.94	10.10
End of Study (LOCF)	Male	93	100.0	92	98.9	6.16	17.07	2.62	9.69
Age									

Baseline	< 65	141	100.0	133	94.3	4.01	11.63	2.01	6.01
Week 4 (Day 29)	< 65	141	100.0	123	87.2	4.61	12.31	2.41	6.81
Week 8 (Day 57)	< 65	127	90.1	113	89.0	6.49	16.58	3.40	9.58
Week 12 (Day 85)	< 65	118	83.7	105	89.0	5.08	15.18	2.14	8.02
Week 16 (Day 113)	< 65	108	76.6	93	86.1	6.09	14.70	3.07	9.12
Week 20 (Day 141)	< 65	100	70.9	97	97.0	4.47	13.29	1.79	7.15
Week 24 (Day 169)	< 65	93	66.0	86	92.5	4.65	12.69	1.93	7.37
Week 28 (Day 197)	< 65	88	62.4	83	94.3	7.63	18.28	3.64	11.62
Week 32 (Day 225)	< 65	83	58.9	73	88.0	3.65	15.28	0.09	7.22
Week 36 (Day 253)	< 65	78	55.3	70	89.7	3.81	13.36	0.62	7.00
Week 40 (Day 281)	< 65	75	53.2	69	92.0	5.31	15.78	1.52	9.11
Week 44 (Day 309)	< 65	71	50.4	65	91.5	6.67	16.87	2.49	10.85
Week 48 (Day 337)	< 65	61	43.3	33	54.1	4.04	11.05	0.12	7.96
Week 52 (Day 365)	< 65	48	34.0	6	12.5	0.00	0.00	NE	NE
Week 56 (Day 393)	< 65	41	29.1	11	26.8	0.00	0.00	NE	NE
Week 60 (Day 421)	< 65	33	23.4	2	6.1	0.00	0.00	NE	NE
Week 64 (Day 449)	< 65	31	22.0	10	32.3	6.67	14.05	-3.39	16.72
Week 68 (Day 477)	< 65	26	18.4	2	7.7	0.00	0.00	NE	NE
Week 72 (Day 505)	< 65	26	18.4	5	19.2	0.00	0.00	NE	NE
Week 76 (Day 533)	< 65	25	17.7	3	12.0	0.00	0.00	NE	NE
Week 80 (Day 561)	< 65	24	17.0	5	20.8	0.00	0.00	NE	NE
Week 84 (Day 589)	< 65	16	11.3	1	6.3	0.00	NE	NE	NE
Week 88 (Day 617)	< 65	13	9.2	2	15.4	0.00	0.00	NE	NE
Week 92 (Day 645)	< 65	7	5.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	3.5	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	2.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	0.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	141	100.0	139	98.6	9.11	19.99	5.76	12.46
End of Study (LOCF)	< 65	141	100.0	139	98.6	8.87	19.89	5.54	12.21
Baseline	>= 65	80	100.0	79	98.8	5.49	14.55	2.23	8.74
Week 4 (Day 29)	>= 65	80	100.0	68	85.0	8.33	18.55	3.84	12.82
Week 8 (Day 57)	>= 65	66	82.5	58	87.9	8.05	18.00	3.31	12.78
Week 12 (Day 85)	>= 65	58	72.5	55	94.8	9.70	19.95	4.30	15.09

Week 16 (Day 113)	>= 65	56	70.0	50	89.3	5.33	14.06	1.34	9.33
Week 20 (Day 141)	>= 65	48	60.0	41	85.4	6.50	17.03	1.13	11.88
Week 24 (Day 169)	>= 65	44	55.0	36	81.8	10.19	22.28	2.65	17.72
Week 28 (Day 197)	>= 65	41	51.3	37	90.2	8.11	21.38	0.98	15.24
Week 32 (Day 225)	>= 65	36	45.0	31	86.1	13.98	24.00	5.18	22.78
Week 36 (Day 253)	>= 65	34	42.5	25	73.5	10.67	20.91	2.04	19.30
Week 40 (Day 281)	>= 65	29	36.3	21	72.4	7.94	14.55	1.31	14.56
Week 44 (Day 309)	>= 65	24	30.0	19	79.2	8.77	18.73	-0.26	17.80
Week 48 (Day 337)	>= 65	20	25.0	12	60.0	2.78	9.62	-3.34	8.89
Week 52 (Day 365)	>= 65	16	20.0	5	31.3	13.33	18.26	-9.34	36.00
Week 56 (Day 393)	>= 65	13	16.3	7	53.8	0.00	0.00	NE	NE
Week 60 (Day 421)	>= 65	10	12.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	10	12.5	2	20.0	0.00	0.00	NE	NE
Week 68 (Day 477)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	6	7.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	6	7.5	1	16.7	0.00	NE	NE	NE
Week 84 (Day 589)	>= 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	2.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	80	100.0	80	100.0	7.50	18.35	3.42	11.58
End of Study (LOCF)	>= 65	80	100.0	80	100.0	7.08	18.14	3.05	11.12
ECOG performance status									
Baseline	0	63	100.0	60	95.2	5.00	13.48	1.52	8.48
Week 4 (Day 29)	0	63	100.0	56	88.9	5.36	16.55	0.93	9.79
Week 8 (Day 57)	0	58	92.1	52	89.7	8.97	18.80	3.74	14.21
Week 12 (Day 85)	0	55	87.3	49	89.1	10.20	20.64	4.27	16.13
Week 16 (Day 113)	0	54	85.7	45	83.3	5.19	14.13	0.94	9.43
Week 20 (Day 141)	0	52	82.5	48	92.3	4.86	13.73	0.87	8.85
Week 24 (Day 169)	0	49	77.8	43	87.8	6.98	17.15	1.70	12.25
Week 28 (Day 197)	0	46	73.0	42	91.3	11.11	25.15	3.27	18.95

Week 32 (Day 225)	0	41	65.1	34	82.9	4.90	16.68	-0.92	10.72
Week 36 (Day 253)	0	39	61.9	31	79.5	3.23	10.02	-0.45	6.90
Week 40 (Day 281)	0	37	58.7	30	81.1	5.56	12.63	0.84	10.27
Week 44 (Day 309)	0	36	57.1	29	80.6	9.20	21.63	0.97	17.42
Week 48 (Day 337)	0	28	44.4	18	64.3	3.70	10.78	-1.66	9.06
Week 52 (Day 365)	0	27	42.9	6	22.2	5.56	13.61	-8.73	19.84
Week 56 (Day 393)	0	24	38.1	8	33.3	0.00	0.00	NE	NE
Week 60 (Day 421)	0	21	33.3	1	4.8	0.00	NE	NE	NE
Week 64 (Day 449)	0	21	33.3	7	33.3	4.76	12.60	-6.89	16.41
Week 68 (Day 477)	0	17	27.0	1	5.9	0.00	NE	NE	NE
Week 72 (Day 505)	0	17	27.0	2	11.8	0.00	0.00	NE	NE
Week 76 (Day 533)	0	15	23.8	2	13.3	0.00	0.00	NE	NE
Week 80 (Day 561)	0	14	22.2	1	7.1	0.00	NE	NE	NE
Week 84 (Day 589)	0	11	17.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	10	15.9	1	10.0	0.00	NE	NE	NE
Week 92 (Day 645)	0	5	7.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	6.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	4.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	63	100.0	63	100.0	13.76	25.84	7.25	20.27
End of Study (LOCF)	0	63	100.0	63	100.0	12.17	25.61	5.72	18.62
Baseline	1	157	100.0	151	96.2	4.42	12.58	2.39	6.44
Week 4 (Day 29)	1	157	100.0	134	85.4	6.22	14.26	3.78	8.66
Week 8 (Day 57)	1	134	85.4	119	88.8	6.16	16.22	3.22	9.11
Week 12 (Day 85)	1	121	77.1	111	91.7	5.11	15.04	2.28	7.93
Week 16 (Day 113)	1	110	70.1	98	89.1	6.12	14.63	3.19	9.06
Week 20 (Day 141)	1	96	61.1	90	93.8	5.19	14.92	2.06	8.31
Week 24 (Day 169)	1	88	56.1	79	89.8	5.91	15.80	2.37	9.45
Week 28 (Day 197)	1	83	52.9	78	94.0	5.98	14.95	2.61	9.35
Week 32 (Day 225)	1	78	49.7	70	89.7	7.62	19.80	2.90	12.34
Week 36 (Day 253)	1	73	46.5	64	87.7	6.77	17.99	2.28	11.27
Week 40 (Day 281)	1	67	42.7	60	89.6	6.11	16.80	1.77	10.45

Week 44 (Day 309)	1	59	37.6	55	93.2	6.06	14.47	2.15	9.97
Week 48 (Day 337)	1	53	33.8	27	50.9	3.70	10.68	-0.52	7.93
Week 52 (Day 365)	1	37	23.6	5	13.5	6.67	14.91	-11.84	25.18
Week 56 (Day 393)	1	30	19.1	10	33.3	0.00	0.00	NE	NE
Week 60 (Day 421)	1	22	14.0	1	4.5	0.00	NE	NE	NE
Week 64 (Day 449)	1	20	12.7	5	25.0	6.67	14.91	-11.84	25.18
Week 68 (Day 477)	1	17	10.8	1	5.9	0.00	NE	NE	NE
Week 72 (Day 505)	1	17	10.8	3	17.6	0.00	0.00	NE	NE
Week 76 (Day 533)	1	16	10.2	1	6.3	0.00	NE	NE	NE
Week 80 (Day 561)	1	16	10.2	5	31.3	0.00	0.00	NE	NE
Week 84 (Day 589)	1	8	5.1	1	12.5	0.00	NE	NE	NE
Week 88 (Day 617)	1	5	3.2	1	20.0	0.00	NE	NE	NE
Week 92 (Day 645)	1	3	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	157	100.0	155	98.7	6.45	15.71	3.96	8.94
End of Study (LOCF)	1	157	100.0	155	98.7	6.67	15.85	4.15	9.18
Baseline	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Geographic region									
Baseline	USA	43	100.0	41	95.3	9.76	17.07	4.37	15.14
Week 4 (Day 29)	USA	43	100.0	38	88.4	8.77	16.77	3.26	14.29
Week 8 (Day 57)	USA	41	95.3	37	90.2	12.61	21.30	5.51	19.72
Week 12 (Day 85)	USA	41	95.3	37	90.2	11.71	22.52	4.20	19.22
Week 16 (Day 113)	USA	40	93.0	33	82.5	11.11	19.84	4.08	18.15
Week 20 (Day 141)	USA	39	90.7	35	89.7	8.57	18.69	2.15	14.99
Week 24 (Day 169)	USA	36	83.7	33	91.7	9.09	17.23	2.98	15.20
Week 28 (Day 197)	USA	35	81.4	31	88.6	10.75	26.37	1.08	20.43
Week 32 (Day 225)	USA	32	74.4	28	87.5	15.48	27.94	4.64	26.31
Week 36 (Day 253)	USA	32	74.4	24	75.0	8.33	17.72	0.85	15.82
Week 40 (Day 281)	USA	29	67.4	22	75.9	15.15	24.62	4.24	26.07

Week 44 (Day 309)	USA	26	60.5	21	80.8	9.52	15.43	2.50	16.55
Week 48 (Day 337)	USA	21	48.8	15	71.4	6.67	13.80	-0.98	14.31
Week 52 (Day 365)	USA	18	41.9	1	5.6	0.00	NE	NE	NE
Week 56 (Day 393)	USA	18	41.9	9	50.0	0.00	0.00	NE	NE
Week 60 (Day 421)	USA	17	39.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	15	34.9	5	33.3	13.33	18.26	-9.34	36.00
Week 68 (Day 477)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	12	27.9	1	8.3	0.00	NE	NE	NE
Week 76 (Day 533)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	12	27.9	2	16.7	0.00	0.00	NE	NE
Week 84 (Day 589)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	6	14.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	11.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	7.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	43	100.0	43	100.0	13.18	21.99	6.41	19.95
End of Study (LOCF)	USA	43	100.0	43	100.0	11.63	21.68	4.96	18.30
Baseline	Europe (EU)	74	100.0	69	93.2	3.86	10.75	1.28	6.45
Week 4 (Day 29)	Europe (EU)	74	100.0	64	86.5	3.12	9.79	0.68	5.57
Week 8 (Day 57)	Europe (EU)	65	87.8	55	84.6	8.48	19.48	3.22	13.75
Week 12 (Day 85)	Europe (EU)	57	77.0	49	86.0	6.80	19.22	1.28	12.32
Week 16 (Day 113)	Europe (EU)	55	74.3	44	80.0	6.82	15.38	2.14	11.50
Week 20 (Day 141)	Europe (EU)	49	66.2	46	93.9	3.62	12.63	-0.13	7.37
Week 24 (Day 169)	Europe (EU)	47	63.5	42	89.4	7.94	20.57	1.53	14.35
Week 28 (Day 197)	Europe (EU)	45	60.8	43	95.6	6.20	15.01	1.58	10.82
Week 32 (Day 225)	Europe (EU)	39	52.7	35	89.7	3.81	13.46	-0.81	8.43
Week 36 (Day 253)	Europe (EU)	34	45.9	30	88.2	4.44	14.47	-0.96	9.85
Week 40 (Day 281)	Europe (EU)	31	41.9	30	96.8	2.22	8.46	-0.94	5.38
Week 44 (Day 309)	Europe (EU)	28	37.8	24	85.7	8.33	24.57	-2.04	18.71

Week 48 (Day 337)	Europe (EU)	22	29.7	16	72.7	2.08	8.33	-2.36	6.52
Week 52 (Day 365)	Europe (EU)	19	25.7	6	31.6	5.56	13.61	-8.73	19.84
Week 56 (Day 393)	Europe (EU)	17	23.0	7	41.2	0.00	0.00	NE	NE
Week 60 (Day 421)	Europe (EU)	15	20.3	2	13.3	0.00	0.00	NE	NE
Week 64 (Day 449)	Europe (EU)	15	20.3	7	46.7	0.00	0.00	NE	NE
Week 68 (Day 477)	Europe (EU)	13	17.6	2	15.4	0.00	0.00	NE	NE
Week 72 (Day 505)	Europe (EU)	13	17.6	4	30.8	0.00	0.00	NE	NE
Week 76 (Day 533)	Europe (EU)	11	14.9	3	27.3	0.00	0.00	NE	NE
Week 80 (Day 561)	Europe (EU)	10	13.5	4	40.0	0.00	0.00	NE	NE
Week 84 (Day 589)	Europe (EU)	6	8.1	1	16.7	0.00	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	4.1	2	66.7	0.00	0.00	NE	NE
Cycle 12 (LOCF)	Europe (EU)	74	100.0	73	98.6	8.22	19.86	3.59	12.85
End of Study (LOCF)	Europe (EU)	74	100.0	73	98.6	8.22	19.86	3.59	12.85
Baseline	Asia (AS)	104	100.0	102	98.1	2.94	11.59	0.67	5.22
Week 4 (Day 29)	Asia (AS)	104	100.0	89	85.6	6.74	16.80	3.20	10.28
Week 8 (Day 57)	Asia (AS)	87	83.7	79	90.8	3.38	11.44	0.81	5.94
Week 12 (Day 85)	Asia (AS)	78	75.0	74	94.9	4.05	10.97	1.51	6.60
Week 16 (Day 113)	Asia (AS)	69	66.3	66	95.7	2.53	8.89	0.34	4.71
Week 20 (Day 141)	Asia (AS)	60	57.7	57	95.0	4.09	12.71	0.72	7.47
Week 24 (Day 169)	Asia (AS)	54	51.9	47	87.0	2.84	9.40	0.08	5.60
Week 28 (Day 197)	Asia (AS)	49	47.1	46	93.9	7.25	17.09	2.17	12.32
Week 32 (Day 225)	Asia (AS)	48	46.2	41	85.4	3.25	12.48	-0.69	7.19
Week 36 (Day 253)	Asia (AS)	46	44.2	41	89.1	4.88	15.92	-0.15	9.90
Week 40 (Day 281)	Asia (AS)	44	42.3	38	86.4	3.51	10.37	0.10	6.92
Week 44 (Day 309)	Asia (AS)	41	39.4	39	95.1	5.13	12.18	1.18	9.08
Week 48 (Day 337)	Asia (AS)	38	36.5	14	36.8	2.38	8.91	-2.76	7.52
Week 52 (Day 365)	Asia (AS)	27	26.0	4	14.8	8.33	16.67	-18.19	34.85
Week 56 (Day 393)	Asia (AS)	19	18.3	2	10.5	0.00	0.00	NE	NE
Week 60 (Day 421)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	5.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	104	100.0	103	99.0	6.80	17.69	3.34	10.25
End of Study (LOCF)	Asia (AS)	104	100.0	103	99.0	6.80	17.69	3.34	10.25
Race/ethnicity									
Baseline	Asian	109	100.0	106	97.2	3.14	11.75	0.88	5.41
Week 4 (Day 29)	Asian	109	100.0	92	84.4	6.52	16.57	3.09	9.95
Week 8 (Day 57)	Asian	91	83.5	80	87.9	3.33	11.38	0.80	5.86
Week 12 (Day 85)	Asian	82	75.2	78	95.1	3.85	10.72	1.43	6.26
Week 16 (Day 113)	Asian	73	67.0	70	95.9	2.86	9.40	0.62	5.10
Week 20 (Day 141)	Asian	64	58.7	60	93.8	5.56	15.24	1.62	9.49
Week 24 (Day 169)	Asian	57	52.3	50	87.7	3.33	10.10	0.46	6.20
Week 28 (Day 197)	Asian	52	47.7	49	94.2	7.48	17.03	2.59	12.37
Week 32 (Day 225)	Asian	50	45.9	43	86.0	3.88	13.03	-0.13	7.89
Week 36 (Day 253)	Asian	48	44.0	43	89.6	5.43	16.15	0.46	10.40
Week 40 (Day 281)	Asian	46	42.2	40	87.0	4.17	11.16	0.60	7.74
Week 44 (Day 309)	Asian	43	39.4	41	95.3	4.88	11.93	1.11	8.64
Week 48 (Day 337)	Asian	40	36.7	15	37.5	2.22	8.61	-2.54	6.99
Week 52 (Day 365)	Asian	29	26.6	5	17.2	6.67	14.91	-11.84	25.18
Week 56 (Day 393)	Asian	21	19.3	3	14.3	0.00	0.00	NE	NE
Week 60 (Day 421)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	5.5	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	4.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	1.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	109	100.0	107	98.2	7.17	18.33	3.65	10.68
End of Study (LOCF)	Asian	109	100.0	107	98.2	7.17	18.33	3.65	10.68
Baseline	Non-Asian	99	100.0	96	97.0	6.60	14.20	3.72	9.47
Week 4 (Day 29)	Non-Asian	99	100.0	89	89.9	5.62	13.52	2.77	8.47
Week 8 (Day 57)	Non-Asian	91	91.9	82	90.1	10.57	20.20	6.13	15.01
Week 12 (Day 85)	Non-Asian	83	83.8	73	88.0	10.50	22.14	5.34	15.67
Week 16 (Day 113)	Non-Asian	80	80.8	68	85.0	8.82	17.86	4.50	13.15
Week 20 (Day 141)	Non-Asian	74	74.7	69	93.2	5.31	14.71	1.78	8.85
Week 24 (Day 169)	Non-Asian	70	70.7	65	92.9	8.72	19.79	3.81	13.62
Week 28 (Day 197)	Non-Asian	67	67.7	63	94.0	7.41	20.25	2.31	12.51
Week 32 (Day 225)	Non-Asian	60	60.6	53	88.3	10.06	23.19	3.67	16.46
Week 36 (Day 253)	Non-Asian	55	55.6	46	83.6	5.07	14.00	0.92	9.23
Week 40 (Day 281)	Non-Asian	49	49.5	43	87.8	7.75	19.02	1.90	13.61
Week 44 (Day 309)	Non-Asian	43	43.4	35	81.4	5.71	12.75	1.34	10.09
Week 48 (Day 337)	Non-Asian	35	35.4	26	74.3	5.13	12.26	0.17	10.08
Week 52 (Day 365)	Non-Asian	29	29.3	6	20.7	5.56	13.61	-8.73	19.84
Week 56 (Day 393)	Non-Asian	27	27.3	14	51.9	0.00	0.00	NE	NE
Week 60 (Day 421)	Non-Asian	26	26.3	2	7.7	0.00	0.00	NE	NE
Week 64 (Day 449)	Non-Asian	24	24.2	9	37.5	3.70	11.11	-4.84	12.24
Week 68 (Day 477)	Non-Asian	20	20.2	2	10.0	0.00	0.00	NE	NE
Week 72 (Day 505)	Non-Asian	20	20.2	3	15.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Non-Asian	18	18.2	3	16.7	0.00	0.00	NE	NE
Week 80 (Day 561)	Non-Asian	17	17.2	5	29.4	0.00	0.00	NE	NE
Week 84 (Day 589)	Non-Asian	11	11.1	1	9.1	0.00	NE	NE	NE
Week 88 (Day 617)	Non-Asian	8	8.1	2	25.0	0.00	0.00	NE	NE
Week 92 (Day 645)	Non-Asian	4	4.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	3.0	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	99	100.0	99	100.0	8.08	17.88	4.52	11.65

End of Study (LOCF)	Non-Asian	99	100.0	99	100.0	7.74	17.71	4.21	11.28
Baseline	Unknown	13	100.0	10	76.9	0.00	0.00	NE	NE
Week 4 (Day 29)	Unknown	13	100.0	10	76.9	3.33	10.54	-4.21	10.87
Week 8 (Day 57)	Unknown	11	84.6	9	81.8	7.41	22.22	-9.67	24.49
Week 12 (Day 85)	Unknown	11	84.6	9	81.8	0.00	0.00	NE	NE
Week 16 (Day 113)	Unknown	11	84.6	5	45.5	6.67	14.91	-11.84	25.18
Week 20 (Day 141)	Unknown	10	76.9	9	90.0	0.00	0.00	NE	NE
Week 24 (Day 169)	Unknown	10	76.9	7	70.0	4.76	12.60	-6.89	16.41
Week 28 (Day 197)	Unknown	10	76.9	8	80.0	12.50	24.80	-8.23	33.23
Week 32 (Day 225)	Unknown	9	69.2	8	88.9	0.00	0.00	NE	NE
Week 36 (Day 253)	Unknown	9	69.2	6	66.7	11.11	27.22	-17.45	39.67
Week 40 (Day 281)	Unknown	9	69.2	7	77.8	4.76	12.60	-6.89	16.41
Week 44 (Day 309)	Unknown	9	69.2	8	88.9	25.00	38.83	-7.46	57.46
Week 48 (Day 337)	Unknown	6	46.2	4	66.7	0.00	0.00	NE	NE
Week 52 (Day 365)	Unknown	6	46.2	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	6	46.2	1	16.7	0.00	NE	NE	NE
Week 60 (Day 421)	Unknown	5	38.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	5	38.5	3	60.0	11.11	19.25	-36.70	58.92
Week 68 (Day 477)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	4	30.8	2	50.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	4	30.8	1	25.0	0.00	NE	NE	NE
Week 84 (Day 589)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	7.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	13	100.0	13	100.0	23.08	31.58	3.99	42.16
End of Study (LOCF)	Unknown	13	100.0	13	100.0	20.51	32.03	1.16	39.87

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TO_QSC30DI_SG.xls
27OCT2021 7:13

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Diarrhoea
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	78	36.8	30.6	43.5
	Cycle 12 (LOCF)	n/a	212	95.9	31	14.6	10.5	20.0
	End of Study (LOCF)	n/a	212	95.9	31	14.6	10.5	20.0
Sex	All visits	Female	123	55.7	48	39.0	30.9	47.9
		Male	89	40.3	30	33.7	24.7	44.0
	Cycle 12 (LOCF)	Female	123	55.7	19	15.4	10.1	22.9
		Male	89	40.3	12	13.5	7.9	22.1
	End of Study (LOCF)	Female	123	55.7	19	15.4	10.1	22.9
		Male	89	40.3	12	13.5	7.9	22.1
Age	All visits	< 65	133	60.2	49	36.8	29.1	45.3
		>= 65	79	35.7	29	36.7	26.9	47.7
	Cycle 12 (LOCF)	< 65	133	60.2	22	16.5	11.2	23.8
		>= 65	79	35.7	9	11.4	6.1	20.3
	End of Study (LOCF)	< 65	133	60.2	22	16.5	11.2	23.8
		>= 65	79	35.7	9	11.4	6.1	20.3
ECOG performance status	All visits	0	60	27.1	32	53.3	40.9	65.4
		1	151	68.3	46	30.5	23.7	38.2
		Missing	1	0.5	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	60	27.1	15	25.0	15.8	37.2
		1	151	68.3	16	10.6	6.6	16.5
		Missing	1	0.5	0	0.0	0.0	79.3
	End of Study (LOCF)	0	60	27.1	13	21.7	13.1	33.6
		1	151	68.3	18	11.9	7.7	18.1
		Missing	1	0.5	0	0.0	0.0	79.3
Geographic region	All visits	USA	41	18.6	21	51.2	36.5	65.7
		Europe (EU)	69	31.2	27	39.1	28.5	50.9
		Asia (AS)	102	46.2	30	29.4	21.4	38.9
	Cycle 12 (LOCF)	USA	41	18.6	9	22.0	12.0	36.7
		Europe (EU)	69	31.2	10	14.5	8.1	24.7
		Asia (AS)	102	46.2	12	11.8	6.9	19.4
	End of Study (LOCF)	USA	41	18.6	8	19.5	10.2	34.0
		Europe (EU)	69	31.2	11	15.9	9.1	26.3
		Asia (AS)	102	46.2	12	11.8	6.9	19.4
Race/ethnicity	All visits	Asian	106	48.0	31	29.2	21.4	38.5
		Non-Asian	96	43.4	40	41.7	32.3	51.7
		Unknown	10	4.5	7	70.0	39.7	89.2
	Cycle 12 (LOCF)	Asian	106	48.0	13	12.3	7.3	19.9

		Non-Asian	96	43.4	12	12.5	7.3	20.6
		Unknown	10	4.5	6	60.0	31.3	83.2
	End of Study (LOCF)	Asian	106	48.0	13	12.3	7.3	19.9
		Non-Asian	96	43.4	13	13.5	8.1	21.8
		Unknown	10	4.5	5	50.0	23.7	76.3

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30DI_W10_SG.xls
15OCT2021 12:51

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Diarrhoea
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

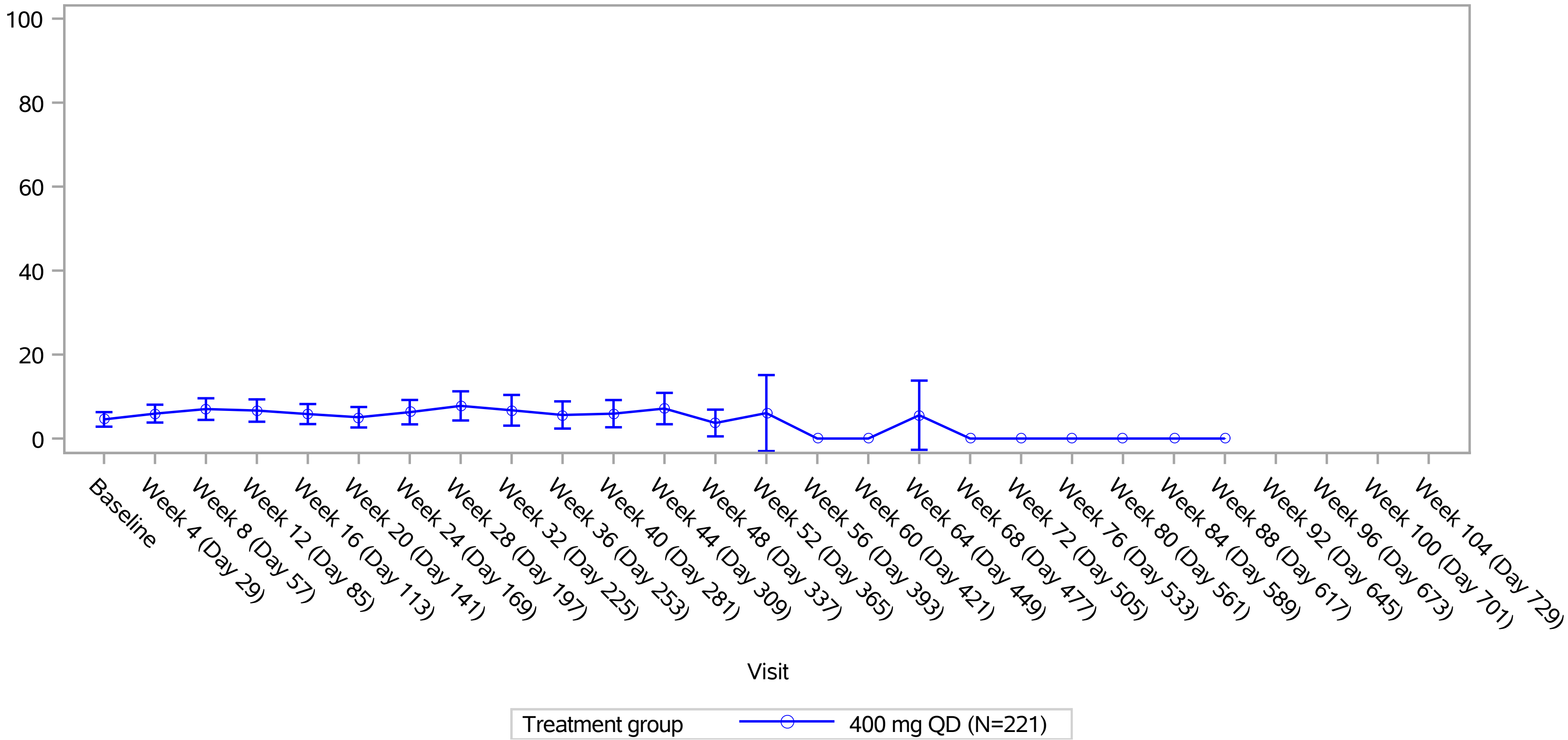
			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	78	36.8	30.6	43.5
	Cycle 12 (LOCF)	n/a	212	95.9	31	14.6	10.5	20.0
	End of Study (LOCF)	n/a	212	95.9	31	14.6	10.5	20.0
Sex	All visits	Female	123	55.7	48	39.0	30.9	47.9
		Male	89	40.3	30	33.7	24.7	44.0
	Cycle 12 (LOCF)	Female	123	55.7	19	15.4	10.1	22.9
		Male	89	40.3	12	13.5	7.9	22.1
	End of Study (LOCF)	Female	123	55.7	19	15.4	10.1	22.9
		Male	89	40.3	12	13.5	7.9	22.1
Age	All visits	< 65	133	60.2	49	36.8	29.1	45.3
		>= 65	79	35.7	29	36.7	26.9	47.7
	Cycle 12 (LOCF)	< 65	133	60.2	22	16.5	11.2	23.8
		>= 65	79	35.7	9	11.4	6.1	20.3
	End of Study (LOCF)	< 65	133	60.2	22	16.5	11.2	23.8
		>= 65	79	35.7	9	11.4	6.1	20.3
ECOG performance status	All visits	0	60	27.1	32	53.3	40.9	65.4
		1	151	68.3	46	30.5	23.7	38.2
		Missing	1	0.5	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	60	27.1	15	25.0	15.8	37.2
		1	151	68.3	16	10.6	6.6	16.5
		Missing	1	0.5	0	0.0	0.0	79.3
	End of Study (LOCF)	0	60	27.1	13	21.7	13.1	33.6
		1	151	68.3	18	11.9	7.7	18.1
		Missing	1	0.5	0	0.0	0.0	79.3
Geographic region	All visits	USA	41	18.6	21	51.2	36.5	65.7
		Europe (EU)	69	31.2	27	39.1	28.5	50.9
		Asia (AS)	102	46.2	30	29.4	21.4	38.9
	Cycle 12 (LOCF)	USA	41	18.6	9	22.0	12.0	36.7
		Europe (EU)	69	31.2	10	14.5	8.1	24.7
		Asia (AS)	102	46.2	12	11.8	6.9	19.4
	End of Study (LOCF)	USA	41	18.6	8	19.5	10.2	34.0
		Europe (EU)	69	31.2	11	15.9	9.1	26.3
		Asia (AS)	102	46.2	12	11.8	6.9	19.4
Race/ethnicity	All visits	Asian	106	48.0	31	29.2	21.4	38.5
		Non-Asian	96	43.4	40	41.7	32.3	51.7
		Unknown	10	4.5	7	70.0	39.7	89.2
	Cycle 12 (LOCF)	Asian	106	48.0	13	12.3	7.3	19.9

		Non-Asian	96	43.4	12	12.5	7.3	20.6
		Unknown	10	4.5	6	60.0	31.3	83.2
	End of Study (LOCF)	Asian	106	48.0	13	12.3	7.3	19.9
		Non-Asian	96	43.4	13	13.5	8.1	21.8
		Unknown	10	4.5	5	50.0	23.7	76.3

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30DI_W15_SG.xls
15OCT2021 12:41

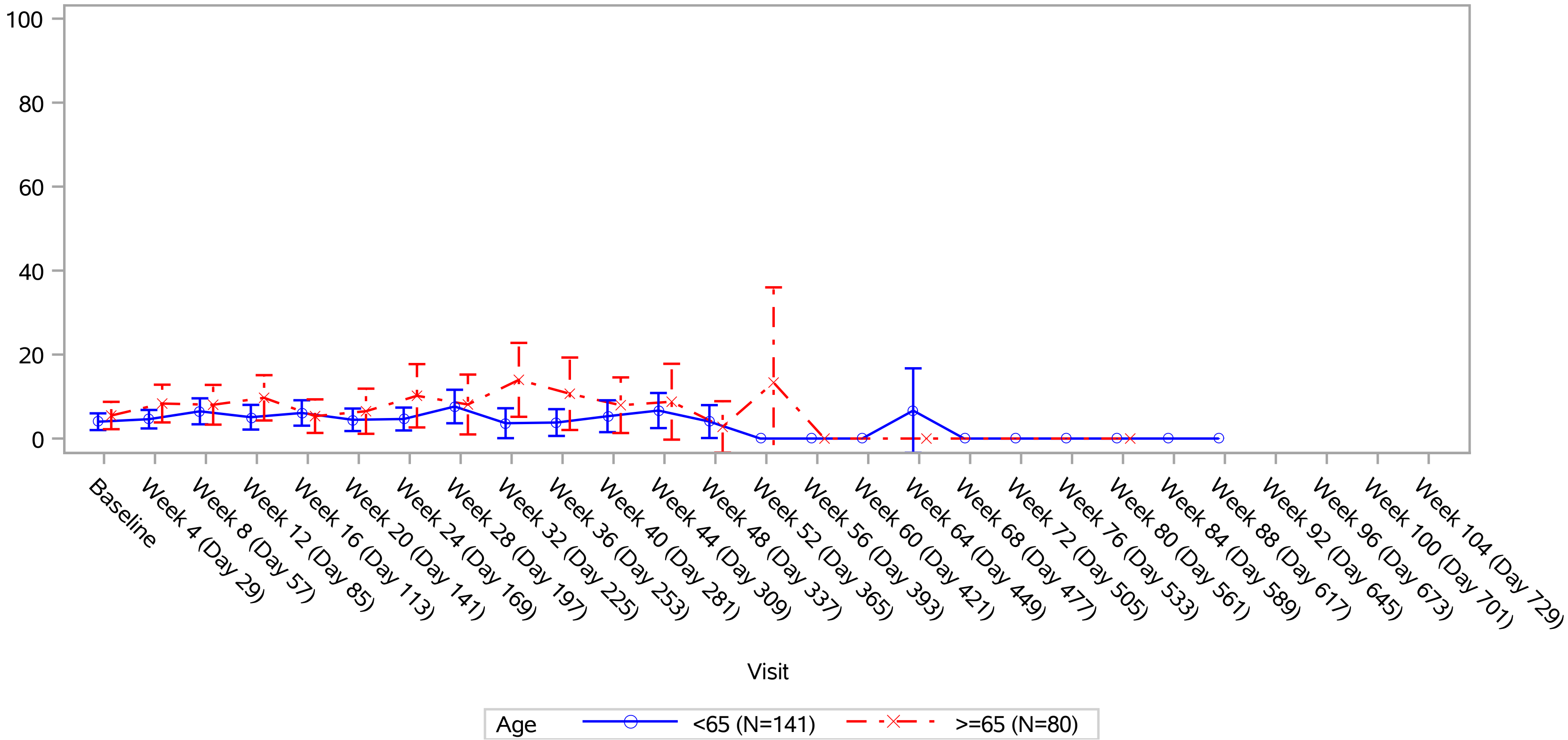
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Diarrhoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30DI.pdf
15OCT2021 17:04

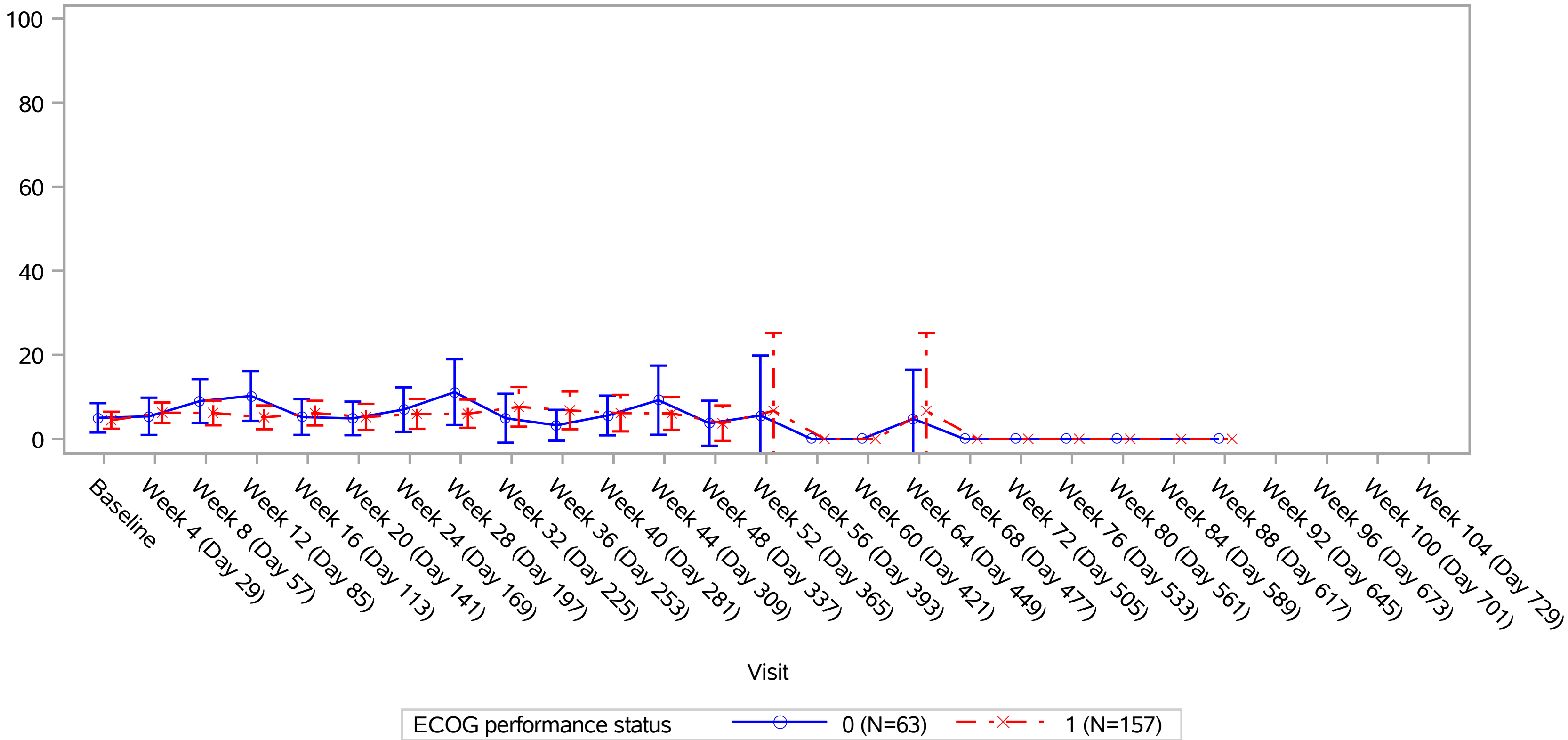
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Diarrhoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30DI_SGAGE65.pdf
15OCT2021 17:33

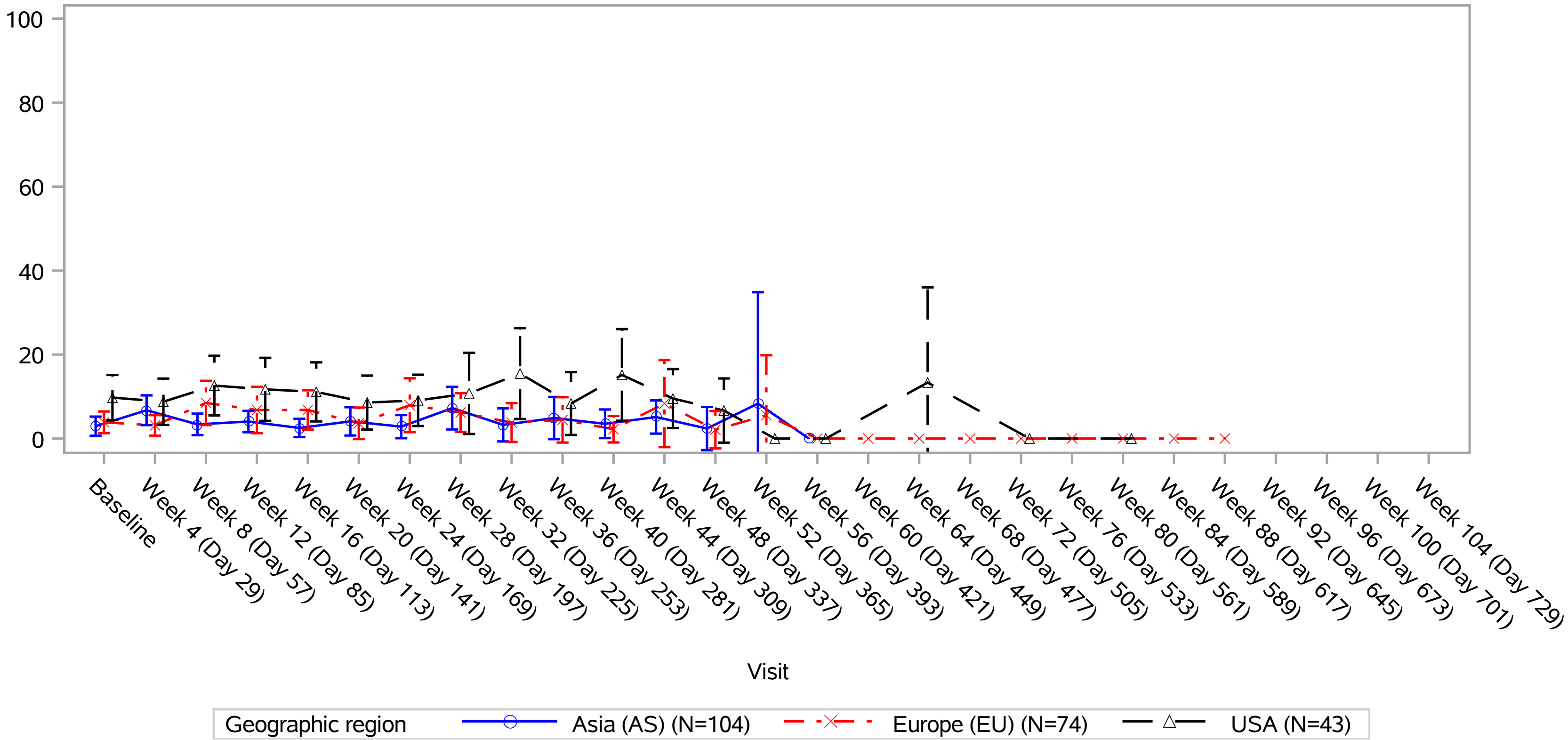
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Diarrhoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30DI_SGECOG.pdf
15OCT2021 18:03

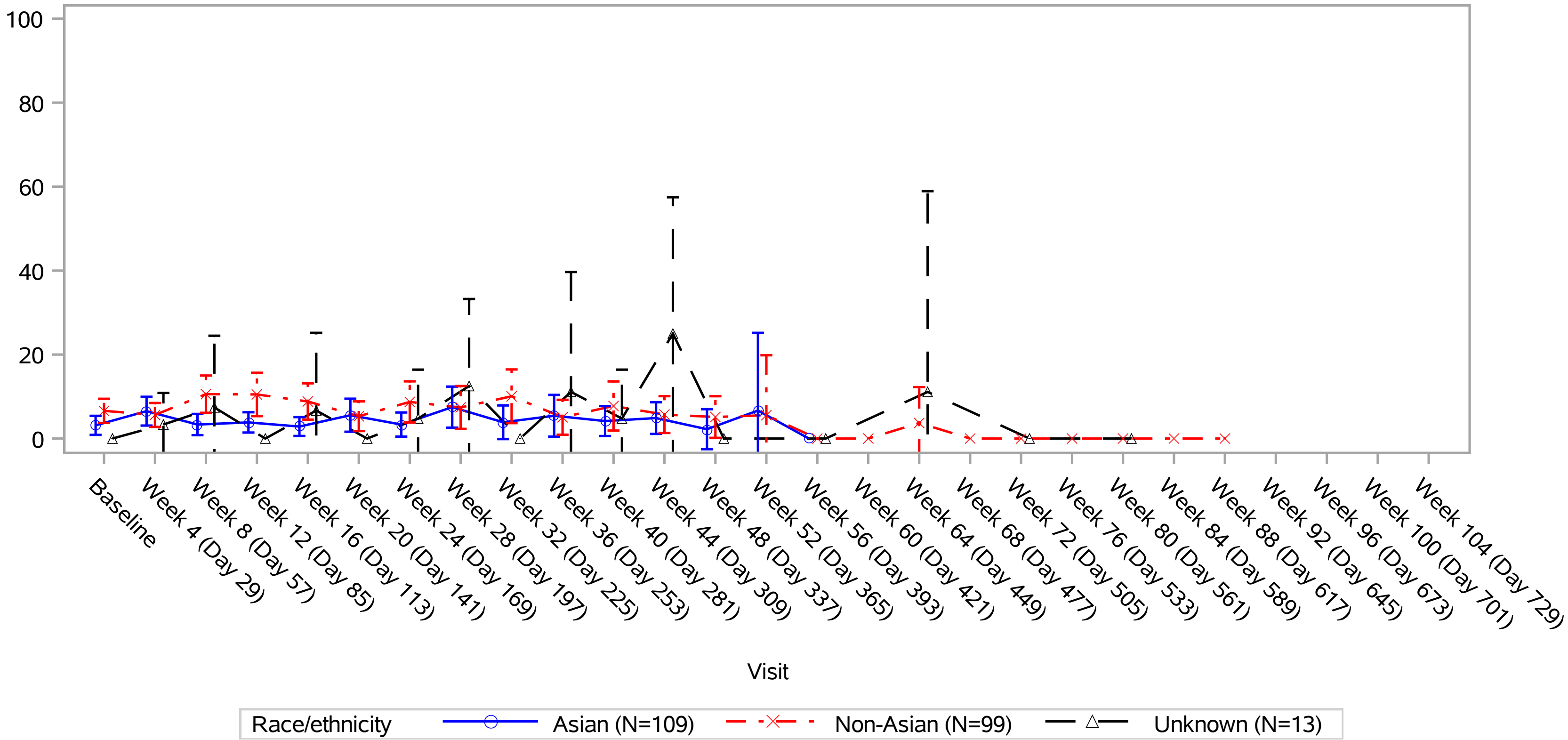
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Diarrhoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30DI_SGGEO.pdf
15OCT2021 18:34

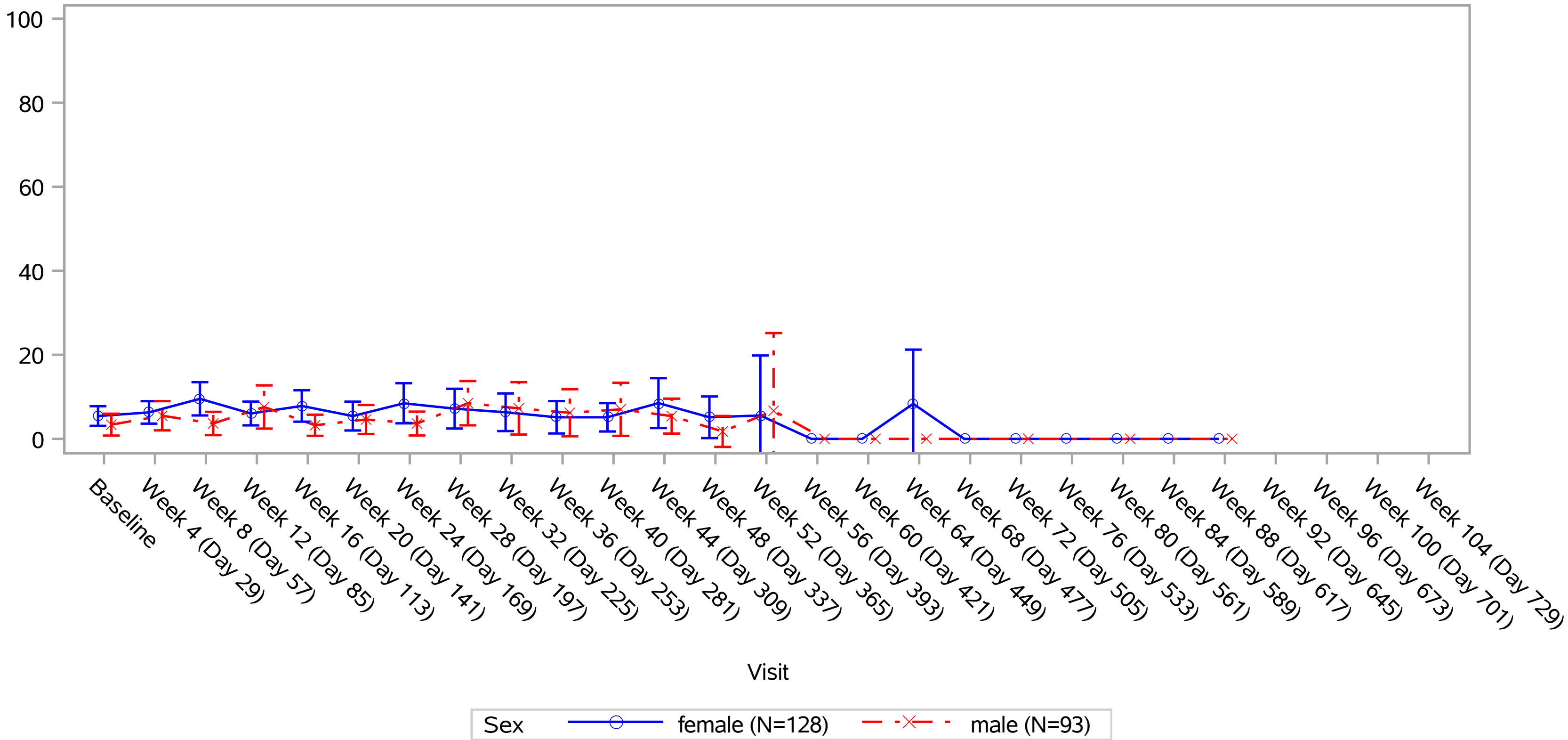
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Diarrhoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30DI_SGRE.pdf
15OCT2021 19:04

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Diarrhoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30DI_SGSEX.pdf
15OCT2021 19:35

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Dyspnoea
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=221)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	221	100.0	211	95.5	31.75	31.83	27.43	36.07
Week 4 (Day 29)	n/a	221	100.0	190	86.0	20.18	23.18	16.86	23.49
Week 8 (Day 57)	n/a	193	87.3	171	88.6	20.27	24.08	16.64	23.91
Week 12 (Day 85)	n/a	176	79.6	161	91.5	18.84	23.80	15.14	22.54
Week 16 (Day 113)	n/a	164	74.2	143	87.2	17.48	20.87	14.03	20.93
Week 20 (Day 141)	n/a	148	67.0	138	93.2	21.01	25.81	16.67	25.36
Week 24 (Day 169)	n/a	137	62.0	122	89.1	17.21	23.56	12.99	21.44
Week 28 (Day 197)	n/a	129	58.4	120	93.0	14.72	21.08	10.91	18.53
Week 32 (Day 225)	n/a	119	53.8	104	87.4	16.03	21.28	11.89	20.16
Week 36 (Day 253)	n/a	112	50.7	95	84.8	15.79	22.72	11.16	20.42
Week 40 (Day 281)	n/a	104	47.1	91	87.5	15.75	20.69	11.44	20.06
Week 44 (Day 309)	n/a	95	43.0	84	88.4	18.25	24.49	12.94	23.57
Week 48 (Day 337)	n/a	81	36.7	45	55.6	18.52	20.79	12.27	24.76
Week 52 (Day 365)	n/a	64	29.0	11	17.2	12.12	16.82	0.82	23.42
Week 56 (Day 393)	n/a	54	24.4	18	33.3	18.52	20.52	8.31	28.72
Week 60 (Day 421)	n/a	43	19.5	2	4.7	16.67	23.57	-195.10	228.44
Week 64 (Day 449)	n/a	41	18.6	12	29.3	19.44	17.16	8.54	30.35
Week 68 (Day 477)	n/a	34	15.4	2	5.9	16.67	23.57	-195.10	228.44
Week 72 (Day 505)	n/a	34	15.4	5	14.7	20.00	29.81	-17.02	57.02
Week 76 (Day 533)	n/a	31	14.0	3	9.7	11.11	19.25	-36.70	58.92
Week 80 (Day 561)	n/a	30	13.6	6	20.0	22.22	17.21	4.16	40.29
Week 84 (Day 589)	n/a	19	8.6	1	5.3	33.33	NE	NE	NE
Week 88 (Day 617)	n/a	15	6.8	2	13.3	16.67	23.57	-195.10	228.44
Week 92 (Day 645)	n/a	8	3.6	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	2.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	1.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	221	100.0	219	99.1	23.90	28.06	20.16	27.63
End of Study (LOCF)	n/a	221	100.0	219	99.1	23.59	27.03	19.99	27.19
Sex									
Baseline	Female	128	100.0	123	96.1	34.69	31.48	29.07	40.31
Week 4 (Day 29)	Female	128	100.0	105	82.0	20.95	20.80	16.93	24.98
Week 8 (Day 57)	Female	112	87.5	98	87.5	23.13	25.96	17.93	28.33
Week 12 (Day 85)	Female	104	81.3	95	91.3	21.75	25.62	16.54	26.97
Week 16 (Day 113)	Female	96	75.0	81	84.4	16.87	20.50	12.34	21.40
Week 20 (Day 141)	Female	86	67.2	80	93.0	23.33	29.24	16.83	29.84
Week 24 (Day 169)	Female	78	60.9	67	85.9	18.91	26.09	12.54	25.27
Week 28 (Day 197)	Female	72	56.3	65	90.3	13.85	20.32	8.81	18.88
Week 32 (Day 225)	Female	69	53.9	58	84.1	16.67	21.85	10.92	22.41
Week 36 (Day 253)	Female	64	50.0	52	81.3	16.67	26.81	9.20	24.13
Week 40 (Day 281)	Female	59	46.1	53	89.8	17.61	22.27	11.47	23.75
Week 44 (Day 309)	Female	56	43.8	47	83.9	20.57	26.52	12.78	28.35
Week 48 (Day 337)	Female	48	37.5	26	54.2	17.95	21.56	9.24	26.66
Week 52 (Day 365)	Female	38	29.7	6	15.8	11.11	17.21	-6.95	29.18
Week 56 (Day 393)	Female	31	24.2	9	29.0	18.52	24.22	-0.10	37.13
Week 60 (Day 421)	Female	27	21.1	1	3.7	33.33	NE	NE	NE
Week 64 (Day 449)	Female	26	20.3	8	30.8	16.67	17.82	1.77	31.56
Week 68 (Day 477)	Female	23	18.0	2	8.7	16.67	23.57	-195.10	228.44
Week 72 (Day 505)	Female	23	18.0	3	13.0	22.22	38.49	-73.39	117.84
Week 76 (Day 533)	Female	21	16.4	3	14.3	11.11	19.25	-36.70	58.92
Week 80 (Day 561)	Female	20	15.6	5	25.0	20.00	18.26	-2.67	42.67
Week 84 (Day 589)	Female	12	9.4	1	8.3	33.33	NE	NE	NE
Week 88 (Day 617)	Female	9	7.0	1	11.1	0.00	NE	NE	NE
Week 92 (Day 645)	Female	6	4.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	3.9	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	1.6	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	0.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	128	100.0	127	99.2	25.20	29.01	20.10	30.29
End of Study (LOCF)	Female	128	100.0	127	99.2	24.41	28.00	19.49	29.33
Baseline	Male	93	100.0	88	94.6	27.65	32.05	20.86	34.44
Week 4 (Day 29)	Male	93	100.0	85	91.4	19.22	25.91	13.63	24.80
Week 8 (Day 57)	Male	81	87.1	73	90.1	16.44	20.88	11.57	21.31
Week 12 (Day 85)	Male	72	77.4	66	91.7	14.65	20.36	9.64	19.65
Week 16 (Day 113)	Male	68	73.1	62	91.2	18.28	21.49	12.82	23.74
Week 20 (Day 141)	Male	62	66.7	58	93.5	17.82	19.96	12.57	23.06
Week 24 (Day 169)	Male	59	63.4	55	93.2	15.15	20.10	9.72	20.59
Week 28 (Day 197)	Male	57	61.3	55	96.5	15.76	22.09	9.79	21.73
Week 32 (Day 225)	Male	50	53.8	46	92.0	15.22	20.74	9.06	21.38
Week 36 (Day 253)	Male	48	51.6	43	89.6	14.73	16.75	9.57	19.88
Week 40 (Day 281)	Male	45	48.4	38	84.4	13.16	18.24	7.16	19.15
Week 44 (Day 309)	Male	39	41.9	37	94.9	15.32	21.65	8.10	22.53
Week 48 (Day 337)	Male	33	35.5	19	57.6	19.30	20.23	9.55	29.05
Week 52 (Day 365)	Male	26	28.0	5	19.2	13.33	18.26	-9.34	36.00
Week 56 (Day 393)	Male	23	24.7	9	39.1	18.52	17.57	5.01	32.02
Week 60 (Day 421)	Male	16	17.2	1	6.3	0.00	NE	NE	NE
Week 64 (Day 449)	Male	15	16.1	4	26.7	25.00	16.67	-1.52	51.52
Week 68 (Day 477)	Male	11	11.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	11	11.8	2	18.2	16.67	23.57	-195.10	228.44
Week 76 (Day 533)	Male	10	10.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	10	10.8	1	10.0	33.33	NE	NE	NE
Week 84 (Day 589)	Male	7	7.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	6	6.5	1	16.7	33.33	NE	NE	NE
Week 92 (Day 645)	Male	2	2.2	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	93	100.0	92	98.9	22.10	26.74	16.56	27.64
End of Study (LOCF)	Male	93	100.0	92	98.9	22.46	25.73	17.14	27.79
Age									

Baseline	< 65	141	100.0	133	94.3	32.58	31.64	27.15	38.01
Week 4 (Day 29)	< 65	141	100.0	122	86.5	18.85	22.67	14.79	22.92
Week 8 (Day 57)	< 65	127	90.1	113	89.0	17.99	22.73	13.76	22.23
Week 12 (Day 85)	< 65	118	83.7	106	89.8	16.35	22.18	12.08	20.62
Week 16 (Day 113)	< 65	108	76.6	93	86.1	15.77	19.41	11.77	19.77
Week 20 (Day 141)	< 65	100	70.9	97	97.0	19.24	25.84	14.04	24.45
Week 24 (Day 169)	< 65	93	66.0	86	92.5	13.95	21.37	9.37	18.53
Week 28 (Day 197)	< 65	88	62.4	83	94.3	13.65	20.19	9.25	18.06
Week 32 (Day 225)	< 65	83	58.9	73	88.0	12.79	18.95	8.36	17.21
Week 36 (Day 253)	< 65	78	55.3	70	89.7	12.86	20.69	7.92	17.79
Week 40 (Day 281)	< 65	75	53.2	69	92.0	13.04	18.27	8.65	17.43
Week 44 (Day 309)	< 65	71	50.4	65	91.5	16.92	25.09	10.71	23.14
Week 48 (Day 337)	< 65	61	43.3	33	54.1	17.17	20.62	9.86	24.48
Week 52 (Day 365)	< 65	48	34.0	6	12.5	5.56	13.61	-8.73	19.84
Week 56 (Day 393)	< 65	41	29.1	11	26.8	21.21	22.47	6.11	36.31
Week 60 (Day 421)	< 65	33	23.4	2	6.1	16.67	23.57	-195.10	228.44
Week 64 (Day 449)	< 65	31	22.0	10	32.3	20.00	17.21	7.69	32.31
Week 68 (Day 477)	< 65	26	18.4	2	7.7	16.67	23.57	-195.10	228.44
Week 72 (Day 505)	< 65	26	18.4	5	19.2	20.00	29.81	-17.02	57.02
Week 76 (Day 533)	< 65	25	17.7	3	12.0	11.11	19.25	-36.70	58.92
Week 80 (Day 561)	< 65	24	17.0	5	20.8	20.00	18.26	-2.67	42.67
Week 84 (Day 589)	< 65	16	11.3	1	6.3	33.33	NE	NE	NE
Week 88 (Day 617)	< 65	13	9.2	2	15.4	16.67	23.57	-195.10	228.44
Week 92 (Day 645)	< 65	7	5.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	3.5	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	2.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	0.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	141	100.0	139	98.6	22.30	28.77	17.48	27.13
End of Study (LOCF)	< 65	141	100.0	139	98.6	22.06	27.08	17.52	26.60
Baseline	>= 65	80	100.0	78	97.5	30.34	32.32	23.06	37.63
Week 4 (Day 29)	>= 65	80	100.0	68	85.0	22.55	24.05	16.73	28.37
Week 8 (Day 57)	>= 65	66	82.5	58	87.9	24.71	26.17	17.83	31.59
Week 12 (Day 85)	>= 65	58	72.5	55	94.8	23.64	26.19	16.56	30.72

Week 16 (Day 113)	>= 65	56	70.0	50	89.3	20.67	23.22	14.07	27.27
Week 20 (Day 141)	>= 65	48	60.0	41	85.4	25.20	25.58	17.13	33.28
Week 24 (Day 169)	>= 65	44	55.0	36	81.8	25.00	26.87	15.91	34.09
Week 28 (Day 197)	>= 65	41	51.3	37	90.2	17.12	23.07	9.43	24.81
Week 32 (Day 225)	>= 65	36	45.0	31	86.1	23.66	24.64	14.62	32.69
Week 36 (Day 253)	>= 65	34	42.5	25	73.5	24.00	26.39	13.11	34.89
Week 40 (Day 281)	>= 65	29	36.3	22	75.9	24.24	25.58	12.90	35.58
Week 44 (Day 309)	>= 65	24	30.0	19	79.2	22.81	22.37	12.03	33.59
Week 48 (Day 337)	>= 65	20	25.0	12	60.0	22.22	21.71	8.43	36.02
Week 52 (Day 365)	>= 65	16	20.0	5	31.3	20.00	18.26	-2.67	42.67
Week 56 (Day 393)	>= 65	13	16.3	7	53.8	14.29	17.82	-2.19	30.76
Week 60 (Day 421)	>= 65	10	12.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	10	12.5	2	20.0	16.67	23.57	-195.10	228.44
Week 68 (Day 477)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	6	7.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	6	7.5	1	16.7	33.33	NE	NE	NE
Week 84 (Day 589)	>= 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	2.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	80	100.0	80	100.0	26.67	26.73	20.72	32.62
End of Study (LOCF)	>= 65	80	100.0	80	100.0	26.25	26.88	20.27	32.23
ECOG performance status									
Baseline	0	63	100.0	60	95.2	27.22	29.75	19.54	34.91
Week 4 (Day 29)	0	63	100.0	55	87.3	18.79	23.80	12.35	25.22
Week 8 (Day 57)	0	58	92.1	52	89.7	23.72	29.77	15.43	32.01
Week 12 (Day 85)	0	55	87.3	50	90.9	18.00	24.48	11.04	24.96
Week 16 (Day 113)	0	54	85.7	45	83.3	13.33	19.33	7.53	19.14
Week 20 (Day 141)	0	52	82.5	48	92.3	20.14	26.40	12.47	27.80
Week 24 (Day 169)	0	49	77.8	43	87.8	10.85	21.48	4.24	17.46
Week 28 (Day 197)	0	46	73.0	42	91.3	13.49	22.16	6.59	20.40

Week 32 (Day 225)	0	41	65.1	34	82.9	10.78	17.83	4.56	17.01
Week 36 (Day 253)	0	39	61.9	31	79.5	13.98	25.49	4.63	23.33
Week 40 (Day 281)	0	37	58.7	30	81.1	20.00	22.49	11.60	28.40
Week 44 (Day 309)	0	36	57.1	29	80.6	19.54	30.23	8.04	31.04
Week 48 (Day 337)	0	28	44.4	18	64.3	14.81	23.49	3.13	26.50
Week 52 (Day 365)	0	27	42.9	6	22.2	5.56	13.61	-8.73	19.84
Week 56 (Day 393)	0	24	38.1	8	33.3	8.33	15.43	-4.57	21.23
Week 60 (Day 421)	0	21	33.3	1	4.8	33.33	NE	NE	NE
Week 64 (Day 449)	0	21	33.3	7	33.3	19.05	17.82	2.57	35.53
Week 68 (Day 477)	0	17	27.0	1	5.9	33.33	NE	NE	NE
Week 72 (Day 505)	0	17	27.0	2	11.8	33.33	47.14	-390.21	456.87
Week 76 (Day 533)	0	15	23.8	2	13.3	16.67	23.57	-195.10	228.44
Week 80 (Day 561)	0	14	22.2	1	7.1	0.00	NE	NE	NE
Week 84 (Day 589)	0	11	17.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	10	15.9	1	10.0	0.00	NE	NE	NE
Week 92 (Day 645)	0	5	7.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	6.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	4.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	63	100.0	63	100.0	25.40	32.63	17.18	33.62
End of Study (LOCF)	0	63	100.0	63	100.0	23.81	30.78	16.06	31.56
Baseline	1	157	100.0	150	95.5	33.78	32.54	28.53	39.03
Week 4 (Day 29)	1	157	100.0	134	85.4	20.65	23.05	16.71	24.59
Week 8 (Day 57)	1	134	85.4	119	88.8	18.77	21.10	14.94	22.60
Week 12 (Day 85)	1	121	77.1	111	91.7	19.22	23.59	14.78	23.66
Week 16 (Day 113)	1	110	70.1	98	89.1	19.39	21.36	15.10	23.67
Week 20 (Day 141)	1	96	61.1	90	93.8	21.48	25.63	16.11	26.85
Week 24 (Day 169)	1	88	56.1	79	89.8	20.68	24.05	15.29	26.06
Week 28 (Day 197)	1	83	52.9	78	94.0	15.38	20.59	10.74	20.03
Week 32 (Day 225)	1	78	49.7	70	89.7	18.57	22.44	13.22	23.92
Week 36 (Day 253)	1	73	46.5	64	87.7	16.67	21.41	11.32	22.02
Week 40 (Day 281)	1	67	42.7	61	91.0	13.66	19.60	8.64	18.68

Week 44 (Day 309)	1	59	37.6	55	93.2	17.58	21.14	11.86	23.29
Week 48 (Day 337)	1	53	33.8	27	50.9	20.99	18.83	13.54	28.44
Week 52 (Day 365)	1	37	23.6	5	13.5	20.00	18.26	-2.67	42.67
Week 56 (Day 393)	1	30	19.1	10	33.3	26.67	21.08	11.59	41.75
Week 60 (Day 421)	1	22	14.0	1	4.5	0.00	NE	NE	NE
Week 64 (Day 449)	1	20	12.7	5	25.0	20.00	18.26	-2.67	42.67
Week 68 (Day 477)	1	17	10.8	1	5.9	0.00	NE	NE	NE
Week 72 (Day 505)	1	17	10.8	3	17.6	11.11	19.25	-36.70	58.92
Week 76 (Day 533)	1	16	10.2	1	6.3	0.00	NE	NE	NE
Week 80 (Day 561)	1	16	10.2	5	31.3	26.67	14.91	8.16	45.18
Week 84 (Day 589)	1	8	5.1	1	12.5	33.33	NE	NE	NE
Week 88 (Day 617)	1	5	3.2	1	20.0	33.33	NE	NE	NE
Week 92 (Day 645)	1	3	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	157	100.0	155	98.7	23.23	26.15	19.08	27.37
End of Study (LOCF)	1	157	100.0	155	98.7	23.44	25.53	19.39	27.49
Baseline	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	33.33	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	33.33	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	33.33	NE	NE	NE
Geographic region									
Baseline	USA	43	100.0	40	93.0	30.83	35.72	19.41	42.26
Week 4 (Day 29)	USA	43	100.0	38	88.4	20.18	21.28	13.18	27.17
Week 8 (Day 57)	USA	41	95.3	37	90.2	17.12	23.07	9.43	24.81
Week 12 (Day 85)	USA	41	95.3	38	92.7	17.54	22.91	10.01	25.07
Week 16 (Day 113)	USA	40	93.0	33	82.5	19.19	22.10	11.36	27.03
Week 20 (Day 141)	USA	39	90.7	35	89.7	22.86	25.27	14.18	31.54
Week 24 (Day 169)	USA	36	83.7	33	91.7	12.12	18.29	5.64	18.61
Week 28 (Day 197)	USA	35	81.4	31	88.6	12.90	18.61	6.08	19.73
Week 32 (Day 225)	USA	32	74.4	28	87.5	20.24	22.84	11.38	29.10
Week 36 (Day 253)	USA	32	74.4	24	75.0	13.89	19.45	5.67	22.10
Week 40 (Day 281)	USA	29	67.4	23	79.3	14.49	16.90	7.19	21.80

Week 44 (Day 309)	USA	26	60.5	21	80.8	15.87	20.05	6.75	25.00
Week 48 (Day 337)	USA	21	48.8	15	71.4	15.56	21.33	3.74	27.37
Week 52 (Day 365)	USA	18	41.9	1	5.6	0.00	NE	NE	NE
Week 56 (Day 393)	USA	18	41.9	9	50.0	14.81	24.22	-3.80	33.43
Week 60 (Day 421)	USA	17	39.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	15	34.9	5	33.3	20.00	18.26	-2.67	42.67
Week 68 (Day 477)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	12	27.9	1	8.3	0.00	NE	NE	NE
Week 76 (Day 533)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	12	27.9	2	16.7	33.33	0.00	NE	NE
Week 84 (Day 589)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	6	14.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	11.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	7.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	43	100.0	43	100.0	17.05	21.05	10.58	23.53
End of Study (LOCF)	USA	43	100.0	43	100.0	15.50	19.72	9.44	21.57
Baseline	Europe (EU)	74	100.0	69	93.2	35.75	34.45	27.47	44.02
Week 4 (Day 29)	Europe (EU)	74	100.0	63	85.1	21.16	24.90	14.89	27.44
Week 8 (Day 57)	Europe (EU)	65	87.8	55	84.6	26.06	28.47	18.37	33.76
Week 12 (Day 85)	Europe (EU)	57	77.0	49	86.0	24.49	31.01	15.58	33.40
Week 16 (Day 113)	Europe (EU)	55	74.3	44	80.0	18.94	22.04	12.24	25.64
Week 20 (Day 141)	Europe (EU)	49	66.2	46	93.9	24.64	29.34	15.92	33.35
Week 24 (Day 169)	Europe (EU)	47	63.5	42	89.4	22.22	28.19	13.44	31.01
Week 28 (Day 197)	Europe (EU)	45	60.8	43	95.6	16.28	22.27	9.43	23.13
Week 32 (Day 225)	Europe (EU)	39	52.7	35	89.7	14.29	18.59	7.90	20.67
Week 36 (Day 253)	Europe (EU)	34	45.9	30	88.2	16.67	25.89	7.00	26.34
Week 40 (Day 281)	Europe (EU)	31	41.9	30	96.8	17.78	24.34	8.69	26.87
Week 44 (Day 309)	Europe (EU)	28	37.8	24	85.7	25.00	29.90	12.38	37.62

Week 48 (Day 337)	Europe (EU)	22	29.7	16	72.7	18.75	17.08	9.65	27.85
Week 52 (Day 365)	Europe (EU)	19	25.7	6	31.6	11.11	17.21	-6.95	29.18
Week 56 (Day 393)	Europe (EU)	17	23.0	7	41.2	19.05	17.82	2.57	35.53
Week 60 (Day 421)	Europe (EU)	15	20.3	2	13.3	16.67	23.57	-195.10	228.44
Week 64 (Day 449)	Europe (EU)	15	20.3	7	46.7	19.05	17.82	2.57	35.53
Week 68 (Day 477)	Europe (EU)	13	17.6	2	15.4	16.67	23.57	-195.10	228.44
Week 72 (Day 505)	Europe (EU)	13	17.6	4	30.8	25.00	31.91	-25.78	75.78
Week 76 (Day 533)	Europe (EU)	11	14.9	3	27.3	11.11	19.25	-36.70	58.92
Week 80 (Day 561)	Europe (EU)	10	13.5	4	40.0	16.67	19.25	-13.96	47.29
Week 84 (Day 589)	Europe (EU)	6	8.1	1	16.7	33.33	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	4.1	2	66.7	16.67	23.57	-195.10	228.44
Cycle 12 (LOCF)	Europe (EU)	74	100.0	73	98.6	31.96	31.64	24.58	39.35
End of Study (LOCF)	Europe (EU)	74	100.0	73	98.6	32.42	29.90	25.44	39.40
Baseline	Asia (AS)	104	100.0	102	98.1	29.41	28.26	23.86	34.96
Week 4 (Day 29)	Asia (AS)	104	100.0	89	85.6	19.48	22.92	14.65	24.30
Week 8 (Day 57)	Asia (AS)	87	83.7	79	90.8	17.72	20.56	13.12	22.33
Week 12 (Day 85)	Asia (AS)	78	75.0	74	94.9	15.77	17.64	11.68	19.85
Week 16 (Day 113)	Asia (AS)	69	66.3	66	95.7	15.66	19.59	10.84	20.47
Week 20 (Day 141)	Asia (AS)	60	57.7	57	95.0	16.96	22.82	10.90	23.01
Week 24 (Day 169)	Asia (AS)	54	51.9	47	87.0	16.31	21.84	9.90	22.72
Week 28 (Day 197)	Asia (AS)	49	47.1	46	93.9	14.49	21.83	8.01	20.98
Week 32 (Day 225)	Asia (AS)	48	46.2	41	85.4	14.63	22.42	7.56	21.71
Week 36 (Day 253)	Asia (AS)	46	44.2	41	89.1	16.26	22.51	9.15	23.37
Week 40 (Day 281)	Asia (AS)	44	42.3	38	86.4	14.91	20.06	8.32	21.50
Week 44 (Day 309)	Asia (AS)	41	39.4	39	95.1	15.38	22.74	8.01	22.76
Week 48 (Day 337)	Asia (AS)	38	36.5	14	36.8	21.43	24.83	7.09	35.77
Week 52 (Day 365)	Asia (AS)	27	26.0	4	14.8	16.67	19.25	-13.96	47.29
Week 56 (Day 393)	Asia (AS)	19	18.3	2	10.5	33.33	0.00	NE	NE
Week 60 (Day 421)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	5.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	104	100.0	103	99.0	21.04	26.81	15.80	26.28
End of Study (LOCF)	Asia (AS)	104	100.0	103	99.0	20.71	26.04	15.62	25.80
Race/ethnicity									
Baseline	Asian	109	100.0	106	97.2	29.25	28.99	23.66	34.83
Week 4 (Day 29)	Asian	109	100.0	92	84.4	19.57	23.26	14.75	24.38
Week 8 (Day 57)	Asian	91	83.5	80	87.9	17.92	20.50	13.35	22.48
Week 12 (Day 85)	Asian	82	75.2	78	95.1	15.38	17.57	11.42	19.35
Week 16 (Day 113)	Asian	73	67.0	70	95.9	14.76	19.36	10.15	19.38
Week 20 (Day 141)	Asian	64	58.7	60	93.8	17.22	22.54	11.40	23.05
Week 24 (Day 169)	Asian	57	52.3	50	87.7	16.00	21.55	9.88	22.12
Week 28 (Day 197)	Asian	52	47.7	49	94.2	14.97	21.58	8.77	21.17
Week 32 (Day 225)	Asian	50	45.9	43	86.0	15.50	23.40	8.30	22.71
Week 36 (Day 253)	Asian	48	44.0	43	89.6	16.28	22.27	9.43	23.13
Week 40 (Day 281)	Asian	46	42.2	40	87.0	15.00	19.90	8.64	21.36
Week 44 (Day 309)	Asian	43	39.4	41	95.3	14.63	22.42	7.56	21.71
Week 48 (Day 337)	Asian	40	36.7	15	37.5	20.00	24.56	6.40	33.60
Week 52 (Day 365)	Asian	29	26.6	5	17.2	13.33	18.26	-9.34	36.00
Week 56 (Day 393)	Asian	21	19.3	3	14.3	22.22	19.25	-25.59	70.03
Week 60 (Day 421)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	5.5	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	4.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	1.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	109	100.0	107	98.2	20.56	26.56	15.47	25.65
End of Study (LOCF)	Asian	109	100.0	107	98.2	20.25	25.80	15.30	25.19
Baseline	Non-Asian	99	100.0	95	96.0	34.39	34.88	27.28	41.49
Week 4 (Day 29)	Non-Asian	99	100.0	89	89.9	19.10	21.25	14.62	23.58
Week 8 (Day 57)	Non-Asian	91	91.9	82	90.1	22.36	26.74	16.48	28.23
Week 12 (Day 85)	Non-Asian	83	83.8	74	89.2	21.17	27.35	14.83	27.51
Week 16 (Day 113)	Non-Asian	80	80.8	68	85.0	20.10	22.41	14.67	25.52
Week 20 (Day 141)	Non-Asian	74	74.7	69	93.2	24.15	28.52	17.30	31.01
Week 24 (Day 169)	Non-Asian	70	70.7	65	92.9	18.46	25.71	12.09	24.83
Week 28 (Day 197)	Non-Asian	67	67.7	63	94.0	13.76	19.52	8.84	18.67
Week 32 (Day 225)	Non-Asian	60	60.6	53	88.3	16.35	19.20	11.06	21.64
Week 36 (Day 253)	Non-Asian	55	55.6	46	83.6	11.59	17.52	6.39	16.80
Week 40 (Day 281)	Non-Asian	49	49.5	44	89.8	13.64	16.58	8.60	18.68
Week 44 (Day 309)	Non-Asian	43	43.4	35	81.4	18.10	23.35	10.07	26.12
Week 48 (Day 337)	Non-Asian	35	35.4	26	74.3	19.23	19.26	11.45	27.01
Week 52 (Day 365)	Non-Asian	29	29.3	6	20.7	11.11	17.21	-6.95	29.18
Week 56 (Day 393)	Non-Asian	27	27.3	14	51.9	19.05	21.54	6.61	31.48
Week 60 (Day 421)	Non-Asian	26	26.3	2	7.7	16.67	23.57	-195.10	228.44
Week 64 (Day 449)	Non-Asian	24	24.2	9	37.5	18.52	17.57	5.01	32.02
Week 68 (Day 477)	Non-Asian	20	20.2	2	10.0	16.67	23.57	-195.10	228.44
Week 72 (Day 505)	Non-Asian	20	20.2	3	15.0	11.11	19.25	-36.70	58.92
Week 76 (Day 533)	Non-Asian	18	18.2	3	16.7	11.11	19.25	-36.70	58.92
Week 80 (Day 561)	Non-Asian	17	17.2	5	29.4	20.00	18.26	-2.67	42.67
Week 84 (Day 589)	Non-Asian	11	11.1	1	9.1	33.33	NE	NE	NE
Week 88 (Day 617)	Non-Asian	8	8.1	2	25.0	16.67	23.57	-195.10	228.44
Week 92 (Day 645)	Non-Asian	4	4.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	3.0	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	99	100.0	99	100.0	25.59	28.90	19.83	31.35

End of Study (LOCF)	Non-Asian	99	100.0	99	100.0	25.25	28.21	19.63	30.88
Baseline	Unknown	13	100.0	10	76.9	33.33	31.43	10.85	55.81
Week 4 (Day 29)	Unknown	13	100.0	9	69.2	37.04	35.14	10.03	64.05
Week 8 (Day 57)	Unknown	11	84.6	9	81.8	22.22	28.87	0.03	44.41
Week 12 (Day 85)	Unknown	11	84.6	9	81.8	29.63	35.14	2.62	56.64
Week 16 (Day 113)	Unknown	11	84.6	5	45.5	20.00	18.26	-2.67	42.67
Week 20 (Day 141)	Unknown	10	76.9	9	90.0	22.22	23.57	4.10	40.34
Week 24 (Day 169)	Unknown	10	76.9	7	70.0	14.29	17.82	-2.19	30.76
Week 28 (Day 197)	Unknown	10	76.9	8	80.0	20.83	30.54	-4.70	46.36
Week 32 (Day 225)	Unknown	9	69.2	8	88.9	16.67	25.20	-4.40	37.73
Week 36 (Day 253)	Unknown	9	69.2	6	66.7	44.44	40.37	2.08	86.81
Week 40 (Day 281)	Unknown	9	69.2	7	77.8	33.33	38.49	-2.26	68.93
Week 44 (Day 309)	Unknown	9	69.2	8	88.9	37.50	33.03	9.88	65.12
Week 48 (Day 337)	Unknown	6	46.2	4	66.7	8.33	16.67	-18.19	34.85
Week 52 (Day 365)	Unknown	6	46.2	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	6	46.2	1	16.7	0.00	NE	NE	NE
Week 60 (Day 421)	Unknown	5	38.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	5	38.5	3	60.0	22.22	19.25	-25.59	70.03
Week 68 (Day 477)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	4	30.8	2	50.0	33.33	47.14	-390.21	456.87
Week 76 (Day 533)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	4	30.8	1	25.0	33.33	NE	NE	NE
Week 84 (Day 589)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	7.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	13	100.0	13	100.0	38.46	29.96	20.36	56.56
End of Study (LOCF)	Unknown	13	100.0	13	100.0	38.46	22.96	24.59	52.33

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TO_QSC30DY_SG.xls
27OCT2021 7:14

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Dyspnoea
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	211	95.5	71	33.6	27.6	40.3
	Cycle 12 (LOCF)	n/a	211	95.5	38	18.0	13.4	23.8
	End of Study (LOCF)	n/a	211	95.5	38	18.0	13.4	23.8
Sex	All visits	Female	123	55.7	38	30.9	23.4	39.5
		Male	88	39.8	33	37.5	28.1	47.9
	Cycle 12 (LOCF)	Female	123	55.7	19	15.4	10.1	22.9
		Male	88	39.8	19	21.6	14.3	31.3
	End of Study (LOCF)	Female	123	55.7	17	13.8	8.8	21.0
		Male	88	39.8	21	23.9	16.2	33.7
Age	All visits	< 65	133	60.2	40	30.1	22.9	38.3
		>= 65	78	35.3	31	39.7	29.6	50.8
	Cycle 12 (LOCF)	< 65	133	60.2	21	15.8	10.6	22.9
		>= 65	78	35.3	17	21.8	14.1	32.2
	End of Study (LOCF)	< 65	133	60.2	22	16.5	11.2	23.8
		>= 65	78	35.3	16	20.5	13.0	30.8
ECOG performance status	All visits	0	60	27.1	23	38.3	27.1	51.0
		1	150	67.9	47	31.3	24.5	39.1
		Missing	1	0.5	1	100.0	20.7	100.0
	Cycle 12 (LOCF)	0	60	27.1	12	20.0	11.8	31.8
		1	150	67.9	25	16.7	11.6	23.4
		Missing	1	0.5	1	100.0	20.7	100.0
	End of Study (LOCF)	0	60	27.1	11	18.3	10.6	29.9
		1	150	67.9	26	17.3	12.1	24.2
		Missing	1	0.5	1	100.0	20.7	100.0
Geographic region	All visits	USA	40	18.1	13	32.5	20.1	48.0
		Europe (EU)	69	31.2	28	40.6	29.8	52.4
		Asia (AS)	102	46.2	30	29.4	21.4	38.9
	Cycle 12 (LOCF)	USA	40	18.1	6	15.0	7.1	29.1
		Europe (EU)	69	31.2	18	26.1	17.2	37.5
		Asia (AS)	102	46.2	14	13.7	8.4	21.7
	End of Study (LOCF)	USA	40	18.1	5	12.5	5.5	26.1
		Europe (EU)	69	31.2	19	27.5	18.4	39.0
		Asia (AS)	102	46.2	14	13.7	8.4	21.7
Race/ethnicity	All visits	Asian	106	48.0	31	29.2	21.4	38.5
		Non-Asian	95	43.0	35	36.8	27.8	46.9
		Unknown	10	4.5	5	50.0	23.7	76.3
	Cycle 12 (LOCF)	Asian	106	48.0	15	14.2	8.8	22.0

		Non-Asian	95	43.0	21	22.1	14.9	31.4
		Unknown	10	4.5	2	20.0	5.7	51.0
	End of Study (LOCF)	Asian	106	48.0	15	14.2	8.8	22.0
		Non-Asian	95	43.0	21	22.1	14.9	31.4
		Unknown	10	4.5	2	20.0	5.7	51.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30DY_W10_SG.xls
15OCT2021 12:52

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Dyspnoea
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

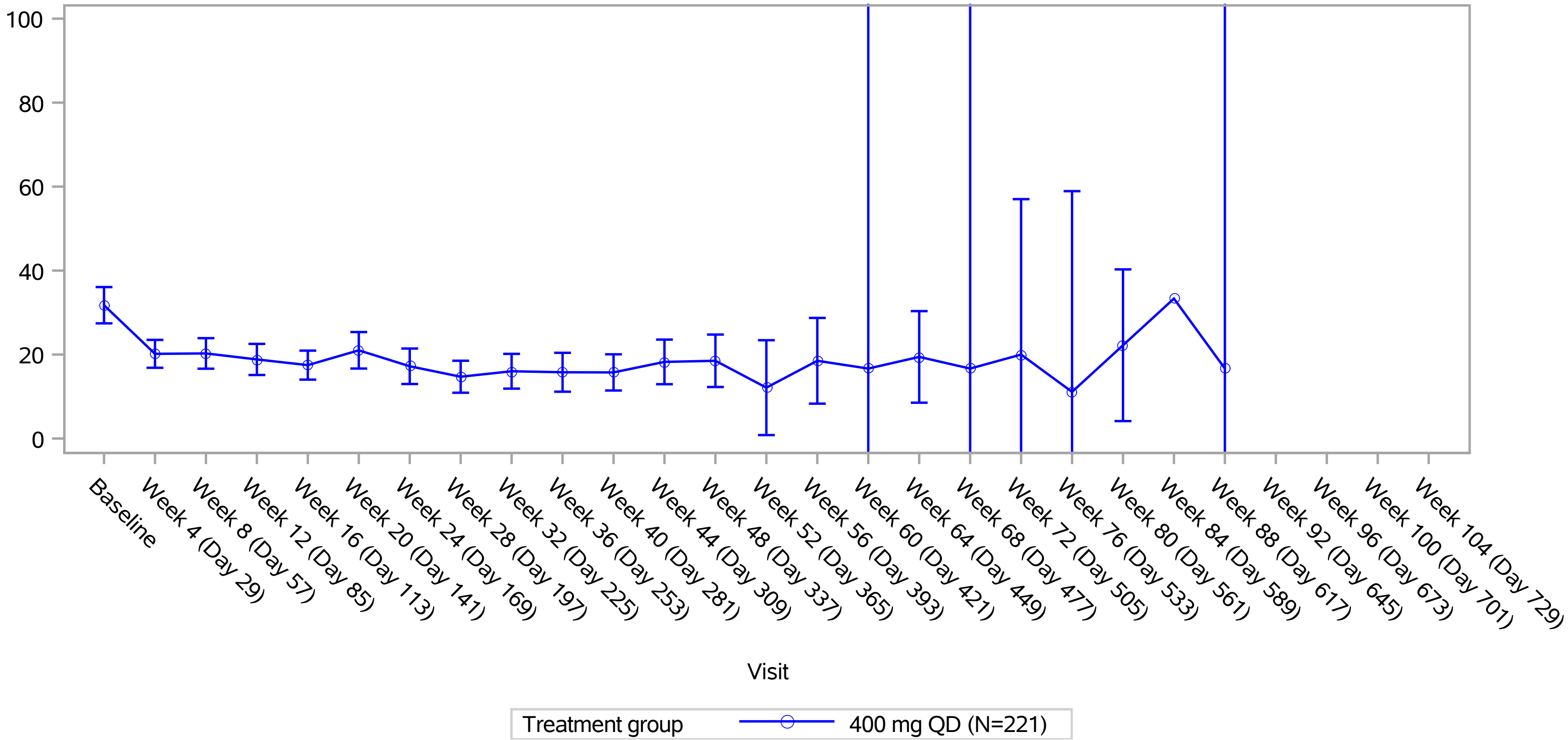
			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	211	95.5	71	33.6	27.6	40.3
	Cycle 12 (LOCF)	n/a	211	95.5	38	18.0	13.4	23.8
	End of Study (LOCF)	n/a	211	95.5	38	18.0	13.4	23.8
Sex	All visits	Female	123	55.7	38	30.9	23.4	39.5
		Male	88	39.8	33	37.5	28.1	47.9
	Cycle 12 (LOCF)	Female	123	55.7	19	15.4	10.1	22.9
		Male	88	39.8	19	21.6	14.3	31.3
	End of Study (LOCF)	Female	123	55.7	17	13.8	8.8	21.0
		Male	88	39.8	21	23.9	16.2	33.7
Age	All visits	< 65	133	60.2	40	30.1	22.9	38.3
		>= 65	78	35.3	31	39.7	29.6	50.8
	Cycle 12 (LOCF)	< 65	133	60.2	21	15.8	10.6	22.9
		>= 65	78	35.3	17	21.8	14.1	32.2
	End of Study (LOCF)	< 65	133	60.2	22	16.5	11.2	23.8
		>= 65	78	35.3	16	20.5	13.0	30.8
ECOG performance status	All visits	0	60	27.1	23	38.3	27.1	51.0
		1	150	67.9	47	31.3	24.5	39.1
		Missing	1	0.5	1	100.0	20.7	100.0
	Cycle 12 (LOCF)	0	60	27.1	12	20.0	11.8	31.8
		1	150	67.9	25	16.7	11.6	23.4
		Missing	1	0.5	1	100.0	20.7	100.0
	End of Study (LOCF)	0	60	27.1	11	18.3	10.6	29.9
		1	150	67.9	26	17.3	12.1	24.2
		Missing	1	0.5	1	100.0	20.7	100.0
Geographic region	All visits	USA	40	18.1	13	32.5	20.1	48.0
		Europe (EU)	69	31.2	28	40.6	29.8	52.4
		Asia (AS)	102	46.2	30	29.4	21.4	38.9
	Cycle 12 (LOCF)	USA	40	18.1	6	15.0	7.1	29.1
		Europe (EU)	69	31.2	18	26.1	17.2	37.5
		Asia (AS)	102	46.2	14	13.7	8.4	21.7
	End of Study (LOCF)	USA	40	18.1	5	12.5	5.5	26.1
		Europe (EU)	69	31.2	19	27.5	18.4	39.0
		Asia (AS)	102	46.2	14	13.7	8.4	21.7
Race/ethnicity	All visits	Asian	106	48.0	31	29.2	21.4	38.5
		Non-Asian	95	43.0	35	36.8	27.8	46.9
		Unknown	10	4.5	5	50.0	23.7	76.3
	Cycle 12 (LOCF)	Asian	106	48.0	15	14.2	8.8	22.0

		Non-Asian	95	43.0	21	22.1	14.9	31.4
		Unknown	10	4.5	2	20.0	5.7	51.0
	End of Study (LOCF)	Asian	106	48.0	15	14.2	8.8	22.0
		Non-Asian	95	43.0	21	22.1	14.9	31.4
		Unknown	10	4.5	2	20.0	5.7	51.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30DY_W15_SG.xls
15OCT2021 12:42

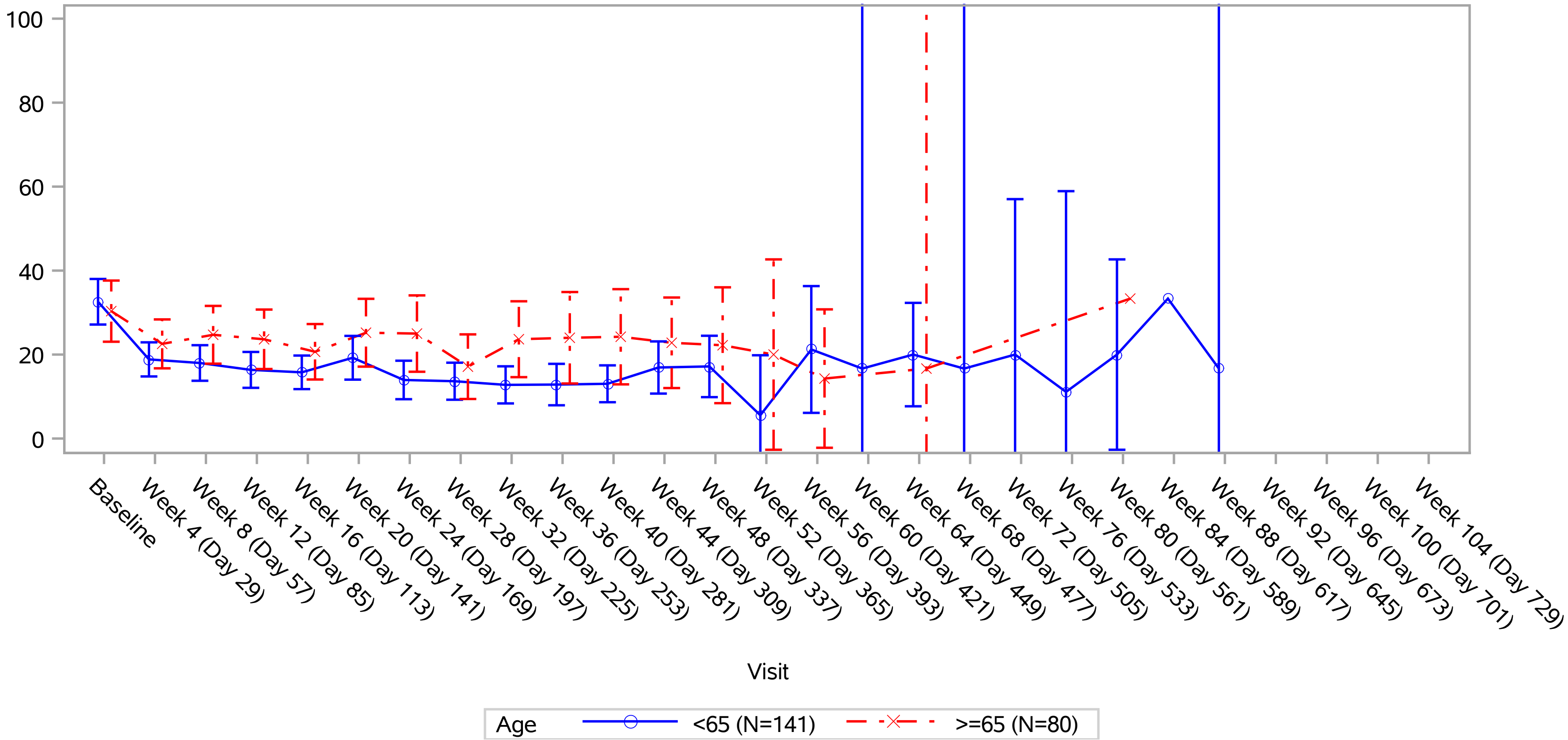
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Dyspnoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30DY.pdf
15OCT2021 17:05

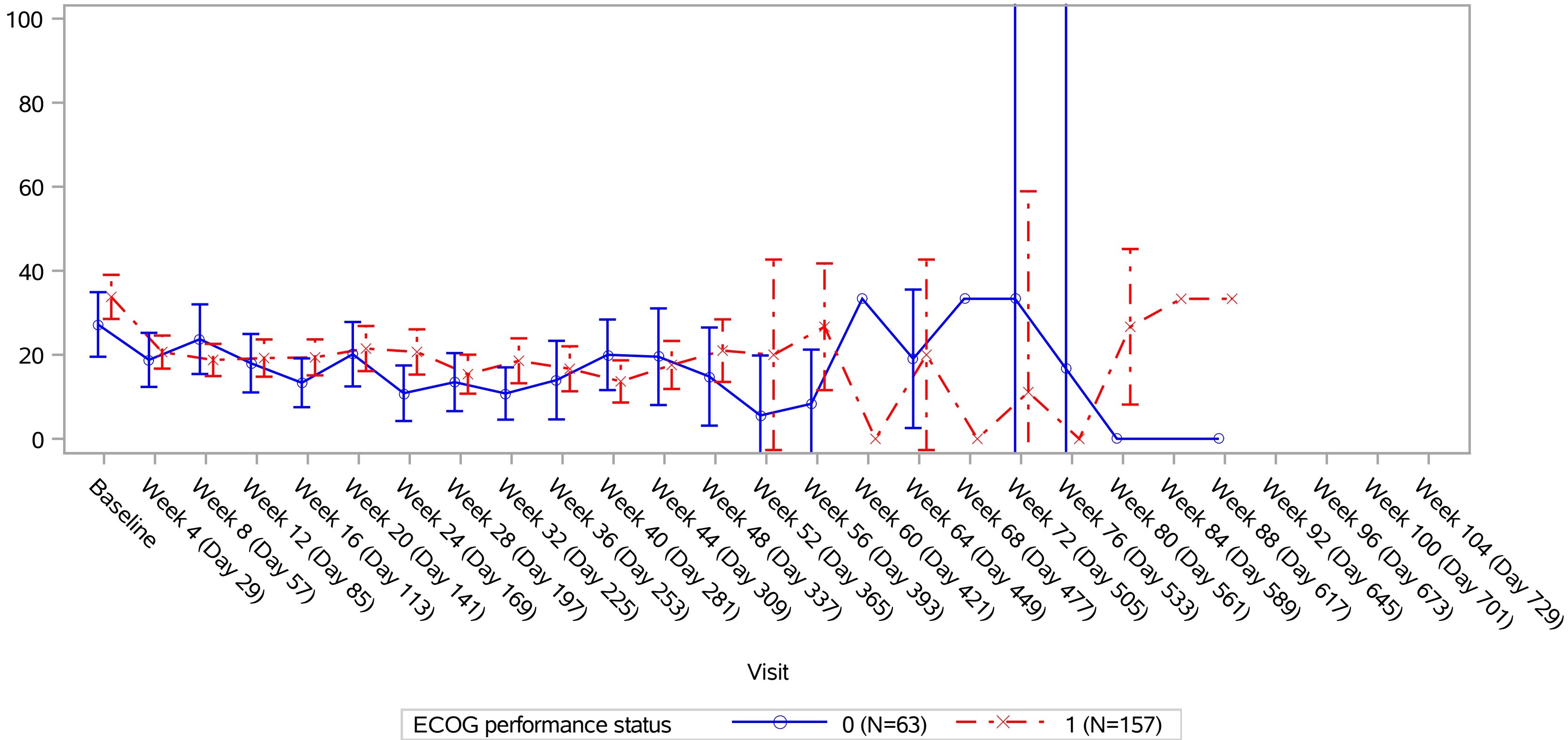
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Dyspnoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30DY_SGAGE65.pdf
15OCT2021 17:34

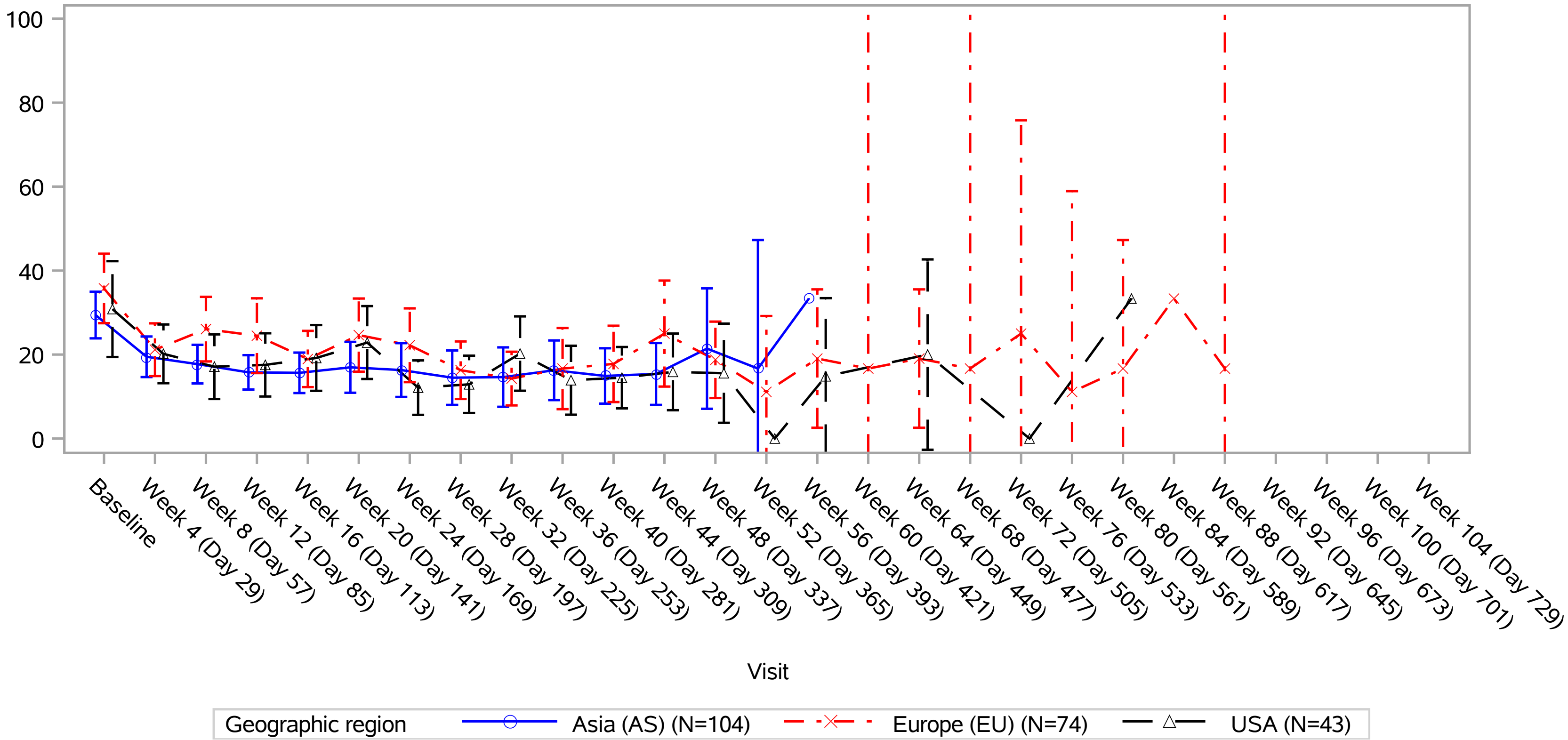
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Dyspnoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30DY_SGECOG.pdf
15OCT2021 18:04

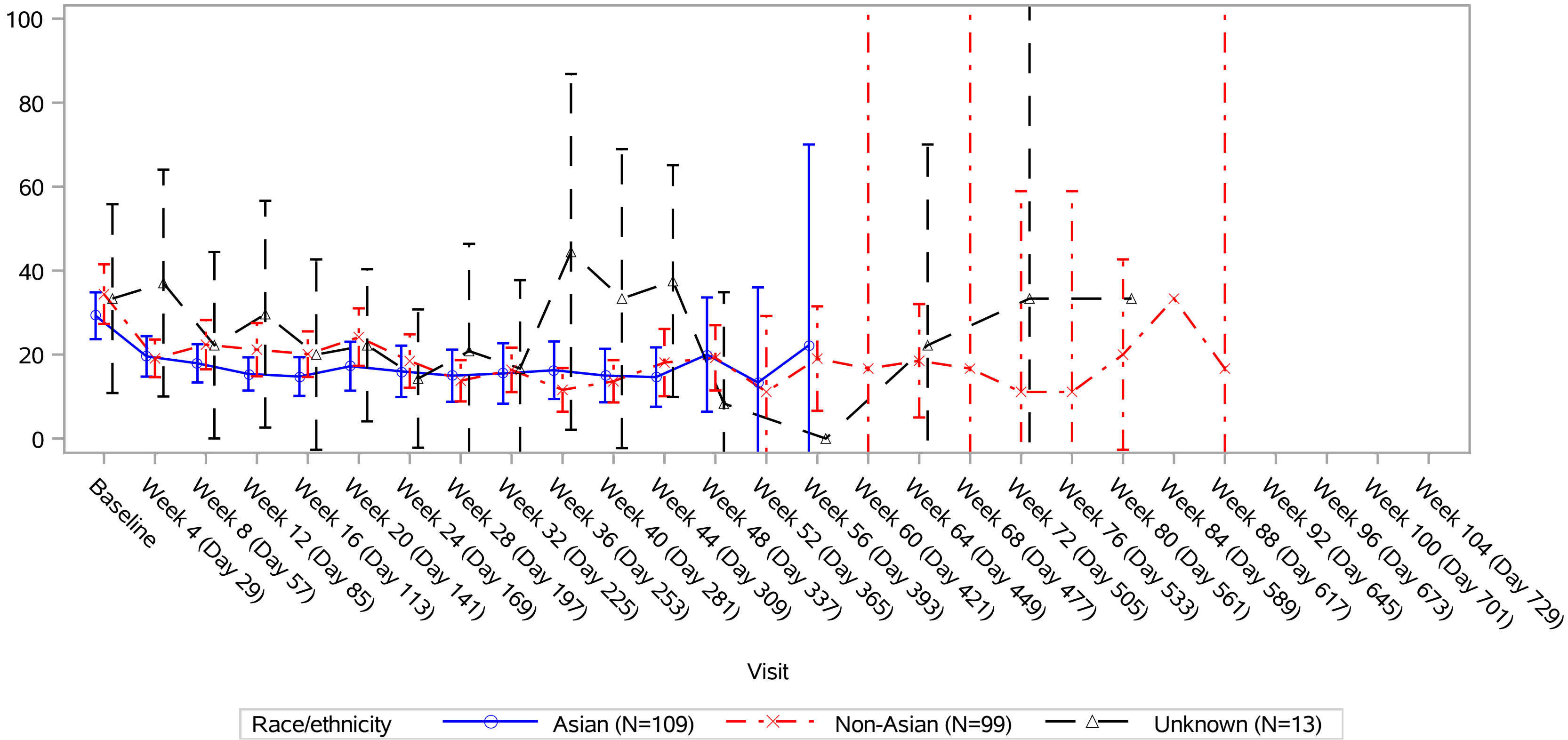
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Dyspnoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30DY_SGGEO.pdf
15OCT2021 18:34

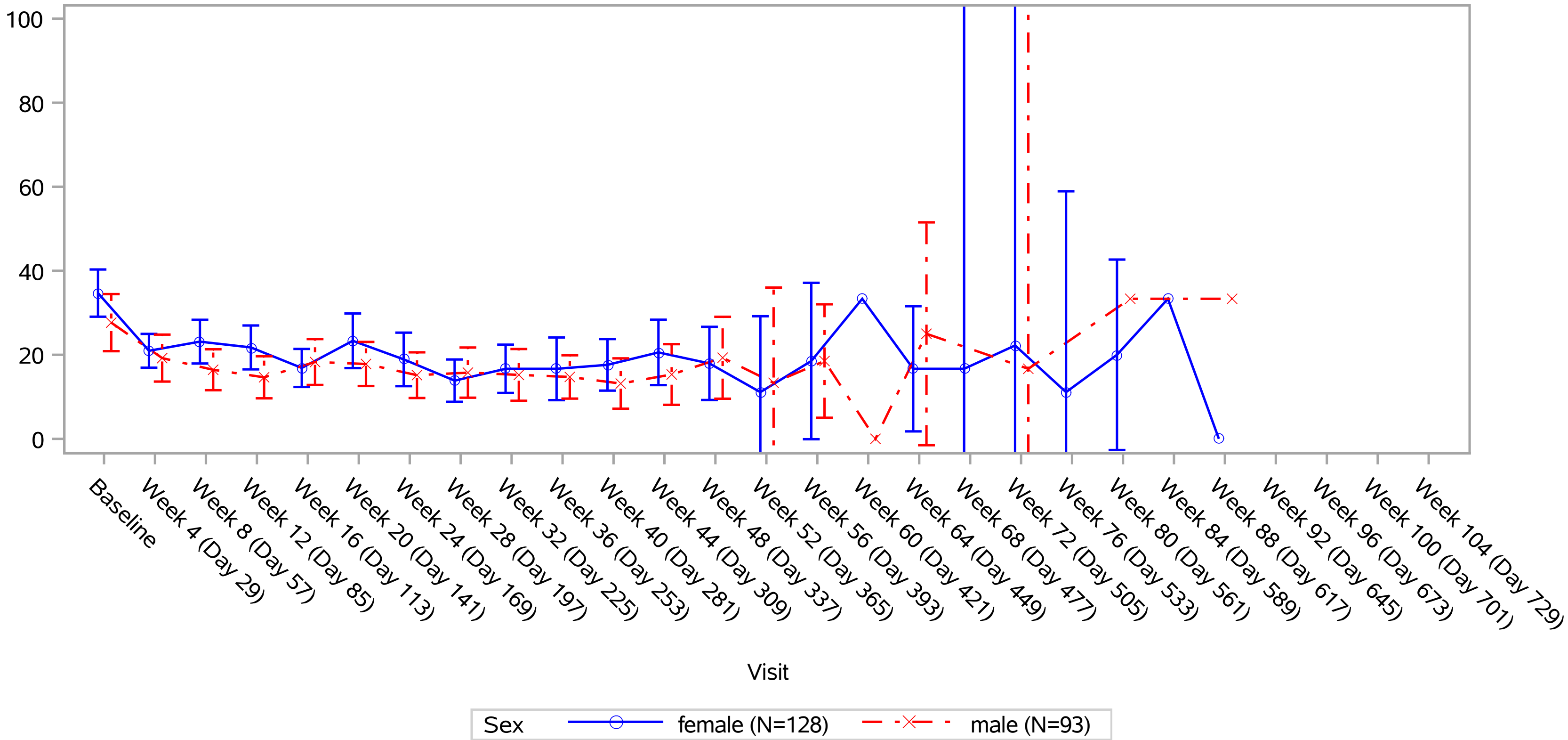
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Dyspnoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30DY_SGRE.pdf
15OCT2021 19:05

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Dyspnoea
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30DY_SGSEX.pdf
15OCT2021 19:36

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Emotional functioning
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=221)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	221	100.0	212	95.9	80.58	21.02	77.74	83.43
Week 4 (Day 29)	n/a	221	100.0	191	86.4	83.99	18.67	81.32	86.65
Week 8 (Day 57)	n/a	193	87.3	171	88.6	85.62	16.74	83.10	88.15
Week 12 (Day 85)	n/a	176	79.6	160	90.9	86.72	17.04	84.06	89.38
Week 16 (Day 113)	n/a	164	74.2	143	87.2	86.32	17.71	83.40	89.25
Week 20 (Day 141)	n/a	148	67.0	138	93.2	84.96	17.67	81.99	87.94
Week 24 (Day 169)	n/a	137	62.0	122	89.1	85.66	17.84	82.46	88.85
Week 28 (Day 197)	n/a	129	58.4	120	93.0	85.76	18.85	82.36	89.17
Week 32 (Day 225)	n/a	119	53.8	104	87.4	85.50	18.40	81.92	89.07
Week 36 (Day 253)	n/a	112	50.7	95	84.8	85.53	18.40	81.78	89.28
Week 40 (Day 281)	n/a	104	47.1	91	87.5	83.24	19.70	79.14	87.34
Week 44 (Day 309)	n/a	95	43.0	84	88.4	84.56	21.93	79.80	89.32
Week 48 (Day 337)	n/a	81	36.7	45	55.6	83.89	18.75	78.26	89.52
Week 52 (Day 365)	n/a	64	29.0	11	17.2	79.55	24.26	63.25	95.84
Week 56 (Day 393)	n/a	54	24.4	18	33.3	80.56	15.91	72.64	88.47
Week 60 (Day 421)	n/a	43	19.5	2	4.7	70.83	17.68	-87.99	229.66
Week 64 (Day 449)	n/a	41	18.6	12	29.3	81.94	17.71	70.69	93.20
Week 68 (Day 477)	n/a	34	15.4	2	5.9	66.67	11.79	-39.22	172.55
Week 72 (Day 505)	n/a	34	15.4	5	14.7	83.33	23.57	54.07	112.60
Week 76 (Day 533)	n/a	31	14.0	3	9.7	83.33	0.00	NE	NE
Week 80 (Day 561)	n/a	30	13.6	6	20.0	79.17	26.74	51.10	107.23
Week 84 (Day 589)	n/a	19	8.6	1	5.3	83.33	NE	NE	NE
Week 88 (Day 617)	n/a	15	6.8	2	13.3	91.67	11.79	-14.22	197.55
Week 92 (Day 645)	n/a	8	3.6	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	2.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	1.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	221	100.0	219	99.1	83.73	20.26	81.03	86.42
End of Study (LOCF)	n/a	221	100.0	219	99.1	83.52	20.04	80.85	86.19
Sex									
Baseline	Female	128	100.0	123	96.1	78.05	22.86	73.97	82.13
Week 4 (Day 29)	Female	128	100.0	106	82.8	83.02	18.25	79.50	86.53
Week 8 (Day 57)	Female	112	87.5	98	87.5	83.59	18.52	79.88	87.30
Week 12 (Day 85)	Female	104	81.3	94	90.4	84.22	18.59	80.41	88.03
Week 16 (Day 113)	Female	96	75.0	81	84.4	84.81	18.92	80.63	88.99
Week 20 (Day 141)	Female	86	67.2	80	93.0	82.50	18.87	78.30	86.70
Week 24 (Day 169)	Female	78	60.9	67	85.9	84.20	19.14	79.53	88.87
Week 28 (Day 197)	Female	72	56.3	65	90.3	82.18	20.72	77.04	87.31
Week 32 (Day 225)	Female	69	53.9	58	84.1	82.18	21.37	76.56	87.80
Week 36 (Day 253)	Female	64	50.0	52	81.3	83.01	20.54	77.29	88.73
Week 40 (Day 281)	Female	59	46.1	53	89.8	81.76	22.17	75.65	87.87
Week 44 (Day 309)	Female	56	43.8	47	83.9	81.21	25.62	73.68	88.73
Week 48 (Day 337)	Female	48	37.5	26	54.2	80.77	19.83	72.76	88.78
Week 52 (Day 365)	Female	38	29.7	6	15.8	76.39	22.00	53.31	99.47
Week 56 (Day 393)	Female	31	24.2	9	29.0	75.93	17.40	62.55	89.30
Week 60 (Day 421)	Female	27	21.1	1	3.7	58.33	NE	NE	NE
Week 64 (Day 449)	Female	26	20.3	8	30.8	79.17	14.09	67.39	90.94
Week 68 (Day 477)	Female	23	18.0	2	8.7	66.67	11.79	-39.22	172.55
Week 72 (Day 505)	Female	23	18.0	3	13.0	72.22	25.46	8.98	135.47
Week 76 (Day 533)	Female	21	16.4	3	14.3	83.33	0.00	NE	NE
Week 80 (Day 561)	Female	20	15.6	5	25.0	75.00	27.64	40.68	109.32
Week 84 (Day 589)	Female	12	9.4	1	8.3	83.33	NE	NE	NE
Week 88 (Day 617)	Female	9	7.0	1	11.1	83.33	NE	NE	NE
Week 92 (Day 645)	Female	6	4.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	3.9	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	1.6	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	0.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	128	100.0	127	99.2	81.96	22.24	78.05	85.86
End of Study (LOCF)	Female	128	100.0	127	99.2	81.36	22.21	77.46	85.26
Baseline	Male	93	100.0	89	95.7	84.08	17.71	80.35	87.81
Week 4 (Day 29)	Male	93	100.0	85	91.4	85.20	19.22	81.05	89.34
Week 8 (Day 57)	Male	81	87.1	73	90.1	88.36	13.66	85.17	91.54
Week 12 (Day 85)	Male	72	77.4	66	91.7	90.28	13.91	86.86	93.70
Week 16 (Day 113)	Male	68	73.1	62	91.2	88.31	15.93	84.26	92.35
Week 20 (Day 141)	Male	62	66.7	58	93.5	88.36	15.37	84.32	92.40
Week 24 (Day 169)	Male	59	63.4	55	93.2	87.42	16.11	83.07	91.78
Week 28 (Day 197)	Male	57	61.3	55	96.5	90.00	15.50	85.81	94.19
Week 32 (Day 225)	Male	50	53.8	46	92.0	89.67	12.81	85.87	93.48
Week 36 (Day 253)	Male	48	51.6	43	89.6	88.57	15.11	83.92	93.22
Week 40 (Day 281)	Male	45	48.4	38	84.4	85.31	15.67	80.16	90.46
Week 44 (Day 309)	Male	39	41.9	37	94.9	88.81	15.39	83.68	93.94
Week 48 (Day 337)	Male	33	35.5	19	57.6	88.16	16.74	80.09	96.23
Week 52 (Day 365)	Male	26	28.0	5	19.2	83.33	28.87	47.49	119.18
Week 56 (Day 393)	Male	23	24.7	9	39.1	85.19	13.68	74.67	95.70
Week 60 (Day 421)	Male	16	17.2	1	6.3	83.33	NE	NE	NE
Week 64 (Day 449)	Male	15	16.1	4	26.7	87.50	25.00	47.72	127.28
Week 68 (Day 477)	Male	11	11.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	11	11.8	2	18.2	100.00	0.00	NE	NE
Week 76 (Day 533)	Male	10	10.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	10	10.8	1	10.0	100.00	NE	NE	NE
Week 84 (Day 589)	Male	7	7.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	6	6.5	1	16.7	100.00	NE	NE	NE
Week 92 (Day 645)	Male	2	2.2	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	93	100.0	92	98.9	86.17	16.96	82.66	89.68
End of Study (LOCF)	Male	93	100.0	92	98.9	86.50	16.24	83.14	89.87
Age									

Baseline	< 65	141	100.0	133	94.3	80.26	20.81	76.69	83.83
Week 4 (Day 29)	< 65	141	100.0	123	87.2	84.15	18.59	80.83	87.46
Week 8 (Day 57)	< 65	127	90.1	113	89.0	86.06	16.31	83.02	89.10
Week 12 (Day 85)	< 65	118	83.7	105	89.0	87.22	17.10	83.91	90.53
Week 16 (Day 113)	< 65	108	76.6	93	86.1	86.05	17.40	82.47	89.63
Week 20 (Day 141)	< 65	100	70.9	97	97.0	83.85	18.51	80.12	87.58
Week 24 (Day 169)	< 65	93	66.0	86	92.5	85.76	17.84	81.93	89.58
Week 28 (Day 197)	< 65	88	62.4	83	94.3	84.54	19.35	80.31	88.76
Week 32 (Day 225)	< 65	83	58.9	73	88.0	85.39	17.39	81.33	89.45
Week 36 (Day 253)	< 65	78	55.3	70	89.7	85.48	18.21	81.13	89.82
Week 40 (Day 281)	< 65	75	53.2	69	92.0	82.97	19.67	78.25	87.70
Week 44 (Day 309)	< 65	71	50.4	65	91.5	84.40	22.86	78.74	90.07
Week 48 (Day 337)	< 65	61	43.3	33	54.1	85.35	16.54	79.49	91.22
Week 52 (Day 365)	< 65	48	34.0	6	12.5	77.78	26.70	49.76	105.80
Week 56 (Day 393)	< 65	41	29.1	11	26.8	80.30	17.19	68.76	91.85
Week 60 (Day 421)	< 65	33	23.4	2	6.1	70.83	17.68	-87.99	229.66
Week 64 (Day 449)	< 65	31	22.0	10	32.3	85.00	17.92	72.18	97.82
Week 68 (Day 477)	< 65	26	18.4	2	7.7	66.67	11.79	-39.22	172.55
Week 72 (Day 505)	< 65	26	18.4	5	19.2	83.33	23.57	54.07	112.60
Week 76 (Day 533)	< 65	25	17.7	3	12.0	83.33	0.00	NE	NE
Week 80 (Day 561)	< 65	24	17.0	5	20.8	81.67	29.11	45.53	117.81
Week 84 (Day 589)	< 65	16	11.3	1	6.3	83.33	NE	NE	NE
Week 88 (Day 617)	< 65	13	9.2	2	15.4	91.67	11.79	-14.22	197.55
Week 92 (Day 645)	< 65	7	5.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	3.5	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	2.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	0.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	141	100.0	139	98.6	84.13	21.05	80.60	87.66
End of Study (LOCF)	< 65	141	100.0	139	98.6	84.17	20.64	80.71	87.63
Baseline	>= 65	80	100.0	79	98.8	81.12	21.50	76.30	85.93
Week 4 (Day 29)	>= 65	80	100.0	68	85.0	83.70	18.96	79.11	88.29
Week 8 (Day 57)	>= 65	66	82.5	58	87.9	84.77	17.67	80.12	89.42
Week 12 (Day 85)	>= 65	58	72.5	55	94.8	85.76	17.02	81.16	90.36

Week 16 (Day 113)	>= 65	56	70.0	50	89.3	86.83	18.45	81.59	92.08
Week 20 (Day 141)	>= 65	48	60.0	41	85.4	87.60	15.38	82.75	92.46
Week 24 (Day 169)	>= 65	44	55.0	36	81.8	85.42	18.08	79.30	91.53
Week 28 (Day 197)	>= 65	41	51.3	37	90.2	88.51	17.61	82.64	94.38
Week 32 (Day 225)	>= 65	36	45.0	31	86.1	85.75	20.88	78.09	93.41
Week 36 (Day 253)	>= 65	34	42.5	25	73.5	85.67	19.32	77.69	93.64
Week 40 (Day 281)	>= 65	29	36.3	22	75.9	84.09	20.23	75.12	93.06
Week 44 (Day 309)	>= 65	24	30.0	19	79.2	85.09	18.96	75.95	94.23
Week 48 (Day 337)	>= 65	20	25.0	12	60.0	79.86	24.22	64.47	95.25
Week 52 (Day 365)	>= 65	16	20.0	5	31.3	81.67	23.86	52.04	111.30
Week 56 (Day 393)	>= 65	13	16.3	7	53.8	80.95	15.00	67.08	94.82
Week 60 (Day 421)	>= 65	10	12.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	10	12.5	2	20.0	66.67	0.00	NE	NE
Week 68 (Day 477)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	6	7.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	6	7.5	1	16.7	66.67	NE	NE	NE
Week 84 (Day 589)	>= 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	2.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	80	100.0	80	100.0	83.02	18.91	78.81	87.23
End of Study (LOCF)	>= 65	80	100.0	80	100.0	82.40	19.03	78.16	86.63
ECOG performance status									
Baseline	0	63	100.0	60	95.2	77.22	22.22	71.48	82.96
Week 4 (Day 29)	0	63	100.0	56	88.9	79.61	20.47	74.13	85.09
Week 8 (Day 57)	0	58	92.1	52	89.7	79.81	19.55	74.36	85.25
Week 12 (Day 85)	0	55	87.3	49	89.1	82.82	20.44	76.95	88.69
Week 16 (Day 113)	0	54	85.7	45	83.3	81.48	20.33	75.37	87.59
Week 20 (Day 141)	0	52	82.5	48	92.3	80.56	20.22	74.68	86.43
Week 24 (Day 169)	0	49	77.8	43	87.8	83.33	19.75	77.25	89.41
Week 28 (Day 197)	0	46	73.0	42	91.3	84.52	20.62	78.10	90.95

Week 32 (Day 225)	0	41	65.1	34	82.9	82.84	18.91	76.25	89.44
Week 36 (Day 253)	0	39	61.9	31	79.5	81.72	21.24	73.93	89.51
Week 40 (Day 281)	0	37	58.7	30	81.1	79.17	20.96	71.34	86.99
Week 44 (Day 309)	0	36	57.1	29	80.6	80.75	27.01	70.47	91.02
Week 48 (Day 337)	0	28	44.4	18	64.3	80.56	22.32	69.45	91.66
Week 52 (Day 365)	0	27	42.9	6	22.2	68.06	27.60	39.09	97.02
Week 56 (Day 393)	0	24	38.1	8	33.3	81.25	17.68	66.47	96.03
Week 60 (Day 421)	0	21	33.3	1	4.8	58.33	NE	NE	NE
Week 64 (Day 449)	0	21	33.3	7	33.3	82.14	19.50	64.11	100.18
Week 68 (Day 477)	0	17	27.0	1	5.9	58.33	NE	NE	NE
Week 72 (Day 505)	0	17	27.0	2	11.8	75.00	35.36	-242.66	392.66
Week 76 (Day 533)	0	15	23.8	2	13.3	83.33	0.00	NE	NE
Week 80 (Day 561)	0	14	22.2	1	7.1	100.00	NE	NE	NE
Week 84 (Day 589)	0	11	17.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	10	15.9	1	10.0	83.33	NE	NE	NE
Week 92 (Day 645)	0	5	7.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	6.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	4.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	63	100.0	63	100.0	80.03	24.16	73.94	86.11
End of Study (LOCF)	0	63	100.0	63	100.0	79.50	23.66	73.54	85.46
Baseline	1	157	100.0	151	96.2	82.12	20.35	78.85	85.39
Week 4 (Day 29)	1	157	100.0	134	85.4	85.95	17.62	82.93	88.96
Week 8 (Day 57)	1	134	85.4	119	88.8	88.17	14.74	85.49	90.84
Week 12 (Day 85)	1	121	77.1	111	91.7	88.44	15.08	85.60	91.28
Week 16 (Day 113)	1	110	70.1	98	89.1	88.55	16.00	85.34	91.76
Week 20 (Day 141)	1	96	61.1	90	93.8	87.31	15.76	84.01	90.62
Week 24 (Day 169)	1	88	56.1	79	89.8	86.92	16.70	83.18	90.66
Week 28 (Day 197)	1	83	52.9	78	94.0	86.43	17.92	82.39	90.47
Week 32 (Day 225)	1	78	49.7	70	89.7	86.79	18.14	82.46	91.11
Week 36 (Day 253)	1	73	46.5	64	87.7	87.37	16.73	83.19	91.55
Week 40 (Day 281)	1	67	42.7	61	91.0	85.25	18.90	80.40	90.09

Week 44 (Day 309)	1	59	37.6	55	93.2	86.57	18.69	81.51	91.62
Week 48 (Day 337)	1	53	33.8	27	50.9	86.11	16.01	79.78	92.45
Week 52 (Day 365)	1	37	23.6	5	13.5	93.33	9.13	82.00	104.67
Week 56 (Day 393)	1	30	19.1	10	33.3	80.00	15.32	69.04	90.96
Week 60 (Day 421)	1	22	14.0	1	4.5	83.33	NE	NE	NE
Week 64 (Day 449)	1	20	12.7	5	25.0	81.67	17.08	60.46	102.87
Week 68 (Day 477)	1	17	10.8	1	5.9	75.00	NE	NE	NE
Week 72 (Day 505)	1	17	10.8	3	17.6	88.89	19.25	41.08	136.70
Week 76 (Day 533)	1	16	10.2	1	6.3	83.33	NE	NE	NE
Week 80 (Day 561)	1	16	10.2	5	31.3	75.00	27.64	40.68	109.32
Week 84 (Day 589)	1	8	5.1	1	12.5	83.33	NE	NE	NE
Week 88 (Day 617)	1	5	3.2	1	20.0	100.00	NE	NE	NE
Week 92 (Day 645)	1	3	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	157	100.0	155	98.7	85.34	18.33	82.43	88.25
End of Study (LOCF)	1	157	100.0	155	98.7	85.27	18.21	82.38	88.16
Baseline	Missing	1	100.0	1	100.0	50.00	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	66.67	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	66.67	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	66.67	NE	NE	NE
Geographic region									
Baseline	USA	43	100.0	41	95.3	80.28	16.64	75.03	85.54
Week 4 (Day 29)	USA	43	100.0	38	88.4	80.92	16.77	75.41	86.43
Week 8 (Day 57)	USA	41	95.3	37	90.2	84.23	14.80	79.30	89.17
Week 12 (Day 85)	USA	41	95.3	37	90.2	85.36	16.94	79.71	91.01
Week 16 (Day 113)	USA	40	93.0	33	82.5	84.09	16.58	78.21	89.97
Week 20 (Day 141)	USA	39	90.7	35	89.7	84.05	15.83	78.61	89.49
Week 24 (Day 169)	USA	36	83.7	33	91.7	83.84	17.17	77.75	89.93
Week 28 (Day 197)	USA	35	81.4	31	88.6	86.83	17.05	80.57	93.08
Week 32 (Day 225)	USA	32	74.4	28	87.5	84.52	18.94	77.18	91.87
Week 36 (Day 253)	USA	32	74.4	24	75.0	82.99	21.91	73.74	92.24
Week 40 (Day 281)	USA	29	67.4	23	79.3	77.90	23.78	67.61	88.18

Week 44 (Day 309)	USA	26	60.5	21	80.8	86.24	16.16	78.89	93.60
Week 48 (Day 337)	USA	21	48.8	15	71.4	84.44	14.73	76.29	92.60
Week 52 (Day 365)	USA	18	41.9	1	5.6	100.00	NE	NE	NE
Week 56 (Day 393)	USA	18	41.9	9	50.0	80.56	17.68	66.97	94.14
Week 60 (Day 421)	USA	17	39.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	15	34.9	5	33.3	85.00	14.91	66.49	103.51
Week 68 (Day 477)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	12	27.9	1	8.3	100.00	NE	NE	NE
Week 76 (Day 533)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	12	27.9	2	16.7	50.00	23.57	-161.77	261.77
Week 84 (Day 589)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	6	14.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	11.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	7.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	43	100.0	43	100.0	86.11	17.54	80.71	91.51
End of Study (LOCF)	USA	43	100.0	43	100.0	83.91	17.95	78.39	89.44
Baseline	Europe (EU)	74	100.0	69	93.2	72.46	24.05	66.69	78.24
Week 4 (Day 29)	Europe (EU)	74	100.0	64	86.5	78.26	20.61	73.11	83.40
Week 8 (Day 57)	Europe (EU)	65	87.8	55	84.6	79.39	18.06	74.51	84.28
Week 12 (Day 85)	Europe (EU)	57	77.0	49	86.0	79.42	19.10	73.94	84.91
Week 16 (Day 113)	Europe (EU)	55	74.3	44	80.0	79.80	20.41	73.59	86.00
Week 20 (Day 141)	Europe (EU)	49	66.2	46	93.9	78.08	20.29	72.05	84.10
Week 24 (Day 169)	Europe (EU)	47	63.5	42	89.4	78.37	21.70	71.61	85.14
Week 28 (Day 197)	Europe (EU)	45	60.8	43	95.6	78.49	20.59	72.15	84.83
Week 32 (Day 225)	Europe (EU)	39	52.7	35	89.7	83.33	15.66	77.96	88.71
Week 36 (Day 253)	Europe (EU)	34	45.9	30	88.2	81.11	15.77	75.22	87.00
Week 40 (Day 281)	Europe (EU)	31	41.9	30	96.8	79.44	17.33	72.97	85.92
Week 44 (Day 309)	Europe (EU)	28	37.8	24	85.7	72.57	29.02	60.31	84.82

Week 48 (Day 337)	Europe (EU)	22	29.7	16	72.7	77.08	17.08	67.98	86.18
Week 52 (Day 365)	Europe (EU)	19	25.7	6	31.6	68.06	27.60	39.09	97.02
Week 56 (Day 393)	Europe (EU)	17	23.0	7	41.2	77.38	15.75	62.82	91.95
Week 60 (Day 421)	Europe (EU)	15	20.3	2	13.3	70.83	17.68	-87.99	229.66
Week 64 (Day 449)	Europe (EU)	15	20.3	7	46.7	79.76	20.33	60.96	98.57
Week 68 (Day 477)	Europe (EU)	13	17.6	2	15.4	66.67	11.79	-39.22	172.55
Week 72 (Day 505)	Europe (EU)	13	17.6	4	30.8	79.17	25.00	39.39	118.95
Week 76 (Day 533)	Europe (EU)	11	14.9	3	27.3	83.33	0.00	NE	NE
Week 80 (Day 561)	Europe (EU)	10	13.5	4	40.0	93.75	12.50	73.86	113.64
Week 84 (Day 589)	Europe (EU)	6	8.1	1	16.7	83.33	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	4.1	2	66.7	91.67	11.79	-14.22	197.55
Cycle 12 (LOCF)	Europe (EU)	74	100.0	73	98.6	76.03	23.85	70.46	81.59
End of Study (LOCF)	Europe (EU)	74	100.0	73	98.6	76.48	23.21	71.07	81.90
Baseline	Asia (AS)	104	100.0	102	98.1	86.19	18.63	82.53	89.85
Week 4 (Day 29)	Asia (AS)	104	100.0	89	85.6	89.42	16.51	85.94	92.90
Week 8 (Day 57)	Asia (AS)	87	83.7	79	90.8	90.61	15.18	87.21	94.01
Week 12 (Day 85)	Asia (AS)	78	75.0	74	94.9	92.23	13.54	89.09	95.37
Week 16 (Day 113)	Asia (AS)	69	66.3	66	95.7	91.79	14.58	88.21	95.38
Week 20 (Day 141)	Asia (AS)	60	57.7	57	95.0	91.08	14.25	87.30	94.86
Week 24 (Day 169)	Asia (AS)	54	51.9	47	87.0	93.44	9.97	90.51	96.37
Week 28 (Day 197)	Asia (AS)	49	47.1	46	93.9	91.85	16.15	87.05	96.64
Week 32 (Day 225)	Asia (AS)	48	46.2	41	85.4	88.01	20.25	81.62	94.40
Week 36 (Day 253)	Asia (AS)	46	44.2	41	89.1	90.24	17.27	84.79	95.70
Week 40 (Day 281)	Asia (AS)	44	42.3	38	86.4	89.47	17.40	83.75	95.19
Week 44 (Day 309)	Asia (AS)	41	39.4	39	95.1	91.03	16.38	85.72	96.33
Week 48 (Day 337)	Asia (AS)	38	36.5	14	36.8	91.07	22.52	78.07	104.07
Week 52 (Day 365)	Asia (AS)	27	26.0	4	14.8	91.67	9.62	76.36	106.98
Week 56 (Day 393)	Asia (AS)	19	18.3	2	10.5	91.67	0.00	NE	NE
Week 60 (Day 421)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	5.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	104	100.0	103	99.0	88.19	16.85	84.89	91.48
End of Study (LOCF)	Asia (AS)	104	100.0	103	99.0	88.35	16.92	85.04	91.66
Race/ethnicity									
Baseline	Asian	109	100.0	106	97.2	86.40	18.38	82.86	89.94
Week 4 (Day 29)	Asian	109	100.0	92	84.4	89.49	16.29	86.12	92.87
Week 8 (Day 57)	Asian	91	83.5	80	87.9	90.73	15.12	87.36	94.09
Week 12 (Day 85)	Asian	82	75.2	78	95.1	92.20	13.25	89.21	95.19
Week 16 (Day 113)	Asian	73	67.0	70	95.9	91.43	14.74	87.91	94.94
Week 20 (Day 141)	Asian	64	58.7	60	93.8	90.83	14.29	87.14	94.52
Week 24 (Day 169)	Asian	57	52.3	50	87.7	93.17	10.06	90.31	96.03
Week 28 (Day 197)	Asian	52	47.7	49	94.2	91.33	16.04	86.72	95.93
Week 32 (Day 225)	Asian	50	45.9	43	86.0	88.37	19.85	82.26	94.48
Week 36 (Day 253)	Asian	48	44.0	43	89.6	90.50	16.92	85.30	95.71
Week 40 (Day 281)	Asian	46	42.2	40	87.0	89.58	16.96	84.16	95.01
Week 44 (Day 309)	Asian	43	39.4	41	95.3	91.46	16.08	86.39	96.54
Week 48 (Day 337)	Asian	40	36.7	15	37.5	91.11	21.70	79.09	103.13
Week 52 (Day 365)	Asian	29	26.6	5	17.2	93.33	9.13	82.00	104.67
Week 56 (Day 393)	Asian	21	19.3	3	14.3	94.44	4.81	82.49	106.40
Week 60 (Day 421)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	5.5	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	4.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	1.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	109	100.0	107	98.2	88.01	16.87	84.77	91.24
End of Study (LOCF)	Asian	109	100.0	107	98.2	88.16	16.94	84.91	91.41
Baseline	Non-Asian	99	100.0	96	97.0	75.09	22.04	70.62	79.55
Week 4 (Day 29)	Non-Asian	99	100.0	89	89.9	79.78	19.05	75.76	83.79
Week 8 (Day 57)	Non-Asian	91	91.9	82	90.1	81.50	17.37	77.69	85.32
Week 12 (Day 85)	Non-Asian	83	83.8	73	88.0	81.39	19.12	76.93	85.85
Week 16 (Day 113)	Non-Asian	80	80.8	68	85.0	81.29	19.52	76.57	86.02
Week 20 (Day 141)	Non-Asian	74	74.7	69	93.2	80.92	18.47	76.48	85.36
Week 24 (Day 169)	Non-Asian	70	70.7	65	92.9	80.51	20.69	75.39	85.64
Week 28 (Day 197)	Non-Asian	67	67.7	63	94.0	82.94	17.55	78.52	87.36
Week 32 (Day 225)	Non-Asian	60	60.6	53	88.3	83.96	17.44	79.16	88.77
Week 36 (Day 253)	Non-Asian	55	55.6	46	83.6	82.07	18.67	76.52	87.61
Week 40 (Day 281)	Non-Asian	49	49.5	44	89.8	78.60	21.52	72.06	85.14
Week 44 (Day 309)	Non-Asian	43	43.4	35	81.4	79.37	25.16	70.72	88.01
Week 48 (Day 337)	Non-Asian	35	35.4	26	74.3	79.81	16.19	73.27	86.35
Week 52 (Day 365)	Non-Asian	29	29.3	6	20.7	68.06	27.60	39.09	97.02
Week 56 (Day 393)	Non-Asian	27	27.3	14	51.9	77.38	16.48	67.86	86.90
Week 60 (Day 421)	Non-Asian	26	26.3	2	7.7	70.83	17.68	-87.99	229.66
Week 64 (Day 449)	Non-Asian	24	24.2	9	37.5	84.26	19.74	69.09	99.43
Week 68 (Day 477)	Non-Asian	20	20.2	2	10.0	66.67	11.79	-39.22	172.55
Week 72 (Day 505)	Non-Asian	20	20.2	3	15.0	100.00	0.00	NE	NE
Week 76 (Day 533)	Non-Asian	18	18.2	3	16.7	83.33	0.00	NE	NE
Week 80 (Day 561)	Non-Asian	17	17.2	5	29.4	80.00	29.81	42.98	117.02
Week 84 (Day 589)	Non-Asian	11	11.1	1	9.1	83.33	NE	NE	NE
Week 88 (Day 617)	Non-Asian	8	8.1	2	25.0	91.67	11.79	-14.22	197.55
Week 92 (Day 645)	Non-Asian	4	4.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	3.0	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	99	100.0	99	100.0	79.91	22.64	75.40	84.42

End of Study (LOCF)	Non-Asian	99	100.0	99	100.0	79.29	22.16	74.87	83.71
Baseline	Unknown	13	100.0	10	76.9	71.67	21.94	55.97	87.36
Week 4 (Day 29)	Unknown	13	100.0	10	76.9	70.83	21.25	55.63	86.03
Week 8 (Day 57)	Unknown	11	84.6	9	81.8	77.78	11.79	68.72	86.84
Week 12 (Day 85)	Unknown	11	84.6	9	81.8	82.41	14.70	71.11	93.71
Week 16 (Day 113)	Unknown	11	84.6	5	45.5	83.33	10.21	70.66	96.01
Week 20 (Day 141)	Unknown	10	76.9	9	90.0	76.85	21.56	60.28	93.43
Week 24 (Day 169)	Unknown	10	76.9	7	70.0	79.76	15.11	65.79	93.73
Week 28 (Day 197)	Unknown	10	76.9	8	80.0	73.96	33.17	46.23	101.69
Week 32 (Day 225)	Unknown	9	69.2	8	88.9	80.21	16.02	66.81	93.60
Week 36 (Day 253)	Unknown	9	69.2	6	66.7	76.39	20.01	55.39	97.39
Week 40 (Day 281)	Unknown	9	69.2	7	77.8	76.19	12.20	64.91	87.47
Week 44 (Day 309)	Unknown	9	69.2	8	88.9	71.88	23.54	52.19	91.56
Week 48 (Day 337)	Unknown	6	46.2	4	66.7	83.33	19.25	52.71	113.96
Week 52 (Day 365)	Unknown	6	46.2	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	6	46.2	1	16.7	83.33	NE	NE	NE
Week 60 (Day 421)	Unknown	5	38.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	5	38.5	3	60.0	75.00	8.33	54.30	95.70
Week 68 (Day 477)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	4	30.8	2	50.0	58.33	11.79	-47.55	164.22
Week 76 (Day 533)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	4	30.8	1	25.0	75.00	NE	NE	NE
Week 84 (Day 589)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	7.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	13	100.0	13	100.0	77.56	20.80	64.99	90.13
End of Study (LOCF)	Unknown	13	100.0	13	100.0	77.56	19.36	65.86	89.26

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.

¹ in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
² mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TO_QSC30EF_SG.xls
27OCT2021 7:14

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Emotional functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	66	31.1	25.3	37.7
	Cycle 12 (LOCF)	n/a	212	95.9	30	14.2	10.1	19.5
	End of Study (LOCF)	n/a	212	95.9	33	15.6	11.3	21.1
Sex	All visits	Female	123	55.7	37	30.1	22.7	38.7
		Male	89	40.3	29	32.6	23.7	42.9
	Cycle 12 (LOCF)	Female	123	55.7	17	13.8	8.8	21.0
		Male	89	40.3	13	14.6	8.7	23.4
	End of Study (LOCF)	Female	123	55.7	19	15.4	10.1	22.9
		Male	89	40.3	14	15.7	9.6	24.7
Age	All visits	< 65	133	60.2	39	29.3	22.3	37.6
		>= 65	79	35.7	27	34.2	24.7	45.2
	Cycle 12 (LOCF)	< 65	133	60.2	18	13.5	8.7	20.4
		>= 65	79	35.7	12	15.2	8.9	24.7
	End of Study (LOCF)	< 65	133	60.2	19	14.3	9.3	21.2
		>= 65	79	35.7	14	17.7	10.9	27.6
ECOG performance status	All visits	0	60	27.1	27	45.0	33.1	57.5
		1	151	68.3	39	25.8	19.5	33.3
		Missing	1	0.5	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	60	27.1	11	18.3	10.6	29.9
		1	151	68.3	19	12.6	8.2	18.8
		Missing	1	0.5	0	0.0	0.0	79.3
	End of Study (LOCF)	0	60	27.1	14	23.3	14.4	35.4
		1	151	68.3	19	12.6	8.2	18.8
		Missing	1	0.5	0	0.0	0.0	79.3
Geographic region	All visits	USA	41	18.6	14	34.1	21.6	49.5
		Europe (EU)	69	31.2	28	40.6	29.8	52.4
		Asia (AS)	102	46.2	24	23.5	16.4	32.6
	Cycle 12 (LOCF)	USA	41	18.6	3	7.3	2.5	19.4
		Europe (EU)	69	31.2	14	20.3	12.5	31.2
		Asia (AS)	102	46.2	13	12.7	7.6	20.6
	End of Study (LOCF)	USA	41	18.6	5	12.2	5.3	25.5
		Europe (EU)	69	31.2	15	21.7	13.6	32.8
		Asia (AS)	102	46.2	13	12.7	7.6	20.6
Race/ethnicity	All visits	Asian	106	48.0	26	24.5	17.3	33.5
		Non-Asian	96	43.4	37	38.5	29.4	48.5
		Unknown	10	4.5	3	30.0	10.8	60.3
	Cycle 12 (LOCF)	Asian	106	48.0	15	14.2	8.8	22.0

		Non-Asian	96	43.4	15	15.6	9.7	24.2
		Unknown	10	4.5	0	0.0	0.0	27.8
	End of Study (LOCF)	Asian	106	48.0	15	14.2	8.8	22.0
		Non-Asian	96	43.4	18	18.8	12.2	27.7
		Unknown	10	4.5	0	0.0	0.0	27.8

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30EF_W10_SG.xls
15OCT2021 12:53

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Emotional functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

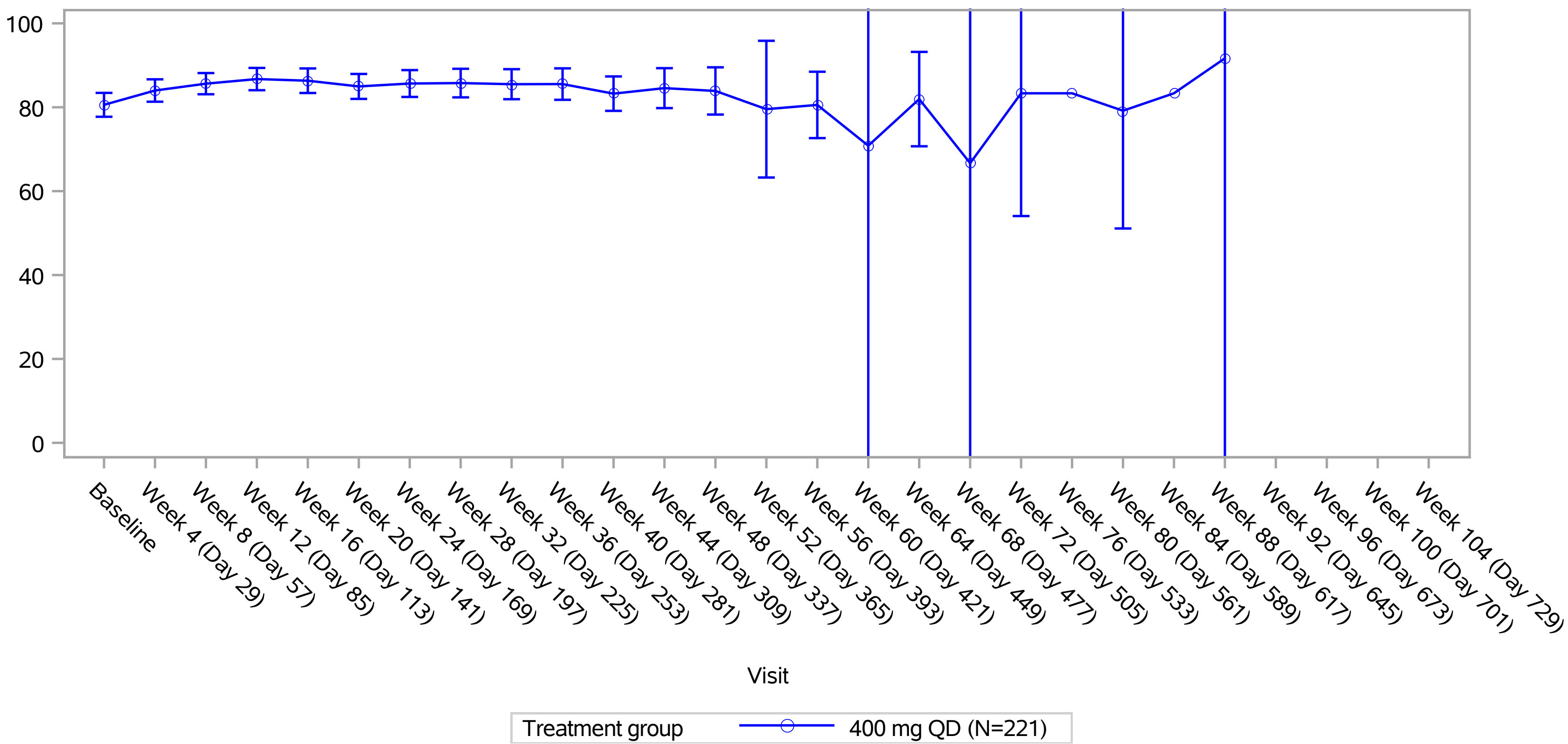
			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	65	30.7	24.8	37.2
	Cycle 12 (LOCF)	n/a	212	95.9	30	14.2	10.1	19.5
	End of Study (LOCF)	n/a	212	95.9	33	15.6	11.3	21.1
Sex	All visits	Female	123	55.7	36	29.3	22.0	37.8
		Male	89	40.3	29	32.6	23.7	42.9
	Cycle 12 (LOCF)	Female	123	55.7	17	13.8	8.8	21.0
		Male	89	40.3	13	14.6	8.7	23.4
	End of Study (LOCF)	Female	123	55.7	19	15.4	10.1	22.9
		Male	89	40.3	14	15.7	9.6	24.7
Age	All visits	< 65	133	60.2	39	29.3	22.3	37.6
		>= 65	79	35.7	26	32.9	23.6	43.9
	Cycle 12 (LOCF)	< 65	133	60.2	18	13.5	8.7	20.4
		>= 65	79	35.7	12	15.2	8.9	24.7
	End of Study (LOCF)	< 65	133	60.2	19	14.3	9.3	21.2
		>= 65	79	35.7	14	17.7	10.9	27.6
ECOG performance status	All visits	0	60	27.1	26	43.3	31.6	55.9
		1	151	68.3	39	25.8	19.5	33.3
		Missing	1	0.5	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	60	27.1	11	18.3	10.6	29.9
		1	151	68.3	19	12.6	8.2	18.8
		Missing	1	0.5	0	0.0	0.0	79.3
	End of Study (LOCF)	0	60	27.1	14	23.3	14.4	35.4
		1	151	68.3	19	12.6	8.2	18.8
		Missing	1	0.5	0	0.0	0.0	79.3
Geographic region	All visits	USA	41	18.6	14	34.1	21.6	49.5
		Europe (EU)	69	31.2	27	39.1	28.5	50.9
		Asia (AS)	102	46.2	24	23.5	16.4	32.6
	Cycle 12 (LOCF)	USA	41	18.6	3	7.3	2.5	19.4
		Europe (EU)	69	31.2	14	20.3	12.5	31.2
		Asia (AS)	102	46.2	13	12.7	7.6	20.6
	End of Study (LOCF)	USA	41	18.6	5	12.2	5.3	25.5
		Europe (EU)	69	31.2	15	21.7	13.6	32.8
		Asia (AS)	102	46.2	13	12.7	7.6	20.6
Race/ethnicity	All visits	Asian	106	48.0	26	24.5	17.3	33.5
		Non-Asian	96	43.4	36	37.5	28.5	47.5
		Unknown	10	4.5	3	30.0	10.8	60.3
	Cycle 12 (LOCF)	Asian	106	48.0	15	14.2	8.8	22.0

		Non-Asian	96	43.4	15	15.6	9.7	24.2
		Unknown	10	4.5	0	0.0	0.0	27.8
	End of Study (LOCF)	Asian	106	48.0	15	14.2	8.8	22.0
		Non-Asian	96	43.4	18	18.8	12.2	27.7
		Unknown	10	4.5	0	0.0	0.0	27.8

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30EF_W15_SG.xls
15OCT2021 12:42

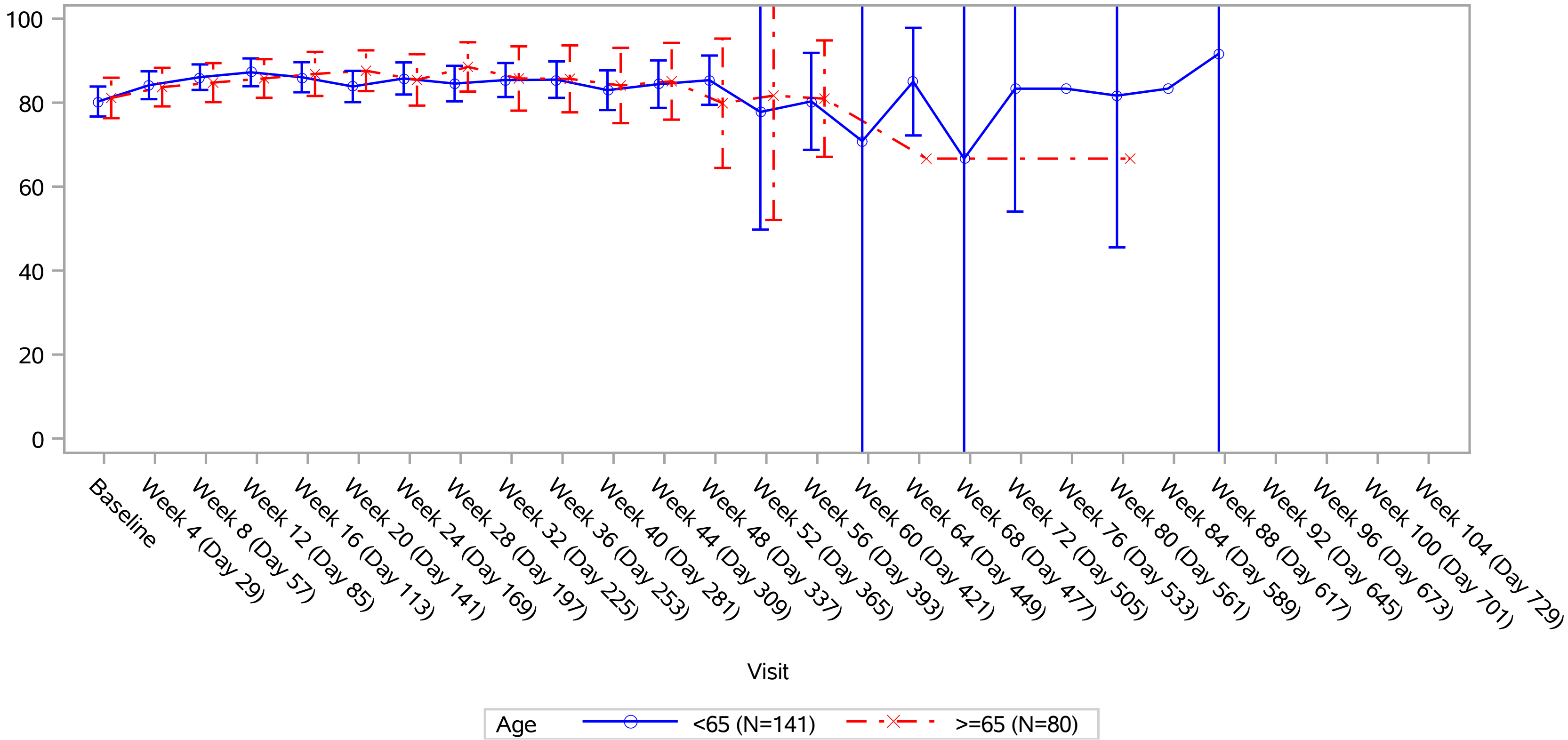
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Emotional functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30EF.pdf
15OCT2021 17:05

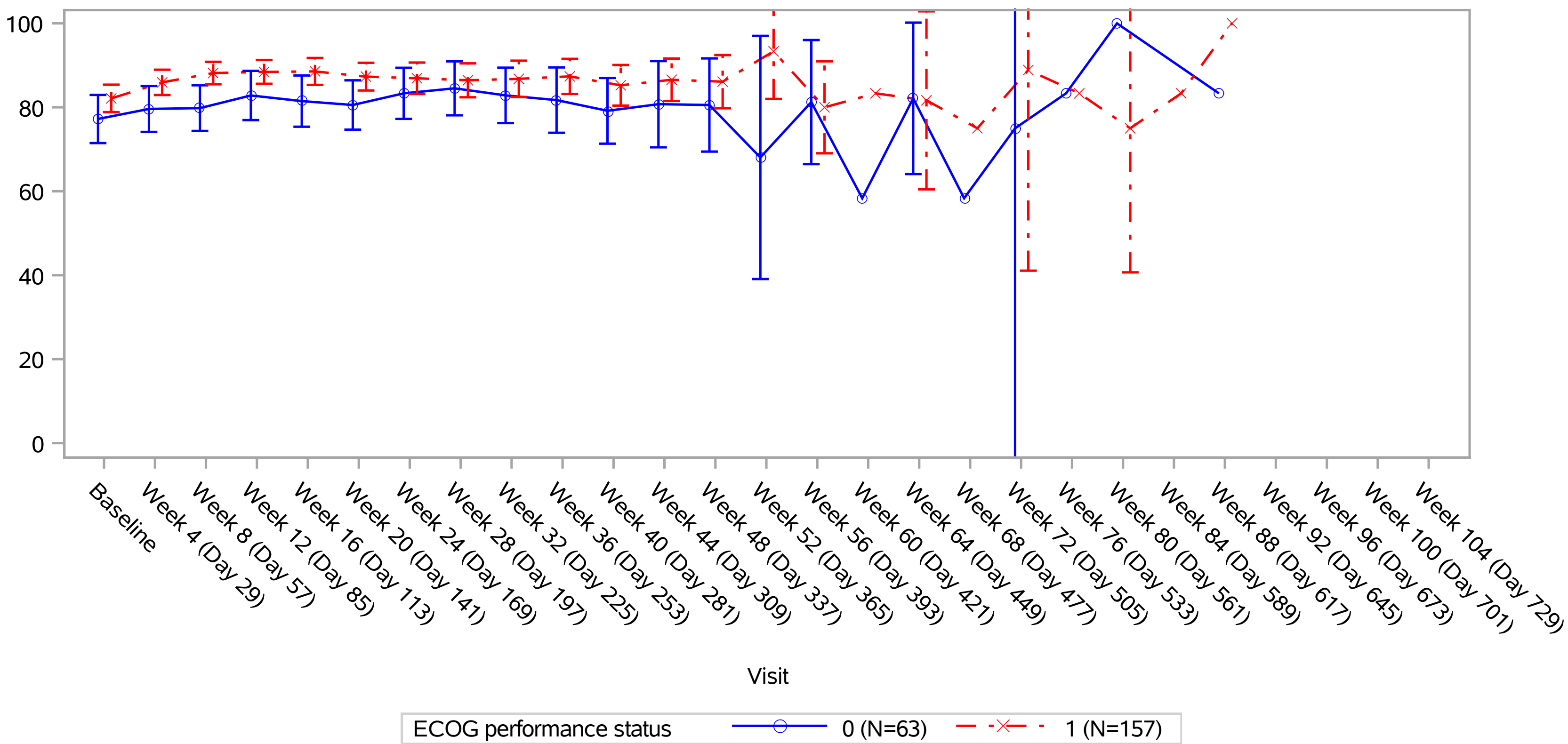
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Emotional functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30EF_SGAGE65.pdf
15OCT2021 17:34

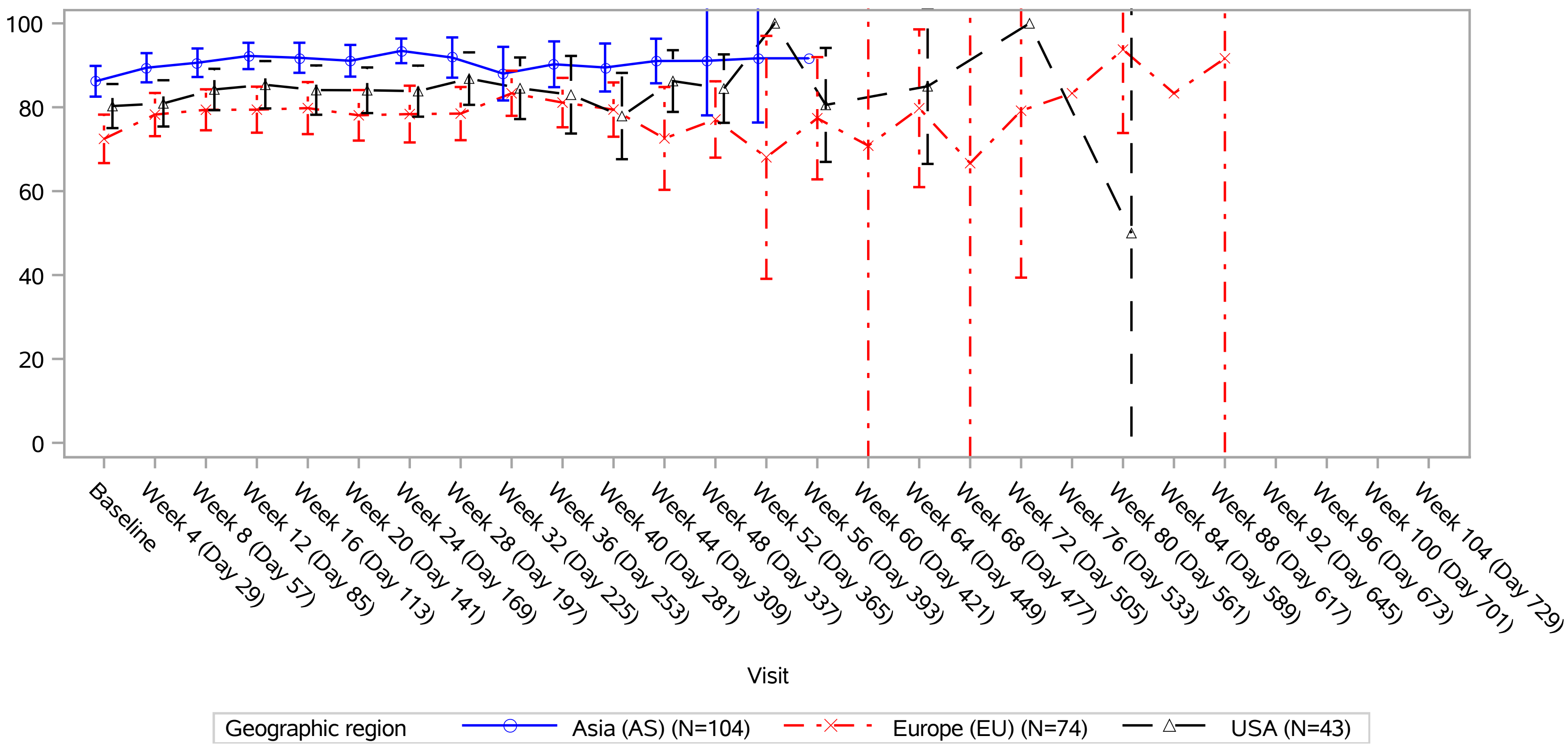
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Emotional functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30EF_SGECOG.pdf
15OCT2021 18:04

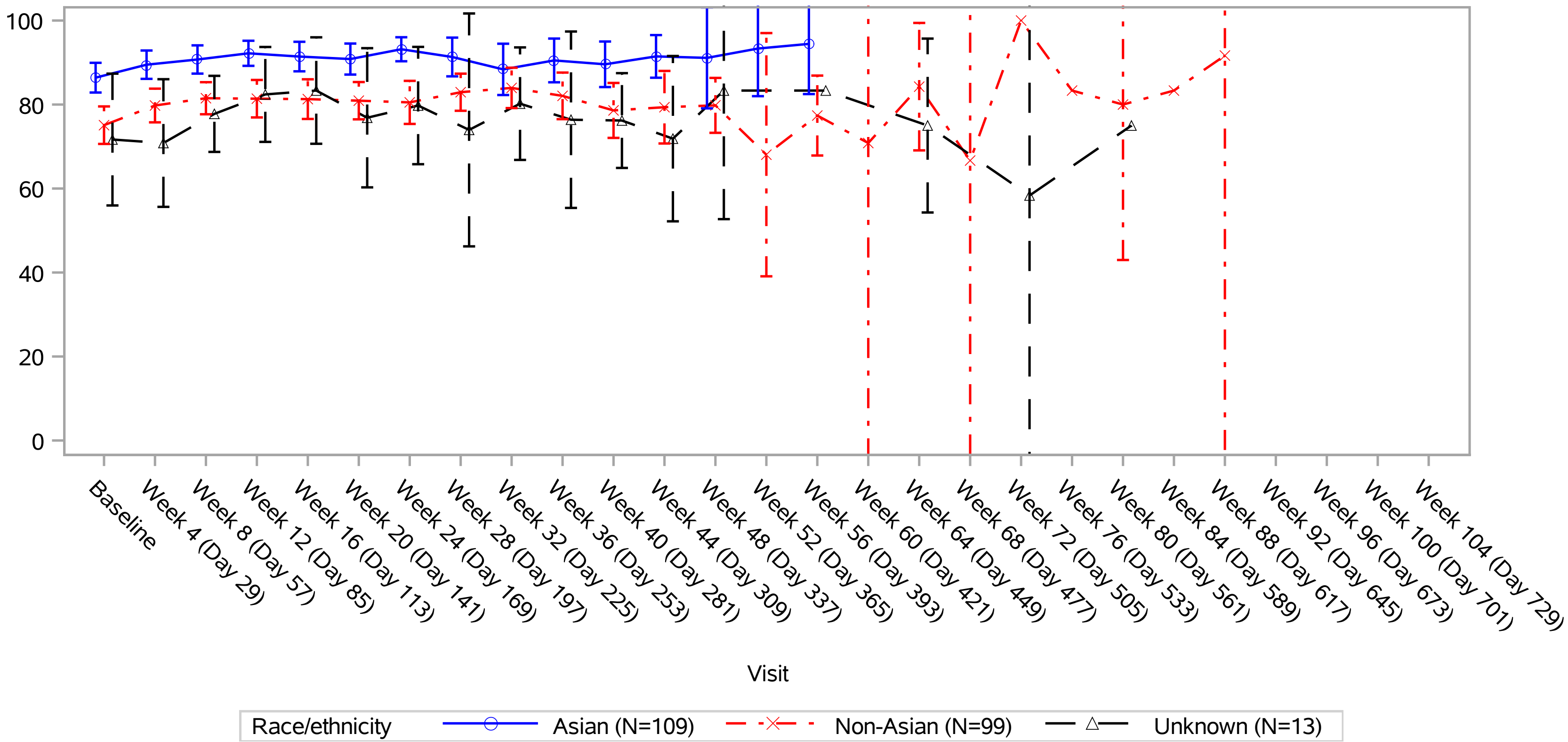
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Emotional functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30EF_SGGEO.pdf
15OCT2021 18:35

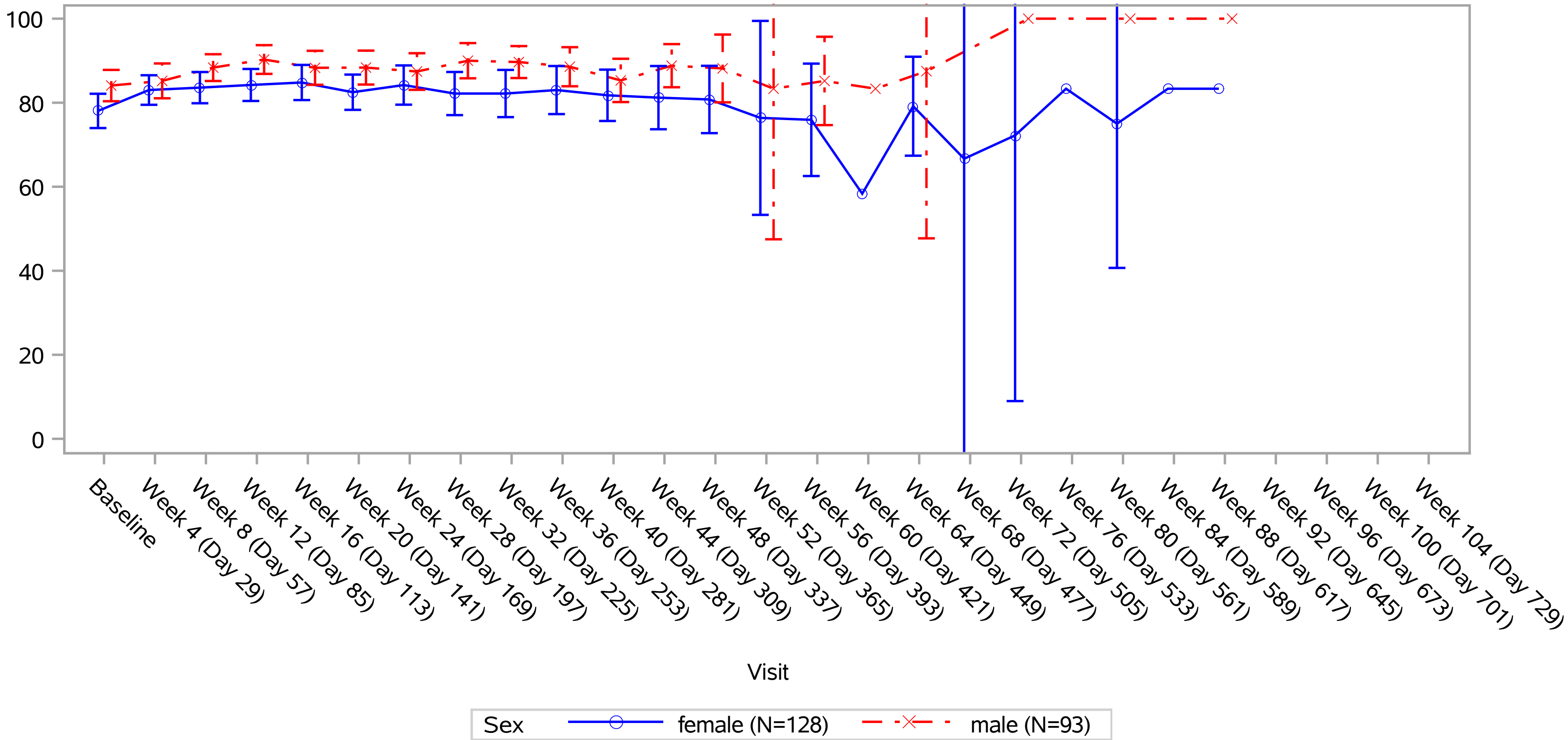
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Emotional functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30EF_SGRE.pdf
15OCT2021 19:06

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Emotional functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30EF_SGSEX.pdf
15OCT2021 19:36

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Fatigue
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=221)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	221	100.0	212	95.9	32.13	26.01	28.61	35.65
Week 4 (Day 29)	n/a	221	100.0	191	86.4	26.29	22.78	23.04	29.55
Week 8 (Day 57)	n/a	193	87.3	171	88.6	26.25	22.05	22.92	29.58
Week 12 (Day 85)	n/a	176	79.6	161	91.5	26.33	20.66	23.11	29.54
Week 16 (Day 113)	n/a	164	74.2	143	87.2	24.83	21.53	21.27	28.39
Week 20 (Day 141)	n/a	148	67.0	138	93.2	25.04	23.33	21.11	28.97
Week 24 (Day 169)	n/a	137	62.0	122	89.1	23.41	21.66	19.52	27.29
Week 28 (Day 197)	n/a	129	58.4	120	93.0	21.39	20.23	17.73	25.04
Week 32 (Day 225)	n/a	119	53.8	104	87.4	22.86	20.88	18.80	26.92
Week 36 (Day 253)	n/a	112	50.7	95	84.8	23.22	21.46	18.85	27.59
Week 40 (Day 281)	n/a	104	47.1	91	87.5	23.20	21.06	18.81	27.58
Week 44 (Day 309)	n/a	95	43.0	84	88.4	25.53	24.86	20.13	30.92
Week 48 (Day 337)	n/a	81	36.7	45	55.6	26.17	22.74	19.34	33.00
Week 52 (Day 365)	n/a	64	29.0	11	17.2	31.31	21.56	16.83	45.79
Week 56 (Day 393)	n/a	54	24.4	18	33.3	25.31	17.38	16.66	33.95
Week 60 (Day 421)	n/a	43	19.5	2	4.7	50.00	23.57	-161.77	261.77
Week 64 (Day 449)	n/a	41	18.6	12	29.3	23.15	22.45	8.88	37.41
Week 68 (Day 477)	n/a	34	15.4	2	5.9	50.00	23.57	-161.77	261.77
Week 72 (Day 505)	n/a	34	15.4	5	14.7	22.22	28.33	-12.95	57.40
Week 76 (Day 533)	n/a	31	14.0	3	9.7	40.74	16.97	-1.42	82.90
Week 80 (Day 561)	n/a	30	13.6	6	20.0	18.52	16.73	0.96	36.07
Week 84 (Day 589)	n/a	19	8.6	1	5.3	22.22	NE	NE	NE
Week 88 (Day 617)	n/a	15	6.8	2	13.3	16.67	7.86	-53.92	87.26
Week 92 (Day 645)	n/a	8	3.6	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	2.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	1.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	221	100.0	219	99.1	28.72	24.74	25.42	32.01
End of Study (LOCF)	n/a	221	100.0	219	99.1	28.11	24.02	24.91	31.31
Sex									
Baseline	Female	128	100.0	123	96.1	35.59	27.33	30.71	40.47
Week 4 (Day 29)	Female	128	100.0	106	82.8	29.87	20.88	25.85	33.90
Week 8 (Day 57)	Female	112	87.5	98	87.5	31.52	23.10	26.89	36.15
Week 12 (Day 85)	Female	104	81.3	95	91.3	30.35	22.23	25.82	34.88
Week 16 (Day 113)	Female	96	75.0	81	84.4	27.78	22.77	22.74	32.81
Week 20 (Day 141)	Female	86	67.2	80	93.0	29.58	26.04	23.79	35.38
Week 24 (Day 169)	Female	78	60.9	67	85.9	25.54	24.08	19.66	31.41
Week 28 (Day 197)	Female	72	56.3	65	90.3	23.25	21.76	17.86	28.64
Week 32 (Day 225)	Female	69	53.9	58	84.1	25.86	22.36	19.98	31.74
Week 36 (Day 253)	Female	64	50.0	52	81.3	25.96	25.10	18.97	32.95
Week 40 (Day 281)	Female	59	46.1	53	89.8	24.11	22.51	17.90	30.31
Week 44 (Day 309)	Female	56	43.8	47	83.9	26.71	26.98	18.79	34.64
Week 48 (Day 337)	Female	48	37.5	26	54.2	27.35	25.58	17.02	37.68
Week 52 (Day 365)	Female	38	29.7	6	15.8	33.33	21.08	11.21	55.46
Week 56 (Day 393)	Female	31	24.2	9	29.0	24.69	22.76	7.20	42.18
Week 60 (Day 421)	Female	27	21.1	1	3.7	66.67	NE	NE	NE
Week 64 (Day 449)	Female	26	20.3	8	30.8	25.00	26.39	2.93	47.07
Week 68 (Day 477)	Female	23	18.0	2	8.7	50.00	23.57	-161.77	261.77
Week 72 (Day 505)	Female	23	18.0	3	13.0	25.93	35.72	-62.80	114.65
Week 76 (Day 533)	Female	21	16.4	3	14.3	40.74	16.97	-1.42	82.90
Week 80 (Day 561)	Female	20	15.6	5	25.0	20.00	18.26	-2.67	42.67
Week 84 (Day 589)	Female	12	9.4	1	8.3	22.22	NE	NE	NE
Week 88 (Day 617)	Female	9	7.0	1	11.1	22.22	NE	NE	NE
Week 92 (Day 645)	Female	6	4.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	3.9	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	1.6	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	0.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	128	100.0	127	99.2	30.88	26.45	26.24	35.53
End of Study (LOCF)	Female	128	100.0	127	99.2	30.62	26.18	26.02	35.22
Baseline	Male	93	100.0	89	95.7	27.34	23.39	22.41	32.27
Week 4 (Day 29)	Male	93	100.0	85	91.4	21.83	24.33	16.58	27.08
Week 8 (Day 57)	Male	81	87.1	73	90.1	19.18	18.45	14.87	23.48
Week 12 (Day 85)	Male	72	77.4	66	91.7	20.54	16.68	16.44	24.64
Week 16 (Day 113)	Male	68	73.1	62	91.2	20.97	19.31	16.06	25.87
Week 20 (Day 141)	Male	62	66.7	58	93.5	18.77	17.31	14.22	23.33
Week 24 (Day 169)	Male	59	63.4	55	93.2	20.81	18.15	15.90	25.72
Week 28 (Day 197)	Male	57	61.3	55	96.5	19.19	18.20	14.27	24.11
Week 32 (Day 225)	Male	50	53.8	46	92.0	19.08	18.39	13.62	24.54
Week 36 (Day 253)	Male	48	51.6	43	89.6	19.90	15.63	15.09	24.71
Week 40 (Day 281)	Male	45	48.4	38	84.4	21.93	19.07	15.66	28.20
Week 44 (Day 309)	Male	39	41.9	37	94.9	24.02	22.15	16.64	31.41
Week 48 (Day 337)	Male	33	35.5	19	57.6	24.56	18.73	15.53	33.59
Week 52 (Day 365)	Male	26	28.0	5	19.2	28.89	24.34	-1.34	59.11
Week 56 (Day 393)	Male	23	24.7	9	39.1	25.93	11.11	17.39	34.47
Week 60 (Day 421)	Male	16	17.2	1	6.3	33.33	NE	NE	NE
Week 64 (Day 449)	Male	15	16.1	4	26.7	19.44	13.98	-2.80	41.69
Week 68 (Day 477)	Male	11	11.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	11	11.8	2	18.2	16.67	23.57	-195.10	228.44
Week 76 (Day 533)	Male	10	10.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	10	10.8	1	10.0	11.11	NE	NE	NE
Week 84 (Day 589)	Male	7	7.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	6	6.5	1	16.7	11.11	NE	NE	NE
Week 92 (Day 645)	Male	2	2.2	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	93	100.0	92	98.9	25.72	21.97	21.17	30.27
End of Study (LOCF)	Male	93	100.0	92	98.9	24.64	20.30	20.43	28.84
Age									

Baseline	< 65	141	100.0	133	94.3	32.58	25.59	28.19	36.97
Week 4 (Day 29)	< 65	141	100.0	123	87.2	25.20	23.42	21.02	29.38
Week 8 (Day 57)	< 65	127	90.1	113	89.0	23.70	21.49	19.69	27.70
Week 12 (Day 85)	< 65	118	83.7	106	89.8	23.95	20.16	20.07	27.83
Week 16 (Day 113)	< 65	108	76.6	93	86.1	21.80	20.98	17.48	26.13
Week 20 (Day 141)	< 65	100	70.9	97	97.0	24.63	23.53	19.89	29.37
Week 24 (Day 169)	< 65	93	66.0	86	92.5	21.71	22.54	16.87	26.54
Week 28 (Day 197)	< 65	88	62.4	83	94.3	19.95	19.38	15.71	24.18
Week 32 (Day 225)	< 65	83	58.9	73	88.0	21.46	20.65	16.64	26.28
Week 36 (Day 253)	< 65	78	55.3	70	89.7	22.06	21.02	17.05	27.08
Week 40 (Day 281)	< 65	75	53.2	69	92.0	22.06	21.35	16.93	27.19
Week 44 (Day 309)	< 65	71	50.4	65	91.5	25.13	26.30	18.61	31.64
Week 48 (Day 337)	< 65	61	43.3	33	54.1	25.25	23.61	16.88	33.63
Week 52 (Day 365)	< 65	48	34.0	6	12.5	31.48	27.59	2.53	60.44
Week 56 (Day 393)	< 65	41	29.1	11	26.8	21.21	18.23	8.97	33.46
Week 60 (Day 421)	< 65	33	23.4	2	6.1	50.00	23.57	-161.77	261.77
Week 64 (Day 449)	< 65	31	22.0	10	32.3	17.78	19.03	4.16	31.39
Week 68 (Day 477)	< 65	26	18.4	2	7.7	50.00	23.57	-161.77	261.77
Week 72 (Day 505)	< 65	26	18.4	5	19.2	22.22	28.33	-12.95	57.40
Week 76 (Day 533)	< 65	25	17.7	3	12.0	40.74	16.97	-1.42	82.90
Week 80 (Day 561)	< 65	24	17.0	5	20.8	15.56	16.85	-5.37	36.48
Week 84 (Day 589)	< 65	16	11.3	1	6.3	22.22	NE	NE	NE
Week 88 (Day 617)	< 65	13	9.2	2	15.4	16.67	7.86	-53.92	87.26
Week 92 (Day 645)	< 65	7	5.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	3.5	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	2.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	0.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	141	100.0	139	98.6	28.14	26.49	23.69	32.58
End of Study (LOCF)	< 65	141	100.0	139	98.6	26.86	25.16	22.64	31.08
Baseline	>= 65	80	100.0	79	98.8	31.36	26.85	25.35	37.38
Week 4 (Day 29)	>= 65	80	100.0	68	85.0	28.27	21.59	23.04	33.49
Week 8 (Day 57)	>= 65	66	82.5	58	87.9	31.23	22.46	25.32	37.13
Week 12 (Day 85)	>= 65	58	72.5	55	94.8	30.91	21.03	25.22	36.59

Week 16 (Day 113)	>= 65	56	70.0	50	89.3	30.44	21.63	24.30	36.59
Week 20 (Day 141)	>= 65	48	60.0	41	85.4	26.02	23.12	18.72	33.31
Week 24 (Day 169)	>= 65	44	55.0	36	81.8	27.47	19.06	21.02	33.92
Week 28 (Day 197)	>= 65	41	51.3	37	90.2	24.62	21.93	17.31	31.94
Week 32 (Day 225)	>= 65	36	45.0	31	86.1	26.16	21.38	18.32	34.01
Week 36 (Day 253)	>= 65	34	42.5	25	73.5	26.44	22.75	17.05	35.84
Week 40 (Day 281)	>= 65	29	36.3	22	75.9	26.77	20.19	17.82	35.72
Week 44 (Day 309)	>= 65	24	30.0	19	79.2	26.90	19.71	17.40	36.40
Week 48 (Day 337)	>= 65	20	25.0	12	60.0	28.70	20.90	15.43	41.98
Week 52 (Day 365)	>= 65	16	20.0	5	31.3	31.11	14.49	13.12	49.10
Week 56 (Day 393)	>= 65	13	16.3	7	53.8	31.75	14.95	17.92	45.57
Week 60 (Day 421)	>= 65	10	12.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	10	12.5	2	20.0	50.00	23.57	-161.77	261.77
Week 68 (Day 477)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	6	7.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	6	7.5	1	16.7	33.33	NE	NE	NE
Week 84 (Day 589)	>= 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	2.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	80	100.0	80	100.0	29.72	21.49	24.94	34.50
End of Study (LOCF)	>= 65	80	100.0	80	100.0	30.28	21.87	25.41	35.14
ECOG performance status									
Baseline	0	63	100.0	60	95.2	29.26	29.29	21.69	36.83
Week 4 (Day 29)	0	63	100.0	56	88.9	25.00	24.73	18.38	31.62
Week 8 (Day 57)	0	58	92.1	52	89.7	30.34	28.70	22.35	38.33
Week 12 (Day 85)	0	55	87.3	50	90.9	27.56	23.46	20.89	34.22
Week 16 (Day 113)	0	54	85.7	45	83.3	25.43	22.17	18.77	32.09
Week 20 (Day 141)	0	52	82.5	48	92.3	27.08	24.89	19.86	34.31
Week 24 (Day 169)	0	49	77.8	43	87.8	25.32	23.55	18.08	32.57
Week 28 (Day 197)	0	46	73.0	42	91.3	21.69	18.03	16.08	27.31

Week 32 (Day 225)	0	41	65.1	34	82.9	18.30	22.03	10.61	25.99
Week 36 (Day 253)	0	39	61.9	31	79.5	24.37	25.24	15.11	33.63
Week 40 (Day 281)	0	37	58.7	30	81.1	25.19	22.78	16.68	33.69
Week 44 (Day 309)	0	36	57.1	29	80.6	26.44	28.24	15.70	37.18
Week 48 (Day 337)	0	28	44.4	18	64.3	26.54	26.44	13.39	39.69
Week 52 (Day 365)	0	27	42.9	6	22.2	44.44	17.21	26.38	62.51
Week 56 (Day 393)	0	24	38.1	8	33.3	22.22	16.80	8.18	36.27
Week 60 (Day 421)	0	21	33.3	1	4.8	66.67	NE	NE	NE
Week 64 (Day 449)	0	21	33.3	7	33.3	23.81	27.54	-1.66	49.28
Week 68 (Day 477)	0	17	27.0	1	5.9	66.67	NE	NE	NE
Week 72 (Day 505)	0	17	27.0	2	11.8	33.33	47.14	-390.21	456.87
Week 76 (Day 533)	0	15	23.8	2	13.3	38.89	23.57	-172.88	250.66
Week 80 (Day 561)	0	14	22.2	1	7.1	0.00	NE	NE	NE
Week 84 (Day 589)	0	11	17.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	10	15.9	1	10.0	22.22	NE	NE	NE
Week 92 (Day 645)	0	5	7.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	6.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	4.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	63	100.0	63	100.0	32.63	29.05	25.31	39.94
End of Study (LOCF)	0	63	100.0	63	100.0	31.57	28.02	24.51	38.63
Baseline	1	157	100.0	151	96.2	33.33	24.68	29.37	37.30
Week 4 (Day 29)	1	157	100.0	134	85.4	26.78	22.06	23.01	30.55
Week 8 (Day 57)	1	134	85.4	119	88.8	24.46	18.27	21.15	27.78
Week 12 (Day 85)	1	121	77.1	111	91.7	25.78	19.36	22.13	29.42
Week 16 (Day 113)	1	110	70.1	98	89.1	24.55	21.34	20.27	28.83
Week 20 (Day 141)	1	96	61.1	90	93.8	23.95	22.53	19.23	28.67
Week 24 (Day 169)	1	88	56.1	79	89.8	22.36	20.63	17.74	26.98
Week 28 (Day 197)	1	83	52.9	78	94.0	21.23	21.43	16.39	26.06
Week 32 (Day 225)	1	78	49.7	70	89.7	25.08	20.08	20.29	29.87
Week 36 (Day 253)	1	73	46.5	64	87.7	22.66	19.56	17.77	27.54
Week 40 (Day 281)	1	67	42.7	61	91.0	22.22	20.29	17.03	27.42

Week 44 (Day 309)	1	59	37.6	55	93.2	25.05	23.15	18.79	31.31
Week 48 (Day 337)	1	53	33.8	27	50.9	25.93	20.44	17.84	34.01
Week 52 (Day 365)	1	37	23.6	5	13.5	15.56	14.91	-2.95	34.07
Week 56 (Day 393)	1	30	19.1	10	33.3	27.78	18.33	14.66	40.89
Week 60 (Day 421)	1	22	14.0	1	4.5	33.33	NE	NE	NE
Week 64 (Day 449)	1	20	12.7	5	25.0	22.22	15.71	2.71	41.73
Week 68 (Day 477)	1	17	10.8	1	5.9	33.33	NE	NE	NE
Week 72 (Day 505)	1	17	10.8	3	17.6	14.81	16.97	-27.35	56.98
Week 76 (Day 533)	1	16	10.2	1	6.3	44.44	NE	NE	NE
Week 80 (Day 561)	1	16	10.2	5	31.3	22.22	15.71	2.71	41.73
Week 84 (Day 589)	1	8	5.1	1	12.5	22.22	NE	NE	NE
Week 88 (Day 617)	1	5	3.2	1	20.0	11.11	NE	NE	NE
Week 92 (Day 645)	1	3	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	157	100.0	155	98.7	27.10	22.76	23.49	30.71
End of Study (LOCF)	1	157	100.0	155	98.7	26.67	22.21	23.14	30.19
Baseline	Missing	1	100.0	1	100.0	22.22	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	33.33	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	33.33	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	33.33	NE	NE	NE
Geographic region									
Baseline	USA	43	100.0	41	95.3	28.73	23.70	21.25	36.21
Week 4 (Day 29)	USA	43	100.0	38	88.4	24.27	22.79	16.78	31.76
Week 8 (Day 57)	USA	41	95.3	37	90.2	27.33	19.88	20.70	33.95
Week 12 (Day 85)	USA	41	95.3	38	92.7	26.90	17.26	21.23	32.57
Week 16 (Day 113)	USA	40	93.0	33	82.5	23.40	17.44	17.22	29.59
Week 20 (Day 141)	USA	39	90.7	35	89.7	24.76	21.57	17.35	32.17
Week 24 (Day 169)	USA	36	83.7	33	91.7	20.88	16.14	15.15	26.60
Week 28 (Day 197)	USA	35	81.4	31	88.6	18.28	15.59	12.56	24.00
Week 32 (Day 225)	USA	32	74.4	28	87.5	23.41	21.88	14.93	31.90
Week 36 (Day 253)	USA	32	74.4	24	75.0	20.37	19.29	12.22	28.52
Week 40 (Day 281)	USA	29	67.4	23	79.3	21.26	21.43	11.99	30.52

Week 44 (Day 309)	USA	26	60.5	21	80.8	24.34	25.49	12.74	35.94
Week 48 (Day 337)	USA	21	48.8	15	71.4	22.96	21.19	11.23	34.70
Week 52 (Day 365)	USA	18	41.9	1	5.6	22.22	NE	NE	NE
Week 56 (Day 393)	USA	18	41.9	9	50.0	22.22	16.67	9.41	35.03
Week 60 (Day 421)	USA	17	39.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	15	34.9	5	33.3	13.33	18.26	-9.34	36.00
Week 68 (Day 477)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	12	27.9	1	8.3	0.00	NE	NE	NE
Week 76 (Day 533)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	12	27.9	2	16.7	33.33	0.00	NE	NE
Week 84 (Day 589)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	6	14.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	11.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	7.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	43	100.0	43	100.0	23.26	23.48	16.03	30.48
End of Study (LOCF)	USA	43	100.0	43	100.0	22.74	20.57	16.41	29.07
Baseline	Europe (EU)	74	100.0	69	93.2	39.29	28.11	32.54	46.04
Week 4 (Day 29)	Europe (EU)	74	100.0	64	86.5	30.03	24.06	24.03	36.04
Week 8 (Day 57)	Europe (EU)	65	87.8	55	84.6	32.53	24.83	25.81	39.24
Week 12 (Day 85)	Europe (EU)	57	77.0	49	86.0	32.09	24.57	25.03	39.14
Week 16 (Day 113)	Europe (EU)	55	74.3	44	80.0	33.33	25.02	25.73	40.94
Week 20 (Day 141)	Europe (EU)	49	66.2	46	93.9	33.33	26.29	25.53	41.14
Week 24 (Day 169)	Europe (EU)	47	63.5	42	89.4	32.80	26.08	24.68	40.93
Week 28 (Day 197)	Europe (EU)	45	60.8	43	95.6	30.49	23.01	23.41	37.57
Week 32 (Day 225)	Europe (EU)	39	52.7	35	89.7	24.13	18.57	17.75	30.51
Week 36 (Day 253)	Europe (EU)	34	45.9	30	88.2	27.96	25.12	18.58	37.34
Week 40 (Day 281)	Europe (EU)	31	41.9	30	96.8	26.30	20.53	18.63	33.96
Week 44 (Day 309)	Europe (EU)	28	37.8	24	85.7	33.33	27.61	21.68	44.99

Week 48 (Day 337)	Europe (EU)	22	29.7	16	72.7	34.03	20.48	23.12	44.94
Week 52 (Day 365)	Europe (EU)	19	25.7	6	31.6	46.30	14.77	30.80	61.79
Week 56 (Day 393)	Europe (EU)	17	23.0	7	41.2	25.40	19.99	6.91	43.89
Week 60 (Day 421)	Europe (EU)	15	20.3	2	13.3	50.00	23.57	-161.77	261.77
Week 64 (Day 449)	Europe (EU)	15	20.3	7	46.7	30.16	23.76	8.19	52.13
Week 68 (Day 477)	Europe (EU)	13	17.6	2	15.4	50.00	23.57	-161.77	261.77
Week 72 (Day 505)	Europe (EU)	13	17.6	4	30.8	27.78	29.40	-19.00	74.56
Week 76 (Day 533)	Europe (EU)	11	14.9	3	27.3	40.74	16.97	-1.42	82.90
Week 80 (Day 561)	Europe (EU)	10	13.5	4	40.0	11.11	15.71	-13.89	36.11
Week 84 (Day 589)	Europe (EU)	6	8.1	1	16.7	22.22	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	4.1	2	66.7	16.67	7.86	-53.92	87.26
Cycle 12 (LOCF)	Europe (EU)	74	100.0	73	98.6	35.01	24.89	29.20	40.82
End of Study (LOCF)	Europe (EU)	74	100.0	73	98.6	33.94	24.42	28.24	39.64
Baseline	Asia (AS)	104	100.0	102	98.1	28.65	24.64	23.81	33.49
Week 4 (Day 29)	Asia (AS)	104	100.0	89	85.6	24.47	21.72	19.89	29.05
Week 8 (Day 57)	Asia (AS)	87	83.7	79	90.8	21.38	19.95	16.91	25.85
Week 12 (Day 85)	Asia (AS)	78	75.0	74	94.9	22.22	18.67	17.90	26.55
Week 16 (Day 113)	Asia (AS)	69	66.3	66	95.7	19.87	19.34	15.11	24.62
Week 20 (Day 141)	Asia (AS)	60	57.7	57	95.0	18.52	19.85	13.25	23.78
Week 24 (Day 169)	Asia (AS)	54	51.9	47	87.0	16.78	17.78	11.57	22.00
Week 28 (Day 197)	Asia (AS)	49	47.1	46	93.9	14.98	17.25	9.85	20.10
Week 32 (Day 225)	Asia (AS)	48	46.2	41	85.4	21.41	22.41	14.33	28.48
Week 36 (Day 253)	Asia (AS)	46	44.2	41	89.1	21.41	19.62	15.21	27.60
Week 40 (Day 281)	Asia (AS)	44	42.3	38	86.4	21.93	21.53	14.85	29.01
Week 44 (Day 309)	Asia (AS)	41	39.4	39	95.1	21.37	22.13	14.19	28.54
Week 48 (Day 337)	Asia (AS)	38	36.5	14	36.8	20.63	25.73	5.78	35.49
Week 52 (Day 365)	Asia (AS)	27	26.0	4	14.8	11.11	12.83	-9.30	31.53
Week 56 (Day 393)	Asia (AS)	19	18.3	2	10.5	38.89	7.86	-31.70	109.48
Week 60 (Day 421)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	5.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	104	100.0	103	99.0	26.54	24.46	21.76	31.32
End of Study (LOCF)	Asia (AS)	104	100.0	103	99.0	26.21	24.45	21.44	30.99
Race/ethnicity									
Baseline	Asian	109	100.0	106	97.2	29.04	24.85	24.25	33.82
Week 4 (Day 29)	Asian	109	100.0	92	84.4	24.15	21.52	19.70	28.61
Week 8 (Day 57)	Asian	91	83.5	80	87.9	21.67	19.99	17.22	26.12
Week 12 (Day 85)	Asian	82	75.2	78	95.1	22.65	18.73	18.43	26.87
Week 16 (Day 113)	Asian	73	67.0	70	95.9	20.16	19.23	15.57	24.74
Week 20 (Day 141)	Asian	64	58.7	60	93.8	19.44	20.42	14.17	24.72
Week 24 (Day 169)	Asian	57	52.3	50	87.7	17.11	17.71	12.08	22.14
Week 28 (Day 197)	Asian	52	47.7	49	94.2	15.87	18.00	10.70	21.04
Week 32 (Day 225)	Asian	50	45.9	43	86.0	21.19	22.20	14.36	28.02
Week 36 (Day 253)	Asian	48	44.0	43	89.6	21.19	19.52	15.18	27.20
Week 40 (Day 281)	Asian	46	42.2	40	87.0	21.67	21.34	14.84	28.49
Week 44 (Day 309)	Asian	43	39.4	41	95.3	21.14	21.92	14.22	28.06
Week 48 (Day 337)	Asian	40	36.7	15	37.5	19.26	25.36	5.22	33.30
Week 52 (Day 365)	Asian	29	26.6	5	17.2	13.33	12.17	-1.78	28.45
Week 56 (Day 393)	Asian	21	19.3	3	14.3	29.63	16.97	-12.53	71.79
Week 60 (Day 421)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	5.5	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	4.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	1.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	109	100.0	107	98.2	26.79	24.47	22.10	31.48
End of Study (LOCF)	Asian	109	100.0	107	98.2	26.58	24.36	21.91	31.25
Baseline	Non-Asian	99	100.0	96	97.0	34.03	26.58	28.64	39.41
Week 4 (Day 29)	Non-Asian	99	100.0	89	89.9	26.22	22.17	21.55	30.89
Week 8 (Day 57)	Non-Asian	91	91.9	82	90.1	30.08	23.39	24.94	35.22
Week 12 (Day 85)	Non-Asian	83	83.8	74	89.2	29.05	21.50	24.07	34.03
Week 16 (Day 113)	Non-Asian	80	80.8	68	85.0	29.49	22.76	23.98	35.00
Week 20 (Day 141)	Non-Asian	74	74.7	69	93.2	29.31	25.49	23.18	35.43
Week 24 (Day 169)	Non-Asian	70	70.7	65	92.9	27.35	23.49	21.53	33.17
Week 28 (Day 197)	Non-Asian	67	67.7	63	94.0	24.34	21.01	19.05	29.63
Week 32 (Day 225)	Non-Asian	60	60.6	53	88.3	23.69	20.21	18.12	29.26
Week 36 (Day 253)	Non-Asian	55	55.6	46	83.6	21.98	19.67	16.14	27.82
Week 40 (Day 281)	Non-Asian	49	49.5	44	89.8	23.74	20.97	17.36	30.11
Week 44 (Day 309)	Non-Asian	43	43.4	35	81.4	27.94	26.04	18.99	36.88
Week 48 (Day 337)	Non-Asian	35	35.4	26	74.3	32.05	20.69	23.70	40.41
Week 52 (Day 365)	Non-Asian	29	29.3	6	20.7	46.30	14.77	30.80	61.79
Week 56 (Day 393)	Non-Asian	27	27.3	14	51.9	26.19	17.22	16.25	36.13
Week 60 (Day 421)	Non-Asian	26	26.3	2	7.7	50.00	23.57	-161.77	261.77
Week 64 (Day 449)	Non-Asian	24	24.2	9	37.5	23.46	21.83	6.67	40.24
Week 68 (Day 477)	Non-Asian	20	20.2	2	10.0	50.00	23.57	-161.77	261.77
Week 72 (Day 505)	Non-Asian	20	20.2	3	15.0	11.11	19.25	-36.70	58.92
Week 76 (Day 533)	Non-Asian	18	18.2	3	16.7	40.74	16.97	-1.42	82.90
Week 80 (Day 561)	Non-Asian	17	17.2	5	29.4	15.56	16.85	-5.37	36.48
Week 84 (Day 589)	Non-Asian	11	11.1	1	9.1	22.22	NE	NE	NE
Week 88 (Day 617)	Non-Asian	8	8.1	2	25.0	16.67	7.86	-53.92	87.26
Week 92 (Day 645)	Non-Asian	4	4.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	3.0	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	99	100.0	99	100.0	29.29	24.20	24.47	34.12

End of Study (LOCF)	Non-Asian	99	100.0	99	100.0	28.73	23.27	24.09	33.37
Baseline	Unknown	13	100.0	10	76.9	46.67	28.59	26.21	67.12
Week 4 (Day 29)	Unknown	13	100.0	10	76.9	46.67	30.90	24.56	68.77
Week 8 (Day 57)	Unknown	11	84.6	9	81.8	32.10	21.11	15.87	48.33
Week 12 (Day 85)	Unknown	11	84.6	9	81.8	35.80	25.32	16.34	55.27
Week 16 (Day 113)	Unknown	11	84.6	5	45.5	26.67	25.58	-5.09	58.43
Week 20 (Day 141)	Unknown	10	76.9	9	90.0	29.63	17.57	16.13	43.13
Week 24 (Day 169)	Unknown	10	76.9	7	70.0	31.75	20.72	12.59	50.91
Week 28 (Day 197)	Unknown	10	76.9	8	80.0	31.94	20.09	15.15	48.74
Week 32 (Day 225)	Unknown	9	69.2	8	88.9	26.39	19.64	9.97	42.81
Week 36 (Day 253)	Unknown	9	69.2	6	66.7	47.22	35.09	10.39	84.05
Week 40 (Day 281)	Unknown	9	69.2	7	77.8	28.57	22.09	8.14	49.00
Week 44 (Day 309)	Unknown	9	69.2	8	88.9	37.50	31.39	11.26	63.74
Week 48 (Day 337)	Unknown	6	46.2	4	66.7	13.89	16.67	-12.63	40.41
Week 52 (Day 365)	Unknown	6	46.2	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	6	46.2	1	16.7	0.00	NE	NE	NE
Week 60 (Day 421)	Unknown	5	38.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	5	38.5	3	60.0	22.22	29.40	-50.80	95.25
Week 68 (Day 477)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	4	30.8	2	50.0	38.89	39.28	-314.06	391.84
Week 76 (Day 533)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	4	30.8	1	25.0	33.33	NE	NE	NE
Week 84 (Day 589)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	7.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	13	100.0	13	100.0	40.17	29.59	22.29	58.05
End of Study (LOCF)	Unknown	13	100.0	13	100.0	35.90	26.89	19.65	52.15

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TO_QSC30FA_SG.xls
27OCT2021 7:15

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Fatigue
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	108	50.9	44.3	57.6
	Cycle 12 (LOCF)	n/a	212	95.9	64	30.2	24.4	36.7
	End of Study (LOCF)	n/a	212	95.9	64	30.2	24.4	36.7
Sex	All visits	Female	123	55.7	64	52.0	43.3	60.7
		Male	89	40.3	44	49.4	39.3	59.6
	Cycle 12 (LOCF)	Female	123	55.7	33	26.8	19.8	35.3
		Male	89	40.3	31	34.8	25.7	45.2
	End of Study (LOCF)	Female	123	55.7	34	27.6	20.5	36.1
		Male	89	40.3	30	33.7	24.7	44.0
Age	All visits	< 65	133	60.2	62	46.6	38.4	55.1
		>= 65	79	35.7	46	58.2	47.2	68.5
	Cycle 12 (LOCF)	< 65	133	60.2	35	26.3	19.6	34.4
		>= 65	79	35.7	29	36.7	26.9	47.7
	End of Study (LOCF)	< 65	133	60.2	33	24.8	18.2	32.8
		>= 65	79	35.7	31	39.2	29.2	50.3
ECOG performance status	All visits	0	60	27.1	42	70.0	57.5	80.1
		1	151	68.3	65	43.0	35.4	51.0
		Missing	1	0.5	1	100.0	20.7	100.0
	Cycle 12 (LOCF)	0	60	27.1	21	35.0	24.2	47.6
		1	151	68.3	42	27.8	21.3	35.4
		Missing	1	0.5	1	100.0	20.7	100.0
	End of Study (LOCF)	0	60	27.1	23	38.3	27.1	51.0
		1	151	68.3	40	26.5	20.1	34.0
		Missing	1	0.5	1	100.0	20.7	100.0
Geographic region	All visits	USA	41	18.6	28	68.3	53.0	80.4
		Europe (EU)	69	31.2	36	52.2	40.6	63.5
		Asia (AS)	102	46.2	44	43.1	33.9	52.8
	Cycle 12 (LOCF)	USA	41	18.6	11	26.8	15.7	41.9
		Europe (EU)	69	31.2	21	30.4	20.8	42.1
		Asia (AS)	102	46.2	32	31.4	23.2	40.9
	End of Study (LOCF)	USA	41	18.6	13	31.7	19.6	47.0
		Europe (EU)	69	31.2	20	29.0	19.6	40.6
		Asia (AS)	102	46.2	31	30.4	22.3	39.9
Race/ethnicity	All visits	Asian	106	48.0	46	43.4	34.4	52.9
		Non-Asian	96	43.4	57	59.4	49.4	68.7
		Unknown	10	4.5	5	50.0	23.7	76.3
	Cycle 12 (LOCF)	Asian	106	48.0	33	31.1	23.1	40.5

		Non-Asian	96	43.4	30	31.3	22.9	41.1
		Unknown	10	4.5	1	10.0	1.8	40.4
	End of Study (LOCF)	Asian	106	48.0	33	31.1	23.1	40.5
		Non-Asian	96	43.4	30	31.3	22.9	41.1
		Unknown	10	4.5	1	10.0	1.8	40.4

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30FA_W10_SG.xls
15OCT2021 12:53

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Fatigue
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

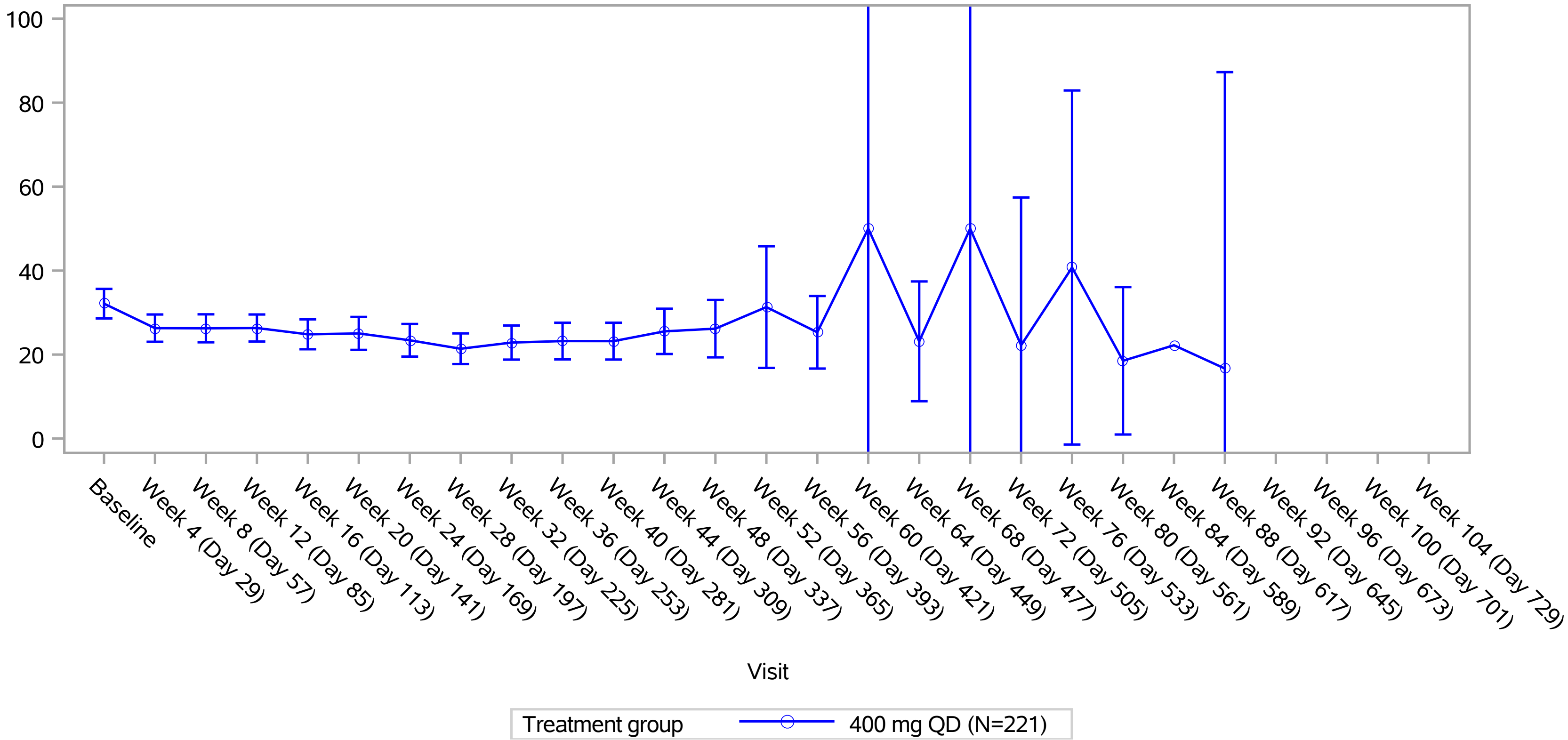
			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	70	33.0	27.0	39.6
	Cycle 12 (LOCF)	n/a	212	95.9	38	17.9	13.3	23.6
	End of Study (LOCF)	n/a	212	95.9	37	17.5	12.9	23.1
Sex	All visits	Female	123	55.7	42	34.1	26.4	42.9
		Male	89	40.3	28	31.5	22.8	41.7
	Cycle 12 (LOCF)	Female	123	55.7	22	17.9	12.1	25.6
		Male	89	40.3	16	18.0	11.4	27.2
	End of Study (LOCF)	Female	123	55.7	23	18.7	12.8	26.5
		Male	89	40.3	14	15.7	9.6	24.7
Age	All visits	< 65	133	60.2	41	30.8	23.6	39.1
		>= 65	79	35.7	29	36.7	26.9	47.7
	Cycle 12 (LOCF)	< 65	133	60.2	24	18.0	12.4	25.4
		>= 65	79	35.7	14	17.7	10.9	27.6
	End of Study (LOCF)	< 65	133	60.2	22	16.5	11.2	23.8
		>= 65	79	35.7	15	19.0	11.9	29.0
ECOG performance status	All visits	0	60	27.1	28	46.7	34.6	59.1
		1	151	68.3	42	27.8	21.3	35.4
		Missing	1	0.5	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	60	27.1	20	33.3	22.7	45.9
		1	151	68.3	18	11.9	7.7	18.1
		Missing	1	0.5	0	0.0	0.0	79.3
	End of Study (LOCF)	0	60	27.1	20	33.3	22.7	45.9
		1	151	68.3	17	11.3	7.1	17.3
		Missing	1	0.5	0	0.0	0.0	79.3
Geographic region	All visits	USA	41	18.6	15	36.6	23.6	51.9
		Europe (EU)	69	31.2	26	37.7	27.2	49.5
		Asia (AS)	102	46.2	29	28.4	20.6	37.8
	Cycle 12 (LOCF)	USA	41	18.6	5	12.2	5.3	25.5
		Europe (EU)	69	31.2	15	21.7	13.6	32.8
		Asia (AS)	102	46.2	18	17.6	11.5	26.2
	End of Study (LOCF)	USA	41	18.6	4	9.8	3.9	22.5
		Europe (EU)	69	31.2	15	21.7	13.6	32.8
		Asia (AS)	102	46.2	18	17.6	11.5	26.2
Race/ethnicity	All visits	Asian	106	48.0	31	29.2	21.4	38.5
		Non-Asian	96	43.4	37	38.5	29.4	48.5
		Unknown	10	4.5	2	20.0	5.7	51.0
	Cycle 12 (LOCF)	Asian	106	48.0	19	17.9	11.8	26.3

		Non-Asian	96	43.4	19	19.8	13.1	28.9
		Unknown	10	4.5	0	0.0	0.0	27.8
	End of Study (LOCF)	Asian	106	48.0	19	17.9	11.8	26.3
		Non-Asian	96	43.4	18	18.8	12.2	27.7
		Unknown	10	4.5	0	0.0	0.0	27.8

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30FA_W15_SG.xls
15OCT2021 12:43

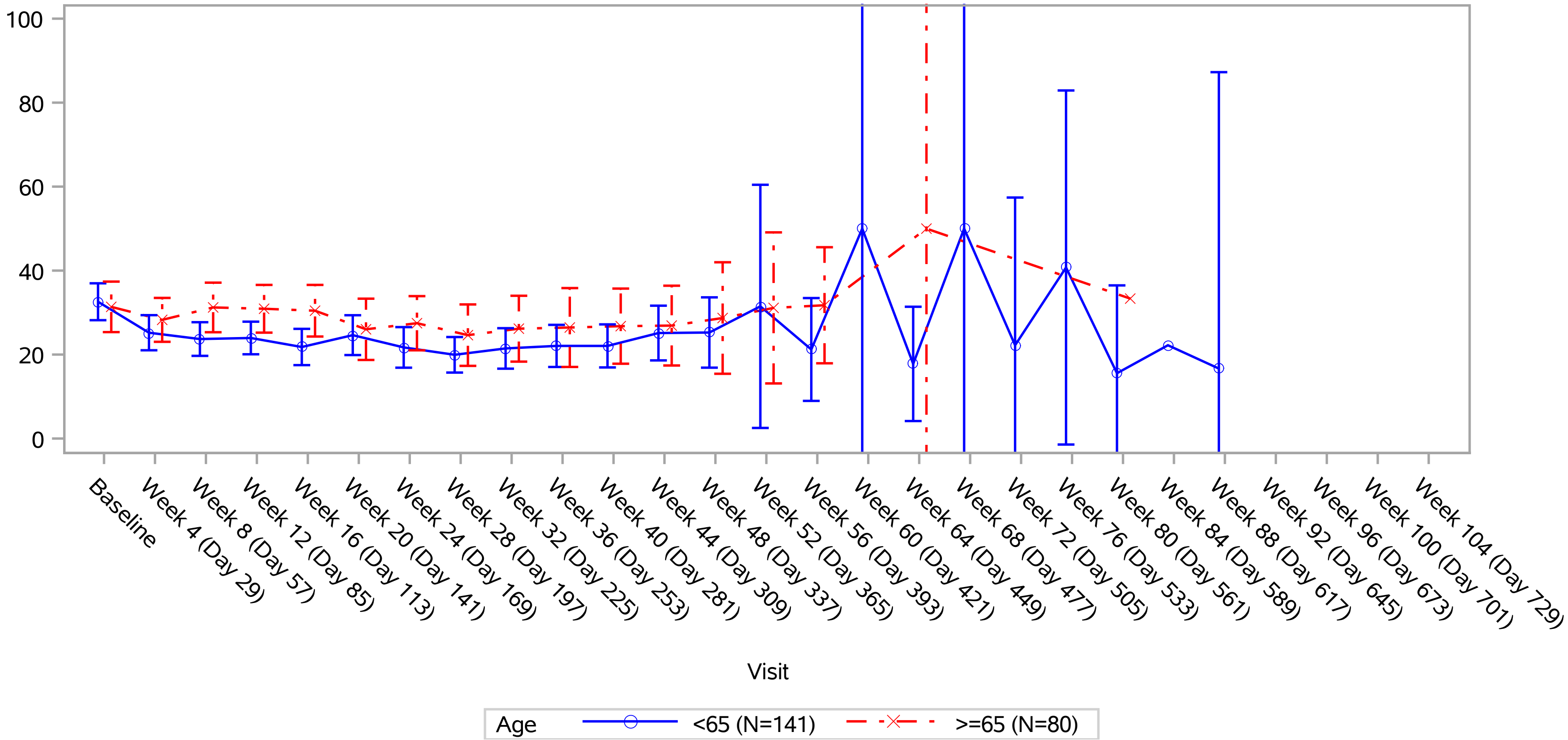
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Fatigue
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30FA.pdf
15OCT2021 17:06

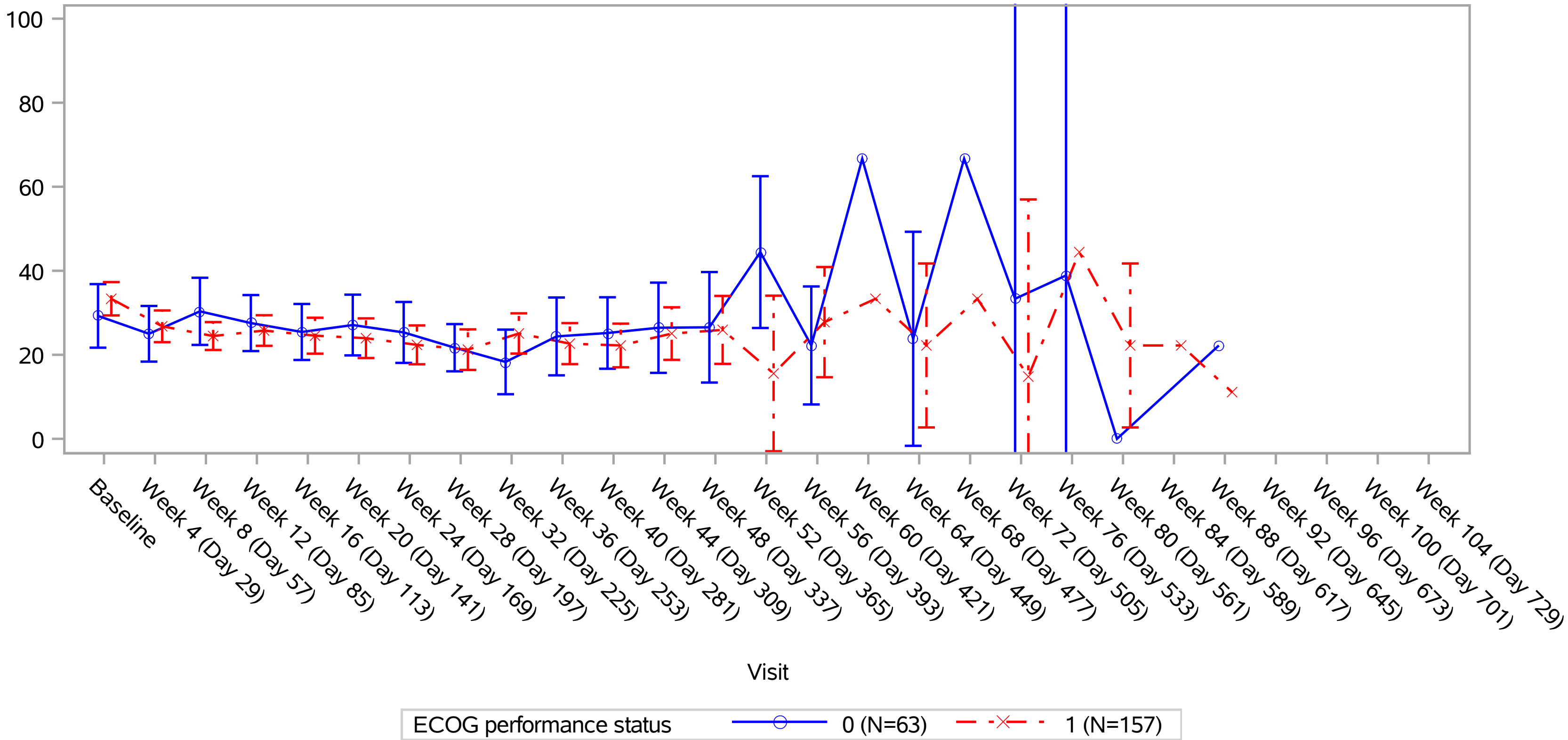
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Fatigue
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30FA_SGAGE65.pdf
15OCT2021 17:35

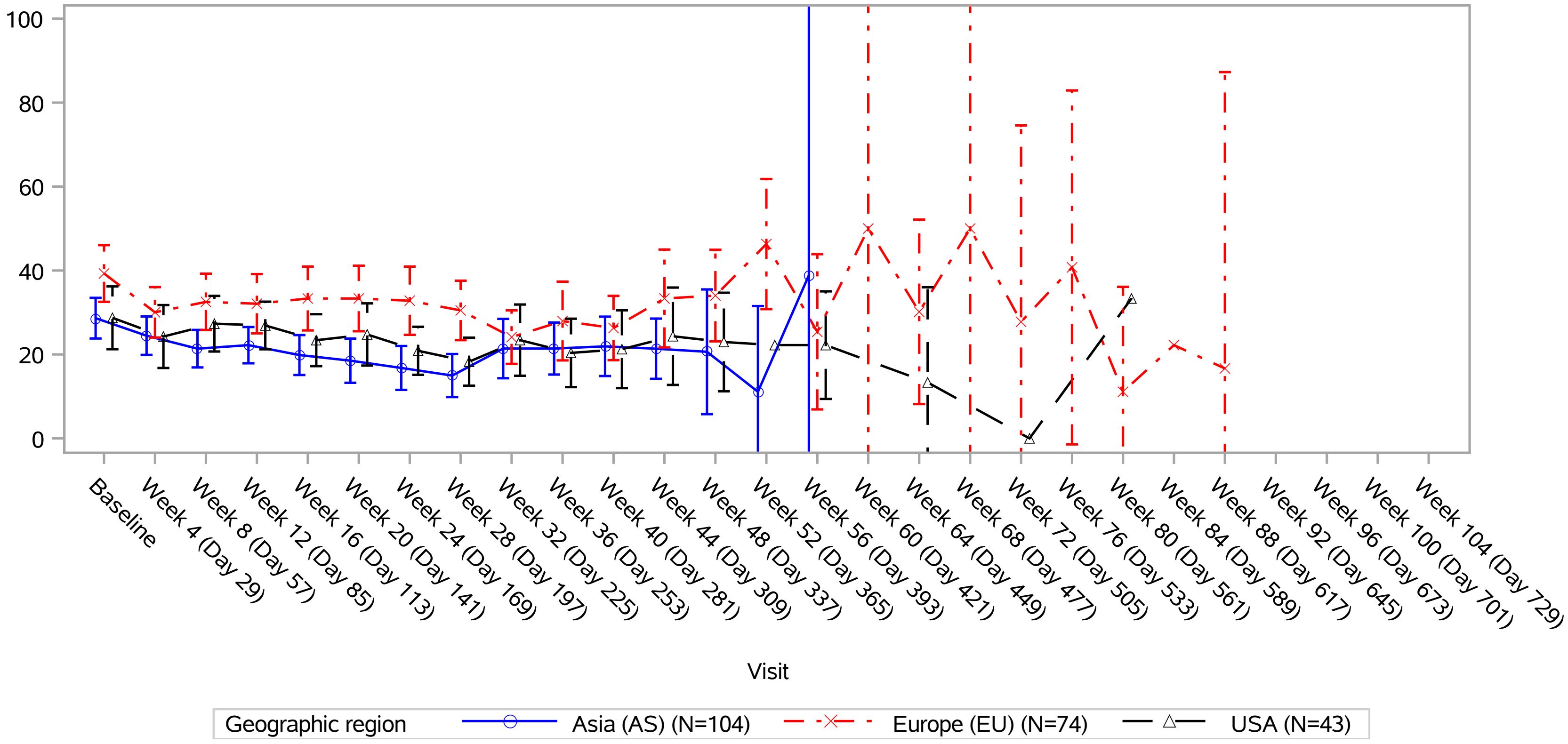
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Fatigue
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30FA_SGECOG.pdf
15OCT2021 18:05

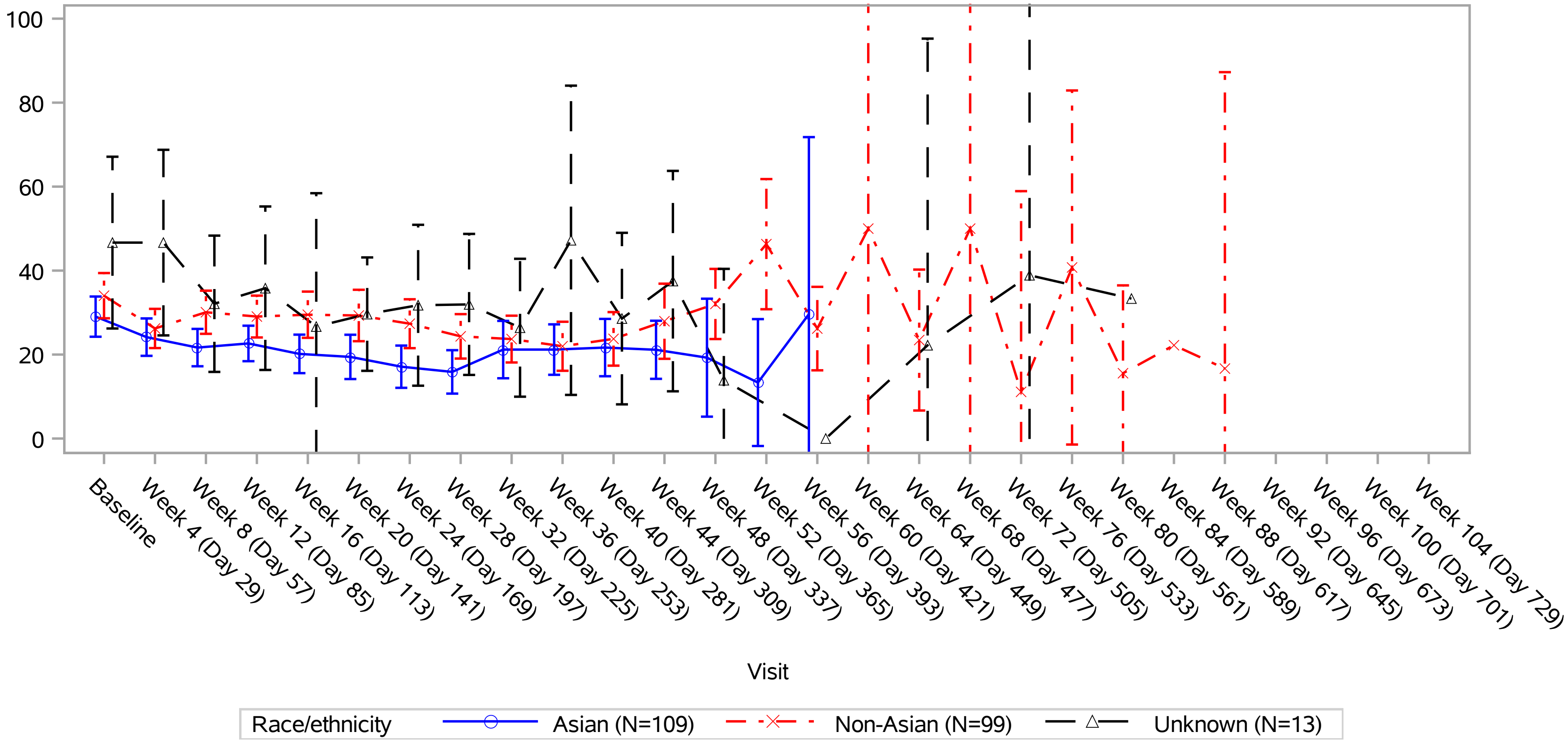
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Fatigue
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30FA_SGGEO.pdf
15OCT2021 18:36

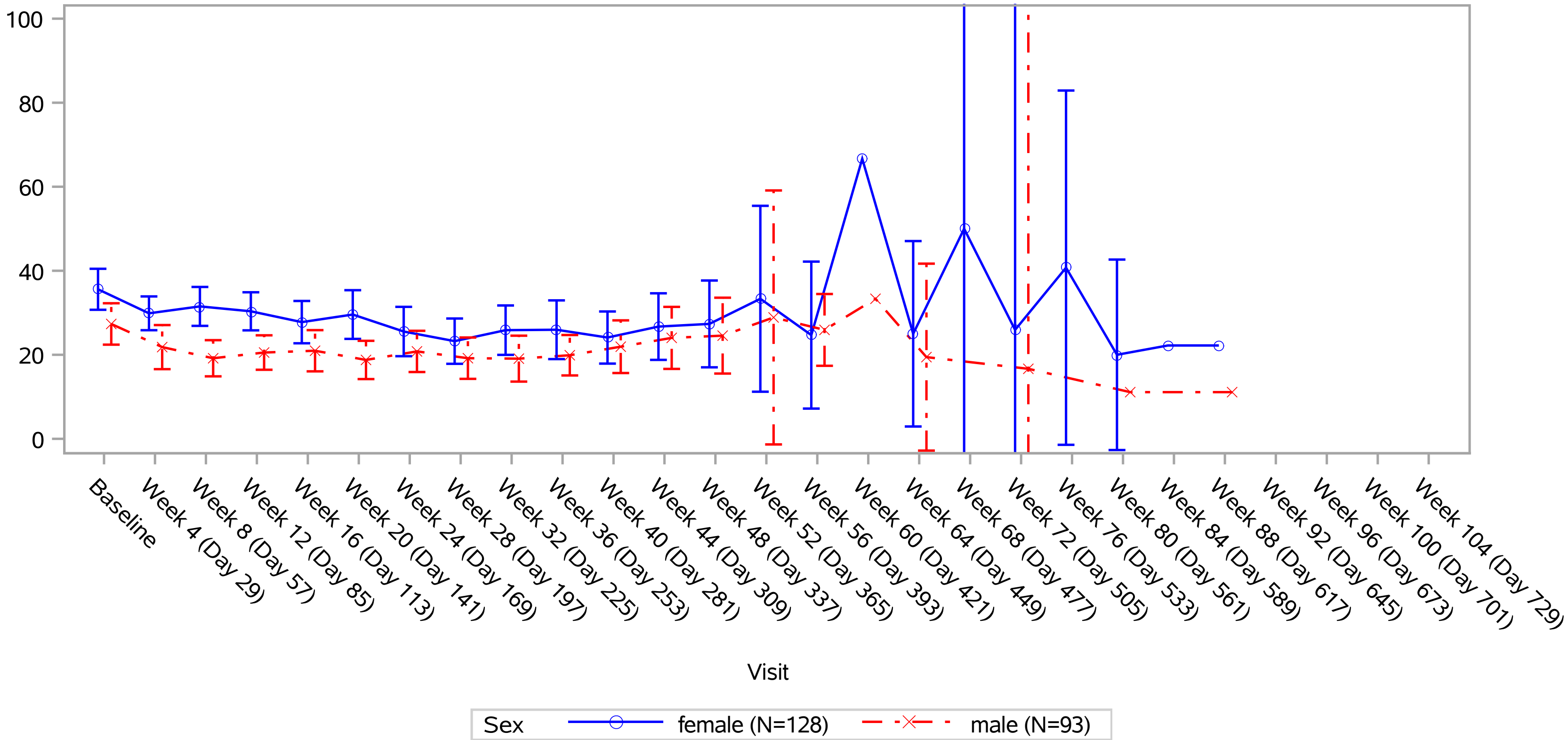
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Fatigue
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30FA_SGRE.pdf
15OCT2021 19:06

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Fatigue
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30FA_SGSEX.pdf
15OCT2021 19:37

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Nausea and vomiting
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=221)							
		Patients				Statistics			
Name Visit	Level	in study¹	%	with value¹	%	mean²	SD	CI LL	CI UL
All									
Baseline	n/a	221	100.0	212	95.9	8.73	17.88	6.31	11.15
Week 4 (Day 29)	n/a	221	100.0	191	86.4	3.14	8.98	1.86	4.42
Week 8 (Day 57)	n/a	193	87.3	171	88.6	3.61	9.13	2.23	4.98
Week 12 (Day 85)	n/a	176	79.6	161	91.5	2.48	8.98	1.09	3.88
Week 16 (Day 113)	n/a	164	74.2	143	87.2	3.03	9.20	1.51	4.55
Week 20 (Day 141)	n/a	148	67.0	138	93.2	3.14	9.13	1.60	4.68
Week 24 (Day 169)	n/a	137	62.0	122	89.1	2.87	10.86	0.92	4.82
Week 28 (Day 197)	n/a	129	58.4	120	93.0	4.58	12.22	2.38	6.79
Week 32 (Day 225)	n/a	119	53.8	104	87.4	4.49	12.77	2.00	6.97
Week 36 (Day 253)	n/a	112	50.7	95	84.8	2.63	7.81	1.04	4.22
Week 40 (Day 281)	n/a	104	47.1	91	87.5	3.30	10.61	1.09	5.51
Week 44 (Day 309)	n/a	95	43.0	84	88.4	5.95	16.08	2.46	9.44
Week 48 (Day 337)	n/a	81	36.7	45	55.6	3.70	12.25	0.02	7.38
Week 52 (Day 365)	n/a	64	29.0	11	17.2	3.03	10.05	-3.72	9.78
Week 56 (Day 393)	n/a	54	24.4	18	33.3	1.85	5.39	-0.83	4.53
Week 60 (Day 421)	n/a	43	19.5	2	4.7	0.00	0.00	NE	NE
Week 64 (Day 449)	n/a	41	18.6	12	29.3	1.39	4.81	-1.67	4.45
Week 68 (Day 477)	n/a	34	15.4	2	5.9	8.33	11.79	-97.55	114.22
Week 72 (Day 505)	n/a	34	15.4	5	14.7	0.00	0.00	NE	NE
Week 76 (Day 533)	n/a	31	14.0	3	9.7	5.56	9.62	-18.35	29.46
Week 80 (Day 561)	n/a	30	13.6	6	20.0	0.00	0.00	NE	NE
Week 84 (Day 589)	n/a	19	8.6	1	5.3	0.00	NE	NE	NE
Week 88 (Day 617)	n/a	15	6.8	2	13.3	0.00	0.00	NE	NE
Week 92 (Day 645)	n/a	8	3.6	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	2.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	1.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	221	100.0	219	99.1	6.09	15.67	4.00	8.18
End of Study (LOCF)	n/a	221	100.0	219	99.1	5.48	15.41	3.43	7.53
Sex									
Baseline	Female	128	100.0	123	96.1	10.03	20.66	6.34	13.71
Week 4 (Day 29)	Female	128	100.0	106	82.8	4.25	10.56	2.21	6.28
Week 8 (Day 57)	Female	112	87.5	98	87.5	4.93	11.02	2.72	7.14
Week 12 (Day 85)	Female	104	81.3	95	91.3	3.68	10.92	1.46	5.91
Week 16 (Day 113)	Female	96	75.0	81	84.4	4.32	10.79	1.93	6.71
Week 20 (Day 141)	Female	86	67.2	80	93.0	4.79	11.00	2.34	7.24
Week 24 (Day 169)	Female	78	60.9	67	85.9	4.23	13.71	0.88	7.57
Week 28 (Day 197)	Female	72	56.3	65	90.3	6.92	14.99	3.21	10.64
Week 32 (Day 225)	Female	69	53.9	58	84.1	6.32	15.56	2.23	10.41
Week 36 (Day 253)	Female	64	50.0	52	81.3	3.85	9.11	1.31	6.38
Week 40 (Day 281)	Female	59	46.1	53	89.8	4.72	12.82	1.18	8.25
Week 44 (Day 309)	Female	56	43.8	47	83.9	9.22	19.60	3.47	14.97
Week 48 (Day 337)	Female	48	37.5	26	54.2	6.41	15.69	0.07	12.75
Week 52 (Day 365)	Female	38	29.7	6	15.8	5.56	13.61	-8.73	19.84
Week 56 (Day 393)	Female	31	24.2	9	29.0	3.70	7.35	-1.95	9.35
Week 60 (Day 421)	Female	27	21.1	1	3.7	0.00	NE	NE	NE
Week 64 (Day 449)	Female	26	20.3	8	30.8	2.08	5.89	-2.84	7.01
Week 68 (Day 477)	Female	23	18.0	2	8.7	8.33	11.79	-97.55	114.22
Week 72 (Day 505)	Female	23	18.0	3	13.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Female	21	16.4	3	14.3	5.56	9.62	-18.35	29.46
Week 80 (Day 561)	Female	20	15.6	5	25.0	0.00	0.00	NE	NE
Week 84 (Day 589)	Female	12	9.4	1	8.3	0.00	NE	NE	NE
Week 88 (Day 617)	Female	9	7.0	1	11.1	0.00	NE	NE	NE
Week 92 (Day 645)	Female	6	4.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	3.9	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	1.6	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	0.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	128	100.0	127	99.2	8.27	18.88	4.95	11.58
End of Study (LOCF)	Female	128	100.0	127	99.2	7.61	18.99	4.28	10.95
Baseline	Male	93	100.0	89	95.7	6.93	13.01	4.19	9.67
Week 4 (Day 29)	Male	93	100.0	85	91.4	1.76	6.31	0.40	3.13
Week 8 (Day 57)	Male	81	87.1	73	90.1	1.83	5.24	0.60	3.05
Week 12 (Day 85)	Male	72	77.4	66	91.7	0.76	4.56	-0.36	1.88
Week 16 (Day 113)	Male	68	73.1	62	91.2	1.34	6.26	-0.24	2.93
Week 20 (Day 141)	Male	62	66.7	58	93.5	0.86	4.86	-0.42	2.14
Week 24 (Day 169)	Male	59	63.4	55	93.2	1.21	5.42	-0.25	2.68
Week 28 (Day 197)	Male	57	61.3	55	96.5	1.82	6.93	-0.06	3.69
Week 32 (Day 225)	Male	50	53.8	46	92.0	2.17	7.54	-0.07	4.41
Week 36 (Day 253)	Male	48	51.6	43	89.6	1.16	5.63	-0.57	2.90
Week 40 (Day 281)	Male	45	48.4	38	84.4	1.32	5.98	-0.65	3.28
Week 44 (Day 309)	Male	39	41.9	37	94.9	1.80	8.59	-1.06	4.67
Week 48 (Day 337)	Male	33	35.5	19	57.6	0.00	0.00	NE	NE
Week 52 (Day 365)	Male	26	28.0	5	19.2	0.00	0.00	NE	NE
Week 56 (Day 393)	Male	23	24.7	9	39.1	0.00	0.00	NE	NE
Week 60 (Day 421)	Male	16	17.2	1	6.3	0.00	NE	NE	NE
Week 64 (Day 449)	Male	15	16.1	4	26.7	0.00	0.00	NE	NE
Week 68 (Day 477)	Male	11	11.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	11	11.8	2	18.2	0.00	0.00	NE	NE
Week 76 (Day 533)	Male	10	10.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	10	10.8	1	10.0	0.00	NE	NE	NE
Week 84 (Day 589)	Male	7	7.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	6	6.5	1	16.7	0.00	NE	NE	NE
Week 92 (Day 645)	Male	2	2.2	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	93	100.0	92	98.9	3.08	8.88	1.24	4.92
End of Study (LOCF)	Male	93	100.0	92	98.9	2.54	7.39	1.01	4.07
Age									

Baseline	< 65	141	100.0	133	94.3	9.40	19.06	6.13	12.67
Week 4 (Day 29)	< 65	141	100.0	123	87.2	2.85	7.90	1.44	4.26
Week 8 (Day 57)	< 65	127	90.1	113	89.0	2.80	7.68	1.37	4.23
Week 12 (Day 85)	< 65	118	83.7	106	89.8	1.89	7.74	0.40	3.38
Week 16 (Day 113)	< 65	108	76.6	93	86.1	2.33	8.37	0.61	4.05
Week 20 (Day 141)	< 65	100	70.9	97	97.0	3.26	9.51	1.35	5.18
Week 24 (Day 169)	< 65	93	66.0	86	92.5	2.13	6.66	0.70	3.56
Week 28 (Day 197)	< 65	88	62.4	83	94.3	5.22	13.51	2.27	8.17
Week 32 (Day 225)	< 65	83	58.9	73	88.0	3.88	11.63	1.17	6.59
Week 36 (Day 253)	< 65	78	55.3	70	89.7	2.86	8.50	0.83	4.88
Week 40 (Day 281)	< 65	75	53.2	69	92.0	2.66	10.55	0.12	5.19
Week 44 (Day 309)	< 65	71	50.4	65	91.5	6.67	17.13	2.42	10.91
Week 48 (Day 337)	< 65	61	43.3	33	54.1	2.53	8.46	-0.47	5.52
Week 52 (Day 365)	< 65	48	34.0	6	12.5	0.00	0.00	NE	NE
Week 56 (Day 393)	< 65	41	29.1	11	26.8	0.00	0.00	NE	NE
Week 60 (Day 421)	< 65	33	23.4	2	6.1	0.00	0.00	NE	NE
Week 64 (Day 449)	< 65	31	22.0	10	32.3	0.00	0.00	NE	NE
Week 68 (Day 477)	< 65	26	18.4	2	7.7	8.33	11.79	-97.55	114.22
Week 72 (Day 505)	< 65	26	18.4	5	19.2	0.00	0.00	NE	NE
Week 76 (Day 533)	< 65	25	17.7	3	12.0	5.56	9.62	-18.35	29.46
Week 80 (Day 561)	< 65	24	17.0	5	20.8	0.00	0.00	NE	NE
Week 84 (Day 589)	< 65	16	11.3	1	6.3	0.00	NE	NE	NE
Week 88 (Day 617)	< 65	13	9.2	2	15.4	0.00	0.00	NE	NE
Week 92 (Day 645)	< 65	7	5.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	3.5	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	2.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	0.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	141	100.0	139	98.6	5.76	14.57	3.31	8.20
End of Study (LOCF)	< 65	141	100.0	139	98.6	4.68	13.61	2.39	6.96
Baseline	>= 65	80	100.0	79	98.8	7.59	15.74	4.07	11.12
Week 4 (Day 29)	>= 65	80	100.0	68	85.0	3.68	10.71	1.08	6.27
Week 8 (Day 57)	>= 65	66	82.5	58	87.9	5.17	11.35	2.19	8.16
Week 12 (Day 85)	>= 65	58	72.5	55	94.8	3.64	10.97	0.67	6.60

Week 16 (Day 113)	>= 65	56	70.0	50	89.3	4.33	10.55	1.34	7.33
Week 20 (Day 141)	>= 65	48	60.0	41	85.4	2.85	8.25	0.24	5.45
Week 24 (Day 169)	>= 65	44	55.0	36	81.8	4.63	17.19	-1.19	10.45
Week 28 (Day 197)	>= 65	41	51.3	37	90.2	3.15	8.64	0.27	6.03
Week 32 (Day 225)	>= 65	36	45.0	31	86.1	5.91	15.24	0.32	11.51
Week 36 (Day 253)	>= 65	34	42.5	25	73.5	2.00	5.53	-0.28	4.28
Week 40 (Day 281)	>= 65	29	36.3	22	75.9	5.30	10.77	0.53	10.08
Week 44 (Day 309)	>= 65	24	30.0	19	79.2	3.51	11.89	-2.22	9.24
Week 48 (Day 337)	>= 65	20	25.0	12	60.0	6.94	19.41	-5.39	19.28
Week 52 (Day 365)	>= 65	16	20.0	5	31.3	6.67	14.91	-11.84	25.18
Week 56 (Day 393)	>= 65	13	16.3	7	53.8	4.76	8.13	-2.76	12.28
Week 60 (Day 421)	>= 65	10	12.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	10	12.5	2	20.0	8.33	11.79	-97.55	114.22
Week 68 (Day 477)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	6	7.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	6	7.5	1	16.7	0.00	NE	NE	NE
Week 84 (Day 589)	>= 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	2.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	80	100.0	80	100.0	6.67	17.51	2.77	10.56
End of Study (LOCF)	>= 65	80	100.0	80	100.0	6.88	18.12	2.84	10.91
ECOG performance status									
Baseline	0	63	100.0	60	95.2	6.11	15.33	2.15	10.07
Week 4 (Day 29)	0	63	100.0	56	88.9	4.17	9.13	1.72	6.61
Week 8 (Day 57)	0	58	92.1	52	89.7	3.85	9.69	1.15	6.54
Week 12 (Day 85)	0	55	87.3	50	90.9	3.67	10.26	0.75	6.58
Week 16 (Day 113)	0	54	85.7	45	83.3	3.33	9.13	0.59	6.08
Week 20 (Day 141)	0	52	82.5	48	92.3	2.43	6.87	0.44	4.42
Week 24 (Day 169)	0	49	77.8	43	87.8	3.10	15.54	-1.68	7.88
Week 28 (Day 197)	0	46	73.0	42	91.3	3.57	11.95	-0.15	7.29

Week 32 (Day 225)	0	41	65.1	34	82.9	2.45	8.34	-0.46	5.36
Week 36 (Day 253)	0	39	61.9	31	79.5	1.61	5.01	-0.22	3.45
Week 40 (Day 281)	0	37	58.7	30	81.1	1.67	6.71	-0.84	4.17
Week 44 (Day 309)	0	36	57.1	29	80.6	6.32	14.37	0.85	11.79
Week 48 (Day 337)	0	28	44.4	18	64.3	4.63	15.97	-3.31	12.57
Week 52 (Day 365)	0	27	42.9	6	22.2	5.56	13.61	-8.73	19.84
Week 56 (Day 393)	0	24	38.1	8	33.3	2.08	5.89	-2.84	7.01
Week 60 (Day 421)	0	21	33.3	1	4.8	0.00	NE	NE	NE
Week 64 (Day 449)	0	21	33.3	7	33.3	2.38	6.30	-3.45	8.21
Week 68 (Day 477)	0	17	27.0	1	5.9	0.00	NE	NE	NE
Week 72 (Day 505)	0	17	27.0	2	11.8	0.00	0.00	NE	NE
Week 76 (Day 533)	0	15	23.8	2	13.3	0.00	0.00	NE	NE
Week 80 (Day 561)	0	14	22.2	1	7.1	0.00	NE	NE	NE
Week 84 (Day 589)	0	11	17.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	10	15.9	1	10.0	0.00	NE	NE	NE
Week 92 (Day 645)	0	5	7.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	6.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	4.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	63	100.0	63	100.0	6.88	17.10	2.57	11.19
End of Study (LOCF)	0	63	100.0	63	100.0	5.56	16.93	1.29	9.82
Baseline	1	157	100.0	151	96.2	9.71	18.79	6.69	12.73
Week 4 (Day 29)	1	157	100.0	134	85.4	2.74	8.95	1.21	4.27
Week 8 (Day 57)	1	134	85.4	119	88.8	3.50	8.91	1.88	5.12
Week 12 (Day 85)	1	121	77.1	111	91.7	1.95	8.33	0.39	3.52
Week 16 (Day 113)	1	110	70.1	98	89.1	2.89	9.28	1.03	4.75
Week 20 (Day 141)	1	96	61.1	90	93.8	3.52	10.15	1.39	5.64
Week 24 (Day 169)	1	88	56.1	79	89.8	2.74	7.27	1.11	4.37
Week 28 (Day 197)	1	83	52.9	78	94.0	5.13	12.40	2.33	7.92
Week 32 (Day 225)	1	78	49.7	70	89.7	5.48	14.39	2.04	8.91
Week 36 (Day 253)	1	73	46.5	64	87.7	3.13	8.85	0.92	5.33
Week 40 (Day 281)	1	67	42.7	61	91.0	4.10	12.04	1.01	7.18

Week 44 (Day 309)	1	59	37.6	55	93.2	5.76	17.04	1.15	10.36
Week 48 (Day 337)	1	53	33.8	27	50.9	3.09	9.29	-0.59	6.76
Week 52 (Day 365)	1	37	23.6	5	13.5	0.00	0.00	NE	NE
Week 56 (Day 393)	1	30	19.1	10	33.3	1.67	5.27	-2.10	5.44
Week 60 (Day 421)	1	22	14.0	1	4.5	0.00	NE	NE	NE
Week 64 (Day 449)	1	20	12.7	5	25.0	0.00	0.00	NE	NE
Week 68 (Day 477)	1	17	10.8	1	5.9	16.67	NE	NE	NE
Week 72 (Day 505)	1	17	10.8	3	17.6	0.00	0.00	NE	NE
Week 76 (Day 533)	1	16	10.2	1	6.3	16.67	NE	NE	NE
Week 80 (Day 561)	1	16	10.2	5	31.3	0.00	0.00	NE	NE
Week 84 (Day 589)	1	8	5.1	1	12.5	0.00	NE	NE	NE
Week 88 (Day 617)	1	5	3.2	1	20.0	0.00	NE	NE	NE
Week 92 (Day 645)	1	3	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	157	100.0	155	98.7	5.81	15.15	3.40	8.21
End of Study (LOCF)	1	157	100.0	155	98.7	5.48	14.85	3.13	7.84
Baseline	Missing	1	100.0	1	100.0	16.67	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Geographic region									
Baseline	USA	43	100.0	41	95.3	6.50	12.84	2.45	10.56
Week 4 (Day 29)	USA	43	100.0	38	88.4	4.39	12.67	0.22	8.55
Week 8 (Day 57)	USA	41	95.3	37	90.2	5.86	11.93	1.88	9.83
Week 12 (Day 85)	USA	41	95.3	38	92.7	3.95	10.57	0.47	7.42
Week 16 (Day 113)	USA	40	93.0	33	82.5	5.05	12.83	0.50	9.60
Week 20 (Day 141)	USA	39	90.7	35	89.7	3.81	8.17	1.00	6.62
Week 24 (Day 169)	USA	36	83.7	33	91.7	2.53	7.36	-0.08	5.14
Week 28 (Day 197)	USA	35	81.4	31	88.6	3.23	7.96	0.31	6.14
Week 32 (Day 225)	USA	32	74.4	28	87.5	4.17	8.64	0.82	7.52
Week 36 (Day 253)	USA	32	74.4	24	75.0	3.47	6.91	0.55	6.39
Week 40 (Day 281)	USA	29	67.4	23	79.3	3.62	7.03	0.58	6.66

Week 44 (Day 309)	USA	26	60.5	21	80.8	7.14	15.43	0.12	14.17
Week 48 (Day 337)	USA	21	48.8	15	71.4	2.22	8.61	-2.54	6.99
Week 52 (Day 365)	USA	18	41.9	1	5.6	0.00	NE	NE	NE
Week 56 (Day 393)	USA	18	41.9	9	50.0	1.85	5.56	-2.42	6.12
Week 60 (Day 421)	USA	17	39.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	15	34.9	5	33.3	0.00	0.00	NE	NE
Week 68 (Day 477)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	12	27.9	1	8.3	0.00	NE	NE	NE
Week 76 (Day 533)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	12	27.9	2	16.7	0.00	0.00	NE	NE
Week 84 (Day 589)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	6	14.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	11.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	7.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	43	100.0	43	100.0	5.81	15.38	1.08	10.55
End of Study (LOCF)	USA	43	100.0	43	100.0	3.10	12.20	-0.65	6.86
Baseline	Europe (EU)	74	100.0	69	93.2	8.70	18.44	4.27	13.12
Week 4 (Day 29)	Europe (EU)	74	100.0	64	86.5	1.82	6.03	0.32	3.33
Week 8 (Day 57)	Europe (EU)	65	87.8	55	84.6	2.73	9.50	0.16	5.29
Week 12 (Day 85)	Europe (EU)	57	77.0	49	86.0	2.72	9.22	0.07	5.37
Week 16 (Day 113)	Europe (EU)	55	74.3	44	80.0	3.41	9.90	0.40	6.42
Week 20 (Day 141)	Europe (EU)	49	66.2	46	93.9	3.62	8.54	1.09	6.16
Week 24 (Day 169)	Europe (EU)	47	63.5	42	89.4	4.37	16.07	-0.64	9.37
Week 28 (Day 197)	Europe (EU)	45	60.8	43	95.6	5.04	12.88	1.08	9.00
Week 32 (Day 225)	Europe (EU)	39	52.7	35	89.7	4.29	13.61	-0.39	8.96
Week 36 (Day 253)	Europe (EU)	34	45.9	30	88.2	1.67	5.09	-0.23	3.57
Week 40 (Day 281)	Europe (EU)	31	41.9	30	96.8	1.11	4.23	-0.47	2.69
Week 44 (Day 309)	Europe (EU)	28	37.8	24	85.7	5.56	15.28	-0.90	12.01

Week 48 (Day 337)	Europe (EU)	22	29.7	16	72.7	4.17	9.62	-0.96	9.29
Week 52 (Day 365)	Europe (EU)	19	25.7	6	31.6	5.56	13.61	-8.73	19.84
Week 56 (Day 393)	Europe (EU)	17	23.0	7	41.2	2.38	6.30	-3.45	8.21
Week 60 (Day 421)	Europe (EU)	15	20.3	2	13.3	0.00	0.00	NE	NE
Week 64 (Day 449)	Europe (EU)	15	20.3	7	46.7	2.38	6.30	-3.45	8.21
Week 68 (Day 477)	Europe (EU)	13	17.6	2	15.4	8.33	11.79	-97.55	114.22
Week 72 (Day 505)	Europe (EU)	13	17.6	4	30.8	0.00	0.00	NE	NE
Week 76 (Day 533)	Europe (EU)	11	14.9	3	27.3	5.56	9.62	-18.35	29.46
Week 80 (Day 561)	Europe (EU)	10	13.5	4	40.0	0.00	0.00	NE	NE
Week 84 (Day 589)	Europe (EU)	6	8.1	1	16.7	0.00	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	4.1	2	66.7	0.00	0.00	NE	NE
Cycle 12 (LOCF)	Europe (EU)	74	100.0	73	98.6	5.94	16.05	2.19	9.68
End of Study (LOCF)	Europe (EU)	74	100.0	73	98.6	5.48	15.97	1.75	9.21
Baseline	Asia (AS)	104	100.0	102	98.1	9.64	19.26	5.86	13.42
Week 4 (Day 29)	Asia (AS)	104	100.0	89	85.6	3.56	8.87	1.69	5.43
Week 8 (Day 57)	Asia (AS)	87	83.7	79	90.8	3.16	7.10	1.57	4.75
Week 12 (Day 85)	Asia (AS)	78	75.0	74	94.9	1.58	7.88	-0.25	3.40
Week 16 (Day 113)	Asia (AS)	69	66.3	66	95.7	1.77	5.94	0.31	3.23
Week 20 (Day 141)	Asia (AS)	60	57.7	57	95.0	2.34	10.18	-0.36	5.04
Week 24 (Day 169)	Asia (AS)	54	51.9	47	87.0	1.77	6.25	-0.06	3.61
Week 28 (Day 197)	Asia (AS)	49	47.1	46	93.9	5.07	14.00	0.92	9.23
Week 32 (Day 225)	Asia (AS)	48	46.2	41	85.4	4.88	14.55	0.29	9.47
Week 36 (Day 253)	Asia (AS)	46	44.2	41	89.1	2.85	9.79	-0.24	5.94
Week 40 (Day 281)	Asia (AS)	44	42.3	38	86.4	4.82	14.96	-0.09	9.74
Week 44 (Day 309)	Asia (AS)	41	39.4	39	95.1	5.56	17.24	-0.03	11.14
Week 48 (Day 337)	Asia (AS)	38	36.5	14	36.8	4.76	17.82	-5.53	15.05
Week 52 (Day 365)	Asia (AS)	27	26.0	4	14.8	0.00	0.00	NE	NE
Week 56 (Day 393)	Asia (AS)	19	18.3	2	10.5	0.00	0.00	NE	NE
Week 60 (Day 421)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	5.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	104	100.0	103	99.0	6.31	15.68	3.25	9.37
End of Study (LOCF)	Asia (AS)	104	100.0	103	99.0	6.47	16.21	3.30	9.64
Race/ethnicity									
Baseline	Asian	109	100.0	106	97.2	9.59	19.10	5.91	13.27
Week 4 (Day 29)	Asian	109	100.0	92	84.4	3.44	8.75	1.63	5.25
Week 8 (Day 57)	Asian	91	83.5	80	87.9	3.33	7.21	1.73	4.94
Week 12 (Day 85)	Asian	82	75.2	78	95.1	1.92	8.49	0.01	3.84
Week 16 (Day 113)	Asian	73	67.0	70	95.9	2.14	6.90	0.50	3.79
Week 20 (Day 141)	Asian	64	58.7	60	93.8	2.50	10.10	-0.11	5.11
Week 24 (Day 169)	Asian	57	52.3	50	87.7	1.67	6.07	-0.06	3.39
Week 28 (Day 197)	Asian	52	47.7	49	94.2	4.76	13.61	0.85	8.67
Week 32 (Day 225)	Asian	50	45.9	43	86.0	5.43	14.87	0.85	10.00
Week 36 (Day 253)	Asian	48	44.0	43	89.6	3.10	9.80	0.09	6.12
Week 40 (Day 281)	Asian	46	42.2	40	87.0	4.58	14.61	-0.09	9.26
Week 44 (Day 309)	Asian	43	39.4	41	95.3	5.28	16.85	-0.03	10.60
Week 48 (Day 337)	Asian	40	36.7	15	37.5	4.44	17.21	-5.09	13.98
Week 52 (Day 365)	Asian	29	26.6	5	17.2	0.00	0.00	NE	NE
Week 56 (Day 393)	Asian	21	19.3	3	14.3	0.00	0.00	NE	NE
Week 60 (Day 421)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	5.5	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	4.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	1.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	109	100.0	107	98.2	6.07	15.42	3.12	9.03
End of Study (LOCF)	Asian	109	100.0	107	98.2	6.23	15.95	3.17	9.29
Baseline	Non-Asian	99	100.0	96	97.0	7.81	16.75	4.42	11.21
Week 4 (Day 29)	Non-Asian	99	100.0	89	89.9	2.81	9.48	0.81	4.81
Week 8 (Day 57)	Non-Asian	91	91.9	82	90.1	4.27	11.05	1.84	6.70
Week 12 (Day 85)	Non-Asian	83	83.8	74	89.2	3.38	9.94	1.08	5.68
Week 16 (Day 113)	Non-Asian	80	80.8	68	85.0	4.17	11.29	1.43	6.90
Week 20 (Day 141)	Non-Asian	74	74.7	69	93.2	3.86	8.64	1.79	5.94
Week 24 (Day 169)	Non-Asian	70	70.7	65	92.9	4.10	13.83	0.68	7.53
Week 28 (Day 197)	Non-Asian	67	67.7	63	94.0	3.97	8.84	1.74	6.19
Week 32 (Day 225)	Non-Asian	60	60.6	53	88.3	4.40	11.85	1.14	7.67
Week 36 (Day 253)	Non-Asian	55	55.6	46	83.6	2.54	6.05	0.74	4.33
Week 40 (Day 281)	Non-Asian	49	49.5	44	89.8	2.65	6.17	0.78	4.53
Week 44 (Day 309)	Non-Asian	43	43.4	35	81.4	6.19	15.70	0.80	11.58
Week 48 (Day 337)	Non-Asian	35	35.4	26	74.3	3.85	9.78	-0.11	7.80
Week 52 (Day 365)	Non-Asian	29	29.3	6	20.7	5.56	13.61	-8.73	19.84
Week 56 (Day 393)	Non-Asian	27	27.3	14	51.9	2.38	6.05	-1.11	5.88
Week 60 (Day 421)	Non-Asian	26	26.3	2	7.7	0.00	0.00	NE	NE
Week 64 (Day 449)	Non-Asian	24	24.2	9	37.5	1.85	5.56	-2.42	6.12
Week 68 (Day 477)	Non-Asian	20	20.2	2	10.0	8.33	11.79	-97.55	114.22
Week 72 (Day 505)	Non-Asian	20	20.2	3	15.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Non-Asian	18	18.2	3	16.7	5.56	9.62	-18.35	29.46
Week 80 (Day 561)	Non-Asian	17	17.2	5	29.4	0.00	0.00	NE	NE
Week 84 (Day 589)	Non-Asian	11	11.1	1	9.1	0.00	NE	NE	NE
Week 88 (Day 617)	Non-Asian	8	8.1	2	25.0	0.00	0.00	NE	NE
Week 92 (Day 645)	Non-Asian	4	4.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	3.0	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	99	100.0	99	100.0	6.06	16.40	2.79	9.33

End of Study (LOCF)	Non-Asian	99	100.0	99	100.0	5.22	15.73	2.08	8.36
Baseline	Unknown	13	100.0	10	76.9	8.33	16.20	-3.25	19.92
Week 4 (Day 29)	Unknown	13	100.0	10	76.9	3.33	7.03	-1.69	8.36
Week 8 (Day 57)	Unknown	11	84.6	9	81.8	0.00	0.00	NE	NE
Week 12 (Day 85)	Unknown	11	84.6	9	81.8	0.00	0.00	NE	NE
Week 16 (Day 113)	Unknown	11	84.6	5	45.5	0.00	0.00	NE	NE
Week 20 (Day 141)	Unknown	10	76.9	9	90.0	1.85	5.56	-2.42	6.12
Week 24 (Day 169)	Unknown	10	76.9	7	70.0	0.00	0.00	NE	NE
Week 28 (Day 197)	Unknown	10	76.9	8	80.0	8.33	23.57	-11.37	28.04
Week 32 (Day 225)	Unknown	9	69.2	8	88.9	0.00	0.00	NE	NE
Week 36 (Day 253)	Unknown	9	69.2	6	66.7	0.00	0.00	NE	NE
Week 40 (Day 281)	Unknown	9	69.2	7	77.8	0.00	0.00	NE	NE
Week 44 (Day 309)	Unknown	9	69.2	8	88.9	8.33	15.43	-4.57	21.23
Week 48 (Day 337)	Unknown	6	46.2	4	66.7	0.00	0.00	NE	NE
Week 52 (Day 365)	Unknown	6	46.2	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	6	46.2	1	16.7	0.00	NE	NE	NE
Week 60 (Day 421)	Unknown	5	38.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	5	38.5	3	60.0	0.00	0.00	NE	NE
Week 68 (Day 477)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	4	30.8	2	50.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	4	30.8	1	25.0	0.00	NE	NE	NE
Week 84 (Day 589)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	7.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	13	100.0	13	100.0	6.41	12.80	-1.32	14.14
End of Study (LOCF)	Unknown	13	100.0	13	100.0	1.28	4.62	-1.51	4.08

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TO_QSC30NV_SG.xls
27OCT2021 7:17

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Nausea and vomiting
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	51	24.1	18.8	30.2
	Cycle 12 (LOCF)	n/a	212	95.9	21	9.9	6.6	14.7
	End of Study (LOCF)	n/a	212	95.9	17	8.0	5.1	12.5
Sex	All visits	Female	123	55.7	37	30.1	22.7	38.7
		Male	89	40.3	14	15.7	9.6	24.7
	Cycle 12 (LOCF)	Female	123	55.7	16	13.0	8.2	20.1
		Male	89	40.3	5	5.6	2.4	12.5
	End of Study (LOCF)	Female	123	55.7	13	10.6	6.3	17.2
		Male	89	40.3	4	4.5	1.8	11.0
Age	All visits	< 65	133	60.2	31	23.3	16.9	31.2
		>= 65	79	35.7	20	25.3	17.0	35.9
	Cycle 12 (LOCF)	< 65	133	60.2	11	8.3	4.7	14.2
		>= 65	79	35.7	10	12.7	7.0	21.8
	End of Study (LOCF)	< 65	133	60.2	7	5.3	2.6	10.5
		>= 65	79	35.7	10	12.7	7.0	21.8
ECOG performance status	All visits	0	60	27.1	20	33.3	22.7	45.9
		1	151	68.3	31	20.5	14.9	27.7
		Missing	1	0.5	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	60	27.1	9	15.0	8.1	26.1
		1	151	68.3	12	7.9	4.6	13.4
		Missing	1	0.5	0	0.0	0.0	79.3
	End of Study (LOCF)	0	60	27.1	7	11.7	5.8	22.2
		1	151	68.3	10	6.6	3.6	11.8
		Missing	1	0.5	0	0.0	0.0	79.3
Geographic region	All visits	USA	41	18.6	13	31.7	19.6	47.0
		Europe (EU)	69	31.2	16	23.2	14.8	34.4
		Asia (AS)	102	46.2	22	21.6	14.7	30.5
	Cycle 12 (LOCF)	USA	41	18.6	5	12.2	5.3	25.5
		Europe (EU)	69	31.2	7	10.1	5.0	19.5
		Asia (AS)	102	46.2	9	8.8	4.7	15.9
	End of Study (LOCF)	USA	41	18.6	2	4.9	1.3	16.1
		Europe (EU)	69	31.2	6	8.7	4.0	17.7
		Asia (AS)	102	46.2	9	8.8	4.7	15.9
Race/ethnicity	All visits	Asian	106	48.0	23	21.7	14.9	30.5
		Non-Asian	96	43.4	25	26.0	18.3	35.6
		Unknown	10	4.5	3	30.0	10.8	60.3
	Cycle 12 (LOCF)	Asian	106	48.0	9	8.5	4.5	15.4

		Non-Asian	96	43.4	11	11.5	6.5	19.4
		Unknown	10	4.5	1	10.0	1.8	40.4
	End of Study (LOCF)	Asian	106	48.0	9	8.5	4.5	15.4
		Non-Asian	96	43.4	8	8.3	4.3	15.6
		Unknown	10	4.5	0	0.0	0.0	27.8

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30NV_W10_SG.xls
15OCT2021 12:54

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Nausea and vomiting
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

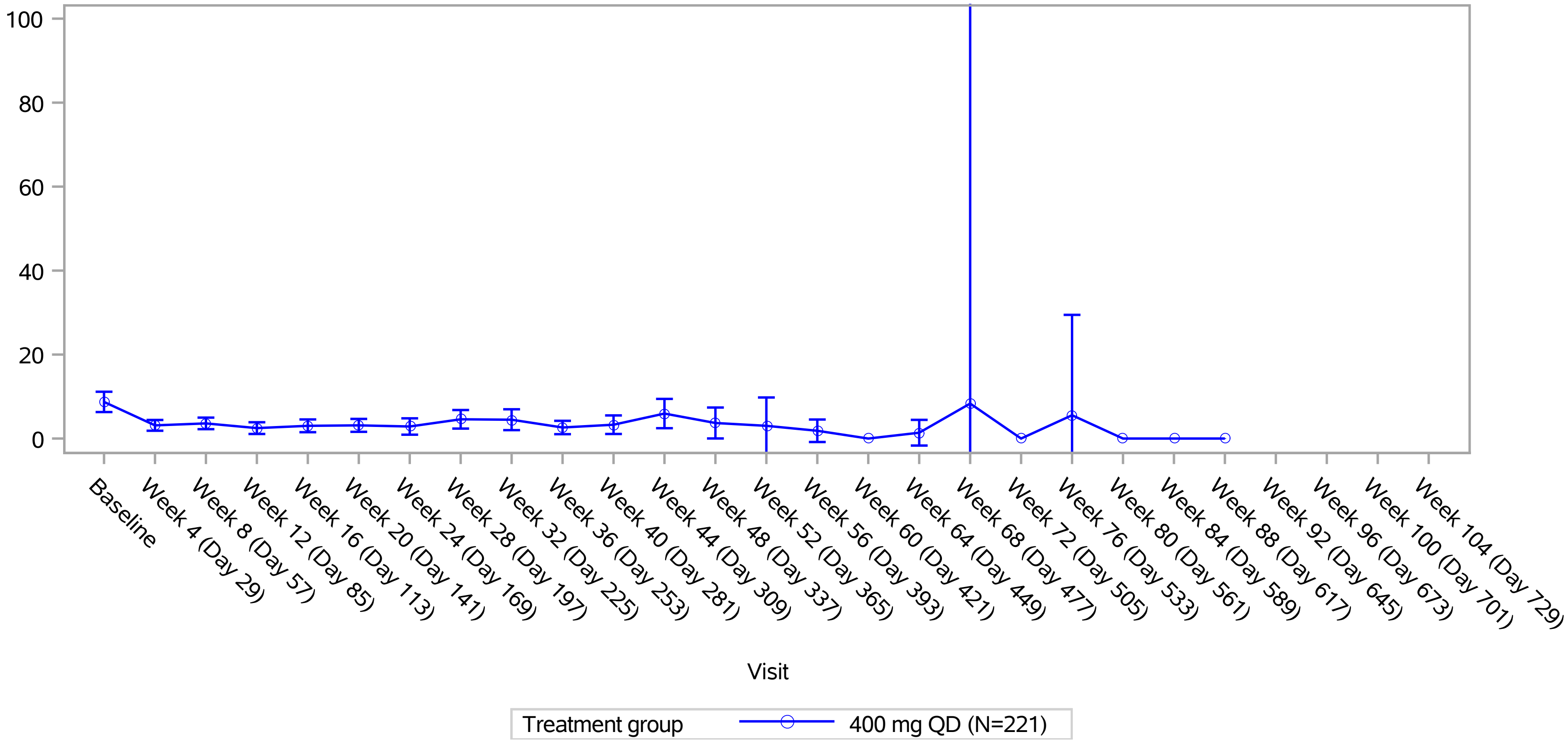
			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	51	24.1	18.8	30.2
	Cycle 12 (LOCF)	n/a	212	95.9	21	9.9	6.6	14.7
	End of Study (LOCF)	n/a	212	95.9	17	8.0	5.1	12.5
Sex	All visits	Female	123	55.7	37	30.1	22.7	38.7
		Male	89	40.3	14	15.7	9.6	24.7
	Cycle 12 (LOCF)	Female	123	55.7	16	13.0	8.2	20.1
		Male	89	40.3	5	5.6	2.4	12.5
	End of Study (LOCF)	Female	123	55.7	13	10.6	6.3	17.2
		Male	89	40.3	4	4.5	1.8	11.0
Age	All visits	< 65	133	60.2	31	23.3	16.9	31.2
		>= 65	79	35.7	20	25.3	17.0	35.9
	Cycle 12 (LOCF)	< 65	133	60.2	11	8.3	4.7	14.2
		>= 65	79	35.7	10	12.7	7.0	21.8
	End of Study (LOCF)	< 65	133	60.2	7	5.3	2.6	10.5
		>= 65	79	35.7	10	12.7	7.0	21.8
ECOG performance status	All visits	0	60	27.1	20	33.3	22.7	45.9
		1	151	68.3	31	20.5	14.9	27.7
		Missing	1	0.5	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	60	27.1	9	15.0	8.1	26.1
		1	151	68.3	12	7.9	4.6	13.4
		Missing	1	0.5	0	0.0	0.0	79.3
	End of Study (LOCF)	0	60	27.1	7	11.7	5.8	22.2
		1	151	68.3	10	6.6	3.6	11.8
		Missing	1	0.5	0	0.0	0.0	79.3
Geographic region	All visits	USA	41	18.6	13	31.7	19.6	47.0
		Europe (EU)	69	31.2	16	23.2	14.8	34.4
		Asia (AS)	102	46.2	22	21.6	14.7	30.5
	Cycle 12 (LOCF)	USA	41	18.6	5	12.2	5.3	25.5
		Europe (EU)	69	31.2	7	10.1	5.0	19.5
		Asia (AS)	102	46.2	9	8.8	4.7	15.9
	End of Study (LOCF)	USA	41	18.6	2	4.9	1.3	16.1
		Europe (EU)	69	31.2	6	8.7	4.0	17.7
		Asia (AS)	102	46.2	9	8.8	4.7	15.9
Race/ethnicity	All visits	Asian	106	48.0	23	21.7	14.9	30.5
		Non-Asian	96	43.4	25	26.0	18.3	35.6
		Unknown	10	4.5	3	30.0	10.8	60.3
	Cycle 12 (LOCF)	Asian	106	48.0	9	8.5	4.5	15.4

		Non-Asian	96	43.4	11	11.5	6.5	19.4
		Unknown	10	4.5	1	10.0	1.8	40.4
	End of Study (LOCF)	Asian	106	48.0	9	8.5	4.5	15.4
		Non-Asian	96	43.4	8	8.3	4.3	15.6
		Unknown	10	4.5	0	0.0	0.0	27.8

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30NV_W15_SG.xls
15OCT2021 12:44

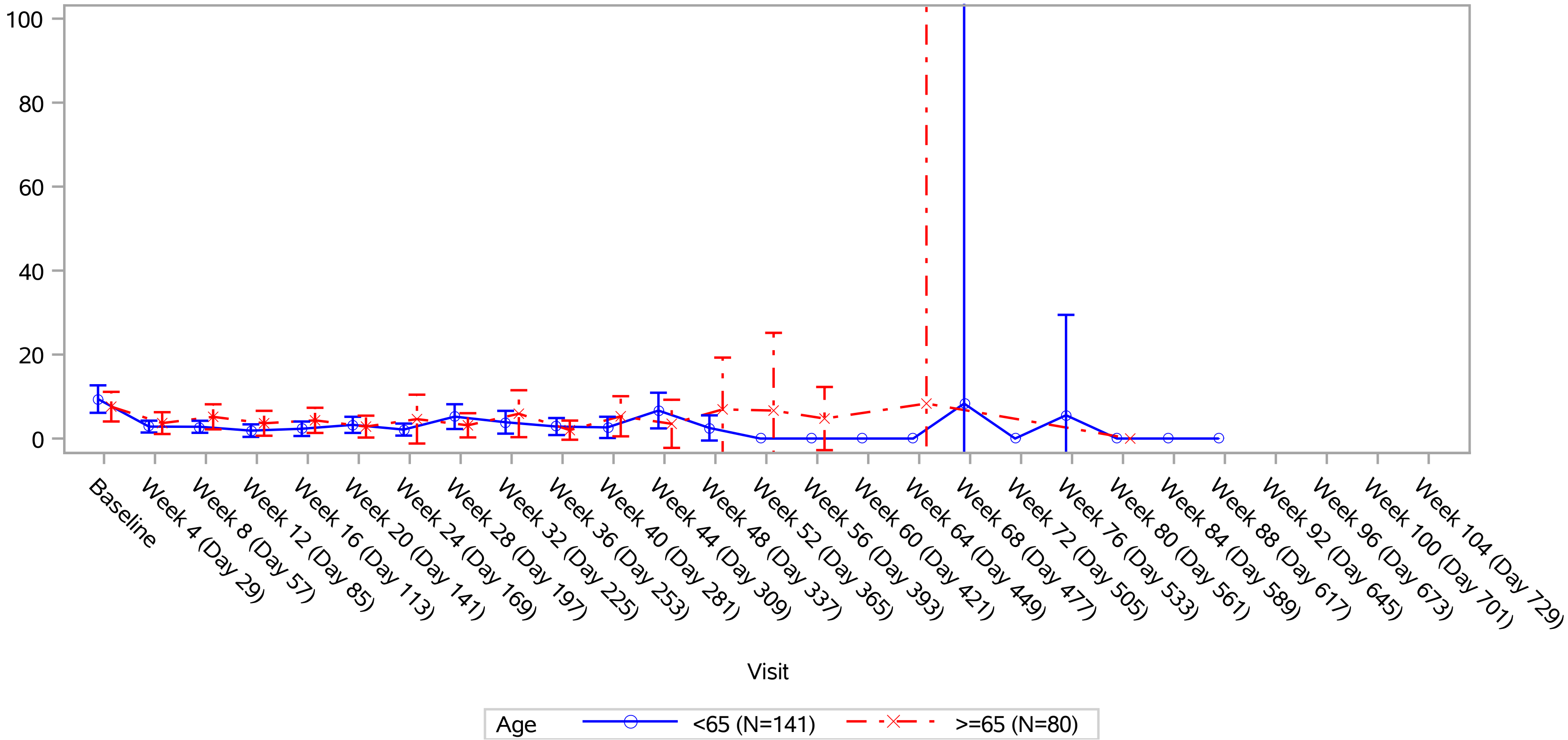
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Nausea and vomiting
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30NV.pdf
15OCT2021 17:08

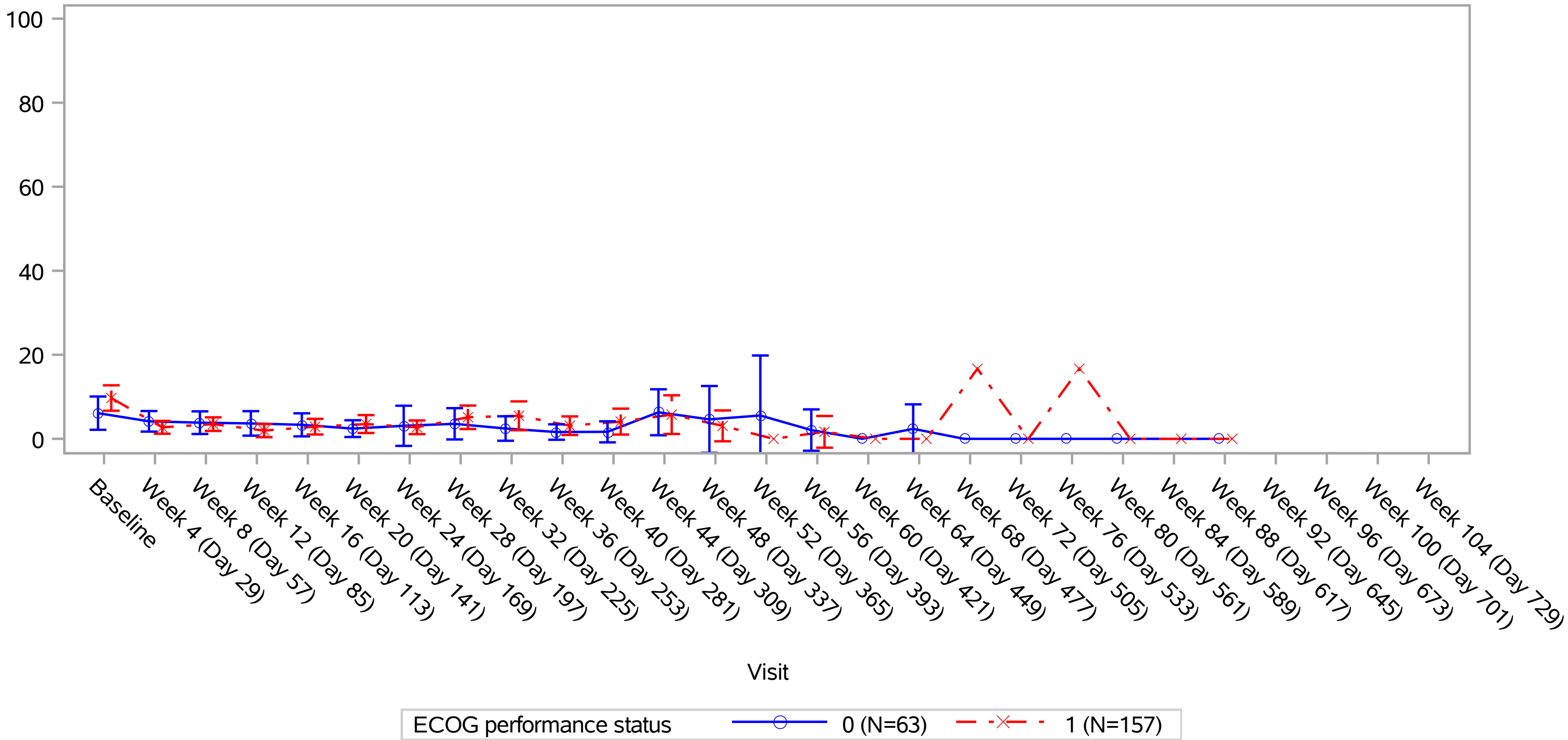
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Nausea and vomiting
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30NV_SGAGE65.pdf
15OCT2021 17:36

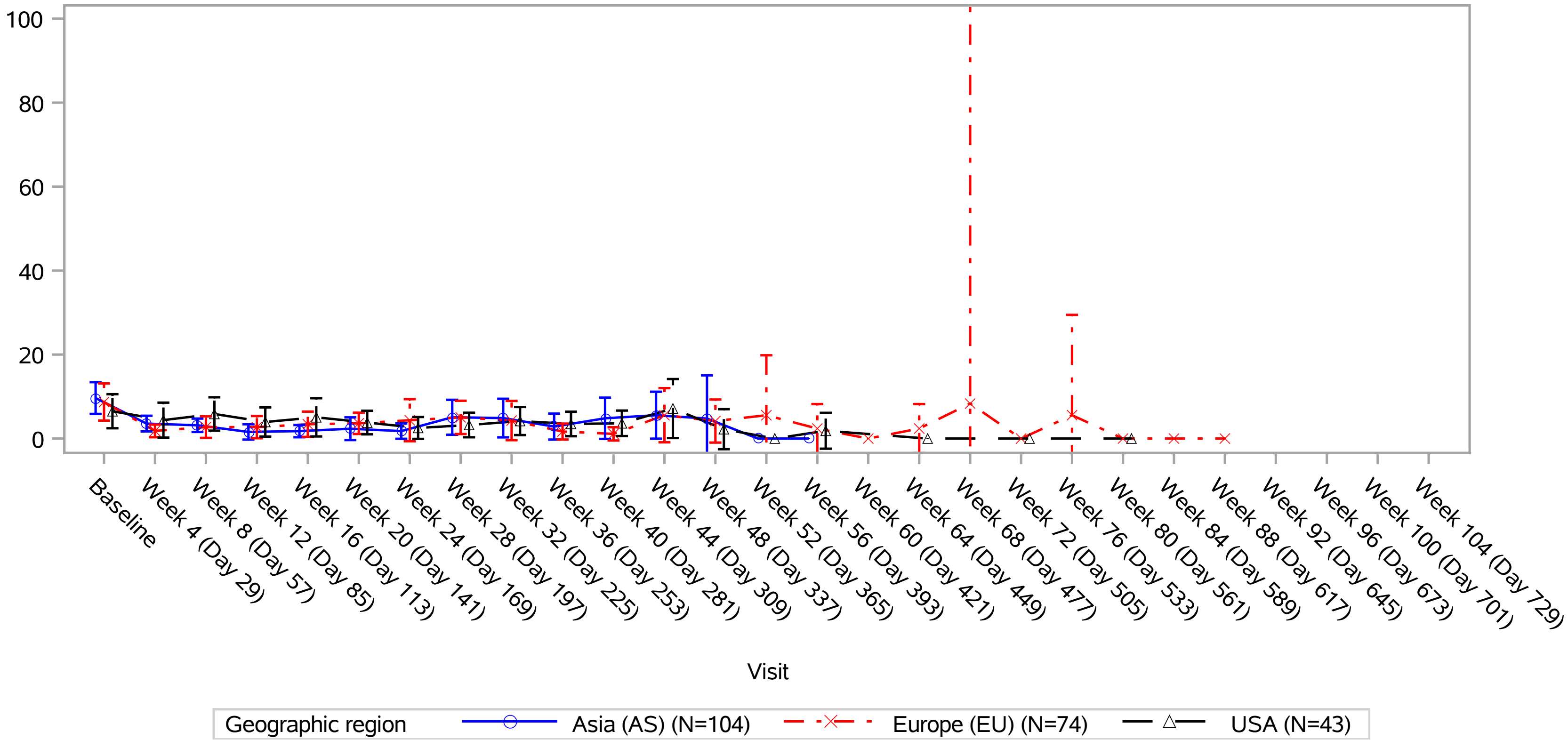
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Nausea and vomiting
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30NV_SGECOG.pdf
15OCT2021 18:06

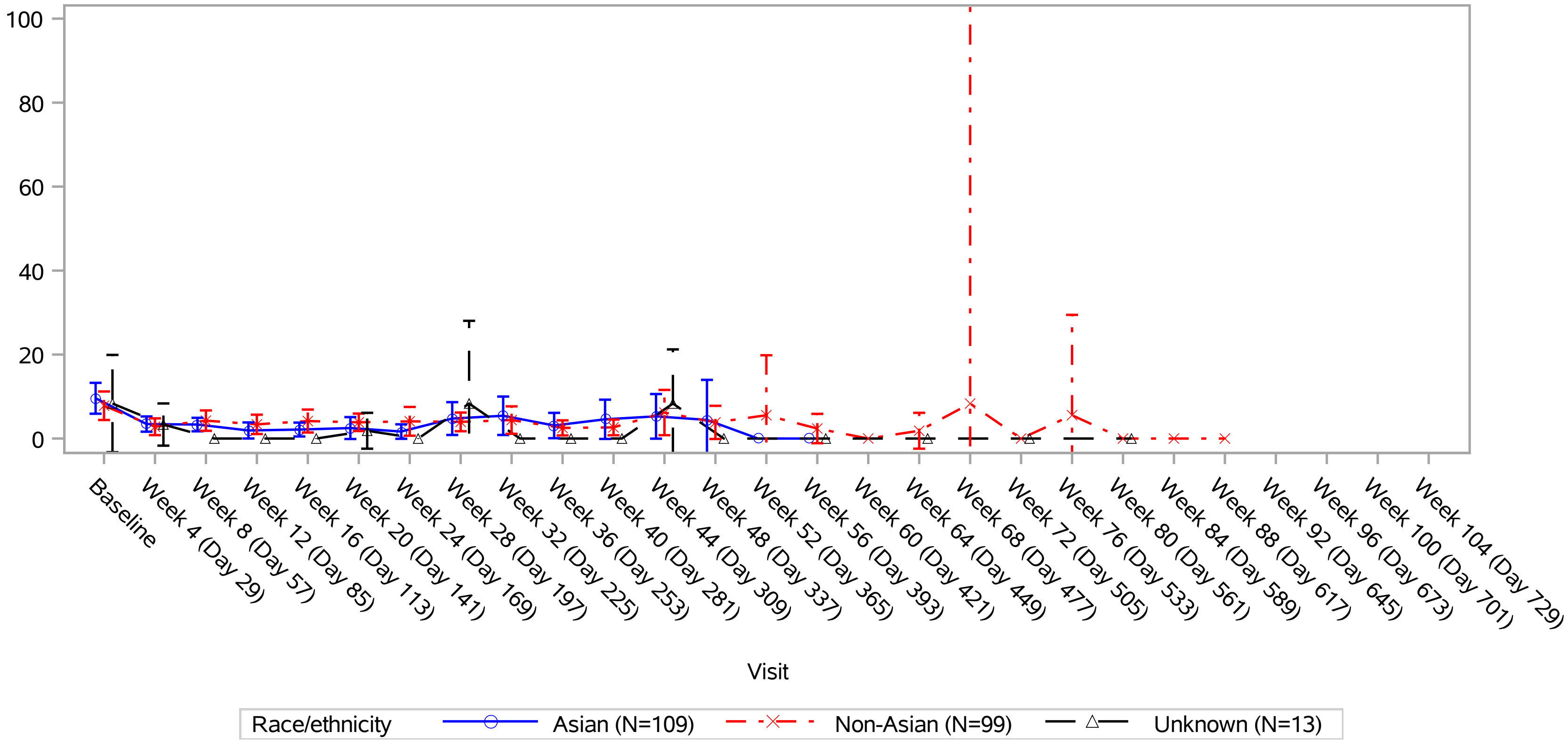
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Nausea and vomiting
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30NV_SGGEO.pdf
15OCT2021 18:37

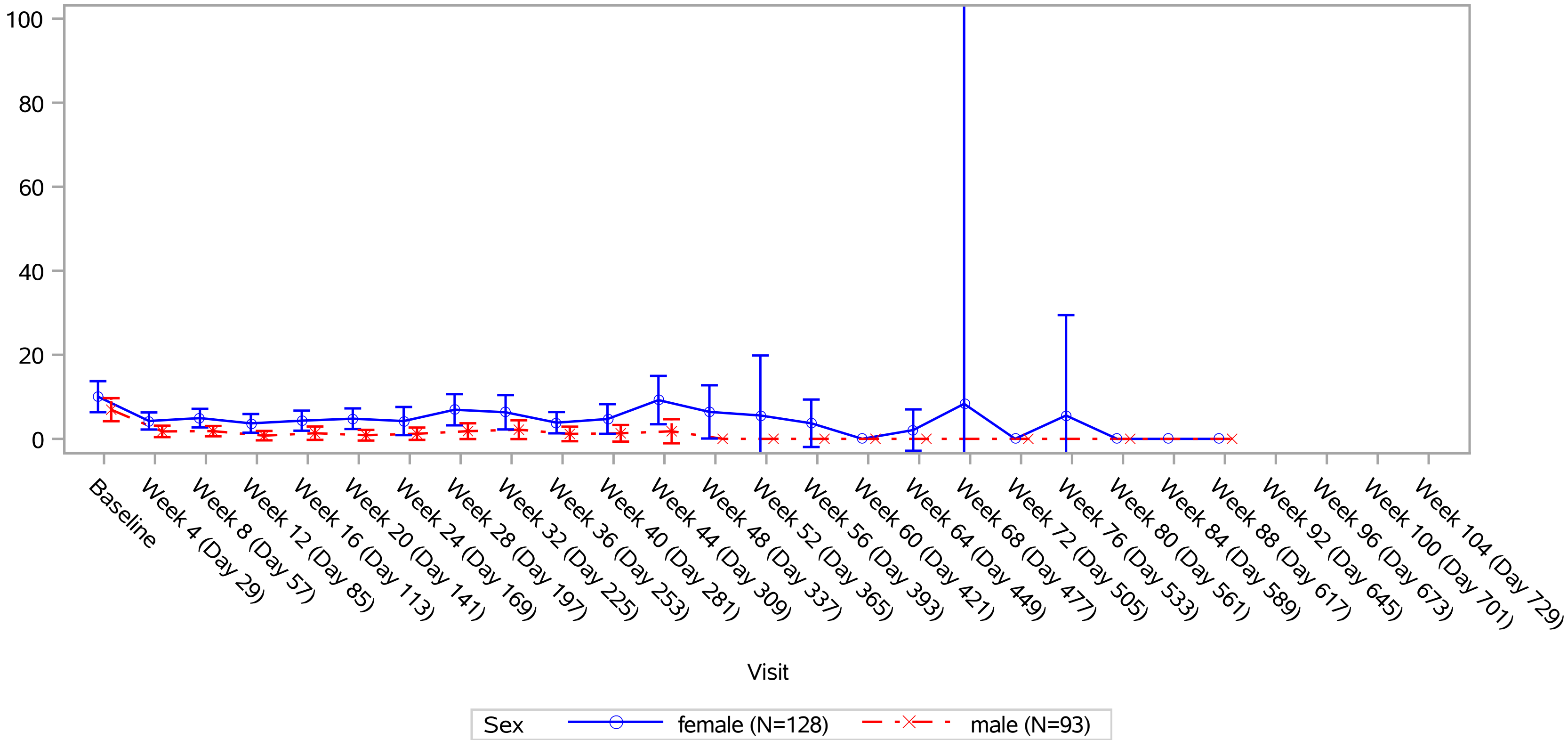
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Nausea and vomiting
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30NV_SGRE.pdf
15OCT2021 19:08

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Nausea and vomiting
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30NV_SGSEX.pdf
15OCT2021 19:38

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Pain
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=221)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	221	100.0	212	95.9	25.47	28.36	21.63	29.31
Week 4 (Day 29)	n/a	221	100.0	191	86.4	14.57	22.13	11.41	17.73
Week 8 (Day 57)	n/a	193	87.3	171	88.6	11.70	19.21	8.80	14.60
Week 12 (Day 85)	n/a	176	79.6	161	91.5	11.70	18.24	8.86	14.54
Week 16 (Day 113)	n/a	164	74.2	143	87.2	11.31	16.85	8.52	14.09
Week 20 (Day 141)	n/a	148	67.0	138	93.2	13.77	19.62	10.47	17.07
Week 24 (Day 169)	n/a	137	62.0	122	89.1	11.61	16.99	8.57	14.66
Week 28 (Day 197)	n/a	129	58.4	120	93.0	13.06	19.59	9.51	16.60
Week 32 (Day 225)	n/a	119	53.8	104	87.4	14.26	20.96	10.19	18.34
Week 36 (Day 253)	n/a	112	50.7	95	84.8	12.28	19.17	8.37	16.19
Week 40 (Day 281)	n/a	104	47.1	91	87.5	14.47	20.52	10.20	18.74
Week 44 (Day 309)	n/a	95	43.0	84	88.4	15.28	23.74	10.13	20.43
Week 48 (Day 337)	n/a	81	36.7	45	55.6	14.07	17.75	8.74	19.41
Week 52 (Day 365)	n/a	64	29.0	11	17.2	13.64	16.36	2.65	24.63
Week 56 (Day 393)	n/a	54	24.4	18	33.3	16.67	22.87	5.30	28.04
Week 60 (Day 421)	n/a	43	19.5	2	4.7	16.67	23.57	-195.10	228.44
Week 64 (Day 449)	n/a	41	18.6	12	29.3	16.67	21.32	3.12	30.21
Week 68 (Day 477)	n/a	34	15.4	2	5.9	8.33	11.79	-97.55	114.22
Week 72 (Day 505)	n/a	34	15.4	5	14.7	6.67	14.91	-11.84	25.18
Week 76 (Day 533)	n/a	31	14.0	3	9.7	16.67	16.67	-24.74	58.07
Week 80 (Day 561)	n/a	30	13.6	6	20.0	11.11	17.21	-6.95	29.18
Week 84 (Day 589)	n/a	19	8.6	1	5.3	16.67	NE	NE	NE
Week 88 (Day 617)	n/a	15	6.8	2	13.3	0.00	0.00	NE	NE
Week 92 (Day 645)	n/a	8	3.6	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	2.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	1.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	221	100.0	219	99.1	15.98	23.48	12.85	19.11
End of Study (LOCF)	n/a	221	100.0	219	99.1	15.98	22.20	13.03	18.94
Sex									
Baseline	Female	128	100.0	123	96.1	29.40	29.58	24.12	34.68
Week 4 (Day 29)	Female	128	100.0	106	82.8	16.04	22.99	11.61	20.47
Week 8 (Day 57)	Female	112	87.5	98	87.5	13.95	20.68	9.80	18.09
Week 12 (Day 85)	Female	104	81.3	95	91.3	12.81	19.21	8.89	16.72
Week 16 (Day 113)	Female	96	75.0	81	84.4	12.76	18.12	8.75	16.76
Week 20 (Day 141)	Female	86	67.2	80	93.0	17.29	22.57	12.27	22.31
Week 24 (Day 169)	Female	78	60.9	67	85.9	12.19	16.56	8.15	16.23
Week 28 (Day 197)	Female	72	56.3	65	90.3	15.38	21.10	10.16	20.61
Week 32 (Day 225)	Female	69	53.9	58	84.1	16.38	20.82	10.90	21.85
Week 36 (Day 253)	Female	64	50.0	52	81.3	12.50	17.43	7.65	17.35
Week 40 (Day 281)	Female	59	46.1	53	89.8	15.41	21.14	9.58	21.24
Week 44 (Day 309)	Female	56	43.8	47	83.9	17.38	24.32	10.24	24.52
Week 48 (Day 337)	Female	48	37.5	26	54.2	16.03	19.71	8.06	23.99
Week 52 (Day 365)	Female	38	29.7	6	15.8	19.44	19.48	-1.00	39.89
Week 56 (Day 393)	Female	31	24.2	9	29.0	14.81	17.57	1.31	28.32
Week 60 (Day 421)	Female	27	21.1	1	3.7	33.33	NE	NE	NE
Week 64 (Day 449)	Female	26	20.3	8	30.8	20.83	23.15	1.48	40.18
Week 68 (Day 477)	Female	23	18.0	2	8.7	8.33	11.79	-97.55	114.22
Week 72 (Day 505)	Female	23	18.0	3	13.0	11.11	19.25	-36.70	58.92
Week 76 (Day 533)	Female	21	16.4	3	14.3	16.67	16.67	-24.74	58.07
Week 80 (Day 561)	Female	20	15.6	5	25.0	13.33	18.26	-9.34	36.00
Week 84 (Day 589)	Female	12	9.4	1	8.3	16.67	NE	NE	NE
Week 88 (Day 617)	Female	9	7.0	1	11.1	0.00	NE	NE	NE
Week 92 (Day 645)	Female	6	4.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	3.9	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	1.6	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	0.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	128	100.0	127	99.2	17.06	24.26	12.80	21.32
End of Study (LOCF)	Female	128	100.0	127	99.2	17.59	23.22	13.51	21.66
Baseline	Male	93	100.0	89	95.7	20.04	25.77	14.61	25.47
Week 4 (Day 29)	Male	93	100.0	85	91.4	12.75	20.99	8.22	17.27
Week 8 (Day 57)	Male	81	87.1	73	90.1	8.68	16.69	4.78	12.57
Week 12 (Day 85)	Male	72	77.4	66	91.7	10.10	16.76	5.98	14.22
Week 16 (Day 113)	Male	68	73.1	62	91.2	9.41	14.97	5.61	13.21
Week 20 (Day 141)	Male	62	66.7	58	93.5	8.91	13.32	5.40	12.41
Week 24 (Day 169)	Male	59	63.4	55	93.2	10.91	17.63	6.14	15.68
Week 28 (Day 197)	Male	57	61.3	55	96.5	10.30	17.42	5.59	15.01
Week 32 (Day 225)	Male	50	53.8	46	92.0	11.59	21.04	5.35	17.84
Week 36 (Day 253)	Male	48	51.6	43	89.6	12.02	21.31	5.46	18.57
Week 40 (Day 281)	Male	45	48.4	38	84.4	13.16	19.82	6.64	19.67
Week 44 (Day 309)	Male	39	41.9	37	94.9	12.61	23.04	4.93	20.30
Week 48 (Day 337)	Male	33	35.5	19	57.6	11.40	14.75	4.29	18.51
Week 52 (Day 365)	Male	26	28.0	5	19.2	6.67	9.13	-4.67	18.00
Week 56 (Day 393)	Male	23	24.7	9	39.1	18.52	28.19	-3.15	40.19
Week 60 (Day 421)	Male	16	17.2	1	6.3	0.00	NE	NE	NE
Week 64 (Day 449)	Male	15	16.1	4	26.7	8.33	16.67	-18.19	34.85
Week 68 (Day 477)	Male	11	11.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	11	11.8	2	18.2	0.00	0.00	NE	NE
Week 76 (Day 533)	Male	10	10.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	10	10.8	1	10.0	0.00	NE	NE	NE
Week 84 (Day 589)	Male	7	7.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	6	6.5	1	16.7	0.00	NE	NE	NE
Week 92 (Day 645)	Male	2	2.2	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	93	100.0	92	98.9	14.49	22.40	9.85	19.13
End of Study (LOCF)	Male	93	100.0	92	98.9	13.77	20.61	9.50	18.04
Age									

Baseline	< 65	141	100.0	133	94.3	29.20	29.04	24.22	34.18
Week 4 (Day 29)	< 65	141	100.0	123	87.2	13.96	21.17	10.18	17.73
Week 8 (Day 57)	< 65	127	90.1	113	89.0	12.09	17.00	8.93	15.26
Week 12 (Day 85)	< 65	118	83.7	106	89.8	11.95	16.71	8.73	15.17
Week 16 (Day 113)	< 65	108	76.6	93	86.1	11.11	16.36	7.74	14.48
Week 20 (Day 141)	< 65	100	70.9	97	97.0	13.57	20.03	9.54	17.61
Week 24 (Day 169)	< 65	93	66.0	86	92.5	12.21	17.23	8.52	15.90
Week 28 (Day 197)	< 65	88	62.4	83	94.3	13.45	20.90	8.89	18.02
Week 32 (Day 225)	< 65	83	58.9	73	88.0	12.33	20.23	7.61	17.05
Week 36 (Day 253)	< 65	78	55.3	70	89.7	10.00	16.64	6.03	13.97
Week 40 (Day 281)	< 65	75	53.2	69	92.0	13.77	21.57	8.59	18.95
Week 44 (Day 309)	< 65	71	50.4	65	91.5	14.62	23.85	8.71	20.52
Week 48 (Day 337)	< 65	61	43.3	33	54.1	13.13	16.54	7.27	19.00
Week 52 (Day 365)	< 65	48	34.0	6	12.5	8.33	13.94	-6.30	22.97
Week 56 (Day 393)	< 65	41	29.1	11	26.8	13.64	17.98	1.56	25.71
Week 60 (Day 421)	< 65	33	23.4	2	6.1	16.67	23.57	-195.10	228.44
Week 64 (Day 449)	< 65	31	22.0	10	32.3	11.67	15.81	0.36	22.98
Week 68 (Day 477)	< 65	26	18.4	2	7.7	8.33	11.79	-97.55	114.22
Week 72 (Day 505)	< 65	26	18.4	5	19.2	6.67	14.91	-11.84	25.18
Week 76 (Day 533)	< 65	25	17.7	3	12.0	16.67	16.67	-24.74	58.07
Week 80 (Day 561)	< 65	24	17.0	5	20.8	6.67	14.91	-11.84	25.18
Week 84 (Day 589)	< 65	16	11.3	1	6.3	16.67	NE	NE	NE
Week 88 (Day 617)	< 65	13	9.2	2	15.4	0.00	0.00	NE	NE
Week 92 (Day 645)	< 65	7	5.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	3.5	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	2.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	0.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	141	100.0	139	98.6	15.47	23.28	11.56	19.37
End of Study (LOCF)	< 65	141	100.0	139	98.6	14.99	20.69	11.52	18.46
Baseline	>= 65	80	100.0	79	98.8	19.20	26.16	13.34	25.06
Week 4 (Day 29)	>= 65	80	100.0	68	85.0	15.69	23.90	9.90	21.47
Week 8 (Day 57)	>= 65	66	82.5	58	87.9	10.92	23.06	4.86	16.98
Week 12 (Day 85)	>= 65	58	72.5	55	94.8	11.21	21.05	5.52	16.90

Week 16 (Day 113)	>= 65	56	70.0	50	89.3	11.67	17.90	6.58	16.75
Week 20 (Day 141)	>= 65	48	60.0	41	85.4	14.23	18.84	8.28	20.17
Week 24 (Day 169)	>= 65	44	55.0	36	81.8	10.19	16.56	4.58	15.79
Week 28 (Day 197)	>= 65	41	51.3	37	90.2	12.16	16.50	6.66	17.66
Week 32 (Day 225)	>= 65	36	45.0	31	86.1	18.82	22.25	10.65	26.98
Week 36 (Day 253)	>= 65	34	42.5	25	73.5	18.67	24.21	8.67	28.66
Week 40 (Day 281)	>= 65	29	36.3	22	75.9	16.67	17.06	9.10	24.23
Week 44 (Day 309)	>= 65	24	30.0	19	79.2	17.54	23.88	6.03	29.05
Week 48 (Day 337)	>= 65	20	25.0	12	60.0	16.67	21.32	3.12	30.21
Week 52 (Day 365)	>= 65	16	20.0	5	31.3	20.00	18.26	-2.67	42.67
Week 56 (Day 393)	>= 65	13	16.3	7	53.8	21.43	29.99	-6.31	49.17
Week 60 (Day 421)	>= 65	10	12.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	10	12.5	2	20.0	41.67	35.36	-275.99	359.32
Week 68 (Day 477)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	6	7.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	6	7.5	1	16.7	33.33	NE	NE	NE
Week 84 (Day 589)	>= 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	2.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	80	100.0	80	100.0	16.88	23.94	11.55	22.20
End of Study (LOCF)	>= 65	80	100.0	80	100.0	17.71	24.64	12.22	23.19
ECOG performance status									
Baseline	0	63	100.0	60	95.2	26.11	29.65	18.45	33.77
Week 4 (Day 29)	0	63	100.0	56	88.9	19.05	27.78	11.61	26.49
Week 8 (Day 57)	0	58	92.1	52	89.7	15.06	21.96	8.95	21.18
Week 12 (Day 85)	0	55	87.3	50	90.9	14.00	17.93	8.90	19.10
Week 16 (Day 113)	0	54	85.7	45	83.3	13.33	20.29	7.24	19.43
Week 20 (Day 141)	0	52	82.5	48	92.3	12.15	18.43	6.80	17.50
Week 24 (Day 169)	0	49	77.8	43	87.8	9.30	14.23	4.92	13.68
Week 28 (Day 197)	0	46	73.0	42	91.3	11.11	19.36	5.08	17.14

Week 32 (Day 225)	0	41	65.1	34	82.9	12.25	18.03	5.96	18.55
Week 36 (Day 253)	0	39	61.9	31	79.5	10.75	18.53	3.95	17.55
Week 40 (Day 281)	0	37	58.7	30	81.1	14.44	18.94	7.37	21.52
Week 44 (Day 309)	0	36	57.1	29	80.6	17.24	27.27	6.87	27.61
Week 48 (Day 337)	0	28	44.4	18	64.3	17.59	20.98	7.16	28.03
Week 52 (Day 365)	0	27	42.9	6	22.2	13.89	22.15	-9.36	37.14
Week 56 (Day 393)	0	24	38.1	8	33.3	22.92	28.08	-0.56	46.40
Week 60 (Day 421)	0	21	33.3	1	4.8	33.33	NE	NE	NE
Week 64 (Day 449)	0	21	33.3	7	33.3	23.81	25.20	0.51	47.11
Week 68 (Day 477)	0	17	27.0	1	5.9	16.67	NE	NE	NE
Week 72 (Day 505)	0	17	27.0	2	11.8	16.67	23.57	-195.10	228.44
Week 76 (Day 533)	0	15	23.8	2	13.3	25.00	11.79	-80.89	130.89
Week 80 (Day 561)	0	14	22.2	1	7.1	0.00	NE	NE	NE
Week 84 (Day 589)	0	11	17.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	10	15.9	1	10.0	0.00	NE	NE	NE
Week 92 (Day 645)	0	5	7.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	6.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	4.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	63	100.0	63	100.0	18.78	26.52	12.10	25.46
End of Study (LOCF)	0	63	100.0	63	100.0	19.05	25.37	12.66	25.44
Baseline	1	157	100.0	151	96.2	25.28	28.01	20.77	29.78
Week 4 (Day 29)	1	157	100.0	134	85.4	12.69	19.19	9.41	15.97
Week 8 (Day 57)	1	134	85.4	119	88.8	10.22	17.78	7.00	13.45
Week 12 (Day 85)	1	121	77.1	111	91.7	10.66	18.37	7.21	14.12
Week 16 (Day 113)	1	110	70.1	98	89.1	10.37	15.04	7.36	13.39
Week 20 (Day 141)	1	96	61.1	90	93.8	14.63	20.27	10.38	18.88
Week 24 (Day 169)	1	88	56.1	79	89.8	12.87	18.29	8.77	16.97
Week 28 (Day 197)	1	83	52.9	78	94.0	14.10	19.75	9.65	18.56
Week 32 (Day 225)	1	78	49.7	70	89.7	15.24	22.30	9.92	20.55
Week 36 (Day 253)	1	73	46.5	64	87.7	13.02	19.58	8.13	17.91
Week 40 (Day 281)	1	67	42.7	61	91.0	14.48	21.40	9.00	19.96

Week 44 (Day 309)	1	59	37.6	55	93.2	14.24	21.85	8.33	20.15
Week 48 (Day 337)	1	53	33.8	27	50.9	11.73	15.20	5.71	17.74
Week 52 (Day 365)	1	37	23.6	5	13.5	13.33	7.45	4.08	22.59
Week 56 (Day 393)	1	30	19.1	10	33.3	11.67	17.66	-0.96	24.30
Week 60 (Day 421)	1	22	14.0	1	4.5	0.00	NE	NE	NE
Week 64 (Day 449)	1	20	12.7	5	25.0	6.67	9.13	-4.67	18.00
Week 68 (Day 477)	1	17	10.8	1	5.9	0.00	NE	NE	NE
Week 72 (Day 505)	1	17	10.8	3	17.6	0.00	0.00	NE	NE
Week 76 (Day 533)	1	16	10.2	1	6.3	0.00	NE	NE	NE
Week 80 (Day 561)	1	16	10.2	5	31.3	13.33	18.26	-9.34	36.00
Week 84 (Day 589)	1	8	5.1	1	12.5	16.67	NE	NE	NE
Week 88 (Day 617)	1	5	3.2	1	20.0	0.00	NE	NE	NE
Week 92 (Day 645)	1	3	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	157	100.0	155	98.7	14.84	22.20	11.32	18.36
End of Study (LOCF)	1	157	100.0	155	98.7	14.73	20.80	11.43	18.03
Baseline	Missing	1	100.0	1	100.0	16.67	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	16.67	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	16.67	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	16.67	NE	NE	NE
Geographic region									
Baseline	USA	43	100.0	41	95.3	21.54	25.07	13.63	29.46
Week 4 (Day 29)	USA	43	100.0	38	88.4	17.11	25.55	8.71	25.50
Week 8 (Day 57)	USA	41	95.3	37	90.2	11.71	20.74	4.80	18.63
Week 12 (Day 85)	USA	41	95.3	38	92.7	12.72	21.38	5.69	19.75
Week 16 (Day 113)	USA	40	93.0	33	82.5	10.10	15.56	4.58	15.62
Week 20 (Day 141)	USA	39	90.7	35	89.7	14.76	21.30	7.44	22.08
Week 24 (Day 169)	USA	36	83.7	33	91.7	9.60	16.68	3.68	15.51
Week 28 (Day 197)	USA	35	81.4	31	88.6	9.68	18.65	2.84	16.52
Week 32 (Day 225)	USA	32	74.4	28	87.5	19.64	25.68	9.68	29.60
Week 36 (Day 253)	USA	32	74.4	24	75.0	16.67	24.08	6.50	26.83
Week 40 (Day 281)	USA	29	67.4	23	79.3	21.01	27.16	9.27	32.76

Week 44 (Day 309)	USA	26	60.5	21	80.8	20.63	29.77	7.08	34.19
Week 48 (Day 337)	USA	21	48.8	15	71.4	12.22	14.73	4.07	20.38
Week 52 (Day 365)	USA	18	41.9	1	5.6	0.00	NE	NE	NE
Week 56 (Day 393)	USA	18	41.9	9	50.0	24.07	27.78	2.72	45.43
Week 60 (Day 421)	USA	17	39.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	15	34.9	5	33.3	10.00	14.91	-8.51	28.51
Week 68 (Day 477)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	12	27.9	1	8.3	0.00	NE	NE	NE
Week 76 (Day 533)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	12	27.9	2	16.7	33.33	0.00	NE	NE
Week 84 (Day 589)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	6	14.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	11.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	7.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	43	100.0	43	100.0	17.83	27.07	9.50	26.16
End of Study (LOCF)	USA	43	100.0	43	100.0	17.83	23.68	10.54	25.12
Baseline	Europe (EU)	74	100.0	69	93.2	32.37	32.58	24.54	40.19
Week 4 (Day 29)	Europe (EU)	74	100.0	64	86.5	16.67	23.19	10.87	22.46
Week 8 (Day 57)	Europe (EU)	65	87.8	55	84.6	16.67	21.75	10.79	22.55
Week 12 (Day 85)	Europe (EU)	57	77.0	49	86.0	14.63	18.20	9.40	19.85
Week 16 (Day 113)	Europe (EU)	55	74.3	44	80.0	18.56	22.51	11.72	25.40
Week 20 (Day 141)	Europe (EU)	49	66.2	46	93.9	17.75	21.49	11.37	24.13
Week 24 (Day 169)	Europe (EU)	47	63.5	42	89.4	17.46	19.81	11.29	23.63
Week 28 (Day 197)	Europe (EU)	45	60.8	43	95.6	16.67	22.42	9.77	23.57
Week 32 (Day 225)	Europe (EU)	39	52.7	35	89.7	13.33	17.99	7.15	19.51
Week 36 (Day 253)	Europe (EU)	34	45.9	30	88.2	10.56	14.83	5.02	16.09
Week 40 (Day 281)	Europe (EU)	31	41.9	30	96.8	11.67	16.46	5.52	17.81
Week 44 (Day 309)	Europe (EU)	28	37.8	24	85.7	18.06	25.50	7.29	28.82

Week 48 (Day 337)	Europe (EU)	22	29.7	16	72.7	19.79	18.48	9.95	29.64
Week 52 (Day 365)	Europe (EU)	19	25.7	6	31.6	16.67	21.08	-5.46	38.79
Week 56 (Day 393)	Europe (EU)	17	23.0	7	41.2	11.90	15.85	-2.76	26.57
Week 60 (Day 421)	Europe (EU)	15	20.3	2	13.3	16.67	23.57	-195.10	228.44
Week 64 (Day 449)	Europe (EU)	15	20.3	7	46.7	21.43	24.93	-1.63	44.49
Week 68 (Day 477)	Europe (EU)	13	17.6	2	15.4	8.33	11.79	-97.55	114.22
Week 72 (Day 505)	Europe (EU)	13	17.6	4	30.8	8.33	16.67	-18.19	34.85
Week 76 (Day 533)	Europe (EU)	11	14.9	3	27.3	16.67	16.67	-24.74	58.07
Week 80 (Day 561)	Europe (EU)	10	13.5	4	40.0	0.00	0.00	NE	NE
Week 84 (Day 589)	Europe (EU)	6	8.1	1	16.7	16.67	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	4.1	2	66.7	0.00	0.00	NE	NE
Cycle 12 (LOCF)	Europe (EU)	74	100.0	73	98.6	18.04	24.49	12.32	23.75
End of Study (LOCF)	Europe (EU)	74	100.0	73	98.6	17.35	22.98	11.99	22.71
Baseline	Asia (AS)	104	100.0	102	98.1	22.39	25.85	17.31	27.46
Week 4 (Day 29)	Asia (AS)	104	100.0	89	85.6	11.99	19.62	7.85	16.12
Week 8 (Day 57)	Asia (AS)	87	83.7	79	90.8	8.23	15.76	4.70	11.76
Week 12 (Day 85)	Asia (AS)	78	75.0	74	94.9	9.23	16.35	5.45	13.02
Week 16 (Day 113)	Asia (AS)	69	66.3	66	95.7	7.07	10.57	4.47	9.67
Week 20 (Day 141)	Asia (AS)	60	57.7	57	95.0	9.94	16.32	5.61	14.27
Week 24 (Day 169)	Asia (AS)	54	51.9	47	87.0	7.80	12.93	4.00	11.60
Week 28 (Day 197)	Asia (AS)	49	47.1	46	93.9	11.96	17.09	6.88	17.03
Week 32 (Day 225)	Asia (AS)	48	46.2	41	85.4	11.38	19.52	5.22	17.54
Week 36 (Day 253)	Asia (AS)	46	44.2	41	89.1	10.98	18.86	5.02	16.93
Week 40 (Day 281)	Asia (AS)	44	42.3	38	86.4	12.72	18.35	6.69	18.75
Week 44 (Day 309)	Asia (AS)	41	39.4	39	95.1	10.68	18.13	4.81	16.56
Week 48 (Day 337)	Asia (AS)	38	36.5	14	36.8	9.52	19.30	-1.62	20.67
Week 52 (Day 365)	Asia (AS)	27	26.0	4	14.8	12.50	8.33	-0.76	25.76
Week 56 (Day 393)	Asia (AS)	19	18.3	2	10.5	0.00	0.00	NE	NE
Week 60 (Day 421)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	5.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	104	100.0	103	99.0	13.75	21.06	9.64	17.87
End of Study (LOCF)	Asia (AS)	104	100.0	103	99.0	14.24	21.06	10.12	18.35
Race/ethnicity									
Baseline	Asian	109	100.0	106	97.2	22.17	26.00	17.16	27.18
Week 4 (Day 29)	Asian	109	100.0	92	84.4	11.78	19.38	7.76	15.79
Week 8 (Day 57)	Asian	91	83.5	80	87.9	8.54	15.91	5.00	12.08
Week 12 (Day 85)	Asian	82	75.2	78	95.1	9.62	16.45	5.91	13.32
Week 16 (Day 113)	Asian	73	67.0	70	95.9	7.38	10.86	4.79	9.97
Week 20 (Day 141)	Asian	64	58.7	60	93.8	11.11	17.80	6.51	15.71
Week 24 (Day 169)	Asian	57	52.3	50	87.7	8.00	13.14	4.26	11.74
Week 28 (Day 197)	Asian	52	47.7	49	94.2	11.56	16.74	6.76	16.37
Week 32 (Day 225)	Asian	50	45.9	43	86.0	12.02	20.03	5.85	18.18
Week 36 (Day 253)	Asian	48	44.0	43	89.6	10.47	18.55	4.76	16.17
Week 40 (Day 281)	Asian	46	42.2	40	87.0	13.33	18.18	7.52	19.15
Week 44 (Day 309)	Asian	43	39.4	41	95.3	10.57	17.78	4.96	16.18
Week 48 (Day 337)	Asian	40	36.7	15	37.5	8.89	18.76	-1.50	19.28
Week 52 (Day 365)	Asian	29	26.6	5	17.2	10.00	9.13	-1.33	21.33
Week 56 (Day 393)	Asian	21	19.3	3	14.3	5.56	9.62	-18.35	29.46
Week 60 (Day 421)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	5.5	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	4.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	1.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	109	100.0	107	98.2	14.02	21.37	9.92	18.11
End of Study (LOCF)	Asian	109	100.0	107	98.2	14.49	21.36	10.39	18.58
Baseline	Non-Asian	99	100.0	96	97.0	28.65	29.09	22.75	34.54
Week 4 (Day 29)	Non-Asian	99	100.0	89	89.9	14.98	20.57	10.65	19.32
Week 8 (Day 57)	Non-Asian	91	91.9	82	90.1	12.60	19.87	8.24	16.97
Week 12 (Day 85)	Non-Asian	83	83.8	74	89.2	12.39	18.92	8.00	16.77
Week 16 (Day 113)	Non-Asian	80	80.8	68	85.0	14.46	20.34	9.54	19.38
Week 20 (Day 141)	Non-Asian	74	74.7	69	93.2	14.98	20.64	10.02	19.93
Week 24 (Day 169)	Non-Asian	70	70.7	65	92.9	13.59	19.07	8.86	18.31
Week 28 (Day 197)	Non-Asian	67	67.7	63	94.0	13.23	20.34	8.11	18.35
Week 32 (Day 225)	Non-Asian	60	60.6	53	88.3	16.67	22.65	10.42	22.91
Week 36 (Day 253)	Non-Asian	55	55.6	46	83.6	13.41	20.07	7.45	19.37
Week 40 (Day 281)	Non-Asian	49	49.5	44	89.8	14.77	22.79	7.84	21.70
Week 44 (Day 309)	Non-Asian	43	43.4	35	81.4	19.05	26.55	9.93	28.17
Week 48 (Day 337)	Non-Asian	35	35.4	26	74.3	17.95	16.95	11.10	24.79
Week 52 (Day 365)	Non-Asian	29	29.3	6	20.7	16.67	21.08	-5.46	38.79
Week 56 (Day 393)	Non-Asian	27	27.3	14	51.9	20.24	24.62	6.03	34.45
Week 60 (Day 421)	Non-Asian	26	26.3	2	7.7	16.67	23.57	-195.10	228.44
Week 64 (Day 449)	Non-Asian	24	24.2	9	37.5	16.67	23.57	-1.45	34.78
Week 68 (Day 477)	Non-Asian	20	20.2	2	10.0	8.33	11.79	-97.55	114.22
Week 72 (Day 505)	Non-Asian	20	20.2	3	15.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Non-Asian	18	18.2	3	16.7	16.67	16.67	-24.74	58.07
Week 80 (Day 561)	Non-Asian	17	17.2	5	29.4	13.33	18.26	-9.34	36.00
Week 84 (Day 589)	Non-Asian	11	11.1	1	9.1	16.67	NE	NE	NE
Week 88 (Day 617)	Non-Asian	8	8.1	2	25.0	0.00	0.00	NE	NE
Week 92 (Day 645)	Non-Asian	4	4.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	3.0	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	99	100.0	99	100.0	17.34	24.62	12.43	22.25

End of Study (LOCF)	Non-Asian	99	100.0	99	100.0	17.51	23.37	12.85	22.17
Baseline	Unknown	13	100.0	10	76.9	30.00	42.16	-0.16	60.16
Week 4 (Day 29)	Unknown	13	100.0	10	76.9	36.67	42.16	6.50	66.83
Week 8 (Day 57)	Unknown	11	84.6	9	81.8	31.48	28.19	9.81	53.15
Week 12 (Day 85)	Unknown	11	84.6	9	81.8	24.07	23.73	5.83	42.32
Week 16 (Day 113)	Unknown	11	84.6	5	45.5	23.33	22.36	-4.43	51.10
Week 20 (Day 141)	Unknown	10	76.9	9	90.0	22.22	22.05	5.27	39.17
Week 24 (Day 169)	Unknown	10	76.9	7	70.0	19.05	17.82	2.57	35.53
Week 28 (Day 197)	Unknown	10	76.9	8	80.0	20.83	29.21	-3.59	45.25
Week 32 (Day 225)	Unknown	9	69.2	8	88.9	10.42	12.40	0.05	20.78
Week 36 (Day 253)	Unknown	9	69.2	6	66.7	16.67	18.26	-2.49	35.83
Week 40 (Day 281)	Unknown	9	69.2	7	77.8	19.05	20.25	0.32	37.78
Week 44 (Day 309)	Unknown	9	69.2	8	88.9	22.92	34.43	-5.87	51.70
Week 48 (Day 337)	Unknown	6	46.2	4	66.7	8.33	16.67	-18.19	34.85
Week 52 (Day 365)	Unknown	6	46.2	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	6	46.2	1	16.7	0.00	NE	NE	NE
Week 60 (Day 421)	Unknown	5	38.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	5	38.5	3	60.0	16.67	16.67	-24.74	58.07
Week 68 (Day 477)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	4	30.8	2	50.0	16.67	23.57	-195.10	228.44
Week 76 (Day 533)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	4	30.8	1	25.0	0.00	NE	NE	NE
Week 84 (Day 589)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	7.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	13	100.0	13	100.0	21.79	30.72	3.23	40.36
End of Study (LOCF)	Unknown	13	100.0	13	100.0	16.67	20.41	4.33	29.00

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TO_QSC30PA_SG.xls
27OCT2021 7:17

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Pain
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	68	32.1	26.2	38.6
	Cycle 12 (LOCF)	n/a	212	95.9	31	14.6	10.5	20.0
	End of Study (LOCF)	n/a	212	95.9	34	16.0	11.7	21.6
Sex	All visits	Female	123	55.7	33	26.8	19.8	35.3
		Male	89	40.3	35	39.3	29.8	49.7
	Cycle 12 (LOCF)	Female	123	55.7	15	12.2	7.5	19.1
		Male	89	40.3	16	18.0	11.4	27.2
	End of Study (LOCF)	Female	123	55.7	19	15.4	10.1	22.9
		Male	89	40.3	15	16.9	10.5	26.0
Age	All visits	< 65	133	60.2	34	25.6	18.9	33.6
		>= 65	79	35.7	34	43.0	32.7	54.0
	Cycle 12 (LOCF)	< 65	133	60.2	13	9.8	5.8	16.0
		>= 65	79	35.7	18	22.8	14.9	33.2
	End of Study (LOCF)	< 65	133	60.2	15	11.3	7.0	17.8
		>= 65	79	35.7	19	24.1	16.0	34.5
ECOG performance status	All visits	0	60	27.1	23	38.3	27.1	51.0
		1	151	68.3	45	29.8	23.1	37.5
		Missing	1	0.5	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	60	27.1	11	18.3	10.6	29.9
		1	151	68.3	20	13.2	8.7	19.6
		Missing	1	0.5	0	0.0	0.0	79.3
	End of Study (LOCF)	0	60	27.1	13	21.7	13.1	33.6
		1	151	68.3	21	13.9	9.3	20.3
		Missing	1	0.5	0	0.0	0.0	79.3
Geographic region	All visits	USA	41	18.6	19	46.3	32.1	61.3
		Europe (EU)	69	31.2	20	29.0	19.6	40.6
		Asia (AS)	102	46.2	29	28.4	20.6	37.8
	Cycle 12 (LOCF)	USA	41	18.6	8	19.5	10.2	34.0
		Europe (EU)	69	31.2	8	11.6	6.0	21.2
		Asia (AS)	102	46.2	15	14.7	9.1	22.9
	End of Study (LOCF)	USA	41	18.6	10	24.4	13.8	39.3
		Europe (EU)	69	31.2	9	13.0	7.0	23.0
		Asia (AS)	102	46.2	15	14.7	9.1	22.9
Race/ethnicity	All visits	Asian	106	48.0	31	29.2	21.4	38.5
		Non-Asian	96	43.4	35	36.5	27.5	46.4
		Unknown	10	4.5	2	20.0	5.7	51.0
	Cycle 12 (LOCF)	Asian	106	48.0	16	15.1	9.5	23.1

		Non-Asian	96	43.4	14	14.6	8.9	23.0
		Unknown	10	4.5	1	10.0	1.8	40.4
	End of Study (LOCF)	Asian	106	48.0	16	15.1	9.5	23.1
		Non-Asian	96	43.4	17	17.7	11.4	26.5
		Unknown	10	4.5	1	10.0	1.8	40.4

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30PA_W10_SG.xls
15OCT2021 12:55

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Pain
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

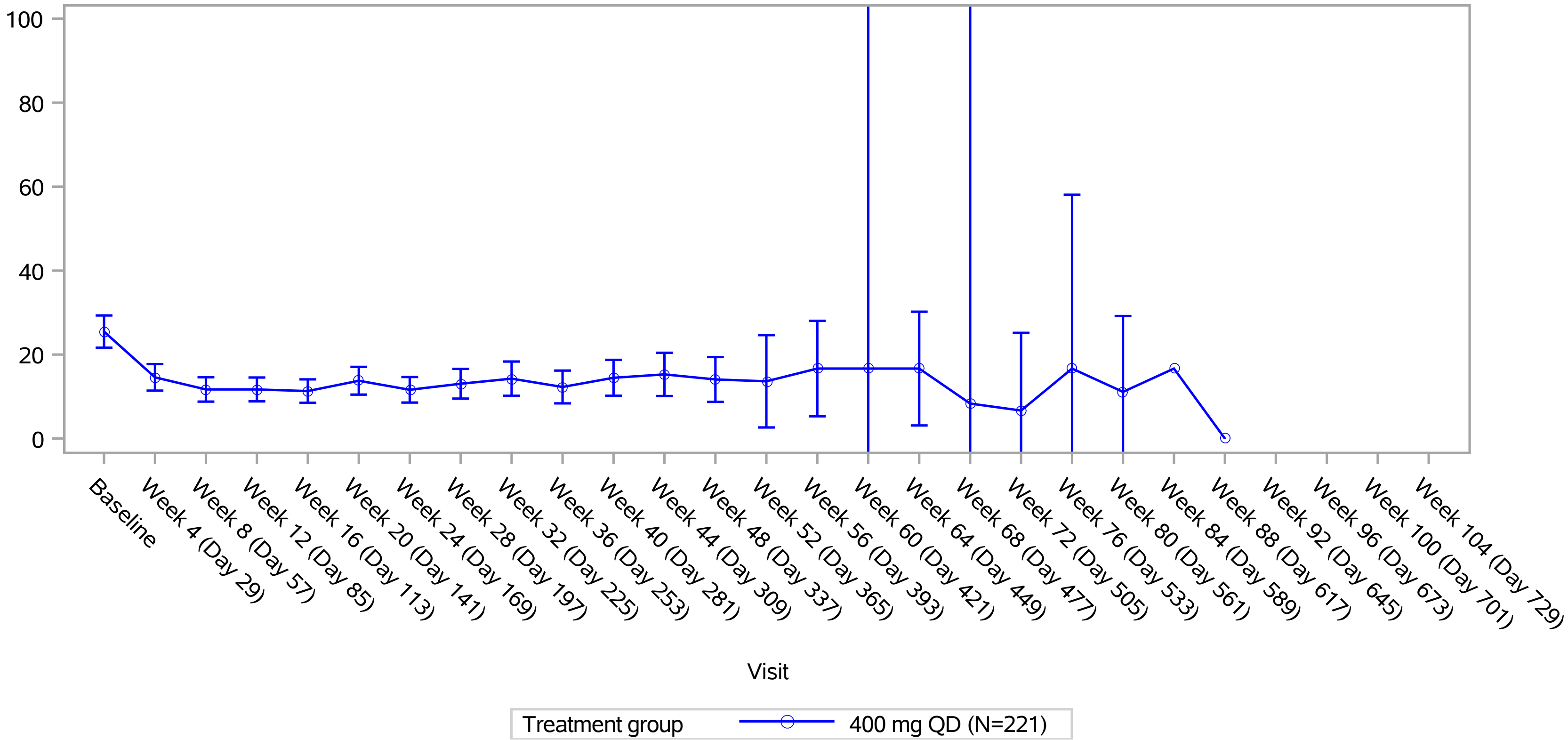
			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	68	32.1	26.2	38.6
	Cycle 12 (LOCF)	n/a	212	95.9	31	14.6	10.5	20.0
	End of Study (LOCF)	n/a	212	95.9	34	16.0	11.7	21.6
Sex	All visits	Female	123	55.7	33	26.8	19.8	35.3
		Male	89	40.3	35	39.3	29.8	49.7
	Cycle 12 (LOCF)	Female	123	55.7	15	12.2	7.5	19.1
		Male	89	40.3	16	18.0	11.4	27.2
	End of Study (LOCF)	Female	123	55.7	19	15.4	10.1	22.9
		Male	89	40.3	15	16.9	10.5	26.0
Age	All visits	< 65	133	60.2	34	25.6	18.9	33.6
		>= 65	79	35.7	34	43.0	32.7	54.0
	Cycle 12 (LOCF)	< 65	133	60.2	13	9.8	5.8	16.0
		>= 65	79	35.7	18	22.8	14.9	33.2
	End of Study (LOCF)	< 65	133	60.2	15	11.3	7.0	17.8
		>= 65	79	35.7	19	24.1	16.0	34.5
ECOG performance status	All visits	0	60	27.1	23	38.3	27.1	51.0
		1	151	68.3	45	29.8	23.1	37.5
		Missing	1	0.5	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	60	27.1	11	18.3	10.6	29.9
		1	151	68.3	20	13.2	8.7	19.6
		Missing	1	0.5	0	0.0	0.0	79.3
	End of Study (LOCF)	0	60	27.1	13	21.7	13.1	33.6
		1	151	68.3	21	13.9	9.3	20.3
		Missing	1	0.5	0	0.0	0.0	79.3
Geographic region	All visits	USA	41	18.6	19	46.3	32.1	61.3
		Europe (EU)	69	31.2	20	29.0	19.6	40.6
		Asia (AS)	102	46.2	29	28.4	20.6	37.8
	Cycle 12 (LOCF)	USA	41	18.6	8	19.5	10.2	34.0
		Europe (EU)	69	31.2	8	11.6	6.0	21.2
		Asia (AS)	102	46.2	15	14.7	9.1	22.9
	End of Study (LOCF)	USA	41	18.6	10	24.4	13.8	39.3
		Europe (EU)	69	31.2	9	13.0	7.0	23.0
		Asia (AS)	102	46.2	15	14.7	9.1	22.9
Race/ethnicity	All visits	Asian	106	48.0	31	29.2	21.4	38.5
		Non-Asian	96	43.4	35	36.5	27.5	46.4
		Unknown	10	4.5	2	20.0	5.7	51.0
	Cycle 12 (LOCF)	Asian	106	48.0	16	15.1	9.5	23.1

		Non-Asian	96	43.4	14	14.6	8.9	23.0
		Unknown	10	4.5	1	10.0	1.8	40.4
	End of Study (LOCF)	Asian	106	48.0	16	15.1	9.5	23.1
		Non-Asian	96	43.4	17	17.7	11.4	26.5
		Unknown	10	4.5	1	10.0	1.8	40.4

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30PA_W15_SG.xls
15OCT2021 12:45

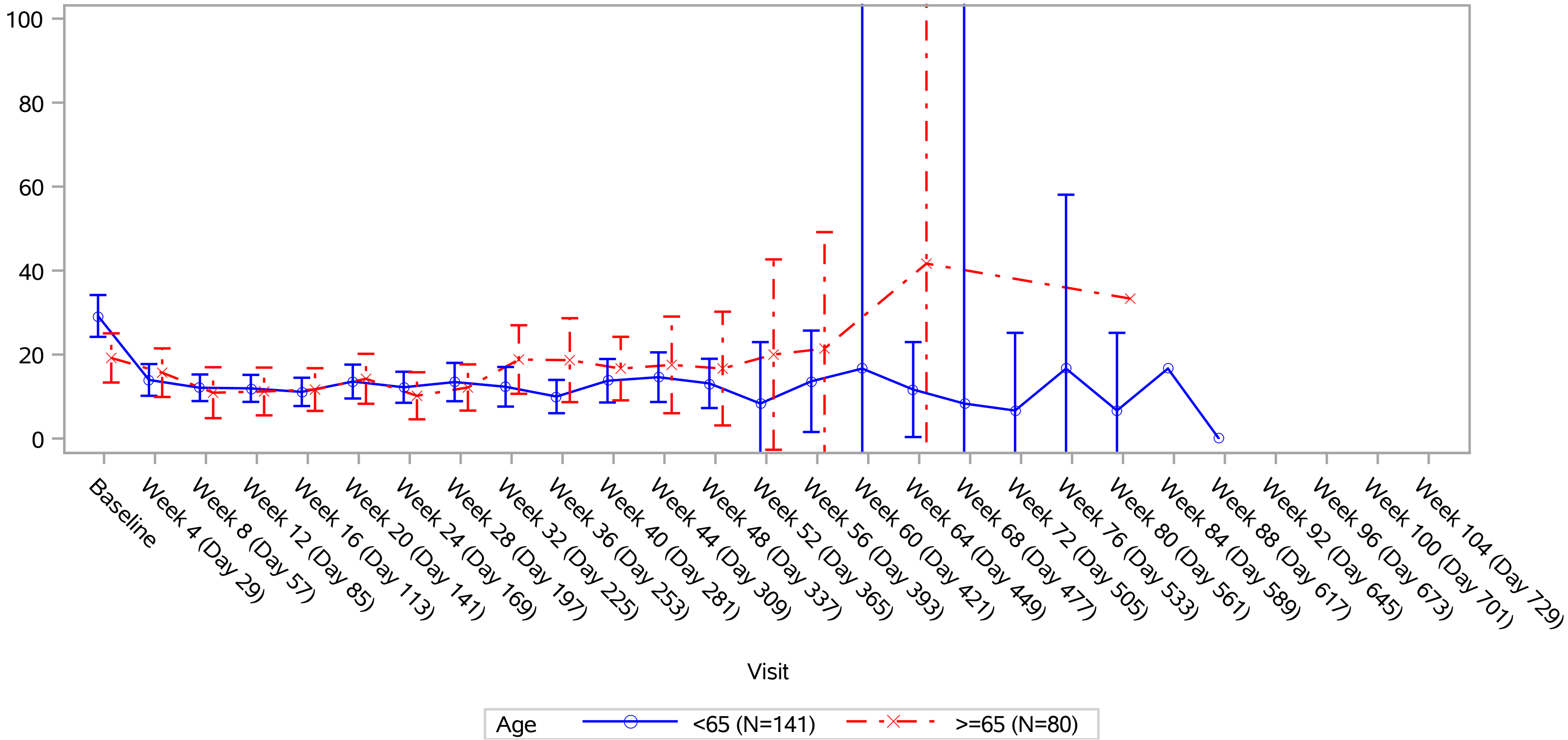
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Pain
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30PA.pdf
15OCT2021 17:08

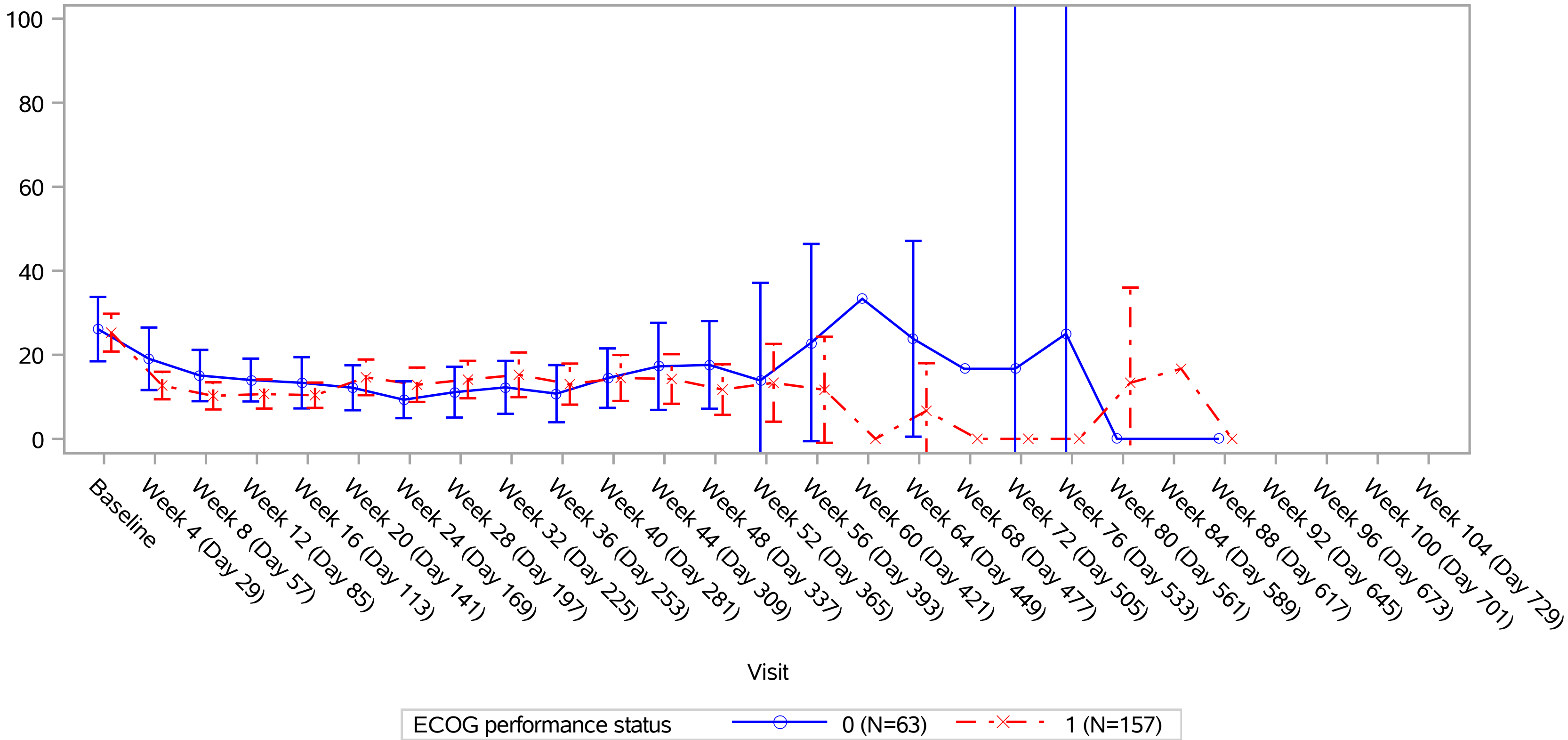
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Pain
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30PA_SGAGE65.pdf
15OCT2021 17:37

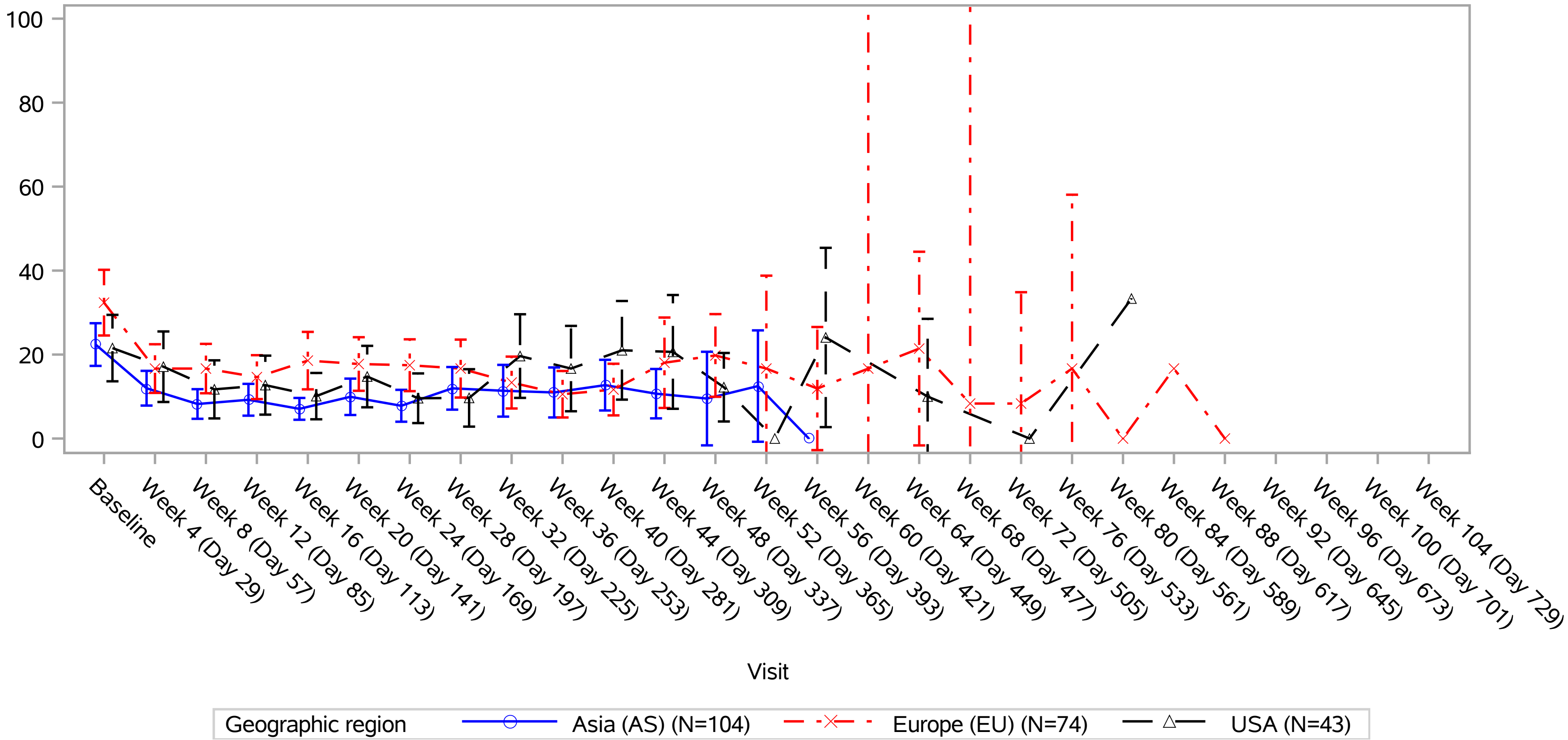
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Pain
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30PA_SGECOG.pdf
15OCT2021 18:07

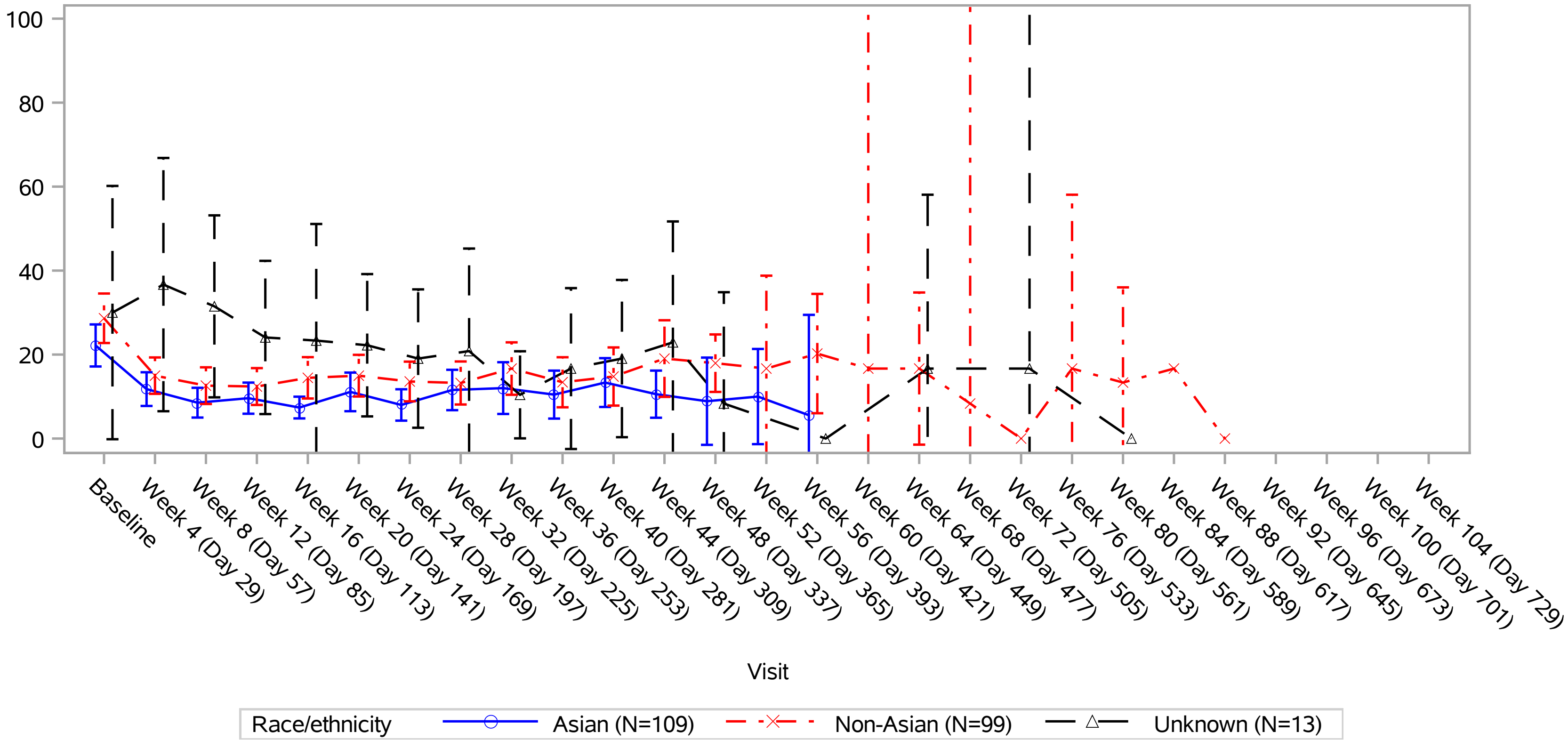
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Pain
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30PA_SGGEO.pdf
15OCT2021 18:38

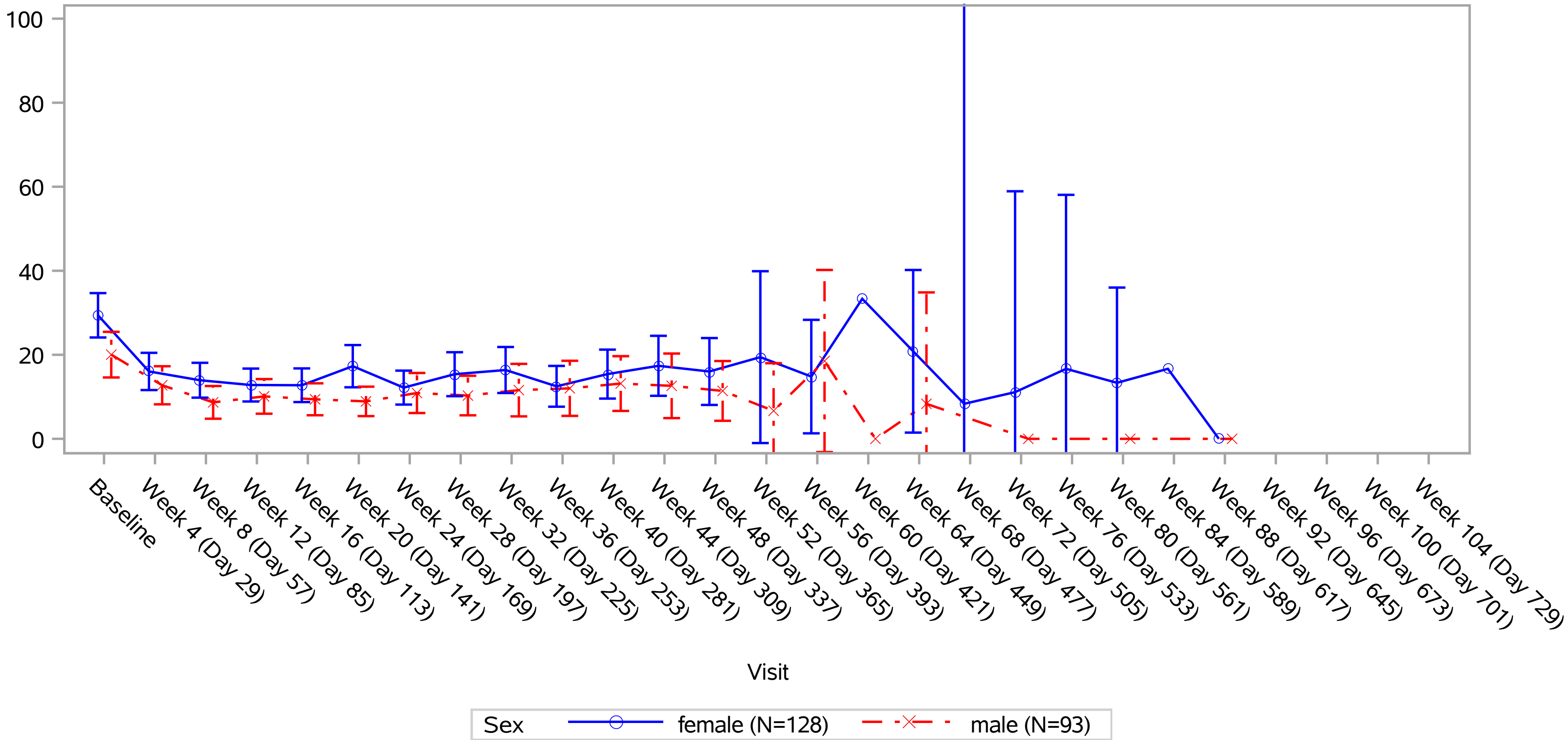
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Pain
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30PA_SGRE.pdf
15OCT2021 19:08

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Pain
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30PA_SGSEX.pdf
15OCT2021 19:39

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Physical functioning
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=221)							
		Patients				Statistics			
Name Visit	Level	in study¹	%	with value¹	%	mean²	SD	CI LL	CI UL
All									
Baseline	n/a	221	100.0	212	95.9	77.52	21.87	74.55	80.48
Week 4 (Day 29)	n/a	221	100.0	191	86.4	84.22	18.11	81.64	86.81
Week 8 (Day 57)	n/a	193	87.3	171	88.6	84.33	16.75	81.80	86.86
Week 12 (Day 85)	n/a	176	79.6	161	91.5	85.07	16.43	82.52	87.63
Week 16 (Day 113)	n/a	164	74.2	143	87.2	83.73	17.52	80.83	86.63
Week 20 (Day 141)	n/a	148	67.0	138	93.2	84.53	18.63	81.39	87.66
Week 24 (Day 169)	n/a	137	62.0	122	89.1	86.12	16.54	83.15	89.09
Week 28 (Day 197)	n/a	129	58.4	120	93.0	86.15	16.67	83.14	89.17
Week 32 (Day 225)	n/a	119	53.8	104	87.4	85.51	18.59	81.90	89.13
Week 36 (Day 253)	n/a	112	50.7	95	84.8	87.65	15.19	84.55	90.74
Week 40 (Day 281)	n/a	104	47.1	91	87.5	87.71	16.16	84.35	91.08
Week 44 (Day 309)	n/a	95	43.0	84	88.4	85.00	20.25	80.61	89.39
Week 48 (Day 337)	n/a	81	36.7	45	55.6	86.22	17.49	80.97	91.48
Week 52 (Day 365)	n/a	64	29.0	11	17.2	80.61	12.81	72.00	89.21
Week 56 (Day 393)	n/a	54	24.4	18	33.3	87.04	11.99	81.08	93.00
Week 60 (Day 421)	n/a	43	19.5	2	4.7	83.33	4.71	40.98	125.69
Week 64 (Day 449)	n/a	41	18.6	12	29.3	88.33	9.90	82.04	94.62
Week 68 (Day 477)	n/a	34	15.4	2	5.9	80.00	0.00	NE	NE
Week 72 (Day 505)	n/a	34	15.4	5	14.7	92.00	10.95	78.40	105.60
Week 76 (Day 533)	n/a	31	14.0	3	9.7	82.22	3.85	72.66	91.78
Week 80 (Day 561)	n/a	30	13.6	6	20.0	92.22	10.68	81.01	103.43
Week 84 (Day 589)	n/a	19	8.6	1	5.3	66.67	NE	NE	NE
Week 88 (Day 617)	n/a	15	6.8	2	13.3	90.00	4.71	47.65	132.35
Week 92 (Day 645)	n/a	8	3.6	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	2.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	1.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	221	100.0	219	99.1	81.16	21.79	78.25	84.06
End of Study (LOCF)	n/a	221	100.0	219	99.1	81.67	20.77	78.91	84.44
Sex									
Baseline	Female	128	100.0	123	96.1	75.01	21.14	71.24	78.79
Week 4 (Day 29)	Female	128	100.0	106	82.8	81.38	18.85	77.75	85.01
Week 8 (Day 57)	Female	112	87.5	98	87.5	80.48	18.44	76.78	84.17
Week 12 (Day 85)	Female	104	81.3	95	91.3	82.05	17.74	78.44	85.67
Week 16 (Day 113)	Female	96	75.0	81	84.4	79.92	19.39	75.63	84.21
Week 20 (Day 141)	Female	86	67.2	80	93.0	81.15	20.69	76.54	85.75
Week 24 (Day 169)	Female	78	60.9	67	85.9	84.18	18.38	79.70	88.66
Week 28 (Day 197)	Female	72	56.3	65	90.3	83.67	19.03	78.95	88.38
Week 32 (Day 225)	Female	69	53.9	58	84.1	82.76	22.37	76.88	88.64
Week 36 (Day 253)	Female	64	50.0	52	81.3	87.31	17.82	82.35	92.27
Week 40 (Day 281)	Female	59	46.1	53	89.8	86.89	16.68	82.29	91.48
Week 44 (Day 309)	Female	56	43.8	47	83.9	82.70	22.91	75.97	89.42
Week 48 (Day 337)	Female	48	37.5	26	54.2	84.62	19.93	76.56	92.67
Week 52 (Day 365)	Female	38	29.7	6	15.8	81.11	9.81	70.81	91.41
Week 56 (Day 393)	Female	31	24.2	9	29.0	88.15	9.88	80.56	95.74
Week 60 (Day 421)	Female	27	21.1	1	3.7	80.00	NE	NE	NE
Week 64 (Day 449)	Female	26	20.3	8	30.8	87.50	11.51	77.88	97.12
Week 68 (Day 477)	Female	23	18.0	2	8.7	80.00	0.00	NE	NE
Week 72 (Day 505)	Female	23	18.0	3	13.0	93.33	11.55	64.65	122.02
Week 76 (Day 533)	Female	21	16.4	3	14.3	82.22	3.85	72.66	91.78
Week 80 (Day 561)	Female	20	15.6	5	25.0	92.00	11.93	77.19	106.81
Week 84 (Day 589)	Female	12	9.4	1	8.3	66.67	NE	NE	NE
Week 88 (Day 617)	Female	9	7.0	1	11.1	86.67	NE	NE	NE
Week 92 (Day 645)	Female	6	4.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	3.9	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	1.6	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	0.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	128	100.0	127	99.2	78.64	22.76	74.64	82.63
End of Study (LOCF)	Female	128	100.0	127	99.2	79.53	21.76	75.71	83.35
Baseline	Male	93	100.0	89	95.7	80.97	22.51	76.23	85.72
Week 4 (Day 29)	Male	93	100.0	85	91.4	87.76	16.58	84.19	91.34
Week 8 (Day 57)	Male	81	87.1	73	90.1	89.50	12.52	86.58	92.42
Week 12 (Day 85)	Male	72	77.4	66	91.7	89.42	13.30	86.15	92.69
Week 16 (Day 113)	Male	68	73.1	62	91.2	88.71	13.31	85.33	92.09
Week 20 (Day 141)	Male	62	66.7	58	93.5	89.20	14.23	85.45	92.94
Week 24 (Day 169)	Male	59	63.4	55	93.2	88.48	13.79	84.76	92.21
Week 28 (Day 197)	Male	57	61.3	55	96.5	89.09	12.92	85.60	92.58
Week 32 (Day 225)	Male	50	53.8	46	92.0	88.99	11.61	85.54	92.43
Week 36 (Day 253)	Male	48	51.6	43	89.6	88.06	11.41	84.55	91.57
Week 40 (Day 281)	Male	45	48.4	38	84.4	88.86	15.54	83.75	93.97
Week 44 (Day 309)	Male	39	41.9	37	94.9	87.93	16.09	82.56	93.29
Week 48 (Day 337)	Male	33	35.5	19	57.6	88.42	13.67	81.83	95.01
Week 52 (Day 365)	Male	26	28.0	5	19.2	80.00	17.00	58.90	101.10
Week 56 (Day 393)	Male	23	24.7	9	39.1	85.93	14.32	74.92	96.93
Week 60 (Day 421)	Male	16	17.2	1	6.3	86.67	NE	NE	NE
Week 64 (Day 449)	Male	15	16.1	4	26.7	90.00	6.67	79.39	100.61
Week 68 (Day 477)	Male	11	11.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	11	11.8	2	18.2	90.00	14.14	-37.06	217.06
Week 76 (Day 533)	Male	10	10.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	10	10.8	1	10.0	93.33	NE	NE	NE
Week 84 (Day 589)	Male	7	7.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	6	6.5	1	16.7	93.33	NE	NE	NE
Week 92 (Day 645)	Male	2	2.2	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	93	100.0	92	98.9	84.64	19.98	80.50	88.78
End of Study (LOCF)	Male	93	100.0	92	98.9	84.64	19.03	80.70	88.58
Age									

Baseline	< 65	141	100.0	133	94.3	77.19	22.05	73.41	80.98
Week 4 (Day 29)	< 65	141	100.0	123	87.2	86.12	16.83	83.12	89.13
Week 8 (Day 57)	< 65	127	90.1	113	89.0	87.26	13.32	84.77	89.74
Week 12 (Day 85)	< 65	118	83.7	106	89.8	87.94	13.38	85.36	90.52
Week 16 (Day 113)	< 65	108	76.6	93	86.1	87.74	13.91	84.88	90.61
Week 20 (Day 141)	< 65	100	70.9	97	97.0	86.53	17.24	83.05	90.00
Week 24 (Day 169)	< 65	93	66.0	86	92.5	87.75	14.99	84.54	90.97
Week 28 (Day 197)	< 65	88	62.4	83	94.3	88.98	13.82	85.96	91.99
Week 32 (Day 225)	< 65	83	58.9	73	88.0	89.13	15.93	85.42	92.85
Week 36 (Day 253)	< 65	78	55.3	70	89.7	90.19	11.89	87.36	93.03
Week 40 (Day 281)	< 65	75	53.2	69	92.0	89.64	14.07	86.26	93.02
Week 44 (Day 309)	< 65	71	50.4	65	91.5	86.26	19.07	81.53	90.98
Week 48 (Day 337)	< 65	61	43.3	33	54.1	88.28	13.23	83.59	92.97
Week 52 (Day 365)	< 65	48	34.0	6	12.5	82.22	13.77	67.77	96.67
Week 56 (Day 393)	< 65	41	29.1	11	26.8	90.30	9.12	84.17	96.43
Week 60 (Day 421)	< 65	33	23.4	2	6.1	83.33	4.71	40.98	125.69
Week 64 (Day 449)	< 65	31	22.0	10	32.3	90.67	9.00	84.23	97.10
Week 68 (Day 477)	< 65	26	18.4	2	7.7	80.00	0.00	NE	NE
Week 72 (Day 505)	< 65	26	18.4	5	19.2	92.00	10.95	78.40	105.60
Week 76 (Day 533)	< 65	25	17.7	3	12.0	82.22	3.85	72.66	91.78
Week 80 (Day 561)	< 65	24	17.0	5	20.8	93.33	11.55	79.00	107.67
Week 84 (Day 589)	< 65	16	11.3	1	6.3	66.67	NE	NE	NE
Week 88 (Day 617)	< 65	13	9.2	2	15.4	90.00	4.71	47.65	132.35
Week 92 (Day 645)	< 65	7	5.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	3.5	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	2.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	0.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	141	100.0	139	98.6	82.83	21.98	79.14	86.52
End of Study (LOCF)	< 65	141	100.0	139	98.6	83.84	20.14	80.46	87.22
Baseline	>= 65	80	100.0	79	98.8	78.06	21.70	73.20	82.92
Week 4 (Day 29)	>= 65	80	100.0	68	85.0	80.78	19.90	75.97	85.60
Week 8 (Day 57)	>= 65	66	82.5	58	87.9	78.62	20.92	73.12	84.12
Week 12 (Day 85)	>= 65	58	72.5	55	94.8	79.55	20.11	74.11	84.98

Week 16 (Day 113)	>= 65	56	70.0	50	89.3	76.27	20.96	70.31	82.22
Week 20 (Day 141)	>= 65	48	60.0	41	85.4	79.80	21.04	73.15	86.44
Week 24 (Day 169)	>= 65	44	55.0	36	81.8	82.22	19.45	75.64	88.80
Week 28 (Day 197)	>= 65	41	51.3	37	90.2	79.82	20.58	72.96	86.68
Week 32 (Day 225)	>= 65	36	45.0	31	86.1	76.99	21.69	69.03	84.95
Week 36 (Day 253)	>= 65	34	42.5	25	73.5	80.53	20.63	72.02	89.05
Week 40 (Day 281)	>= 65	29	36.3	22	75.9	81.67	20.67	72.50	90.83
Week 44 (Day 309)	>= 65	24	30.0	19	79.2	80.70	23.92	69.17	92.23
Week 48 (Day 337)	>= 65	20	25.0	12	60.0	80.56	25.81	64.15	96.96
Week 52 (Day 365)	>= 65	16	20.0	5	31.3	78.67	12.82	62.74	94.59
Week 56 (Day 393)	>= 65	13	16.3	7	53.8	81.90	14.76	68.25	95.56
Week 60 (Day 421)	>= 65	10	12.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	10	12.5	2	20.0	76.67	4.71	34.31	119.02
Week 68 (Day 477)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	6	7.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	6	7.5	1	16.7	86.67	NE	NE	NE
Week 84 (Day 589)	>= 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	2.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	80	100.0	80	100.0	78.25	21.29	73.51	82.99
End of Study (LOCF)	>= 65	80	100.0	80	100.0	77.92	21.42	73.15	82.68
ECOG performance status									
Baseline	0	63	100.0	60	95.2	81.11	22.44	75.31	86.91
Week 4 (Day 29)	0	63	100.0	56	88.9	84.52	22.28	78.56	90.49
Week 8 (Day 57)	0	58	92.1	52	89.7	83.21	21.91	77.10	89.31
Week 12 (Day 85)	0	55	87.3	50	90.9	86.47	17.92	81.37	91.56
Week 16 (Day 113)	0	54	85.7	45	83.3	86.52	19.57	80.64	92.40
Week 20 (Day 141)	0	52	82.5	48	92.3	86.81	19.71	81.08	92.53
Week 24 (Day 169)	0	49	77.8	43	87.8	89.46	17.95	83.93	94.98
Week 28 (Day 197)	0	46	73.0	42	91.3	88.89	16.70	83.68	94.09

Week 32 (Day 225)	0	41	65.1	34	82.9	88.82	22.49	80.98	96.67
Week 36 (Day 253)	0	39	61.9	31	79.5	90.32	16.67	84.21	96.44
Week 40 (Day 281)	0	37	58.7	30	81.1	86.61	18.18	79.82	93.40
Week 44 (Day 309)	0	36	57.1	29	80.6	84.14	27.34	73.74	94.54
Week 48 (Day 337)	0	28	44.4	18	64.3	86.30	23.26	74.73	97.86
Week 52 (Day 365)	0	27	42.9	6	22.2	78.89	12.94	65.31	92.47
Week 56 (Day 393)	0	24	38.1	8	33.3	90.83	10.65	81.93	99.74
Week 60 (Day 421)	0	21	33.3	1	4.8	80.00	NE	NE	NE
Week 64 (Day 449)	0	21	33.3	7	33.3	86.67	10.89	76.60	96.74
Week 68 (Day 477)	0	17	27.0	1	5.9	80.00	NE	NE	NE
Week 72 (Day 505)	0	17	27.0	2	11.8	90.00	14.14	-37.06	217.06
Week 76 (Day 533)	0	15	23.8	2	13.3	83.33	4.71	40.98	125.69
Week 80 (Day 561)	0	14	22.2	1	7.1	100.00	NE	NE	NE
Week 84 (Day 589)	0	11	17.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	10	15.9	1	10.0	86.67	NE	NE	NE
Week 92 (Day 645)	0	5	7.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	6.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	4.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	63	100.0	63	100.0	80.00	25.79	73.50	86.50
End of Study (LOCF)	0	63	100.0	63	100.0	81.48	22.73	75.76	87.21
Baseline	1	157	100.0	151	96.2	75.98	21.58	72.51	79.45
Week 4 (Day 29)	1	157	100.0	134	85.4	84.03	16.21	81.26	86.80
Week 8 (Day 57)	1	134	85.4	119	88.8	84.82	13.99	82.28	87.36
Week 12 (Day 85)	1	121	77.1	111	91.7	84.44	15.76	81.48	87.41
Week 16 (Day 113)	1	110	70.1	98	89.1	82.45	16.45	79.15	85.75
Week 20 (Day 141)	1	96	61.1	90	93.8	83.31	18.02	79.54	87.09
Week 24 (Day 169)	1	88	56.1	79	89.8	84.30	15.54	80.82	87.79
Week 28 (Day 197)	1	83	52.9	78	94.0	84.68	16.57	80.94	88.42
Week 32 (Day 225)	1	78	49.7	70	89.7	83.90	16.31	80.02	87.79
Week 36 (Day 253)	1	73	46.5	64	87.7	86.35	14.37	82.76	89.94
Week 40 (Day 281)	1	67	42.7	61	91.0	88.25	15.20	84.36	92.14

Week 44 (Day 309)	1	59	37.6	55	93.2	85.45	15.56	81.25	89.66
Week 48 (Day 337)	1	53	33.8	27	50.9	86.17	12.80	81.11	91.24
Week 52 (Day 365)	1	37	23.6	5	13.5	82.67	13.82	65.50	99.83
Week 56 (Day 393)	1	30	19.1	10	33.3	84.00	12.65	74.95	93.05
Week 60 (Day 421)	1	22	14.0	1	4.5	86.67	NE	NE	NE
Week 64 (Day 449)	1	20	12.7	5	25.0	90.67	8.94	79.56	101.77
Week 68 (Day 477)	1	17	10.8	1	5.9	80.00	NE	NE	NE
Week 72 (Day 505)	1	17	10.8	3	17.6	93.33	11.55	64.65	122.02
Week 76 (Day 533)	1	16	10.2	1	6.3	80.00	NE	NE	NE
Week 80 (Day 561)	1	16	10.2	5	31.3	90.67	11.16	76.82	104.52
Week 84 (Day 589)	1	8	5.1	1	12.5	66.67	NE	NE	NE
Week 88 (Day 617)	1	5	3.2	1	20.0	93.33	NE	NE	NE
Week 92 (Day 645)	1	3	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	157	100.0	155	98.7	81.55	20.07	78.36	84.73
End of Study (LOCF)	1	157	100.0	155	98.7	81.68	20.04	78.50	84.86
Baseline	Missing	1	100.0	1	100.0	93.33	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	93.33	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	93.33	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	93.33	NE	NE	NE
Geographic region									
Baseline	USA	43	100.0	41	95.3	81.14	21.02	74.50	87.77
Week 4 (Day 29)	USA	43	100.0	38	88.4	88.60	16.76	83.09	94.10
Week 8 (Day 57)	USA	41	95.3	37	90.2	86.13	15.35	81.01	91.24
Week 12 (Day 85)	USA	41	95.3	38	92.7	90.39	12.41	86.32	94.47
Week 16 (Day 113)	USA	40	93.0	33	82.5	87.27	13.88	82.35	92.19
Week 20 (Day 141)	USA	39	90.7	35	89.7	88.76	15.23	83.53	94.00
Week 24 (Day 169)	USA	36	83.7	33	91.7	90.30	11.07	86.38	94.23
Week 28 (Day 197)	USA	35	81.4	31	88.6	90.97	11.10	86.90	95.04
Week 32 (Day 225)	USA	32	74.4	28	87.5	85.00	20.74	76.96	93.04
Week 36 (Day 253)	USA	32	74.4	24	75.0	88.89	13.14	83.34	94.44
Week 40 (Day 281)	USA	29	67.4	23	79.3	88.77	17.38	81.25	96.28

Week 44 (Day 309)	USA	26	60.5	21	80.8	89.21	14.83	82.46	95.96
Week 48 (Day 337)	USA	21	48.8	15	71.4	92.00	13.14	84.72	99.28
Week 52 (Day 365)	USA	18	41.9	1	5.6	100.00	NE	NE	NE
Week 56 (Day 393)	USA	18	41.9	9	50.0	89.63	11.11	81.09	98.17
Week 60 (Day 421)	USA	17	39.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	15	34.9	5	33.3	90.67	8.94	79.56	101.77
Week 68 (Day 477)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	12	27.9	1	8.3	100.00	NE	NE	NE
Week 76 (Day 533)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	12	27.9	2	16.7	80.00	9.43	-4.71	164.71
Week 84 (Day 589)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	6	14.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	11.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	7.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	43	100.0	43	100.0	86.20	20.02	80.04	92.36
End of Study (LOCF)	USA	43	100.0	43	100.0	86.36	19.35	80.40	92.31
Baseline	Europe (EU)	74	100.0	69	93.2	73.62	22.59	68.20	79.05
Week 4 (Day 29)	Europe (EU)	74	100.0	64	86.5	81.56	19.69	76.64	86.48
Week 8 (Day 57)	Europe (EU)	65	87.8	55	84.6	81.45	19.44	76.20	86.71
Week 12 (Day 85)	Europe (EU)	57	77.0	49	86.0	80.85	20.52	74.96	86.74
Week 16 (Day 113)	Europe (EU)	55	74.3	44	80.0	79.85	22.06	73.14	86.56
Week 20 (Day 141)	Europe (EU)	49	66.2	46	93.9	81.85	20.92	75.64	88.06
Week 24 (Day 169)	Europe (EU)	47	63.5	42	89.4	82.06	22.64	75.01	89.12
Week 28 (Day 197)	Europe (EU)	45	60.8	43	95.6	82.29	19.38	76.32	88.25
Week 32 (Day 225)	Europe (EU)	39	52.7	35	89.7	86.86	17.15	80.97	92.75
Week 36 (Day 253)	Europe (EU)	34	45.9	30	88.2	88.89	13.60	83.81	93.97
Week 40 (Day 281)	Europe (EU)	31	41.9	30	96.8	87.11	13.89	81.92	92.30
Week 44 (Day 309)	Europe (EU)	28	37.8	24	85.7	79.72	24.59	69.34	90.11

Week 48 (Day 337)	Europe (EU)	22	29.7	16	72.7	84.17	12.62	77.44	90.89
Week 52 (Day 365)	Europe (EU)	19	25.7	6	31.6	73.33	8.43	64.48	82.18
Week 56 (Day 393)	Europe (EU)	17	23.0	7	41.2	84.76	13.72	72.07	97.45
Week 60 (Day 421)	Europe (EU)	15	20.3	2	13.3	83.33	4.71	40.98	125.69
Week 64 (Day 449)	Europe (EU)	15	20.3	7	46.7	86.67	10.89	76.60	96.74
Week 68 (Day 477)	Europe (EU)	13	17.6	2	15.4	80.00	0.00	NE	NE
Week 72 (Day 505)	Europe (EU)	13	17.6	4	30.8	90.00	11.55	71.63	108.37
Week 76 (Day 533)	Europe (EU)	11	14.9	3	27.3	82.22	3.85	72.66	91.78
Week 80 (Day 561)	Europe (EU)	10	13.5	4	40.0	98.33	3.33	93.03	103.64
Week 84 (Day 589)	Europe (EU)	6	8.1	1	16.7	66.67	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	4.1	2	66.7	90.00	4.71	47.65	132.35
Cycle 12 (LOCF)	Europe (EU)	74	100.0	73	98.6	77.26	23.43	71.79	82.73
End of Study (LOCF)	Europe (EU)	74	100.0	73	98.6	78.45	21.73	73.38	83.52
Baseline	Asia (AS)	104	100.0	102	98.1	78.69	21.54	74.46	82.92
Week 4 (Day 29)	Asia (AS)	104	100.0	89	85.6	84.27	17.30	80.63	87.91
Week 8 (Day 57)	Asia (AS)	87	83.7	79	90.8	85.49	15.24	82.07	88.90
Week 12 (Day 85)	Asia (AS)	78	75.0	74	94.9	85.14	14.49	81.78	88.49
Week 16 (Day 113)	Asia (AS)	69	66.3	66	95.7	84.55	15.39	80.76	88.33
Week 20 (Day 141)	Asia (AS)	60	57.7	57	95.0	84.09	18.42	79.21	88.98
Week 24 (Day 169)	Asia (AS)	54	51.9	47	87.0	86.81	12.24	83.22	90.40
Week 28 (Day 197)	Asia (AS)	49	47.1	46	93.9	86.52	16.48	81.63	91.42
Week 32 (Day 225)	Asia (AS)	48	46.2	41	85.4	84.72	18.63	78.83	90.60
Week 36 (Day 253)	Asia (AS)	46	44.2	41	89.1	86.02	17.44	80.51	91.52
Week 40 (Day 281)	Asia (AS)	44	42.3	38	86.4	87.54	17.41	81.82	93.27
Week 44 (Day 309)	Asia (AS)	41	39.4	39	95.1	85.98	19.63	79.62	92.35
Week 48 (Day 337)	Asia (AS)	38	36.5	14	36.8	82.38	24.61	68.17	96.59
Week 52 (Day 365)	Asia (AS)	27	26.0	4	14.8	86.67	12.17	67.30	106.03
Week 56 (Day 393)	Asia (AS)	19	18.3	2	10.5	83.33	14.14	-43.73	210.40
Week 60 (Day 421)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	5.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	104	100.0	103	99.0	81.81	20.98	77.71	85.91
End of Study (LOCF)	Asia (AS)	104	100.0	103	99.0	82.01	20.43	78.01	86.00
Race/ethnicity									
Baseline	Asian	109	100.0	106	97.2	78.49	21.80	74.29	82.69
Week 4 (Day 29)	Asian	109	100.0	92	84.4	84.57	17.17	81.01	88.12
Week 8 (Day 57)	Asian	91	83.5	80	87.9	85.50	15.14	82.13	88.87
Week 12 (Day 85)	Asian	82	75.2	78	95.1	84.98	14.34	81.75	88.21
Week 16 (Day 113)	Asian	73	67.0	70	95.9	84.76	15.23	81.13	88.39
Week 20 (Day 141)	Asian	64	58.7	60	93.8	84.22	18.08	79.55	88.89
Week 24 (Day 169)	Asian	57	52.3	50	87.7	87.20	12.18	83.74	90.66
Week 28 (Day 197)	Asian	52	47.7	49	94.2	86.94	16.21	82.28	91.60
Week 32 (Day 225)	Asian	50	45.9	43	86.0	84.81	18.42	79.14	90.48
Week 36 (Day 253)	Asian	48	44.0	43	89.6	86.20	17.18	80.92	91.49
Week 40 (Day 281)	Asian	46	42.2	40	87.0	87.75	17.09	82.29	93.21
Week 44 (Day 309)	Asian	43	39.4	41	95.3	86.18	19.29	80.09	92.27
Week 48 (Day 337)	Asian	40	36.7	15	37.5	83.56	24.15	70.18	96.93
Week 52 (Day 365)	Asian	29	26.6	5	17.2	89.33	12.11	74.30	104.37
Week 56 (Day 393)	Asian	21	19.3	3	14.3	88.89	13.88	54.41	123.36
Week 60 (Day 421)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	5.5	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	4.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	1.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	109	100.0	107	98.2	82.12	20.73	78.14	86.09
End of Study (LOCF)	Asian	109	100.0	107	98.2	82.31	20.19	78.44	86.17
Baseline	Non-Asian	99	100.0	96	97.0	77.71	20.79	73.50	81.92
Week 4 (Day 29)	Non-Asian	99	100.0	89	89.9	84.94	17.80	81.20	88.69
Week 8 (Day 57)	Non-Asian	91	91.9	82	90.1	82.68	18.68	78.58	86.79
Week 12 (Day 85)	Non-Asian	83	83.8	74	89.2	85.52	17.89	81.37	89.66
Week 16 (Day 113)	Non-Asian	80	80.8	68	85.0	82.65	19.52	77.92	87.37
Week 20 (Day 141)	Non-Asian	74	74.7	69	93.2	84.64	19.81	79.88	89.40
Week 24 (Day 169)	Non-Asian	70	70.7	65	92.9	84.92	19.84	80.01	89.84
Week 28 (Day 197)	Non-Asian	67	67.7	63	94.0	86.22	16.96	81.95	90.49
Week 32 (Day 225)	Non-Asian	60	60.6	53	88.3	88.05	14.16	84.15	91.95
Week 36 (Day 253)	Non-Asian	55	55.6	46	83.6	89.86	11.40	86.47	93.24
Week 40 (Day 281)	Non-Asian	49	49.5	44	89.8	88.60	15.04	84.03	93.17
Week 44 (Day 309)	Non-Asian	43	43.4	35	81.4	86.67	16.01	81.17	92.17
Week 48 (Day 337)	Non-Asian	35	35.4	26	74.3	86.67	13.98	81.02	92.31
Week 52 (Day 365)	Non-Asian	29	29.3	6	20.7	73.33	8.43	64.48	82.18
Week 56 (Day 393)	Non-Asian	27	27.3	14	51.9	85.71	11.94	78.82	92.61
Week 60 (Day 421)	Non-Asian	26	26.3	2	7.7	83.33	4.71	40.98	125.69
Week 64 (Day 449)	Non-Asian	24	24.2	9	37.5	88.89	9.43	81.64	96.14
Week 68 (Day 477)	Non-Asian	20	20.2	2	10.0	80.00	0.00	NE	NE
Week 72 (Day 505)	Non-Asian	20	20.2	3	15.0	93.33	11.55	64.65	122.02
Week 76 (Day 533)	Non-Asian	18	18.2	3	16.7	82.22	3.85	72.66	91.78
Week 80 (Day 561)	Non-Asian	17	17.2	5	29.4	90.67	11.16	76.82	104.52
Week 84 (Day 589)	Non-Asian	11	11.1	1	9.1	66.67	NE	NE	NE
Week 88 (Day 617)	Non-Asian	8	8.1	2	25.0	90.00	4.71	47.65	132.35
Week 92 (Day 645)	Non-Asian	4	4.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	3.0	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	99	100.0	99	100.0	81.41	20.52	77.32	85.51

End of Study (LOCF)	Non-Asian	99	100.0	99	100.0	81.35	20.29	77.30	85.39
Baseline	Unknown	13	100.0	10	76.9	65.33	30.60	43.44	87.22
Week 4 (Day 29)	Unknown	13	100.0	10	76.9	74.67	27.18	55.22	94.11
Week 8 (Day 57)	Unknown	11	84.6	9	81.8	88.89	10.00	81.20	96.58
Week 12 (Day 85)	Unknown	11	84.6	9	81.8	82.22	22.11	65.23	99.22
Week 16 (Day 113)	Unknown	11	84.6	5	45.5	84.00	21.91	56.80	111.20
Week 20 (Day 141)	Unknown	10	76.9	9	90.0	85.74	13.92	75.04	96.44
Week 24 (Day 169)	Unknown	10	76.9	7	70.0	89.52	8.48	81.68	97.37
Week 28 (Day 197)	Unknown	10	76.9	8	80.0	80.83	18.32	65.52	96.15
Week 32 (Day 225)	Unknown	9	69.2	8	88.9	72.50	36.24	42.20	102.80
Week 36 (Day 253)	Unknown	9	69.2	6	66.7	81.11	24.01	55.92	106.30
Week 40 (Day 281)	Unknown	9	69.2	7	77.8	81.90	18.74	64.57	99.24
Week 44 (Day 309)	Unknown	9	69.2	8	88.9	71.67	35.59	41.91	101.42
Week 48 (Day 337)	Unknown	6	46.2	4	66.7	93.33	5.44	84.67	101.99
Week 52 (Day 365)	Unknown	6	46.2	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	6	46.2	1	16.7	100.00	NE	NE	NE
Week 60 (Day 421)	Unknown	5	38.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	5	38.5	3	60.0	86.67	13.33	53.54	119.79
Week 68 (Day 477)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	4	30.8	2	50.0	90.00	14.14	-37.06	217.06
Week 76 (Day 533)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	4	30.8	1	25.0	100.00	NE	NE	NE
Week 84 (Day 589)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	7.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	13	100.0	13	100.0	71.28	35.73	49.69	92.88
End of Study (LOCF)	Unknown	13	100.0	13	100.0	78.97	29.29	61.27	96.68

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TO_QSC30PF_SG.xls
27OCT2021 7:19

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Physical functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	71	33.5	27.5	40.1
	Cycle 12 (LOCF)	n/a	212	95.9	35	16.5	12.1	22.1
	End of Study (LOCF)	n/a	212	95.9	36	17.0	12.5	22.6
Sex	All visits	Female	123	55.7	43	35.0	27.1	43.7
		Male	89	40.3	28	31.5	22.8	41.7
	Cycle 12 (LOCF)	Female	123	55.7	21	17.1	11.4	24.7
		Male	89	40.3	14	15.7	9.6	24.7
	End of Study (LOCF)	Female	123	55.7	21	17.1	11.4	24.7
		Male	89	40.3	15	16.9	10.5	26.0
Age	All visits	< 65	133	60.2	38	28.6	21.6	36.8
		>= 65	79	35.7	33	41.8	31.5	52.8
	Cycle 12 (LOCF)	< 65	133	60.2	20	15.0	10.0	22.1
		>= 65	79	35.7	15	19.0	11.9	29.0
	End of Study (LOCF)	< 65	133	60.2	19	14.3	9.3	21.2
		>= 65	79	35.7	17	21.5	13.9	31.8
ECOG performance status	All visits	0	60	27.1	26	43.3	31.6	55.9
		1	151	68.3	45	29.8	23.1	37.5
		Missing	1	0.5	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	60	27.1	13	21.7	13.1	33.6
		1	151	68.3	22	14.6	9.8	21.1
		Missing	1	0.5	0	0.0	0.0	79.3
	End of Study (LOCF)	0	60	27.1	13	21.7	13.1	33.6
		1	151	68.3	23	15.2	10.4	21.8
		Missing	1	0.5	0	0.0	0.0	79.3
Geographic region	All visits	USA	41	18.6	15	36.6	23.6	51.9
		Europe (EU)	69	31.2	27	39.1	28.5	50.9
		Asia (AS)	102	46.2	29	28.4	20.6	37.8
	Cycle 12 (LOCF)	USA	41	18.6	5	12.2	5.3	25.5
		Europe (EU)	69	31.2	13	18.8	11.4	29.6
		Asia (AS)	102	46.2	17	16.7	10.7	25.1
	End of Study (LOCF)	USA	41	18.6	4	9.8	3.9	22.5
		Europe (EU)	69	31.2	13	18.8	11.4	29.6
		Asia (AS)	102	46.2	19	18.6	12.3	27.3
Race/ethnicity	All visits	Asian	106	48.0	30	28.3	20.6	37.5
		Non-Asian	96	43.4	37	38.5	29.4	48.5
		Unknown	10	4.5	4	40.0	16.8	68.7
	Cycle 12 (LOCF)	Asian	106	48.0	17	16.0	10.3	24.2

		Non-Asian	96	43.4	17	17.7	11.4	26.5
		Unknown	10	4.5	1	10.0	1.8	40.4
	End of Study (LOCF)	Asian	106	48.0	19	17.9	11.8	26.3
		Non-Asian	96	43.4	16	16.7	10.5	25.4
		Unknown	10	4.5	1	10.0	1.8	40.4

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30PF_W10_SG.xls
15OCT2021 12:56

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Physical functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

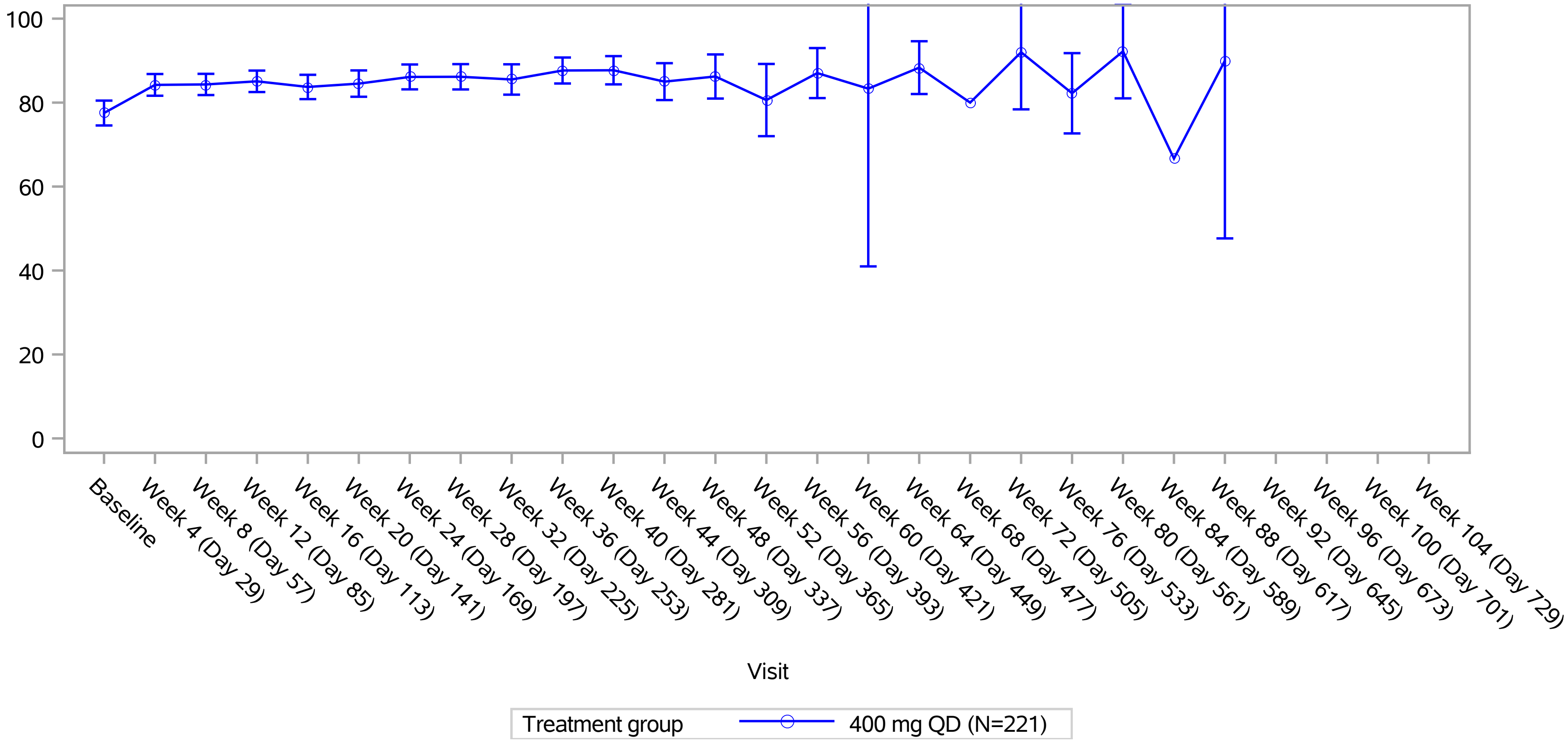
			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	46	21.7	16.7	27.7
	Cycle 12 (LOCF)	n/a	212	95.9	25	11.8	8.1	16.8
	End of Study (LOCF)	n/a	212	95.9	23	10.8	7.3	15.8
Sex	All visits	Female	123	55.7	27	22.0	15.5	30.1
		Male	89	40.3	19	21.3	14.1	31.0
	Cycle 12 (LOCF)	Female	123	55.7	16	13.0	8.2	20.1
		Male	89	40.3	9	10.1	5.4	18.1
	End of Study (LOCF)	Female	123	55.7	15	12.2	7.5	19.1
		Male	89	40.3	8	9.0	4.6	16.7
Age	All visits	< 65	133	60.2	25	18.8	13.1	26.3
		>= 65	79	35.7	21	26.6	18.1	37.2
	Cycle 12 (LOCF)	< 65	133	60.2	14	10.5	6.4	16.9
		>= 65	79	35.7	11	13.9	8.0	23.2
	End of Study (LOCF)	< 65	133	60.2	12	9.0	5.2	15.1
		>= 65	79	35.7	11	13.9	8.0	23.2
ECOG performance status	All visits	0	60	27.1	16	26.7	17.1	39.0
		1	151	68.3	30	19.9	14.3	26.9
		Missing	1	0.5	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	60	27.1	10	16.7	9.3	28.0
		1	151	68.3	15	9.9	6.1	15.7
		Missing	1	0.5	0	0.0	0.0	79.3
	End of Study (LOCF)	0	60	27.1	10	16.7	9.3	28.0
		1	151	68.3	13	8.6	5.1	14.2
		Missing	1	0.5	0	0.0	0.0	79.3
Geographic region	All visits	USA	41	18.6	10	24.4	13.8	39.3
		Europe (EU)	69	31.2	16	23.2	14.8	34.4
		Asia (AS)	102	46.2	20	19.6	13.1	28.4
	Cycle 12 (LOCF)	USA	41	18.6	4	9.8	3.9	22.5
		Europe (EU)	69	31.2	10	14.5	8.1	24.7
		Asia (AS)	102	46.2	11	10.8	6.1	18.3
	End of Study (LOCF)	USA	41	18.6	3	7.3	2.5	19.4
		Europe (EU)	69	31.2	9	13.0	7.0	23.0
		Asia (AS)	102	46.2	11	10.8	6.1	18.3
Race/ethnicity	All visits	Asian	106	48.0	21	19.8	13.3	28.4
		Non-Asian	96	43.4	22	22.9	15.6	32.3
		Unknown	10	4.5	3	30.0	10.8	60.3
	Cycle 12 (LOCF)	Asian	106	48.0	11	10.4	5.9	17.6

		Non-Asian	96	43.4	13	13.5	8.1	21.8
		Unknown	10	4.5	1	10.0	1.8	40.4
	End of Study (LOCF)	Asian	106	48.0	11	10.4	5.9	17.6
		Non-Asian	96	43.4	11	11.5	6.5	19.4
		Unknown	10	4.5	1	10.0	1.8	40.4

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30PF_W15_SG.xls
15OCT2021 12:46

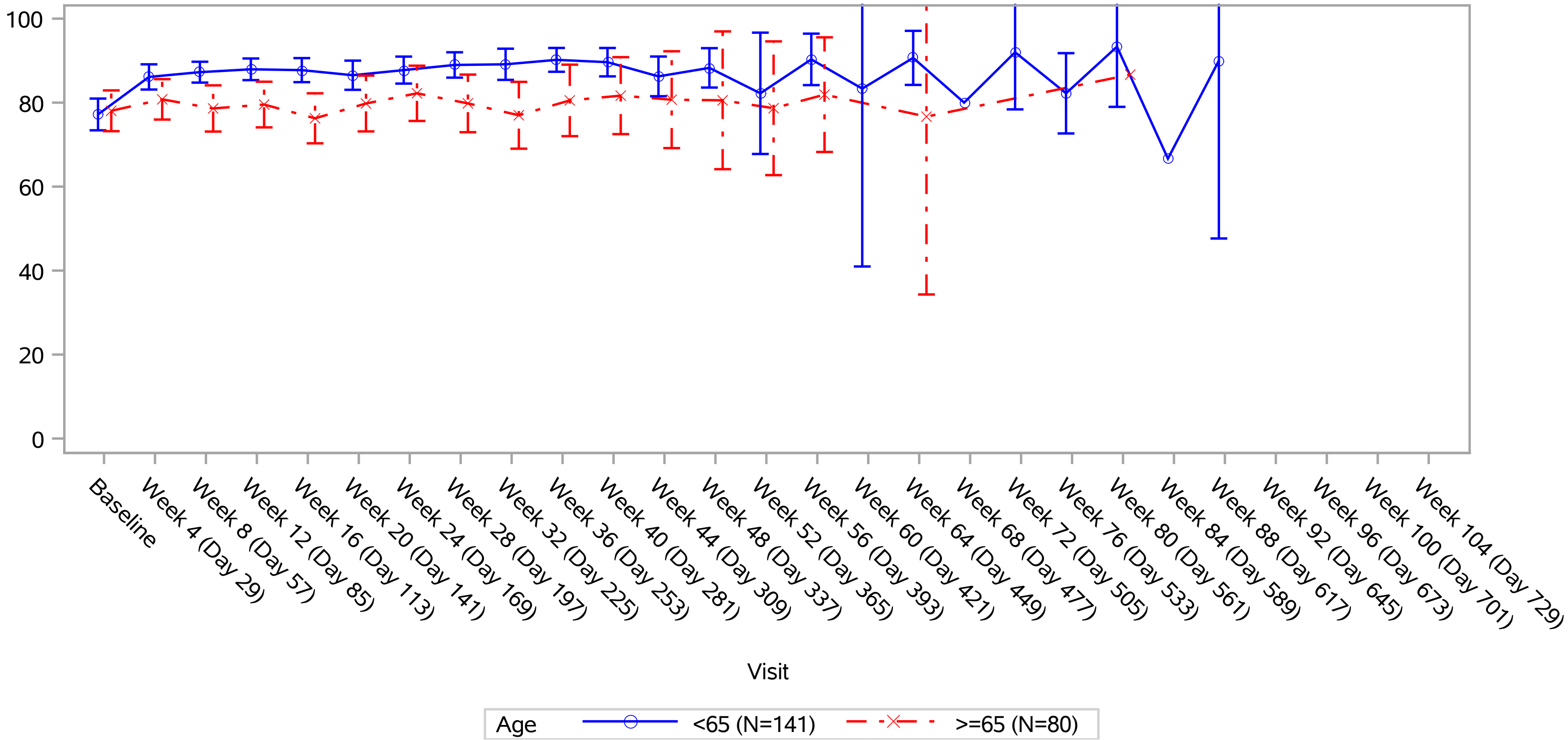
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Physical functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30PF.pdf
15OCT2021 17:09

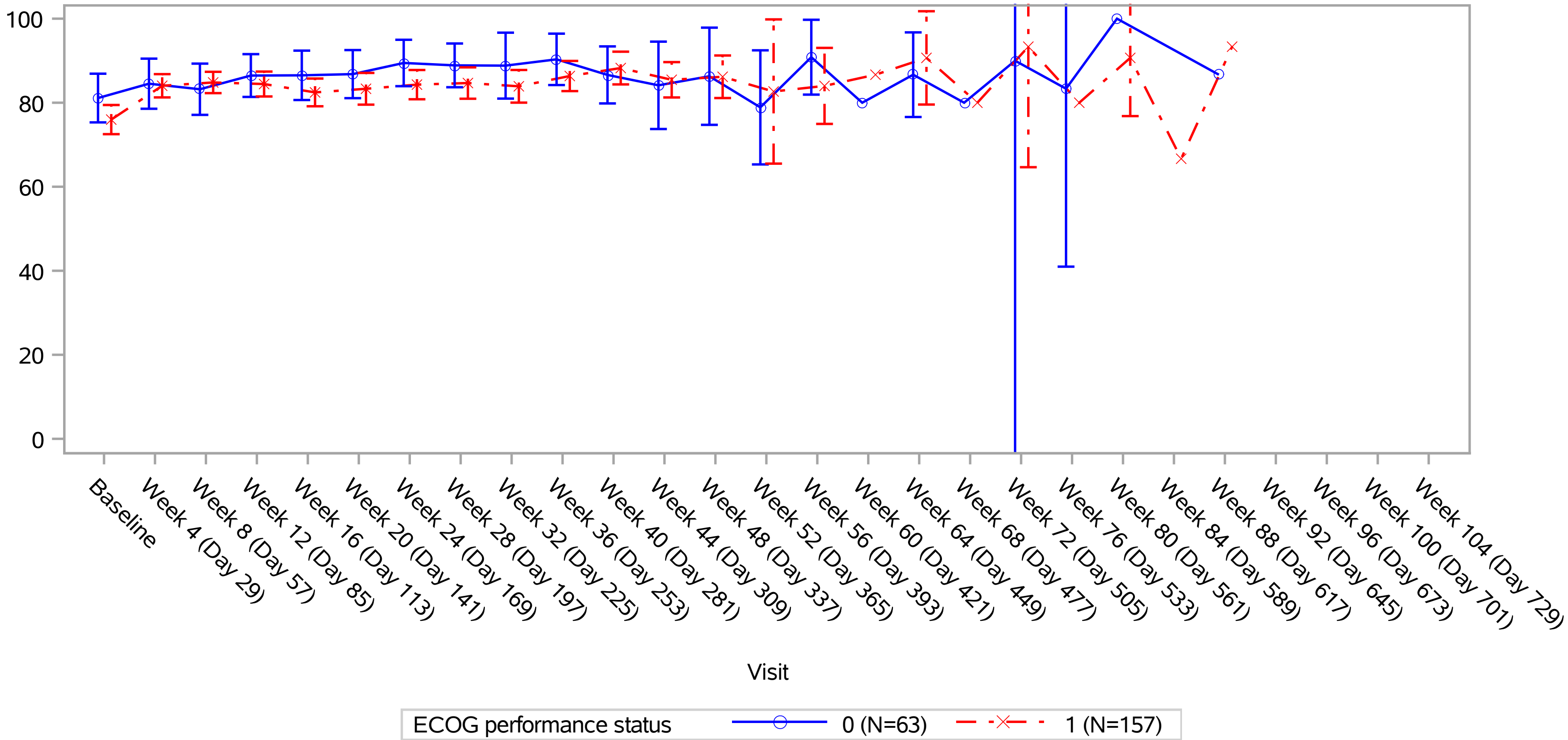
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Physical functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30PF_SGAGE65.pdf
15OCT2021 17:38

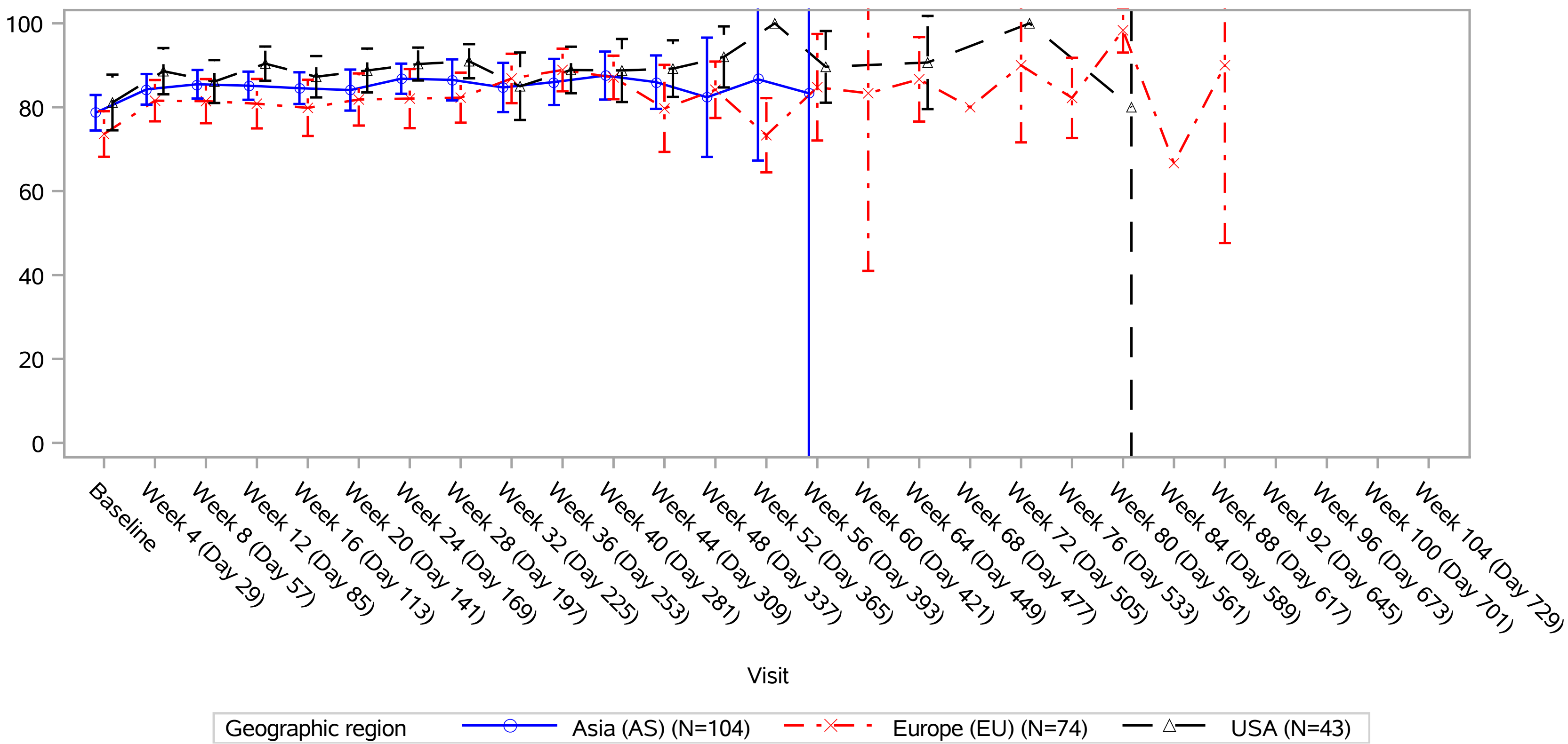
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Physical functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30PF_SGECOG.pdf
15OCT2021 18:08

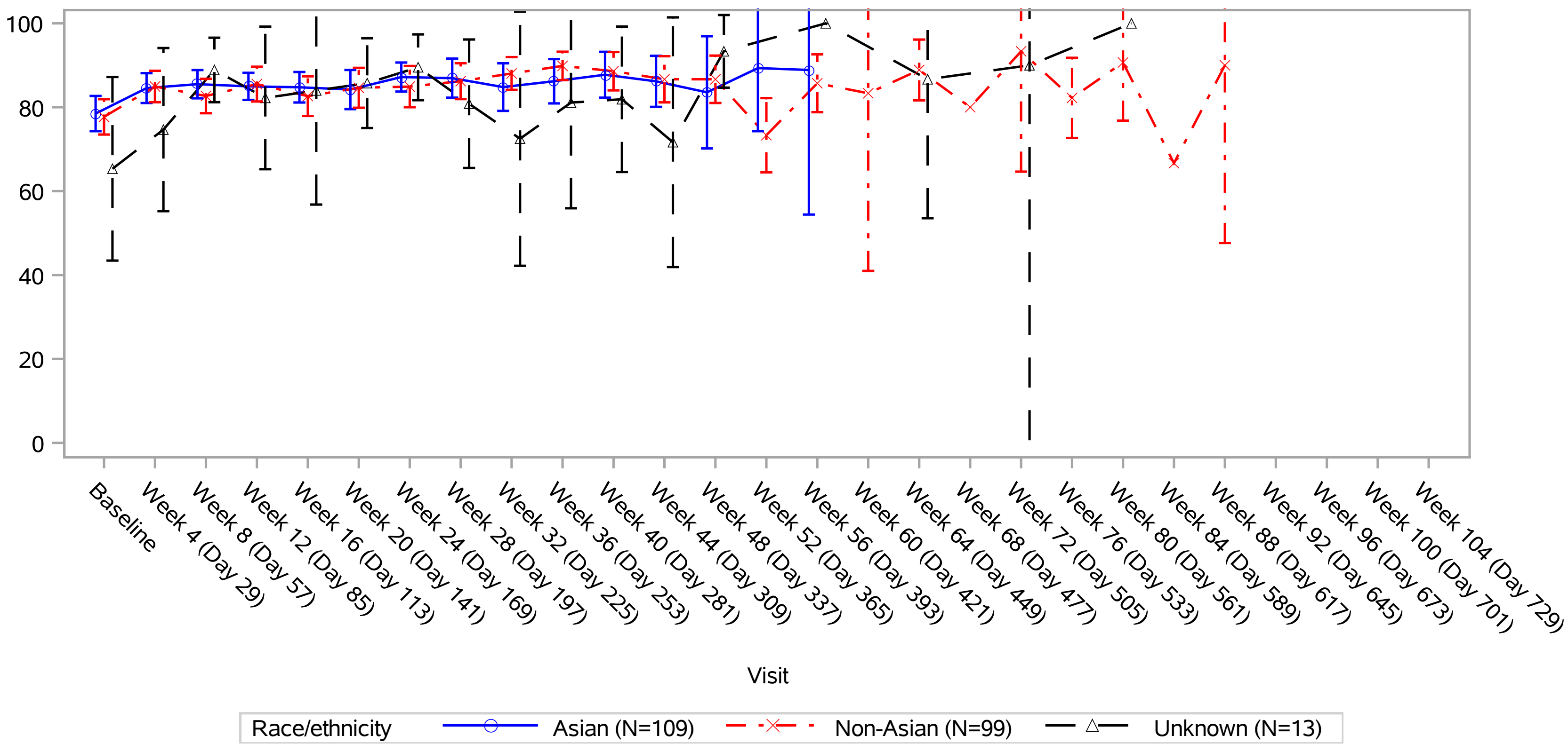
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Physical functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30PF_SGGEO.pdf
15OCT2021 18:39

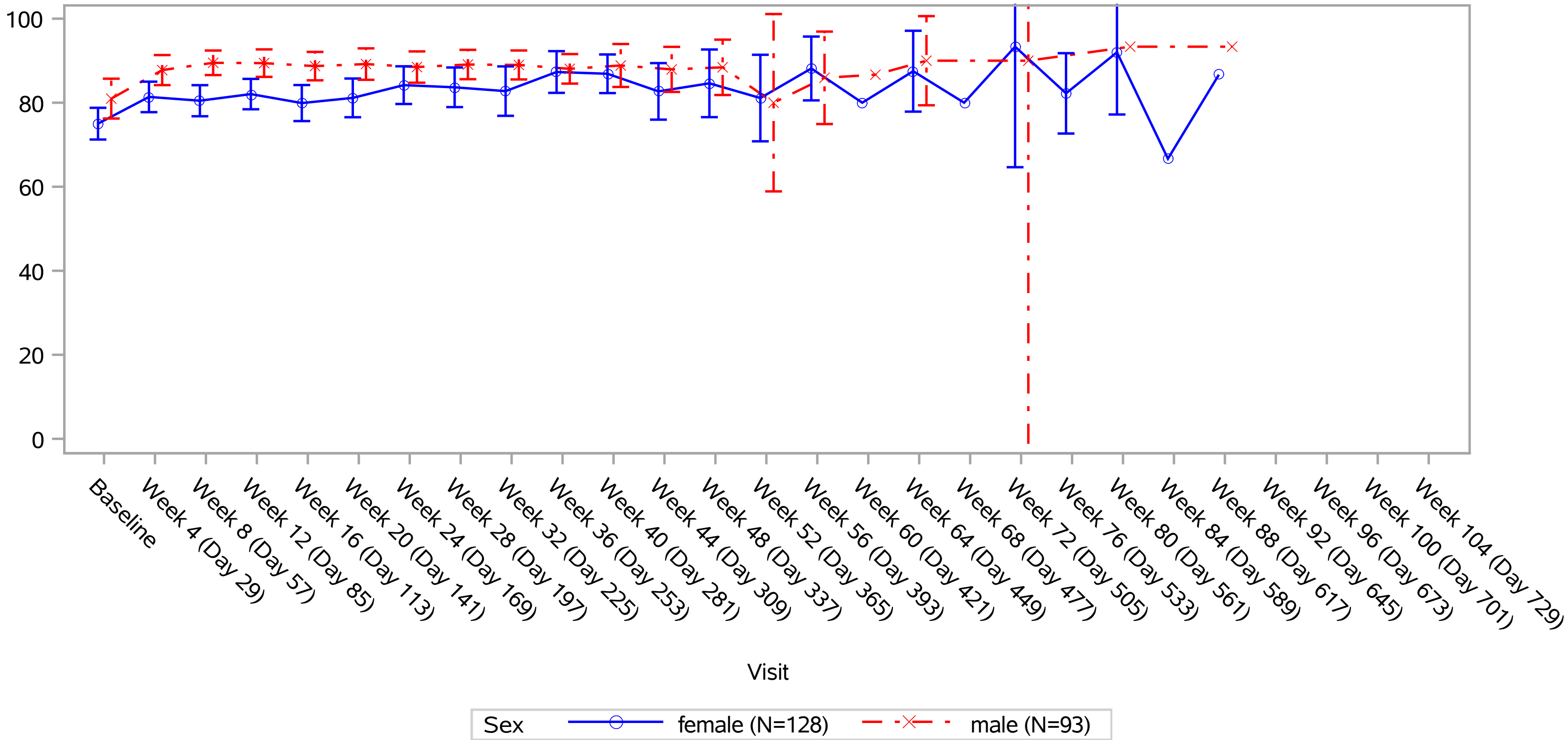
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Physical functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30PF_SGRE.pdf
15OCT2021 19:09

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Physical functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30PF_SGSEX.pdf
15OCT2021 19:40

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Global health status
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=221)							
		Patients				Statistics			
Name Visit	Level	in study¹	%	with value¹	%	mean²	SD	CI LL	CI UL
All									
Baseline	n/a	221	100.0	212	95.9	63.09	23.79	59.87	66.31
Week 4 (Day 29)	n/a	221	100.0	191	86.4	69.94	20.97	66.95	72.93
Week 8 (Day 57)	n/a	193	87.3	171	88.6	72.08	19.35	69.15	75.00
Week 12 (Day 85)	n/a	176	79.6	160	90.9	73.96	18.83	71.02	76.90
Week 16 (Day 113)	n/a	164	74.2	143	87.2	72.03	20.28	68.68	75.38
Week 20 (Day 141)	n/a	148	67.0	138	93.2	71.26	20.31	67.84	74.68
Week 24 (Day 169)	n/a	137	62.0	122	89.1	74.25	18.34	70.96	77.54
Week 28 (Day 197)	n/a	129	58.4	120	93.0	73.82	18.02	70.56	77.08
Week 32 (Day 225)	n/a	119	53.8	104	87.4	72.52	19.91	68.64	76.39
Week 36 (Day 253)	n/a	112	50.7	95	84.8	73.25	20.01	69.17	77.32
Week 40 (Day 281)	n/a	104	47.1	91	87.5	71.61	20.52	67.34	75.89
Week 44 (Day 309)	n/a	95	43.0	84	88.4	70.24	22.38	65.38	75.09
Week 48 (Day 337)	n/a	81	36.7	45	55.6	73.52	19.65	67.62	79.42
Week 52 (Day 365)	n/a	64	29.0	11	17.2	71.21	15.53	60.78	81.64
Week 56 (Day 393)	n/a	54	24.4	18	33.3	73.15	18.65	63.88	82.42
Week 60 (Day 421)	n/a	43	19.5	2	4.7	75.00	11.79	-30.89	180.89
Week 64 (Day 449)	n/a	41	18.6	12	29.3	63.19	27.17	45.93	80.46
Week 68 (Day 477)	n/a	34	15.4	2	5.9	62.50	5.89	9.56	115.44
Week 72 (Day 505)	n/a	34	15.4	5	14.7	78.33	22.52	50.38	106.29
Week 76 (Day 533)	n/a	31	14.0	3	9.7	61.11	9.62	37.21	85.01
Week 80 (Day 561)	n/a	30	13.6	6	20.0	77.78	14.59	62.46	93.09
Week 84 (Day 589)	n/a	19	8.6	1	5.3	50.00	NE	NE	NE
Week 88 (Day 617)	n/a	15	6.8	2	13.3	83.33	23.57	-128.44	295.10
Week 92 (Day 645)	n/a	8	3.6	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	2.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	1.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	221	100.0	219	99.1	68.04	21.57	65.16	70.91
End of Study (LOCF)	n/a	221	100.0	219	99.1	68.80	21.19	65.98	71.62
Sex									
Baseline	Female	128	100.0	123	96.1	61.86	24.98	57.40	66.31
Week 4 (Day 29)	Female	128	100.0	106	82.8	68.87	19.36	65.14	72.60
Week 8 (Day 57)	Female	112	87.5	98	87.5	70.07	21.47	65.76	74.37
Week 12 (Day 85)	Female	104	81.3	94	90.4	71.37	20.25	67.22	75.51
Week 16 (Day 113)	Female	96	75.0	81	84.4	70.58	20.92	65.95	75.20
Week 20 (Day 141)	Female	86	67.2	80	93.0	70.42	21.42	65.65	75.18
Week 24 (Day 169)	Female	78	60.9	67	85.9	73.51	19.57	68.73	78.28
Week 28 (Day 197)	Female	72	56.3	65	90.3	72.69	19.85	67.77	77.61
Week 32 (Day 225)	Female	69	53.9	58	84.1	70.83	21.98	65.05	76.61
Week 36 (Day 253)	Female	64	50.0	52	81.3	72.76	22.21	66.57	78.94
Week 40 (Day 281)	Female	59	46.1	53	89.8	71.38	21.22	65.54	77.23
Week 44 (Day 309)	Female	56	43.8	47	83.9	69.33	23.51	62.42	76.23
Week 48 (Day 337)	Female	48	37.5	26	54.2	74.04	20.05	65.94	82.13
Week 52 (Day 365)	Female	38	29.7	6	15.8	70.83	10.21	60.12	81.54
Week 56 (Day 393)	Female	31	24.2	9	29.0	77.78	19.98	62.42	93.14
Week 60 (Day 421)	Female	27	21.1	1	3.7	66.67	NE	NE	NE
Week 64 (Day 449)	Female	26	20.3	8	30.8	61.46	32.41	34.36	88.55
Week 68 (Day 477)	Female	23	18.0	2	8.7	62.50	5.89	9.56	115.44
Week 72 (Day 505)	Female	23	18.0	3	13.0	75.00	30.05	0.36	149.64
Week 76 (Day 533)	Female	21	16.4	3	14.3	61.11	9.62	37.21	85.01
Week 80 (Day 561)	Female	20	15.6	5	25.0	78.33	16.24	58.16	98.50
Week 84 (Day 589)	Female	12	9.4	1	8.3	50.00	NE	NE	NE
Week 88 (Day 617)	Female	9	7.0	1	11.1	100.00	NE	NE	NE
Week 92 (Day 645)	Female	6	4.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	3.9	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	1.6	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	0.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	128	100.0	127	99.2	66.93	22.37	63.00	70.86
End of Study (LOCF)	Female	128	100.0	127	99.2	67.59	22.13	63.70	71.47
Baseline	Male	93	100.0	89	95.7	64.79	22.07	60.14	69.44
Week 4 (Day 29)	Male	93	100.0	85	91.4	71.27	22.88	66.34	76.21
Week 8 (Day 57)	Male	81	87.1	73	90.1	74.77	15.83	71.08	78.47
Week 12 (Day 85)	Male	72	77.4	66	91.7	77.65	16.02	73.71	81.59
Week 16 (Day 113)	Male	68	73.1	62	91.2	73.92	19.41	69.00	78.85
Week 20 (Day 141)	Male	62	66.7	58	93.5	72.41	18.81	67.47	77.36
Week 24 (Day 169)	Male	59	63.4	55	93.2	75.15	16.86	70.59	79.71
Week 28 (Day 197)	Male	57	61.3	55	96.5	75.15	15.67	70.91	79.39
Week 32 (Day 225)	Male	50	53.8	46	92.0	74.64	16.94	69.61	79.67
Week 36 (Day 253)	Male	48	51.6	43	89.6	73.84	17.21	68.54	79.13
Week 40 (Day 281)	Male	45	48.4	38	84.4	71.93	19.80	65.42	78.44
Week 44 (Day 309)	Male	39	41.9	37	94.9	71.40	21.11	64.36	78.44
Week 48 (Day 337)	Male	33	35.5	19	57.6	72.81	19.61	63.35	82.26
Week 52 (Day 365)	Male	26	28.0	5	19.2	71.67	21.73	44.68	98.65
Week 56 (Day 393)	Male	23	24.7	9	39.1	68.52	17.07	55.40	81.64
Week 60 (Day 421)	Male	16	17.2	1	6.3	83.33	NE	NE	NE
Week 64 (Day 449)	Male	15	16.1	4	26.7	66.67	15.21	42.46	90.88
Week 68 (Day 477)	Male	11	11.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	11	11.8	2	18.2	83.33	11.79	-22.55	189.22
Week 76 (Day 533)	Male	10	10.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	10	10.8	1	10.0	75.00	NE	NE	NE
Week 84 (Day 589)	Male	7	7.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	6	6.5	1	16.7	66.67	NE	NE	NE
Week 92 (Day 645)	Male	2	2.2	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	93	100.0	92	98.9	69.57	20.43	65.33	73.80
End of Study (LOCF)	Male	93	100.0	92	98.9	70.47	19.82	66.37	74.58
Age									

Baseline	< 65	141	100.0	133	94.3	61.28	24.47	57.08	65.48
Week 4 (Day 29)	< 65	141	100.0	123	87.2	70.93	19.77	67.41	74.46
Week 8 (Day 57)	< 65	127	90.1	113	89.0	73.53	17.96	70.18	76.87
Week 12 (Day 85)	< 65	118	83.7	105	89.0	74.84	17.18	71.52	78.17
Week 16 (Day 113)	< 65	108	76.6	93	86.1	73.57	19.30	69.59	77.54
Week 20 (Day 141)	< 65	100	70.9	97	97.0	71.56	20.82	67.37	75.76
Week 24 (Day 169)	< 65	93	66.0	86	92.5	74.81	17.99	70.95	78.66
Week 28 (Day 197)	< 65	88	62.4	83	94.3	75.20	17.41	71.40	79.00
Week 32 (Day 225)	< 65	83	58.9	73	88.0	75.00	17.95	70.81	79.19
Week 36 (Day 253)	< 65	78	55.3	70	89.7	74.29	20.00	69.52	79.05
Week 40 (Day 281)	< 65	75	53.2	69	92.0	72.83	19.73	68.09	77.57
Week 44 (Day 309)	< 65	71	50.4	65	91.5	69.36	23.16	63.62	75.10
Week 48 (Day 337)	< 65	61	43.3	33	54.1	74.49	19.20	67.69	81.30
Week 52 (Day 365)	< 65	48	34.0	6	12.5	66.67	14.91	51.02	82.31
Week 56 (Day 393)	< 65	41	29.1	11	26.8	75.76	18.43	63.38	88.14
Week 60 (Day 421)	< 65	33	23.4	2	6.1	75.00	11.79	-30.89	180.89
Week 64 (Day 449)	< 65	31	22.0	10	32.3	65.00	28.00	44.97	85.03
Week 68 (Day 477)	< 65	26	18.4	2	7.7	62.50	5.89	9.56	115.44
Week 72 (Day 505)	< 65	26	18.4	5	19.2	78.33	22.52	50.38	106.29
Week 76 (Day 533)	< 65	25	17.7	3	12.0	61.11	9.62	37.21	85.01
Week 80 (Day 561)	< 65	24	17.0	5	20.8	76.67	16.03	56.76	96.57
Week 84 (Day 589)	< 65	16	11.3	1	6.3	50.00	NE	NE	NE
Week 88 (Day 617)	< 65	13	9.2	2	15.4	83.33	23.57	-128.44	295.10
Week 92 (Day 645)	< 65	7	5.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	3.5	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	2.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	0.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	141	100.0	139	98.6	68.88	22.02	65.19	72.58
End of Study (LOCF)	< 65	141	100.0	139	98.6	70.26	21.02	66.74	73.79
Baseline	>= 65	80	100.0	79	98.8	66.14	22.42	61.12	71.16
Week 4 (Day 29)	>= 65	80	100.0	68	85.0	68.14	23.03	62.56	73.71
Week 8 (Day 57)	>= 65	66	82.5	58	87.9	69.25	21.70	63.55	74.96
Week 12 (Day 85)	>= 65	58	72.5	55	94.8	72.27	21.70	66.41	78.14

Week 16 (Day 113)	>= 65	56	70.0	50	89.3	69.17	21.90	62.94	75.39
Week 20 (Day 141)	>= 65	48	60.0	41	85.4	70.53	19.28	64.44	76.62
Week 24 (Day 169)	>= 65	44	55.0	36	81.8	72.92	19.35	66.37	79.46
Week 28 (Day 197)	>= 65	41	51.3	37	90.2	70.72	19.21	64.32	77.12
Week 32 (Day 225)	>= 65	36	45.0	31	86.1	66.67	23.17	58.17	75.17
Week 36 (Day 253)	>= 65	34	42.5	25	73.5	70.33	20.14	62.02	78.65
Week 40 (Day 281)	>= 65	29	36.3	22	75.9	67.80	22.90	57.65	77.96
Week 44 (Day 309)	>= 65	24	30.0	19	79.2	73.25	19.76	63.72	82.77
Week 48 (Day 337)	>= 65	20	25.0	12	60.0	70.83	21.47	57.19	84.47
Week 52 (Day 365)	>= 65	16	20.0	5	31.3	76.67	16.03	56.76	96.57
Week 56 (Day 393)	>= 65	13	16.3	7	53.8	69.05	19.67	50.86	87.24
Week 60 (Day 421)	>= 65	10	12.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	10	12.5	2	20.0	54.17	29.46	-210.55	318.88
Week 68 (Day 477)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	6	7.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	6	7.5	1	16.7	83.33	NE	NE	NE
Week 84 (Day 589)	>= 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	2.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	80	100.0	80	100.0	66.56	20.82	61.93	71.20
End of Study (LOCF)	>= 65	80	100.0	80	100.0	66.25	21.38	61.49	71.01
ECOG performance status									
Baseline	0	63	100.0	60	95.2	68.61	24.42	62.30	74.92
Week 4 (Day 29)	0	63	100.0	56	88.9	68.15	24.42	61.62	74.69
Week 8 (Day 57)	0	58	92.1	52	89.7	70.83	23.07	64.41	77.26
Week 12 (Day 85)	0	55	87.3	49	89.1	75.34	18.55	70.01	80.67
Week 16 (Day 113)	0	54	85.7	45	83.3	71.48	20.76	65.25	77.72
Week 20 (Day 141)	0	52	82.5	48	92.3	69.79	22.65	63.21	76.37
Week 24 (Day 169)	0	49	77.8	43	87.8	75.97	19.09	70.09	81.84
Week 28 (Day 197)	0	46	73.0	42	91.3	76.19	19.18	70.21	82.17

Week 32 (Day 225)	0	41	65.1	34	82.9	77.45	18.86	70.87	84.03
Week 36 (Day 253)	0	39	61.9	31	79.5	72.85	22.56	64.57	81.13
Week 40 (Day 281)	0	37	58.7	30	81.1	69.44	21.81	61.30	77.59
Week 44 (Day 309)	0	36	57.1	29	80.6	69.54	25.71	59.76	79.32
Week 48 (Day 337)	0	28	44.4	18	64.3	73.15	25.65	60.39	85.91
Week 52 (Day 365)	0	27	42.9	6	22.2	70.83	18.07	51.87	89.79
Week 56 (Day 393)	0	24	38.1	8	33.3	69.79	21.33	51.96	87.63
Week 60 (Day 421)	0	21	33.3	1	4.8	66.67	NE	NE	NE
Week 64 (Day 449)	0	21	33.3	7	33.3	65.48	23.78	43.48	87.47
Week 68 (Day 477)	0	17	27.0	1	5.9	66.67	NE	NE	NE
Week 72 (Day 505)	0	17	27.0	2	11.8	66.67	35.36	-250.99	384.32
Week 76 (Day 533)	0	15	23.8	2	13.3	66.67	0.00	NE	NE
Week 80 (Day 561)	0	14	22.2	1	7.1	83.33	NE	NE	NE
Week 84 (Day 589)	0	11	17.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	10	15.9	1	10.0	100.00	NE	NE	NE
Week 92 (Day 645)	0	5	7.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	6.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	4.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	63	100.0	63	100.0	65.74	26.06	59.18	72.30
End of Study (LOCF)	0	63	100.0	63	100.0	66.93	26.69	60.21	73.65
Baseline	1	157	100.0	151	96.2	60.82	23.31	57.07	64.56
Week 4 (Day 29)	1	157	100.0	134	85.4	70.65	19.49	67.32	73.98
Week 8 (Day 57)	1	134	85.4	119	88.8	72.62	17.57	69.43	75.81
Week 12 (Day 85)	1	121	77.1	111	91.7	73.35	19.00	69.78	76.92
Week 16 (Day 113)	1	110	70.1	98	89.1	72.28	20.16	68.24	76.32
Week 20 (Day 141)	1	96	61.1	90	93.8	72.04	19.04	68.05	76.02
Week 24 (Day 169)	1	88	56.1	79	89.8	73.31	17.97	69.29	77.34
Week 28 (Day 197)	1	83	52.9	78	94.0	72.54	17.36	68.63	76.46
Week 32 (Day 225)	1	78	49.7	70	89.7	70.12	20.09	65.33	74.91
Week 36 (Day 253)	1	73	46.5	64	87.7	73.44	18.83	68.73	78.14
Week 40 (Day 281)	1	67	42.7	61	91.0	72.68	19.96	67.57	77.79

Week 44 (Day 309)	1	59	37.6	55	93.2	70.61	20.65	65.02	76.19
Week 48 (Day 337)	1	53	33.8	27	50.9	73.77	14.93	67.86	79.67
Week 52 (Day 365)	1	37	23.6	5	13.5	71.67	13.94	54.35	88.98
Week 56 (Day 393)	1	30	19.1	10	33.3	75.83	16.87	63.76	87.90
Week 60 (Day 421)	1	22	14.0	1	4.5	83.33	NE	NE	NE
Week 64 (Day 449)	1	20	12.7	5	25.0	60.00	34.05	17.72	102.28
Week 68 (Day 477)	1	17	10.8	1	5.9	58.33	NE	NE	NE
Week 72 (Day 505)	1	17	10.8	3	17.6	86.11	12.73	54.49	117.73
Week 76 (Day 533)	1	16	10.2	1	6.3	50.00	NE	NE	NE
Week 80 (Day 561)	1	16	10.2	5	31.3	76.67	16.03	56.76	96.57
Week 84 (Day 589)	1	8	5.1	1	12.5	50.00	NE	NE	NE
Week 88 (Day 617)	1	5	3.2	1	20.0	66.67	NE	NE	NE
Week 92 (Day 645)	1	3	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	157	100.0	155	98.7	68.92	19.54	65.82	72.03
End of Study (LOCF)	1	157	100.0	155	98.7	69.52	18.62	66.56	72.47
Baseline	Missing	1	100.0	1	100.0	75.00	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	75.00	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	75.00	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	75.00	NE	NE	NE
Geographic region									
Baseline	USA	43	100.0	41	95.3	71.54	22.12	64.56	78.53
Week 4 (Day 29)	USA	43	100.0	38	88.4	78.51	19.63	72.06	84.96
Week 8 (Day 57)	USA	41	95.3	37	90.2	78.15	16.12	72.78	83.53
Week 12 (Day 85)	USA	41	95.3	37	90.2	77.70	16.90	72.07	83.34
Week 16 (Day 113)	USA	40	93.0	33	82.5	78.03	16.90	72.04	84.02
Week 20 (Day 141)	USA	39	90.7	35	89.7	79.05	15.83	73.61	84.49
Week 24 (Day 169)	USA	36	83.7	33	91.7	83.59	14.95	78.29	88.89
Week 28 (Day 197)	USA	35	81.4	31	88.6	83.33	13.26	78.47	88.20
Week 32 (Day 225)	USA	32	74.4	28	87.5	78.27	17.62	71.44	85.11
Week 36 (Day 253)	USA	32	74.4	24	75.0	79.17	18.22	71.47	86.86
Week 40 (Day 281)	USA	29	67.4	23	79.3	73.91	21.95	64.42	83.40

Week 44 (Day 309)	USA	26	60.5	21	80.8	76.19	21.29	66.50	85.88
Week 48 (Day 337)	USA	21	48.8	15	71.4	81.11	16.51	71.97	90.25
Week 52 (Day 365)	USA	18	41.9	1	5.6	100.00	NE	NE	NE
Week 56 (Day 393)	USA	18	41.9	9	50.0	75.00	22.82	57.46	92.54
Week 60 (Day 421)	USA	17	39.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	15	34.9	5	33.3	81.67	12.36	66.32	97.01
Week 68 (Day 477)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	12	27.9	1	8.3	91.67	NE	NE	NE
Week 76 (Day 533)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	12	27.9	2	16.7	70.83	17.68	-87.99	229.66
Week 84 (Day 589)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	6	14.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	11.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	7.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	43	100.0	43	100.0	75.39	18.54	69.68	81.09
End of Study (LOCF)	USA	43	100.0	43	100.0	77.33	16.70	72.19	82.46
Baseline	Europe (EU)	74	100.0	69	93.2	58.45	22.66	53.01	63.90
Week 4 (Day 29)	Europe (EU)	74	100.0	64	86.5	66.93	20.52	61.80	72.05
Week 8 (Day 57)	Europe (EU)	65	87.8	55	84.6	68.79	21.89	62.87	74.70
Week 12 (Day 85)	Europe (EU)	57	77.0	49	86.0	69.22	20.43	63.35	75.08
Week 16 (Day 113)	Europe (EU)	55	74.3	44	80.0	67.99	22.87	61.04	74.95
Week 20 (Day 141)	Europe (EU)	49	66.2	46	93.9	65.04	22.54	58.34	71.73
Week 24 (Day 169)	Europe (EU)	47	63.5	42	89.4	67.26	19.77	61.10	73.42
Week 28 (Day 197)	Europe (EU)	45	60.8	43	95.6	66.47	18.32	60.83	72.11
Week 32 (Day 225)	Europe (EU)	39	52.7	35	89.7	72.62	18.91	66.12	79.12
Week 36 (Day 253)	Europe (EU)	34	45.9	30	88.2	69.44	22.78	60.94	77.95
Week 40 (Day 281)	Europe (EU)	31	41.9	30	96.8	67.22	21.55	59.18	75.27
Week 44 (Day 309)	Europe (EU)	28	37.8	24	85.7	64.58	25.45	53.84	75.33

Week 48 (Day 337)	Europe (EU)	22	29.7	16	72.7	71.87	15.77	63.47	80.28
Week 52 (Day 365)	Europe (EU)	19	25.7	6	31.6	66.67	11.79	54.30	79.03
Week 56 (Day 393)	Europe (EU)	17	23.0	7	41.2	70.24	15.85	55.58	84.90
Week 60 (Day 421)	Europe (EU)	15	20.3	2	13.3	75.00	11.79	-30.89	180.89
Week 64 (Day 449)	Europe (EU)	15	20.3	7	46.7	50.00	27.64	24.44	75.56
Week 68 (Day 477)	Europe (EU)	13	17.6	2	15.4	62.50	5.89	9.56	115.44
Week 72 (Day 505)	Europe (EU)	13	17.6	4	30.8	75.00	24.53	35.96	114.04
Week 76 (Day 533)	Europe (EU)	11	14.9	3	27.3	61.11	9.62	37.21	85.01
Week 80 (Day 561)	Europe (EU)	10	13.5	4	40.0	81.25	14.23	58.60	103.90
Week 84 (Day 589)	Europe (EU)	6	8.1	1	16.7	50.00	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	4.1	2	66.7	83.33	23.57	-128.44	295.10
Cycle 12 (LOCF)	Europe (EU)	74	100.0	73	98.6	63.93	22.22	58.74	69.11
End of Study (LOCF)	Europe (EU)	74	100.0	73	98.6	65.18	21.22	60.23	70.13
Baseline	Asia (AS)	104	100.0	102	98.1	62.83	24.48	58.02	67.63
Week 4 (Day 29)	Asia (AS)	104	100.0	89	85.6	68.45	21.11	64.00	72.89
Week 8 (Day 57)	Asia (AS)	87	83.7	79	90.8	71.52	18.42	67.39	75.65
Week 12 (Day 85)	Asia (AS)	78	75.0	74	94.9	75.23	18.25	71.00	79.45
Week 16 (Day 113)	Asia (AS)	69	66.3	66	95.7	71.72	19.55	66.91	76.52
Week 20 (Day 141)	Asia (AS)	60	57.7	57	95.0	71.49	19.48	66.32	76.66
Week 24 (Day 169)	Asia (AS)	54	51.9	47	87.0	73.94	16.54	69.08	78.79
Week 28 (Day 197)	Asia (AS)	49	47.1	46	93.9	74.28	17.73	69.01	79.54
Week 32 (Day 225)	Asia (AS)	48	46.2	41	85.4	68.50	21.61	61.67	75.32
Week 36 (Day 253)	Asia (AS)	46	44.2	41	89.1	72.56	18.47	66.73	78.39
Week 40 (Day 281)	Asia (AS)	44	42.3	38	86.4	73.68	18.74	67.53	79.84
Week 44 (Day 309)	Asia (AS)	41	39.4	39	95.1	70.51	20.58	63.84	77.18
Week 48 (Day 337)	Asia (AS)	38	36.5	14	36.8	67.26	24.78	52.96	81.57
Week 52 (Day 365)	Asia (AS)	27	26.0	4	14.8	70.83	15.96	45.44	96.22
Week 56 (Day 393)	Asia (AS)	19	18.3	2	10.5	75.00	11.79	-30.89	180.89
Week 60 (Day 421)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	5.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	104	100.0	103	99.0	67.88	21.66	63.65	72.11
End of Study (LOCF)	Asia (AS)	104	100.0	103	99.0	67.80	22.05	63.49	72.11
Race/ethnicity									
Baseline	Asian	109	100.0	106	97.2	62.81	24.48	58.10	67.53
Week 4 (Day 29)	Asian	109	100.0	92	84.4	68.93	20.97	64.59	73.27
Week 8 (Day 57)	Asian	91	83.5	80	87.9	71.46	18.31	67.38	75.53
Week 12 (Day 85)	Asian	82	75.2	78	95.1	75.21	17.87	71.19	79.24
Week 16 (Day 113)	Asian	73	67.0	70	95.9	71.67	19.27	67.07	76.26
Week 20 (Day 141)	Asian	64	58.7	60	93.8	71.39	19.00	66.48	76.30
Week 24 (Day 169)	Asian	57	52.3	50	87.7	74.67	16.32	70.03	79.30
Week 28 (Day 197)	Asian	52	47.7	49	94.2	74.66	17.43	69.65	79.67
Week 32 (Day 225)	Asian	50	45.9	43	86.0	68.41	21.41	61.82	75.00
Week 36 (Day 253)	Asian	48	44.0	43	89.6	73.26	18.51	67.56	78.95
Week 40 (Day 281)	Asian	46	42.2	40	87.0	73.75	18.35	67.88	79.62
Week 44 (Day 309)	Asian	43	39.4	41	95.3	71.34	20.42	64.90	77.79
Week 48 (Day 337)	Asian	40	36.7	15	37.5	68.89	24.69	55.21	82.56
Week 52 (Day 365)	Asian	29	26.6	5	17.2	76.67	19.00	53.07	100.26
Week 56 (Day 393)	Asian	21	19.3	3	14.3	80.56	12.73	48.93	112.18
Week 60 (Day 421)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	5.5	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	4.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	1.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	109	100.0	107	98.2	68.22	21.42	64.12	72.33
End of Study (LOCF)	Asian	109	100.0	107	98.2	68.15	21.80	63.97	72.33
Baseline	Non-Asian	99	100.0	96	97.0	64.06	23.05	59.39	68.73
Week 4 (Day 29)	Non-Asian	99	100.0	89	89.9	72.19	19.86	68.01	76.37
Week 8 (Day 57)	Non-Asian	91	91.9	82	90.1	72.56	20.68	68.02	77.11
Week 12 (Day 85)	Non-Asian	83	83.8	73	88.0	73.29	19.44	68.75	77.82
Week 16 (Day 113)	Non-Asian	80	80.8	68	85.0	71.94	21.78	66.66	77.21
Week 20 (Day 141)	Non-Asian	74	74.7	69	93.2	71.01	21.42	65.87	76.16
Week 24 (Day 169)	Non-Asian	70	70.7	65	92.9	74.10	20.10	69.12	79.08
Week 28 (Day 197)	Non-Asian	67	67.7	63	94.0	74.21	17.24	69.86	78.55
Week 32 (Day 225)	Non-Asian	60	60.6	53	88.3	75.31	18.49	70.22	80.41
Week 36 (Day 253)	Non-Asian	55	55.6	46	83.6	75.18	20.07	69.22	81.14
Week 40 (Day 281)	Non-Asian	49	49.5	44	89.8	70.27	20.68	63.98	76.55
Week 44 (Day 309)	Non-Asian	43	43.4	35	81.4	69.05	23.36	61.02	77.07
Week 48 (Day 337)	Non-Asian	35	35.4	26	74.3	74.68	16.91	67.85	81.51
Week 52 (Day 365)	Non-Asian	29	29.3	6	20.7	66.67	11.79	54.30	79.03
Week 56 (Day 393)	Non-Asian	27	27.3	14	51.9	70.83	20.08	59.24	82.43
Week 60 (Day 421)	Non-Asian	26	26.3	2	7.7	75.00	11.79	-30.89	180.89
Week 64 (Day 449)	Non-Asian	24	24.2	9	37.5	60.19	29.69	37.36	83.01
Week 68 (Day 477)	Non-Asian	20	20.2	2	10.0	62.50	5.89	9.56	115.44
Week 72 (Day 505)	Non-Asian	20	20.2	3	15.0	88.89	12.73	57.27	120.51
Week 76 (Day 533)	Non-Asian	18	18.2	3	16.7	61.11	9.62	37.21	85.01
Week 80 (Day 561)	Non-Asian	17	17.2	5	29.4	80.00	15.14	61.20	98.80
Week 84 (Day 589)	Non-Asian	11	11.1	1	9.1	50.00	NE	NE	NE
Week 88 (Day 617)	Non-Asian	8	8.1	2	25.0	83.33	23.57	-128.44	295.10
Week 92 (Day 645)	Non-Asian	4	4.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	3.0	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	99	100.0	99	100.0	67.59	21.42	63.32	71.87

End of Study (LOCF)	Non-Asian	99	100.0	99	100.0	68.86	21.05	64.66	73.05
Baseline	Unknown	13	100.0	10	76.9	56.67	24.78	38.94	74.40
Week 4 (Day 29)	Unknown	13	100.0	10	76.9	59.17	28.18	39.01	79.32
Week 8 (Day 57)	Unknown	11	84.6	9	81.8	73.15	17.57	59.64	86.65
Week 12 (Day 85)	Unknown	11	84.6	9	81.8	68.52	22.74	51.04	86.00
Week 16 (Day 113)	Unknown	11	84.6	5	45.5	78.33	13.94	61.02	95.65
Week 20 (Day 141)	Unknown	10	76.9	9	90.0	72.22	22.44	54.97	89.47
Week 24 (Day 169)	Unknown	10	76.9	7	70.0	72.62	17.16	56.75	88.49
Week 28 (Day 197)	Unknown	10	76.9	8	80.0	65.63	26.89	43.15	88.10
Week 32 (Day 225)	Unknown	9	69.2	8	88.9	76.04	19.13	60.05	92.03
Week 36 (Day 253)	Unknown	9	69.2	6	66.7	58.33	26.87	30.13	86.54
Week 40 (Day 281)	Unknown	9	69.2	7	77.8	67.86	31.71	38.53	97.18
Week 44 (Day 309)	Unknown	9	69.2	8	88.9	69.79	29.86	44.83	94.76
Week 48 (Day 337)	Unknown	6	46.2	4	66.7	83.33	13.61	61.68	104.99
Week 52 (Day 365)	Unknown	6	46.2	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	6	46.2	1	16.7	83.33	NE	NE	NE
Week 60 (Day 421)	Unknown	5	38.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	5	38.5	3	60.0	72.22	19.25	24.41	120.03
Week 68 (Day 477)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	4	30.8	2	50.0	62.50	29.46	-202.21	327.21
Week 76 (Day 533)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	4	30.8	1	25.0	66.67	NE	NE	NE
Week 84 (Day 589)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	7.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	13	100.0	13	100.0	69.87	25.35	54.55	85.19
End of Study (LOCF)	Unknown	13	100.0	13	100.0	73.72	17.63	63.07	84.37

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.

¹ in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
² mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TO_QSC30QL_SG.xls
27OCT2021 7:19

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Global health status
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	87	41.0	34.6	47.8
	Cycle 12 (LOCF)	n/a	212	95.9	41	19.3	14.6	25.2
	End of Study (LOCF)	n/a	212	95.9	40	18.9	14.2	24.7
Sex	All visits	Female	123	55.7	52	42.3	33.9	51.1
		Male	89	40.3	35	39.3	29.8	49.7
	Cycle 12 (LOCF)	Female	123	55.7	23	18.7	12.8	26.5
		Male	89	40.3	18	20.2	13.2	29.7
	End of Study (LOCF)	Female	123	55.7	22	17.9	12.1	25.6
		Male	89	40.3	18	20.2	13.2	29.7
Age	All visits	< 65	133	60.2	49	36.8	29.1	45.3
		>= 65	79	35.7	38	48.1	37.4	58.9
	Cycle 12 (LOCF)	< 65	133	60.2	22	16.5	11.2	23.8
		>= 65	79	35.7	19	24.1	16.0	34.5
	End of Study (LOCF)	< 65	133	60.2	21	15.8	10.6	22.9
		>= 65	79	35.7	19	24.1	16.0	34.5
ECOG performance status	All visits	0	60	27.1	35	58.3	45.7	69.9
		1	151	68.3	52	34.4	27.3	42.3
		Missing	1	0.5	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	60	27.1	19	31.7	21.3	44.2
		1	151	68.3	22	14.6	9.8	21.1
		Missing	1	0.5	0	0.0	0.0	79.3
	End of Study (LOCF)	0	60	27.1	20	33.3	22.7	45.9
		1	151	68.3	20	13.2	8.7	19.6
		Missing	1	0.5	0	0.0	0.0	79.3
Geographic region	All visits	USA	41	18.6	17	41.5	27.8	56.6
		Europe (EU)	69	31.2	34	49.3	37.8	60.8
		Asia (AS)	102	46.2	36	35.3	26.7	44.9
	Cycle 12 (LOCF)	USA	41	18.6	5	12.2	5.3	25.5
		Europe (EU)	69	31.2	15	21.7	13.6	32.8
		Asia (AS)	102	46.2	21	20.6	13.9	29.4
	End of Study (LOCF)	USA	41	18.6	5	12.2	5.3	25.5
		Europe (EU)	69	31.2	15	21.7	13.6	32.8
		Asia (AS)	102	46.2	20	19.6	13.1	28.4
Race/ethnicity	All visits	Asian	106	48.0	37	34.9	26.5	44.4
		Non-Asian	96	43.4	47	49.0	39.2	58.8
		Unknown	10	4.5	3	30.0	10.8	60.3
	Cycle 12 (LOCF)	Asian	106	48.0	21	19.8	13.3	28.4

		Non-Asian	96	43.4	20	20.8	13.9	30.0
		Unknown	10	4.5	0	0.0	0.0	27.8
	End of Study (LOCF)	Asian	106	48.0	20	18.9	12.6	27.4
		Non-Asian	96	43.4	20	20.8	13.9	30.0
		Unknown	10	4.5	0	0.0	0.0	27.8

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30QL_W10_SG.xls
15OCT2021 12:56

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Global health status
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

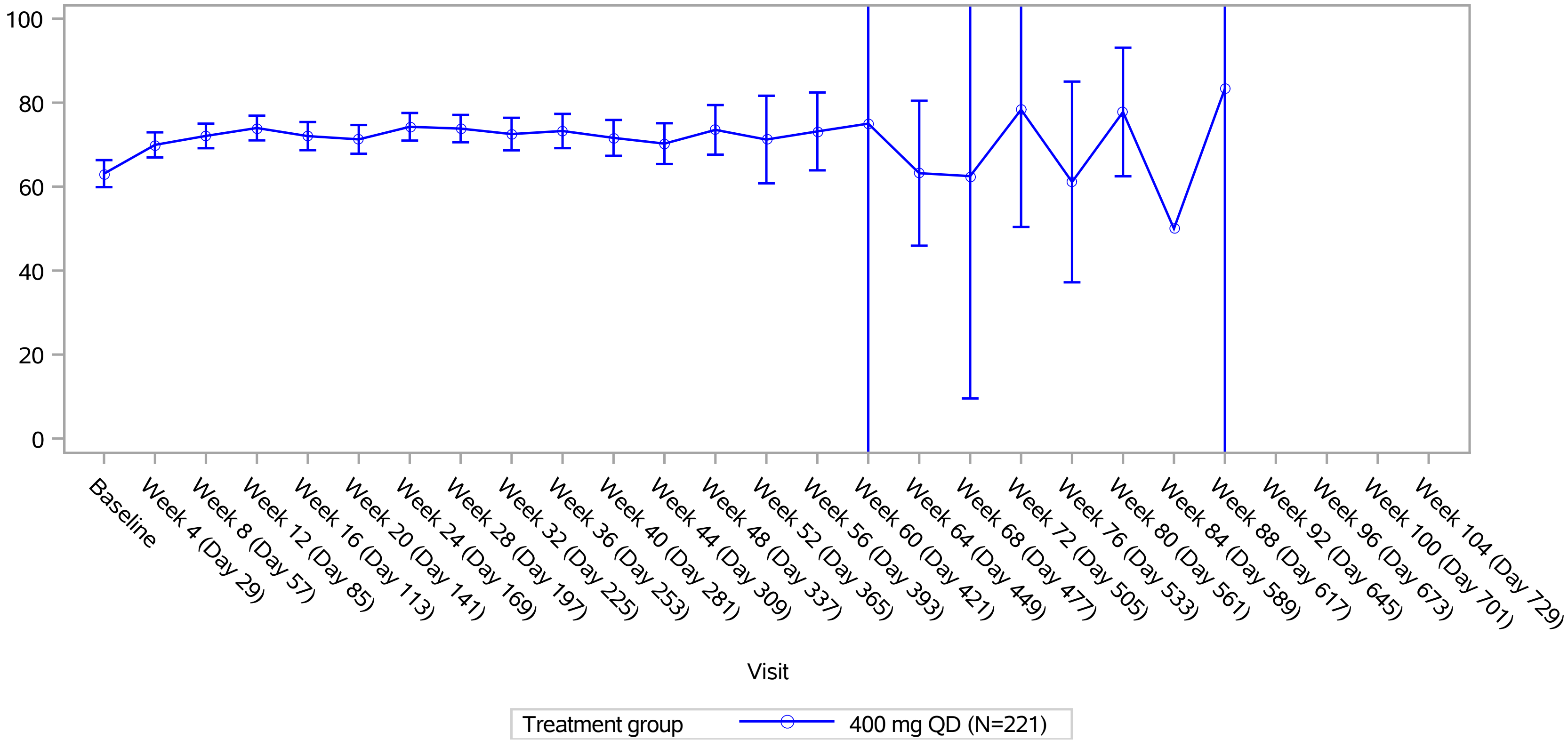
			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	87	41.0	34.6	47.8
	Cycle 12 (LOCF)	n/a	212	95.9	41	19.3	14.6	25.2
	End of Study (LOCF)	n/a	212	95.9	40	18.9	14.2	24.7
Sex	All visits	Female	123	55.7	52	42.3	33.9	51.1
		Male	89	40.3	35	39.3	29.8	49.7
	Cycle 12 (LOCF)	Female	123	55.7	23	18.7	12.8	26.5
		Male	89	40.3	18	20.2	13.2	29.7
	End of Study (LOCF)	Female	123	55.7	22	17.9	12.1	25.6
		Male	89	40.3	18	20.2	13.2	29.7
Age	All visits	< 65	133	60.2	49	36.8	29.1	45.3
		>= 65	79	35.7	38	48.1	37.4	58.9
	Cycle 12 (LOCF)	< 65	133	60.2	22	16.5	11.2	23.8
		>= 65	79	35.7	19	24.1	16.0	34.5
	End of Study (LOCF)	< 65	133	60.2	21	15.8	10.6	22.9
		>= 65	79	35.7	19	24.1	16.0	34.5
ECOG performance status	All visits	0	60	27.1	35	58.3	45.7	69.9
		1	151	68.3	52	34.4	27.3	42.3
		Missing	1	0.5	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	60	27.1	19	31.7	21.3	44.2
		1	151	68.3	22	14.6	9.8	21.1
		Missing	1	0.5	0	0.0	0.0	79.3
	End of Study (LOCF)	0	60	27.1	20	33.3	22.7	45.9
		1	151	68.3	20	13.2	8.7	19.6
		Missing	1	0.5	0	0.0	0.0	79.3
Geographic region	All visits	USA	41	18.6	17	41.5	27.8	56.6
		Europe (EU)	69	31.2	34	49.3	37.8	60.8
		Asia (AS)	102	46.2	36	35.3	26.7	44.9
	Cycle 12 (LOCF)	USA	41	18.6	5	12.2	5.3	25.5
		Europe (EU)	69	31.2	15	21.7	13.6	32.8
		Asia (AS)	102	46.2	21	20.6	13.9	29.4
	End of Study (LOCF)	USA	41	18.6	5	12.2	5.3	25.5
		Europe (EU)	69	31.2	15	21.7	13.6	32.8
		Asia (AS)	102	46.2	20	19.6	13.1	28.4
Race/ethnicity	All visits	Asian	106	48.0	37	34.9	26.5	44.4
		Non-Asian	96	43.4	47	49.0	39.2	58.8
		Unknown	10	4.5	3	30.0	10.8	60.3
	Cycle 12 (LOCF)	Asian	106	48.0	21	19.8	13.3	28.4

		Non-Asian	96	43.4	20	20.8	13.9	30.0
		Unknown	10	4.5	0	0.0	0.0	27.8
	End of Study (LOCF)	Asian	106	48.0	20	18.9	12.6	27.4
		Non-Asian	96	43.4	20	20.8	13.9	30.0
		Unknown	10	4.5	0	0.0	0.0	27.8

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30QL_W15_SG.xls
15OCT2021 12:46

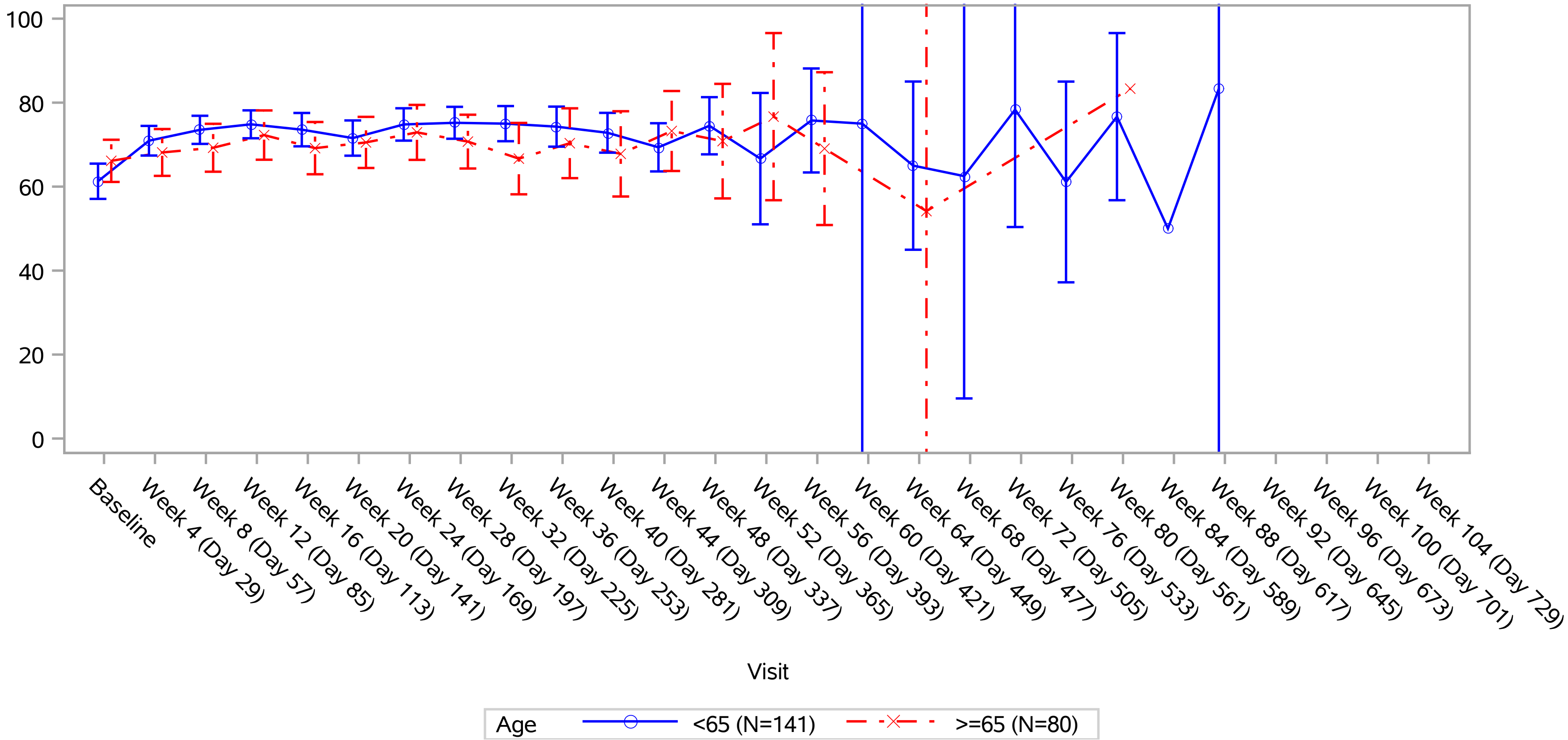
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Global health status
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30QL.pdf
15OCT2021 17:10

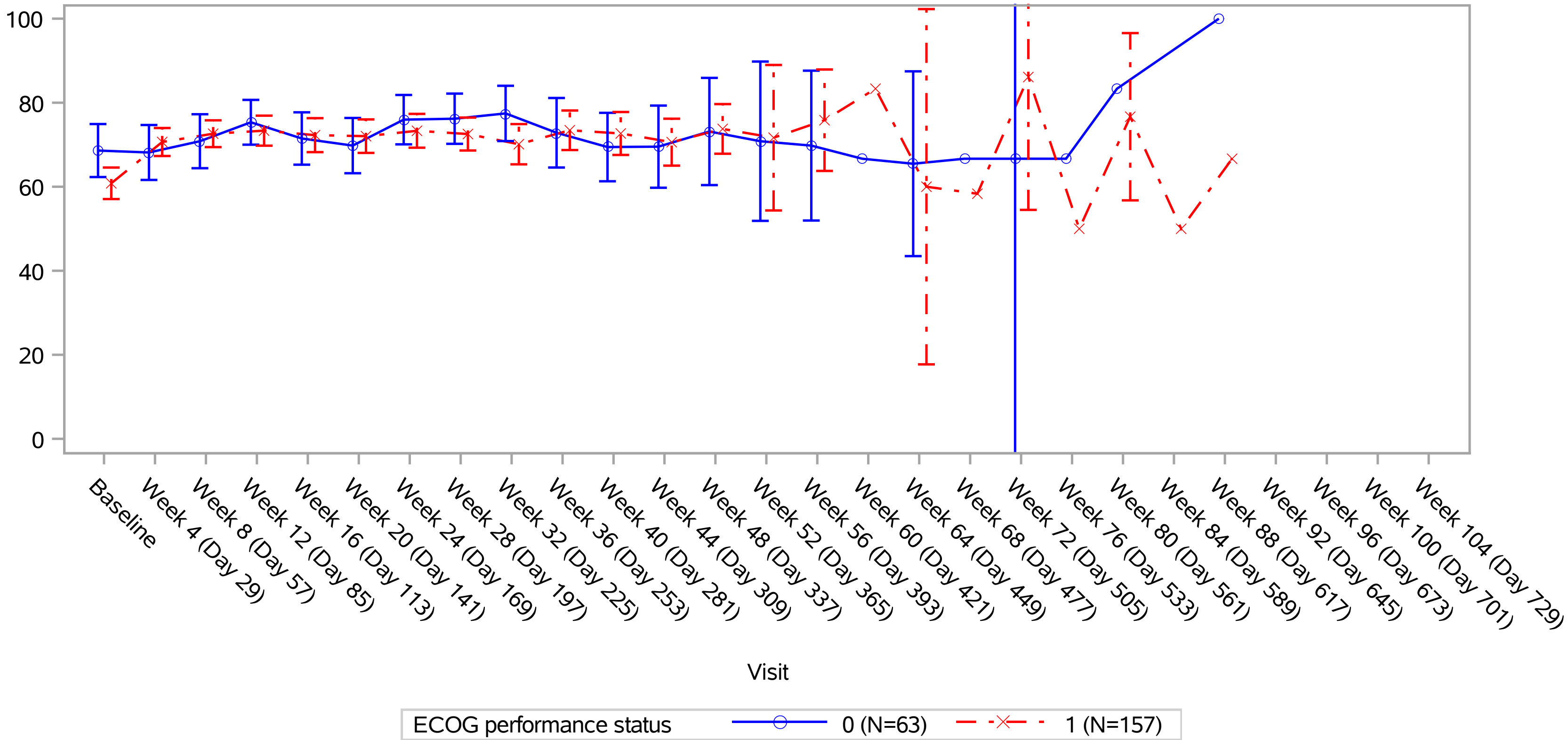
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Global health status
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30QL_SGAGE65.pdf
15OCT2021 17:38

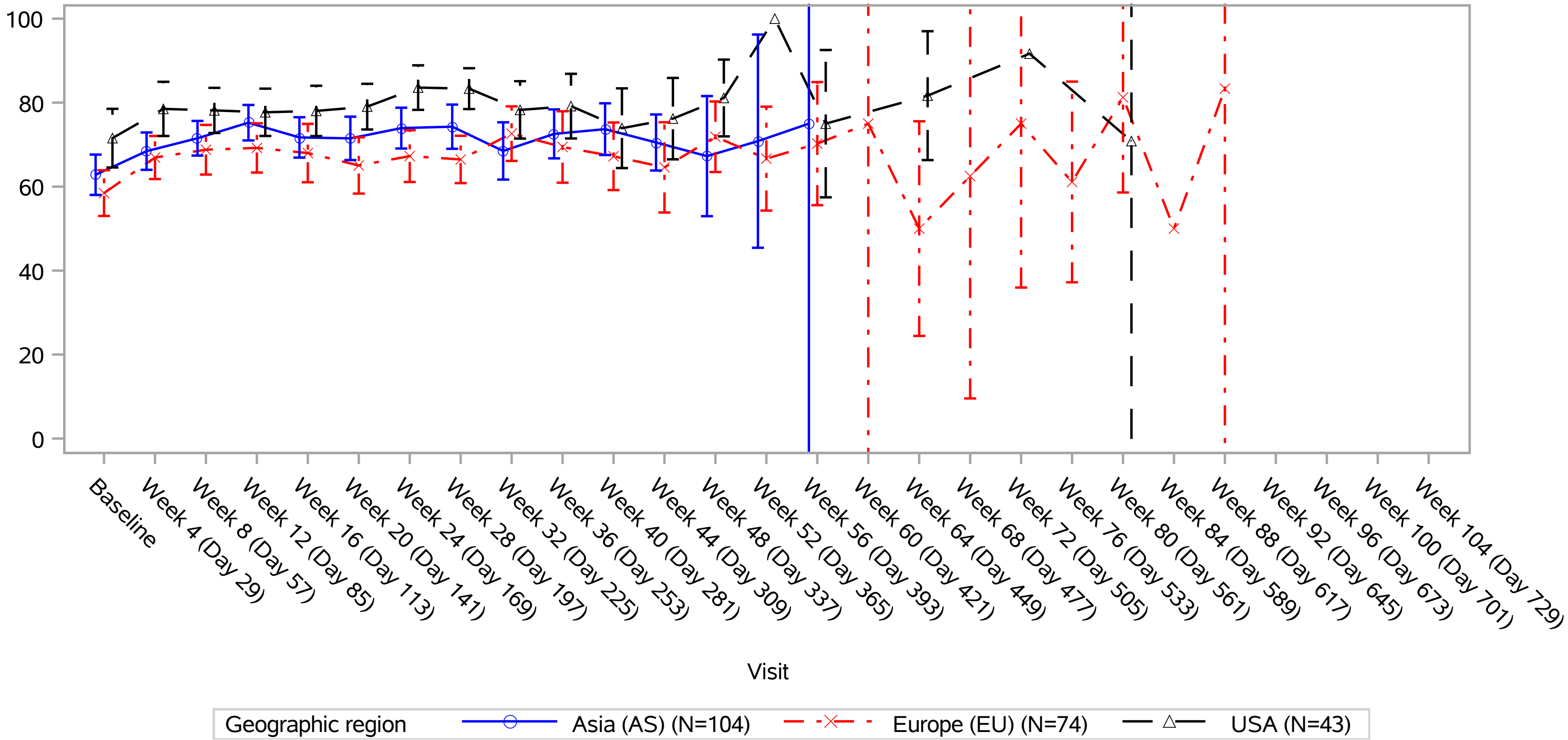
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Global health status
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30QL_SGECOG.pdf
15OCT2021 18:08

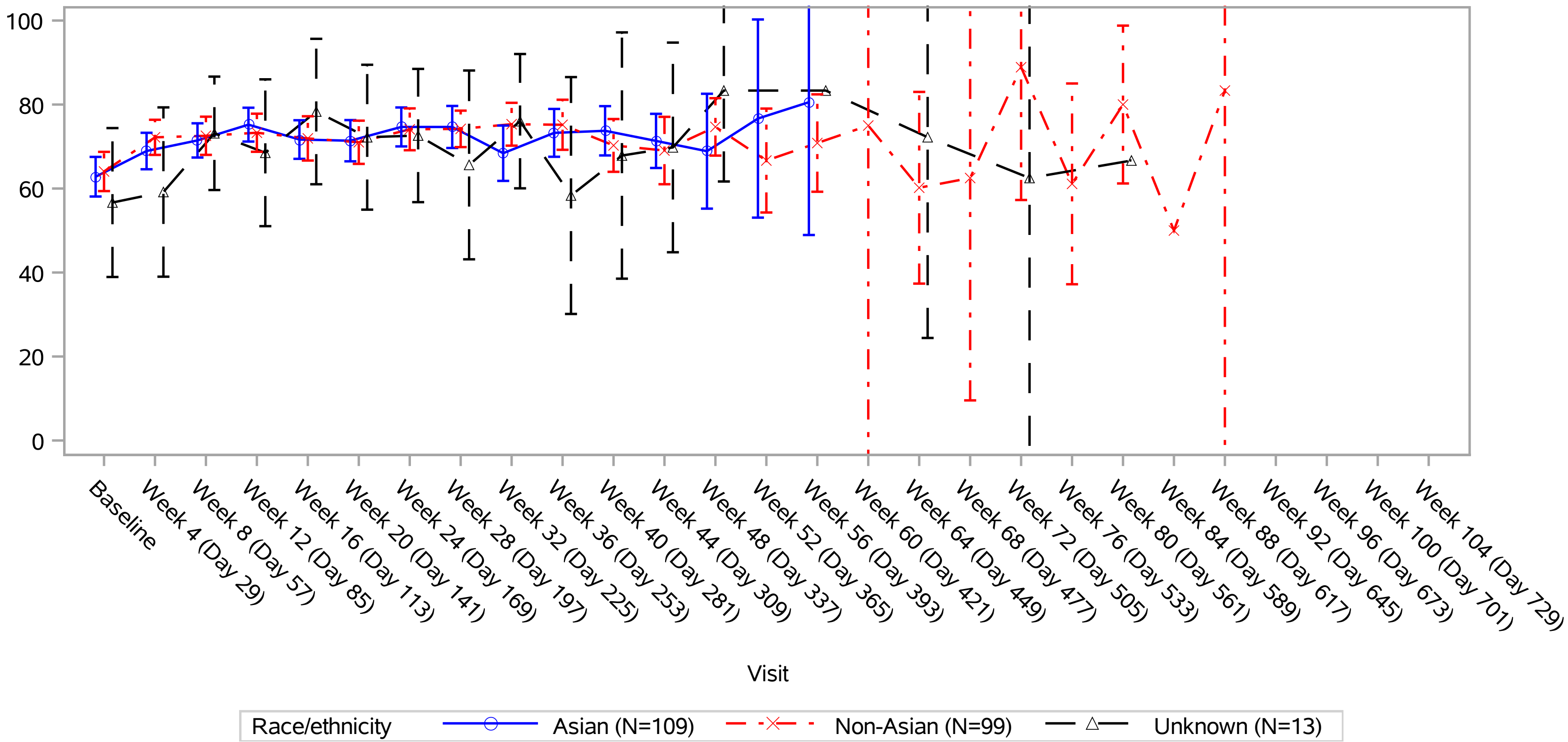
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Global health status
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30QL_SGGEO.pdf
15OCT2021 18:39

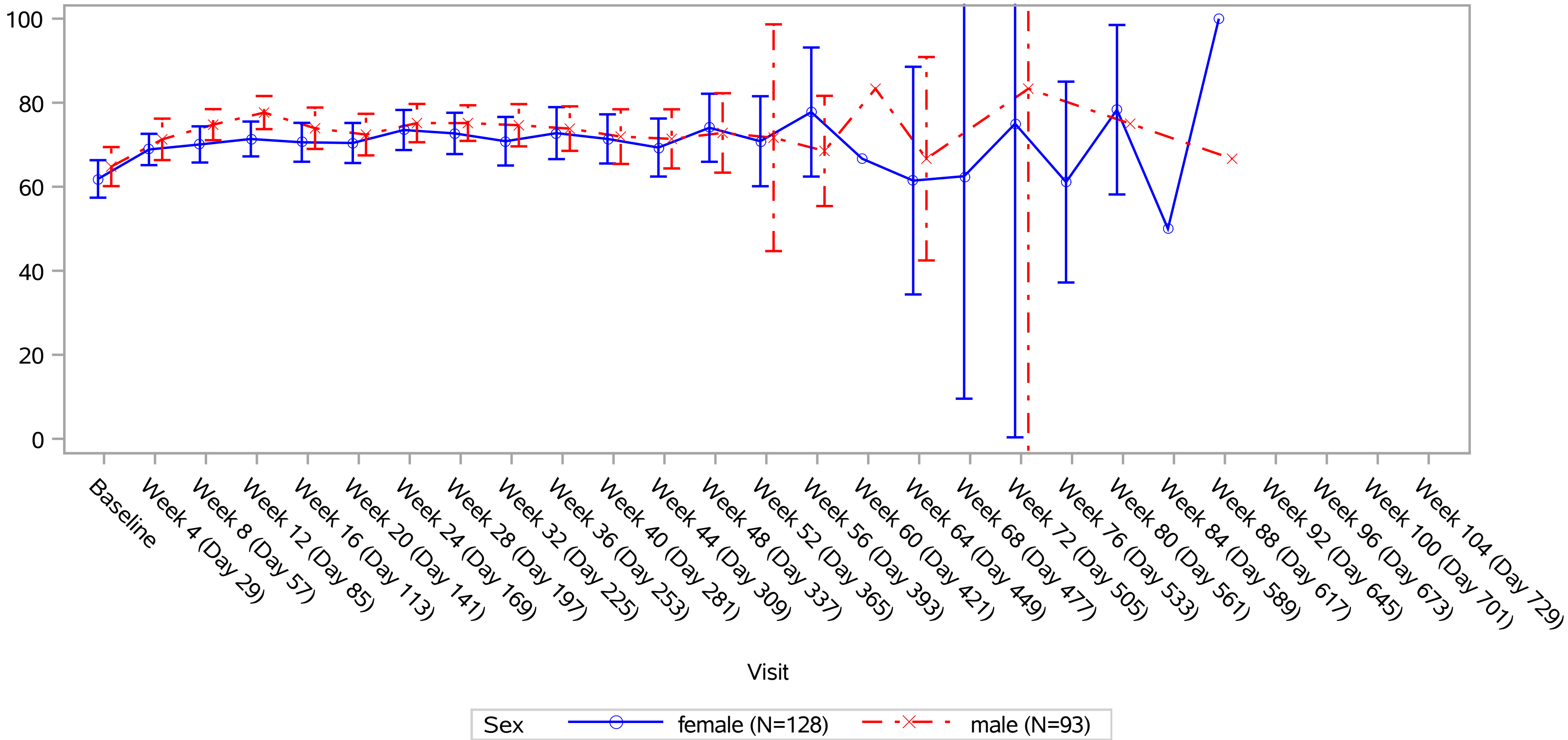
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Global health status
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30QL_SGRE.pdf
15OCT2021 19:10

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Global health status
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30QL_SGSEX.pdf
15OCT2021 19:40

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Role functioning
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=221)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	221	100.0	212	95.9	73.74	30.65	69.59	77.89
Week 4 (Day 29)	n/a	221	100.0	191	86.4	79.49	25.59	75.84	83.15
Week 8 (Day 57)	n/a	193	87.3	171	88.6	81.58	25.12	77.79	85.37
Week 12 (Day 85)	n/a	176	79.6	161	91.5	81.78	22.73	78.24	85.32
Week 16 (Day 113)	n/a	164	74.2	143	87.2	79.84	23.22	76.00	83.68
Week 20 (Day 141)	n/a	148	67.0	138	93.2	78.99	25.50	74.69	83.28
Week 24 (Day 169)	n/a	137	62.0	122	89.1	82.38	23.89	78.10	86.66
Week 28 (Day 197)	n/a	129	58.4	120	93.0	81.39	23.39	77.16	85.62
Week 32 (Day 225)	n/a	119	53.8	104	87.4	79.81	24.32	75.08	84.54
Week 36 (Day 253)	n/a	112	50.7	95	84.8	80.18	23.86	75.32	85.04
Week 40 (Day 281)	n/a	104	47.1	91	87.5	82.23	23.28	77.39	87.08
Week 44 (Day 309)	n/a	95	43.0	84	88.4	78.77	26.68	72.98	84.56
Week 48 (Day 337)	n/a	81	36.7	45	55.6	85.56	23.46	78.51	92.60
Week 52 (Day 365)	n/a	64	29.0	11	17.2	81.82	22.92	66.42	97.21
Week 56 (Day 393)	n/a	54	24.4	18	33.3	87.96	19.64	78.20	97.73
Week 60 (Day 421)	n/a	43	19.5	2	4.7	75.00	35.36	-242.66	392.66
Week 64 (Day 449)	n/a	41	18.6	12	29.3	86.11	15.62	76.18	96.04
Week 68 (Day 477)	n/a	34	15.4	2	5.9	58.33	11.79	-47.55	164.22
Week 72 (Day 505)	n/a	34	15.4	5	14.7	86.67	21.73	59.68	113.65
Week 76 (Day 533)	n/a	31	14.0	3	9.7	66.67	0.00	NE	NE
Week 80 (Day 561)	n/a	30	13.6	6	20.0	83.33	18.26	64.17	102.49
Week 84 (Day 589)	n/a	19	8.6	1	5.3	66.67	NE	NE	NE
Week 88 (Day 617)	n/a	15	6.8	2	13.3	100.00	0.00	NE	NE
Week 92 (Day 645)	n/a	8	3.6	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	2.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	1.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	221	100.0	219	99.1	76.86	27.51	73.20	80.53
End of Study (LOCF)	n/a	221	100.0	219	99.1	77.63	26.46	74.10	81.15
Sex									
Baseline	Female	128	100.0	123	96.1	71.54	31.42	65.94	77.15
Week 4 (Day 29)	Female	128	100.0	106	82.8	76.57	26.51	71.47	81.68
Week 8 (Day 57)	Female	112	87.5	98	87.5	80.10	27.87	74.51	85.69
Week 12 (Day 85)	Female	104	81.3	95	91.3	80.88	23.82	76.03	85.73
Week 16 (Day 113)	Female	96	75.0	81	84.4	77.37	25.32	71.77	82.96
Week 20 (Day 141)	Female	86	67.2	80	93.0	76.46	29.13	69.97	82.94
Week 24 (Day 169)	Female	78	60.9	67	85.9	81.09	25.44	74.89	87.30
Week 28 (Day 197)	Female	72	56.3	65	90.3	78.97	25.39	72.68	85.27
Week 32 (Day 225)	Female	69	53.9	58	84.1	78.45	25.75	71.68	85.22
Week 36 (Day 253)	Female	64	50.0	52	81.3	77.88	27.16	70.32	85.45
Week 40 (Day 281)	Female	59	46.1	53	89.8	80.50	24.84	73.66	87.35
Week 44 (Day 309)	Female	56	43.8	47	83.9	76.60	29.42	67.96	85.23
Week 48 (Day 337)	Female	48	37.5	26	54.2	84.62	26.21	74.03	95.20
Week 52 (Day 365)	Female	38	29.7	6	15.8	83.33	21.08	61.21	105.46
Week 56 (Day 393)	Female	31	24.2	9	29.0	90.74	14.70	79.44	102.04
Week 60 (Day 421)	Female	27	21.1	1	3.7	50.00	NE	NE	NE
Week 64 (Day 449)	Female	26	20.3	8	30.8	87.50	14.77	75.15	99.85
Week 68 (Day 477)	Female	23	18.0	2	8.7	58.33	11.79	-47.55	164.22
Week 72 (Day 505)	Female	23	18.0	3	13.0	83.33	28.87	11.62	155.04
Week 76 (Day 533)	Female	21	16.4	3	14.3	66.67	0.00	NE	NE
Week 80 (Day 561)	Female	20	15.6	5	25.0	80.00	18.26	57.33	102.67
Week 84 (Day 589)	Female	12	9.4	1	8.3	66.67	NE	NE	NE
Week 88 (Day 617)	Female	9	7.0	1	11.1	100.00	NE	NE	NE
Week 92 (Day 645)	Female	6	4.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	3.9	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	1.6	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	0.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	128	100.0	127	99.2	75.98	28.38	71.00	80.97
End of Study (LOCF)	Female	128	100.0	127	99.2	76.90	26.98	72.17	81.64
Baseline	Male	93	100.0	89	95.7	76.78	29.48	70.57	82.99
Week 4 (Day 29)	Male	93	100.0	85	91.4	83.14	24.06	77.95	88.33
Week 8 (Day 57)	Male	81	87.1	73	90.1	83.56	20.88	78.69	88.43
Week 12 (Day 85)	Male	72	77.4	66	91.7	83.08	21.18	77.87	88.29
Week 16 (Day 113)	Male	68	73.1	62	91.2	83.06	19.90	78.01	88.12
Week 20 (Day 141)	Male	62	66.7	58	93.5	82.47	19.10	77.45	87.49
Week 24 (Day 169)	Male	59	63.4	55	93.2	83.94	21.98	78.00	89.88
Week 28 (Day 197)	Male	57	61.3	55	96.5	84.24	20.64	78.66	89.82
Week 32 (Day 225)	Male	50	53.8	46	92.0	81.52	22.56	74.82	88.22
Week 36 (Day 253)	Male	48	51.6	43	89.6	82.95	19.07	77.08	88.81
Week 40 (Day 281)	Male	45	48.4	38	84.4	84.65	21.00	77.75	91.55
Week 44 (Day 309)	Male	39	41.9	37	94.9	81.53	22.83	73.92	89.14
Week 48 (Day 337)	Male	33	35.5	19	57.6	86.84	19.70	77.35	96.34
Week 52 (Day 365)	Male	26	28.0	5	19.2	80.00	27.39	46.00	114.00
Week 56 (Day 393)	Male	23	24.7	9	39.1	85.19	24.22	66.57	103.80
Week 60 (Day 421)	Male	16	17.2	1	6.3	100.00	NE	NE	NE
Week 64 (Day 449)	Male	15	16.1	4	26.7	83.33	19.25	52.71	113.96
Week 68 (Day 477)	Male	11	11.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	11	11.8	2	18.2	91.67	11.79	-14.22	197.55
Week 76 (Day 533)	Male	10	10.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	10	10.8	1	10.0	100.00	NE	NE	NE
Week 84 (Day 589)	Male	7	7.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	6	6.5	1	16.7	100.00	NE	NE	NE
Week 92 (Day 645)	Male	2	2.2	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	93	100.0	92	98.9	78.08	26.37	72.62	83.54
End of Study (LOCF)	Male	93	100.0	92	98.9	78.62	25.83	73.27	83.97
Age									

Baseline	< 65	141	100.0	133	94.3	70.55	31.51	65.15	75.96
Week 4 (Day 29)	< 65	141	100.0	123	87.2	79.81	26.24	75.13	84.49
Week 8 (Day 57)	< 65	127	90.1	113	89.0	84.96	22.60	80.74	89.17
Week 12 (Day 85)	< 65	118	83.7	106	89.8	82.70	20.17	78.82	86.59
Week 16 (Day 113)	< 65	108	76.6	93	86.1	81.36	22.23	76.78	85.94
Week 20 (Day 141)	< 65	100	70.9	97	97.0	78.87	25.74	73.68	84.05
Week 24 (Day 169)	< 65	93	66.0	86	92.5	82.75	23.63	77.69	87.82
Week 28 (Day 197)	< 65	88	62.4	83	94.3	82.13	22.51	77.21	87.04
Week 32 (Day 225)	< 65	83	58.9	73	88.0	82.88	21.15	77.94	87.81
Week 36 (Day 253)	< 65	78	55.3	70	89.7	82.62	22.42	77.27	87.97
Week 40 (Day 281)	< 65	75	53.2	69	92.0	82.85	22.68	77.40	88.30
Week 44 (Day 309)	< 65	71	50.4	65	91.5	79.23	26.85	72.58	85.88
Week 48 (Day 337)	< 65	61	43.3	33	54.1	85.35	21.15	77.86	92.85
Week 52 (Day 365)	< 65	48	34.0	6	12.5	77.78	29.19	47.15	108.41
Week 56 (Day 393)	< 65	41	29.1	11	26.8	86.36	16.36	75.37	97.35
Week 60 (Day 421)	< 65	33	23.4	2	6.1	75.00	35.36	-242.66	392.66
Week 64 (Day 449)	< 65	31	22.0	10	32.3	85.00	16.57	73.14	96.86
Week 68 (Day 477)	< 65	26	18.4	2	7.7	58.33	11.79	-47.55	164.22
Week 72 (Day 505)	< 65	26	18.4	5	19.2	86.67	21.73	59.68	113.65
Week 76 (Day 533)	< 65	25	17.7	3	12.0	66.67	0.00	NE	NE
Week 80 (Day 561)	< 65	24	17.0	5	20.8	86.67	18.26	64.00	109.34
Week 84 (Day 589)	< 65	16	11.3	1	6.3	66.67	NE	NE	NE
Week 88 (Day 617)	< 65	13	9.2	2	15.4	100.00	0.00	NE	NE
Week 92 (Day 645)	< 65	7	5.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	3.5	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	2.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	0.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	141	100.0	139	98.6	77.34	28.30	72.59	82.09
End of Study (LOCF)	< 65	141	100.0	139	98.6	78.78	26.45	74.34	83.21
Baseline	>= 65	80	100.0	79	98.8	79.11	28.55	72.72	85.51
Week 4 (Day 29)	>= 65	80	100.0	68	85.0	78.92	24.54	72.98	84.86
Week 8 (Day 57)	>= 65	66	82.5	58	87.9	75.00	28.49	67.51	82.49
Week 12 (Day 85)	>= 65	58	72.5	55	94.8	80.00	27.10	72.67	87.33

Week 16 (Day 113)	>= 65	56	70.0	50	89.3	77.00	24.95	69.91	84.09
Week 20 (Day 141)	>= 65	48	60.0	41	85.4	79.27	25.22	71.31	87.23
Week 24 (Day 169)	>= 65	44	55.0	36	81.8	81.48	24.81	73.09	89.88
Week 28 (Day 197)	>= 65	41	51.3	37	90.2	79.73	25.50	71.23	88.23
Week 32 (Day 225)	>= 65	36	45.0	31	86.1	72.58	29.67	61.70	83.47
Week 36 (Day 253)	>= 65	34	42.5	25	73.5	73.33	26.79	62.28	84.39
Week 40 (Day 281)	>= 65	29	36.3	22	75.9	80.30	25.53	68.98	91.62
Week 44 (Day 309)	>= 65	24	30.0	19	79.2	77.19	26.77	64.29	90.09
Week 48 (Day 337)	>= 65	20	25.0	12	60.0	86.11	30.01	67.04	105.18
Week 52 (Day 365)	>= 65	16	20.0	5	31.3	86.67	13.94	69.35	103.98
Week 56 (Day 393)	>= 65	13	16.3	7	53.8	90.48	25.20	67.17	113.78
Week 60 (Day 421)	>= 65	10	12.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	10	12.5	2	20.0	91.67	11.79	-14.22	197.55
Week 68 (Day 477)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	6	7.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	6	7.5	1	16.7	66.67	NE	NE	NE
Week 84 (Day 589)	>= 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	2.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	80	100.0	80	100.0	76.04	26.23	70.20	81.88
End of Study (LOCF)	>= 65	80	100.0	80	100.0	75.63	26.51	69.73	81.52
ECOG performance status									
Baseline	0	63	100.0	60	95.2	75.56	31.06	67.53	83.58
Week 4 (Day 29)	0	63	100.0	56	88.9	76.79	30.10	68.73	84.85
Week 8 (Day 57)	0	58	92.1	52	89.7	75.96	32.07	67.03	84.89
Week 12 (Day 85)	0	55	87.3	50	90.9	79.33	25.77	72.01	86.66
Week 16 (Day 113)	0	54	85.7	45	83.3	80.00	25.03	72.48	87.52
Week 20 (Day 141)	0	52	82.5	48	92.3	77.08	29.70	68.46	85.71
Week 24 (Day 169)	0	49	77.8	43	87.8	82.56	24.11	75.14	89.98
Week 28 (Day 197)	0	46	73.0	42	91.3	81.35	25.02	73.55	89.15

Week 32 (Day 225)	0	41	65.1	34	82.9	81.86	23.70	73.59	90.13
Week 36 (Day 253)	0	39	61.9	31	79.5	82.80	25.63	73.39	92.20
Week 40 (Day 281)	0	37	58.7	30	81.1	83.33	21.88	75.16	91.51
Week 44 (Day 309)	0	36	57.1	29	80.6	78.16	30.57	66.53	89.79
Week 48 (Day 337)	0	28	44.4	18	64.3	81.48	29.09	67.02	95.95
Week 52 (Day 365)	0	27	42.9	6	22.2	77.78	29.19	47.15	108.41
Week 56 (Day 393)	0	24	38.1	8	33.3	83.33	25.20	62.27	104.40
Week 60 (Day 421)	0	21	33.3	1	4.8	50.00	NE	NE	NE
Week 64 (Day 449)	0	21	33.3	7	33.3	83.33	16.67	67.92	98.75
Week 68 (Day 477)	0	17	27.0	1	5.9	50.00	NE	NE	NE
Week 72 (Day 505)	0	17	27.0	2	11.8	75.00	35.36	-242.66	392.66
Week 76 (Day 533)	0	15	23.8	2	13.3	66.67	0.00	NE	NE
Week 80 (Day 561)	0	14	22.2	1	7.1	100.00	NE	NE	NE
Week 84 (Day 589)	0	11	17.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	10	15.9	1	10.0	100.00	NE	NE	NE
Week 92 (Day 645)	0	5	7.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	6.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	4.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	63	100.0	63	100.0	74.60	31.37	66.70	82.50
End of Study (LOCF)	0	63	100.0	63	100.0	75.40	29.76	67.90	82.89
Baseline	1	157	100.0	151	96.2	72.96	30.66	68.03	77.89
Week 4 (Day 29)	1	157	100.0	134	85.4	80.72	23.56	76.70	84.75
Week 8 (Day 57)	1	134	85.4	119	88.8	84.03	21.08	80.21	87.86
Week 12 (Day 85)	1	121	77.1	111	91.7	82.88	21.26	78.88	86.88
Week 16 (Day 113)	1	110	70.1	98	89.1	79.76	22.48	75.25	84.27
Week 20 (Day 141)	1	96	61.1	90	93.8	80.00	23.06	75.17	84.83
Week 24 (Day 169)	1	88	56.1	79	89.8	82.28	23.92	76.92	87.64
Week 28 (Day 197)	1	83	52.9	78	94.0	81.41	22.63	76.31	86.51
Week 32 (Day 225)	1	78	49.7	70	89.7	78.81	24.72	72.91	84.70
Week 36 (Day 253)	1	73	46.5	64	87.7	78.91	23.05	73.15	84.66
Week 40 (Day 281)	1	67	42.7	61	91.0	81.69	24.10	75.52	87.87

Week 44 (Day 309)	1	59	37.6	55	93.2	79.09	24.68	72.42	85.76
Week 48 (Day 337)	1	53	33.8	27	50.9	88.27	18.95	80.77	95.77
Week 52 (Day 365)	1	37	23.6	5	13.5	86.67	13.94	69.35	103.98
Week 56 (Day 393)	1	30	19.1	10	33.3	91.67	14.16	81.53	101.80
Week 60 (Day 421)	1	22	14.0	1	4.5	100.00	NE	NE	NE
Week 64 (Day 449)	1	20	12.7	5	25.0	90.00	14.91	71.49	108.51
Week 68 (Day 477)	1	17	10.8	1	5.9	66.67	NE	NE	NE
Week 72 (Day 505)	1	17	10.8	3	17.6	94.44	9.62	70.54	118.35
Week 76 (Day 533)	1	16	10.2	1	6.3	66.67	NE	NE	NE
Week 80 (Day 561)	1	16	10.2	5	31.3	80.00	18.26	57.33	102.67
Week 84 (Day 589)	1	8	5.1	1	12.5	66.67	NE	NE	NE
Week 88 (Day 617)	1	5	3.2	1	20.0	100.00	NE	NE	NE
Week 92 (Day 645)	1	3	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	157	100.0	155	98.7	77.85	25.91	73.74	81.96
End of Study (LOCF)	1	157	100.0	155	98.7	78.60	25.11	74.62	82.59
Baseline	Missing	1	100.0	1	100.0	83.33	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	66.67	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	66.67	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	66.67	NE	NE	NE
Geographic region									
Baseline	USA	43	100.0	41	95.3	71.54	33.18	61.07	82.02
Week 4 (Day 29)	USA	43	100.0	38	88.4	85.09	23.18	77.47	92.71
Week 8 (Day 57)	USA	41	95.3	37	90.2	87.39	17.75	81.47	93.30
Week 12 (Day 85)	USA	41	95.3	38	92.7	85.53	20.57	78.77	92.29
Week 16 (Day 113)	USA	40	93.0	33	82.5	79.80	22.34	71.88	87.72
Week 20 (Day 141)	USA	39	90.7	35	89.7	82.38	20.19	75.45	89.32
Week 24 (Day 169)	USA	36	83.7	33	91.7	85.35	21.55	77.71	93.00
Week 28 (Day 197)	USA	35	81.4	31	88.6	86.02	18.81	79.12	92.92
Week 32 (Day 225)	USA	32	74.4	28	87.5	77.38	24.93	67.71	87.05
Week 36 (Day 253)	USA	32	74.4	24	75.0	77.78	22.34	68.34	87.21
Week 40 (Day 281)	USA	29	67.4	23	79.3	81.88	26.55	70.40	93.36

Week 44 (Day 309)	USA	26	60.5	21	80.8	80.16	24.51	69.00	91.31
Week 48 (Day 337)	USA	21	48.8	15	71.4	88.89	19.59	78.04	99.74
Week 52 (Day 365)	USA	18	41.9	1	5.6	100.00	NE	NE	NE
Week 56 (Day 393)	USA	18	41.9	9	50.0	85.19	24.22	66.57	103.80
Week 60 (Day 421)	USA	17	39.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	15	34.9	5	33.3	93.33	14.91	74.82	111.84
Week 68 (Day 477)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	12	27.9	1	8.3	100.00	NE	NE	NE
Week 76 (Day 533)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	12	27.9	2	16.7	66.67	0.00	NE	NE
Week 84 (Day 589)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	6	14.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	11.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	7.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	43	100.0	43	100.0	81.40	24.72	73.79	89.00
End of Study (LOCF)	USA	43	100.0	43	100.0	81.78	24.35	74.29	89.28
Baseline	Europe (EU)	74	100.0	69	93.2	64.01	31.78	56.38	71.64
Week 4 (Day 29)	Europe (EU)	74	100.0	64	86.5	73.44	25.50	67.07	79.81
Week 8 (Day 57)	Europe (EU)	65	87.8	55	84.6	74.24	31.56	65.71	82.77
Week 12 (Day 85)	Europe (EU)	57	77.0	49	86.0	73.81	26.35	66.24	81.38
Week 16 (Day 113)	Europe (EU)	55	74.3	44	80.0	74.62	28.19	66.05	83.19
Week 20 (Day 141)	Europe (EU)	49	66.2	46	93.9	71.01	31.12	61.77	80.26
Week 24 (Day 169)	Europe (EU)	47	63.5	42	89.4	75.79	29.26	66.67	84.91
Week 28 (Day 197)	Europe (EU)	45	60.8	43	95.6	75.58	25.55	67.72	83.44
Week 32 (Day 225)	Europe (EU)	39	52.7	35	89.7	81.90	23.00	74.00	89.81
Week 36 (Day 253)	Europe (EU)	34	45.9	30	88.2	81.11	23.87	72.20	90.02
Week 40 (Day 281)	Europe (EU)	31	41.9	30	96.8	81.67	21.15	73.77	89.56
Week 44 (Day 309)	Europe (EU)	28	37.8	24	85.7	72.92	31.40	59.66	86.17

Week 48 (Day 337)	Europe (EU)	22	29.7	16	72.7	81.25	23.47	68.74	93.76
Week 52 (Day 365)	Europe (EU)	19	25.7	6	31.6	75.00	27.39	46.26	103.74
Week 56 (Day 393)	Europe (EU)	17	23.0	7	41.2	88.10	15.85	73.43	102.76
Week 60 (Day 421)	Europe (EU)	15	20.3	2	13.3	75.00	35.36	-242.66	392.66
Week 64 (Day 449)	Europe (EU)	15	20.3	7	46.7	80.95	15.00	67.08	94.82
Week 68 (Day 477)	Europe (EU)	13	17.6	2	15.4	58.33	11.79	-47.55	164.22
Week 72 (Day 505)	Europe (EU)	13	17.6	4	30.8	83.33	23.57	45.83	120.84
Week 76 (Day 533)	Europe (EU)	11	14.9	3	27.3	66.67	0.00	NE	NE
Week 80 (Day 561)	Europe (EU)	10	13.5	4	40.0	91.67	16.67	65.15	118.19
Week 84 (Day 589)	Europe (EU)	6	8.1	1	16.7	66.67	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	4.1	2	66.7	100.00	0.00	NE	NE
Cycle 12 (LOCF)	Europe (EU)	74	100.0	73	98.6	69.41	30.18	62.37	76.45
End of Study (LOCF)	Europe (EU)	74	100.0	73	98.6	70.55	28.13	63.99	77.11
Baseline	Asia (AS)	104	100.0	102	98.1	81.21	26.91	75.92	86.50
Week 4 (Day 29)	Asia (AS)	104	100.0	89	85.6	81.46	26.04	75.97	86.95
Week 8 (Day 57)	Asia (AS)	87	83.7	79	90.8	83.97	21.92	79.06	88.88
Week 12 (Day 85)	Asia (AS)	78	75.0	74	94.9	85.14	20.00	80.50	89.77
Week 16 (Day 113)	Asia (AS)	69	66.3	66	95.7	83.33	19.39	78.57	88.10
Week 20 (Day 141)	Asia (AS)	60	57.7	57	95.0	83.33	22.05	77.48	89.18
Week 24 (Day 169)	Asia (AS)	54	51.9	47	87.0	86.17	18.82	80.65	91.70
Week 28 (Day 197)	Asia (AS)	49	47.1	46	93.9	83.70	23.44	76.74	90.66
Week 32 (Day 225)	Asia (AS)	48	46.2	41	85.4	79.67	25.42	71.65	87.70
Week 36 (Day 253)	Asia (AS)	46	44.2	41	89.1	80.89	25.16	72.95	88.83
Week 40 (Day 281)	Asia (AS)	44	42.3	38	86.4	82.89	23.41	75.20	90.59
Week 44 (Day 309)	Asia (AS)	41	39.4	39	95.1	81.62	24.72	73.61	89.64
Week 48 (Day 337)	Asia (AS)	38	36.5	14	36.8	86.90	27.87	70.81	103.00
Week 52 (Day 365)	Asia (AS)	27	26.0	4	14.8	87.50	15.96	62.11	112.89
Week 56 (Day 393)	Asia (AS)	19	18.3	2	10.5	100.00	0.00	NE	NE
Week 60 (Day 421)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	5.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	104	100.0	103	99.0	80.26	25.75	75.23	85.29
End of Study (LOCF)	Asia (AS)	104	100.0	103	99.0	80.91	25.29	75.96	85.85
Race/ethnicity									
Baseline	Asian	109	100.0	106	97.2	80.82	27.29	75.56	86.07
Week 4 (Day 29)	Asian	109	100.0	92	84.4	81.70	25.80	76.36	87.05
Week 8 (Day 57)	Asian	91	83.5	80	87.9	83.75	21.86	78.88	88.62
Week 12 (Day 85)	Asian	82	75.2	78	95.1	84.19	20.61	79.54	88.84
Week 16 (Day 113)	Asian	73	67.0	70	95.9	83.57	19.14	79.01	88.13
Week 20 (Day 141)	Asian	64	58.7	60	93.8	83.61	21.80	77.98	89.24
Week 24 (Day 169)	Asian	57	52.3	50	87.7	86.00	18.55	80.73	91.27
Week 28 (Day 197)	Asian	52	47.7	49	94.2	84.01	22.81	77.46	90.57
Week 32 (Day 225)	Asian	50	45.9	43	86.0	79.07	26.00	71.07	87.07
Week 36 (Day 253)	Asian	48	44.0	43	89.6	81.01	24.82	73.37	88.65
Week 40 (Day 281)	Asian	46	42.2	40	87.0	82.92	23.11	75.53	90.31
Week 44 (Day 309)	Asian	43	39.4	41	95.3	81.71	24.38	74.01	89.40
Week 48 (Day 337)	Asian	40	36.7	15	37.5	87.78	27.07	72.79	102.77
Week 52 (Day 365)	Asian	29	26.6	5	17.2	90.00	14.91	71.49	108.51
Week 56 (Day 393)	Asian	21	19.3	3	14.3	100.00	0.00	NE	NE
Week 60 (Day 421)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	5.5	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	4.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	1.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	109	100.0	107	98.2	80.53	25.44	75.65	85.41
End of Study (LOCF)	Asian	109	100.0	107	98.2	81.15	24.98	76.36	85.94
Baseline	Non-Asian	99	100.0	96	97.0	67.71	30.95	61.44	73.98
Week 4 (Day 29)	Non-Asian	99	100.0	89	89.9	79.21	24.01	74.16	84.27
Week 8 (Day 57)	Non-Asian	91	91.9	82	90.1	80.28	27.23	74.30	86.27
Week 12 (Day 85)	Non-Asian	83	83.8	74	89.2	80.86	24.00	75.30	86.42
Week 16 (Day 113)	Non-Asian	80	80.8	68	85.0	76.23	26.60	69.79	82.66
Week 20 (Day 141)	Non-Asian	74	74.7	69	93.2	75.12	28.67	68.23	82.01
Week 24 (Day 169)	Non-Asian	70	70.7	65	92.9	80.26	27.78	73.37	87.14
Week 28 (Day 197)	Non-Asian	67	67.7	63	94.0	80.95	22.77	75.22	86.69
Week 32 (Day 225)	Non-Asian	60	60.6	53	88.3	81.45	21.60	75.49	87.40
Week 36 (Day 253)	Non-Asian	55	55.6	46	83.6	82.25	20.31	76.22	88.28
Week 40 (Day 281)	Non-Asian	49	49.5	44	89.8	82.95	23.70	75.75	90.16
Week 44 (Day 309)	Non-Asian	43	43.4	35	81.4	76.67	26.87	67.44	85.90
Week 48 (Day 337)	Non-Asian	35	35.4	26	74.3	83.33	22.61	74.20	92.46
Week 52 (Day 365)	Non-Asian	29	29.3	6	20.7	75.00	27.39	46.26	103.74
Week 56 (Day 393)	Non-Asian	27	27.3	14	51.9	84.52	21.15	72.31	96.73
Week 60 (Day 421)	Non-Asian	26	26.3	2	7.7	75.00	35.36	-242.66	392.66
Week 64 (Day 449)	Non-Asian	24	24.2	9	37.5	87.04	16.20	74.59	99.49
Week 68 (Day 477)	Non-Asian	20	20.2	2	10.0	58.33	11.79	-47.55	164.22
Week 72 (Day 505)	Non-Asian	20	20.2	3	15.0	94.44	9.62	70.54	118.35
Week 76 (Day 533)	Non-Asian	18	18.2	3	16.7	66.67	0.00	NE	NE
Week 80 (Day 561)	Non-Asian	17	17.2	5	29.4	86.67	18.26	64.00	109.34
Week 84 (Day 589)	Non-Asian	11	11.1	1	9.1	66.67	NE	NE	NE
Week 88 (Day 617)	Non-Asian	8	8.1	2	25.0	100.00	0.00	NE	NE
Week 92 (Day 645)	Non-Asian	4	4.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	3.0	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	99	100.0	99	100.0	74.24	27.79	68.70	79.79

End of Study (LOCF)	Non-Asian	99	100.0	99	100.0	74.92	26.87	69.56	80.28
Baseline	Unknown	13	100.0	10	76.9	56.67	43.89	25.27	88.06
Week 4 (Day 29)	Unknown	13	100.0	10	76.9	61.67	32.44	38.46	84.87
Week 8 (Day 57)	Unknown	11	84.6	9	81.8	74.07	32.39	49.17	98.97
Week 12 (Day 85)	Unknown	11	84.6	9	81.8	68.52	26.93	47.82	89.22
Week 16 (Day 113)	Unknown	11	84.6	5	45.5	76.67	22.36	48.90	104.43
Week 20 (Day 141)	Unknown	10	76.9	9	90.0	77.78	18.63	63.45	92.10
Week 24 (Day 169)	Unknown	10	76.9	7	70.0	76.19	16.27	61.15	91.23
Week 28 (Day 197)	Unknown	10	76.9	8	80.0	68.75	30.13	43.56	93.94
Week 32 (Day 225)	Unknown	9	69.2	8	88.9	72.92	33.26	45.11	100.72
Week 36 (Day 253)	Unknown	9	69.2	6	66.7	58.33	34.56	22.06	94.60
Week 40 (Day 281)	Unknown	9	69.2	7	77.8	73.81	23.29	52.27	95.35
Week 44 (Day 309)	Unknown	9	69.2	8	88.9	72.92	37.73	41.37	104.46
Week 48 (Day 337)	Unknown	6	46.2	4	66.7	91.67	16.67	65.15	118.19
Week 52 (Day 365)	Unknown	6	46.2	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	6	46.2	1	16.7	100.00	NE	NE	NE
Week 60 (Day 421)	Unknown	5	38.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	5	38.5	3	60.0	83.33	16.67	41.93	124.74
Week 68 (Day 477)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	4	30.8	2	50.0	75.00	35.36	-242.66	392.66
Week 76 (Day 533)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	4	30.8	1	25.0	66.67	NE	NE	NE
Week 84 (Day 589)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	7.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	13	100.0	13	100.0	66.67	37.88	43.77	89.56
End of Study (LOCF)	Unknown	13	100.0	13	100.0	69.23	32.52	49.58	88.88

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TO_QSC30RF_SG.xls
27OCT2021 7:20

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Role functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	97	45.8	39.2	52.5
	Cycle 12 (LOCF)	n/a	212	95.9	55	25.9	20.5	32.2
	End of Study (LOCF)	n/a	212	95.9	51	24.1	18.8	30.2
Sex	All visits	Female	123	55.7	56	45.5	37.0	54.3
		Male	89	40.3	41	46.1	36.1	56.4
	Cycle 12 (LOCF)	Female	123	55.7	31	25.2	18.4	33.5
		Male	89	40.3	24	27.0	18.8	37.0
	End of Study (LOCF)	Female	123	55.7	30	24.4	17.7	32.7
		Male	89	40.3	21	23.6	16.0	33.4
Age	All visits	< 65	133	60.2	51	38.3	30.5	46.8
		>= 65	79	35.7	46	58.2	47.2	68.5
	Cycle 12 (LOCF)	< 65	133	60.2	28	21.1	15.0	28.7
		>= 65	79	35.7	27	34.2	24.7	45.2
	End of Study (LOCF)	< 65	133	60.2	24	18.0	12.4	25.4
		>= 65	79	35.7	27	34.2	24.7	45.2
ECOG performance status	All visits	0	60	27.1	35	58.3	45.7	69.9
		1	151	68.3	61	40.4	32.9	48.4
		Missing	1	0.5	1	100.0	20.7	100.0
	Cycle 12 (LOCF)	0	60	27.1	16	26.7	17.1	39.0
		1	151	68.3	38	25.2	18.9	32.6
		Missing	1	0.5	1	100.0	20.7	100.0
	End of Study (LOCF)	0	60	27.1	16	26.7	17.1	39.0
		1	151	68.3	34	22.5	16.6	29.8
		Missing	1	0.5	1	100.0	20.7	100.0
Geographic region	All visits	USA	41	18.6	20	48.8	34.3	63.5
		Europe (EU)	69	31.2	35	50.7	39.2	62.2
		Asia (AS)	102	46.2	42	41.2	32.1	50.9
	Cycle 12 (LOCF)	USA	41	18.6	6	14.6	6.9	28.4
		Europe (EU)	69	31.2	22	31.9	22.1	43.6
		Asia (AS)	102	46.2	27	26.5	18.9	35.8
	End of Study (LOCF)	USA	41	18.6	5	12.2	5.3	25.5
		Europe (EU)	69	31.2	20	29.0	19.6	40.6
		Asia (AS)	102	46.2	26	25.5	18.0	34.7
Race/ethnicity	All visits	Asian	106	48.0	44	41.5	32.6	51.0
		Non-Asian	96	43.4	48	50.0	40.2	59.8
		Unknown	10	4.5	5	50.0	23.7	76.3
	Cycle 12 (LOCF)	Asian	106	48.0	28	26.4	19.0	35.5

		Non-Asian	96	43.4	25	26.0	18.3	35.6
		Unknown	10	4.5	2	20.0	5.7	51.0
	End of Study (LOCF)	Asian	106	48.0	27	25.5	18.1	34.5
		Non-Asian	96	43.4	22	22.9	15.6	32.3
		Unknown	10	4.5	2	20.0	5.7	51.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30RF_W10_SG.xls
15OCT2021 12:57

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Role functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

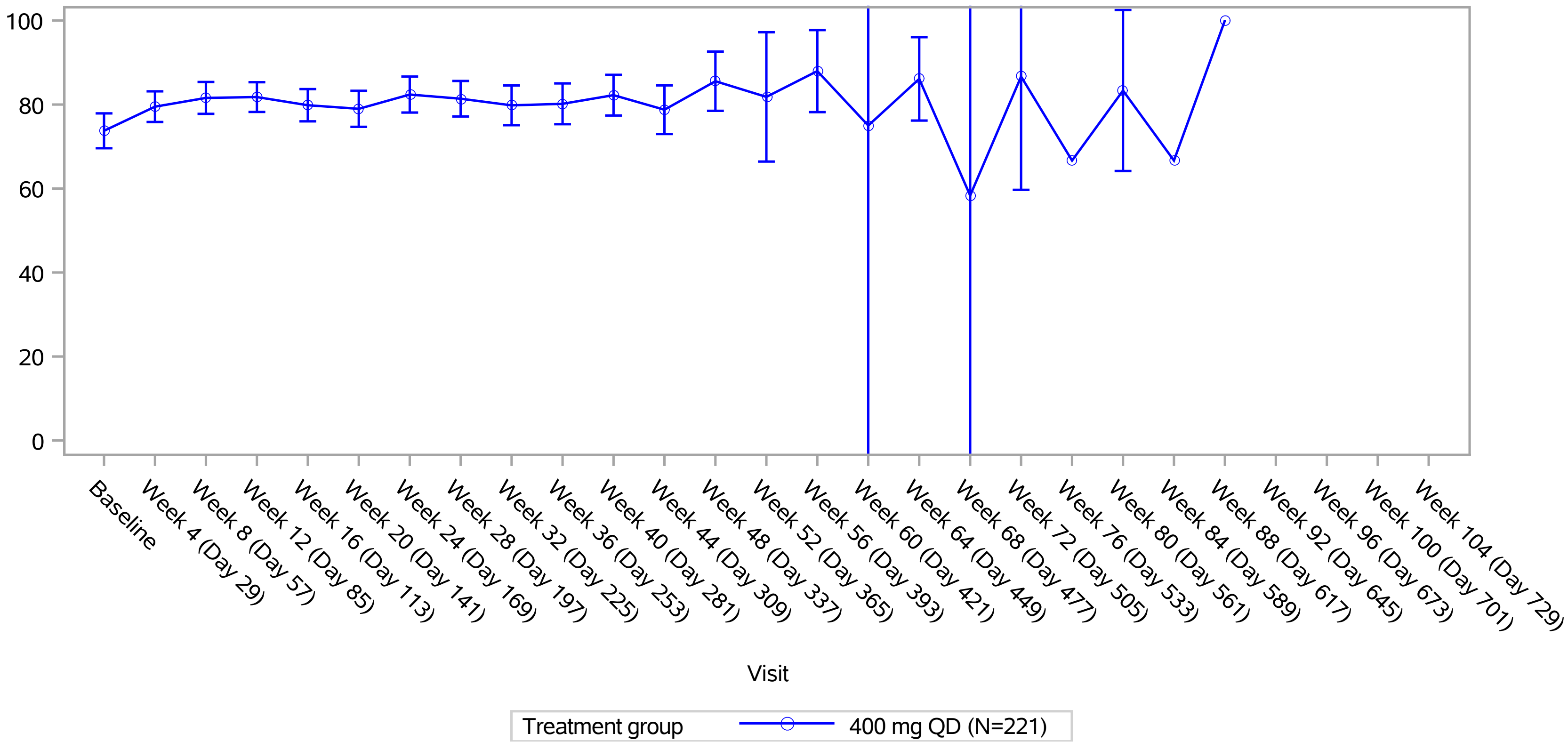
			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	97	45.8	39.2	52.5
	Cycle 12 (LOCF)	n/a	212	95.9	55	25.9	20.5	32.2
	End of Study (LOCF)	n/a	212	95.9	51	24.1	18.8	30.2
Sex	All visits	Female	123	55.7	56	45.5	37.0	54.3
		Male	89	40.3	41	46.1	36.1	56.4
	Cycle 12 (LOCF)	Female	123	55.7	31	25.2	18.4	33.5
		Male	89	40.3	24	27.0	18.8	37.0
	End of Study (LOCF)	Female	123	55.7	30	24.4	17.7	32.7
		Male	89	40.3	21	23.6	16.0	33.4
Age	All visits	< 65	133	60.2	51	38.3	30.5	46.8
		>= 65	79	35.7	46	58.2	47.2	68.5
	Cycle 12 (LOCF)	< 65	133	60.2	28	21.1	15.0	28.7
		>= 65	79	35.7	27	34.2	24.7	45.2
	End of Study (LOCF)	< 65	133	60.2	24	18.0	12.4	25.4
		>= 65	79	35.7	27	34.2	24.7	45.2
ECOG performance status	All visits	0	60	27.1	35	58.3	45.7	69.9
		1	151	68.3	61	40.4	32.9	48.4
		Missing	1	0.5	1	100.0	20.7	100.0
	Cycle 12 (LOCF)	0	60	27.1	16	26.7	17.1	39.0
		1	151	68.3	38	25.2	18.9	32.6
		Missing	1	0.5	1	100.0	20.7	100.0
	End of Study (LOCF)	0	60	27.1	16	26.7	17.1	39.0
		1	151	68.3	34	22.5	16.6	29.8
		Missing	1	0.5	1	100.0	20.7	100.0
Geographic region	All visits	USA	41	18.6	20	48.8	34.3	63.5
		Europe (EU)	69	31.2	35	50.7	39.2	62.2
		Asia (AS)	102	46.2	42	41.2	32.1	50.9
	Cycle 12 (LOCF)	USA	41	18.6	6	14.6	6.9	28.4
		Europe (EU)	69	31.2	22	31.9	22.1	43.6
		Asia (AS)	102	46.2	27	26.5	18.9	35.8
	End of Study (LOCF)	USA	41	18.6	5	12.2	5.3	25.5
		Europe (EU)	69	31.2	20	29.0	19.6	40.6
		Asia (AS)	102	46.2	26	25.5	18.0	34.7
Race/ethnicity	All visits	Asian	106	48.0	44	41.5	32.6	51.0
		Non-Asian	96	43.4	48	50.0	40.2	59.8
		Unknown	10	4.5	5	50.0	23.7	76.3
	Cycle 12 (LOCF)	Asian	106	48.0	28	26.4	19.0	35.5

		Non-Asian	96	43.4	25	26.0	18.3	35.6
		Unknown	10	4.5	2	20.0	5.7	51.0
	End of Study (LOCF)	Asian	106	48.0	27	25.5	18.1	34.5
		Non-Asian	96	43.4	22	22.9	15.6	32.3
		Unknown	10	4.5	2	20.0	5.7	51.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30RF_W15_SG.xls
15OCT2021 12:47

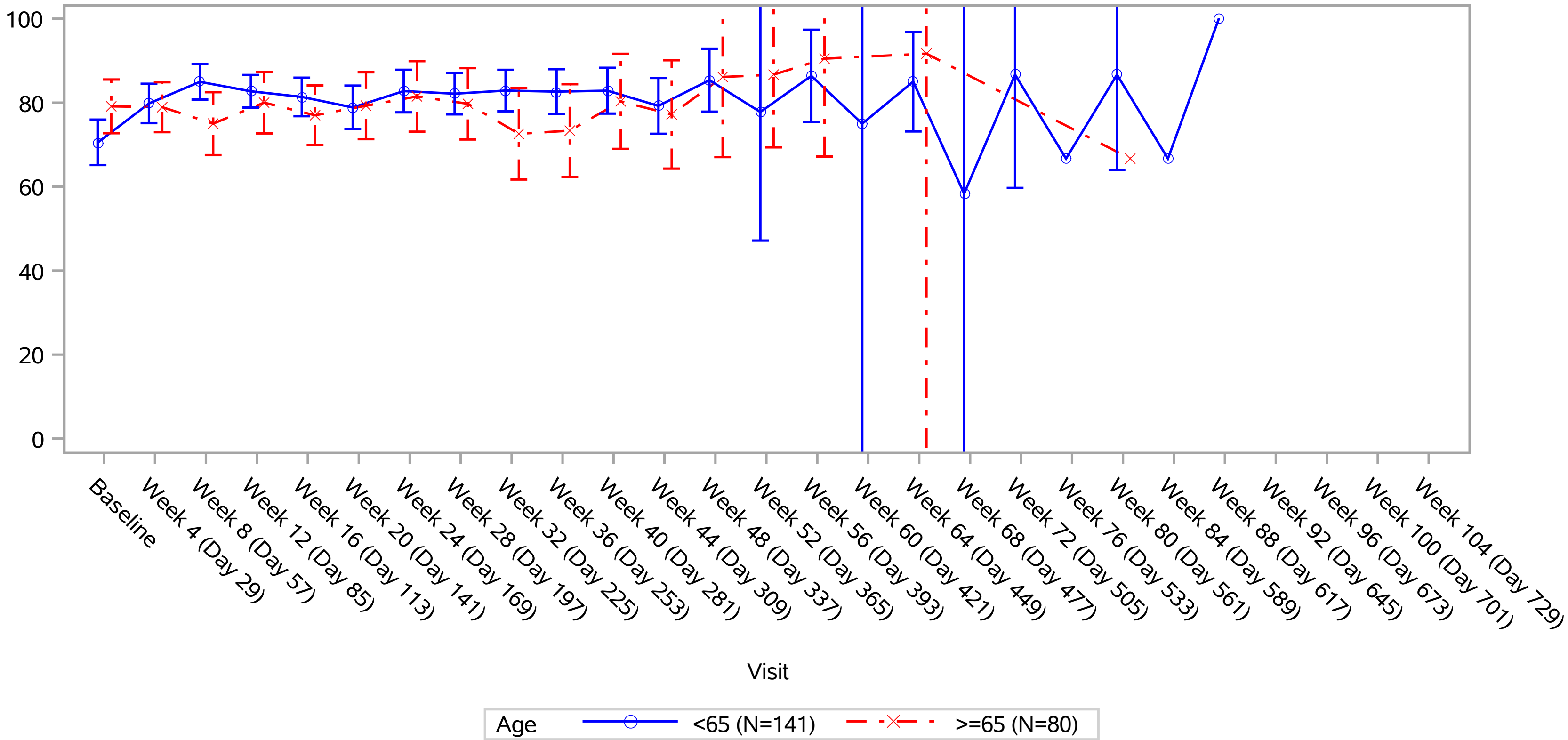
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Role functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30RF.pdf
15OCT2021 17:10

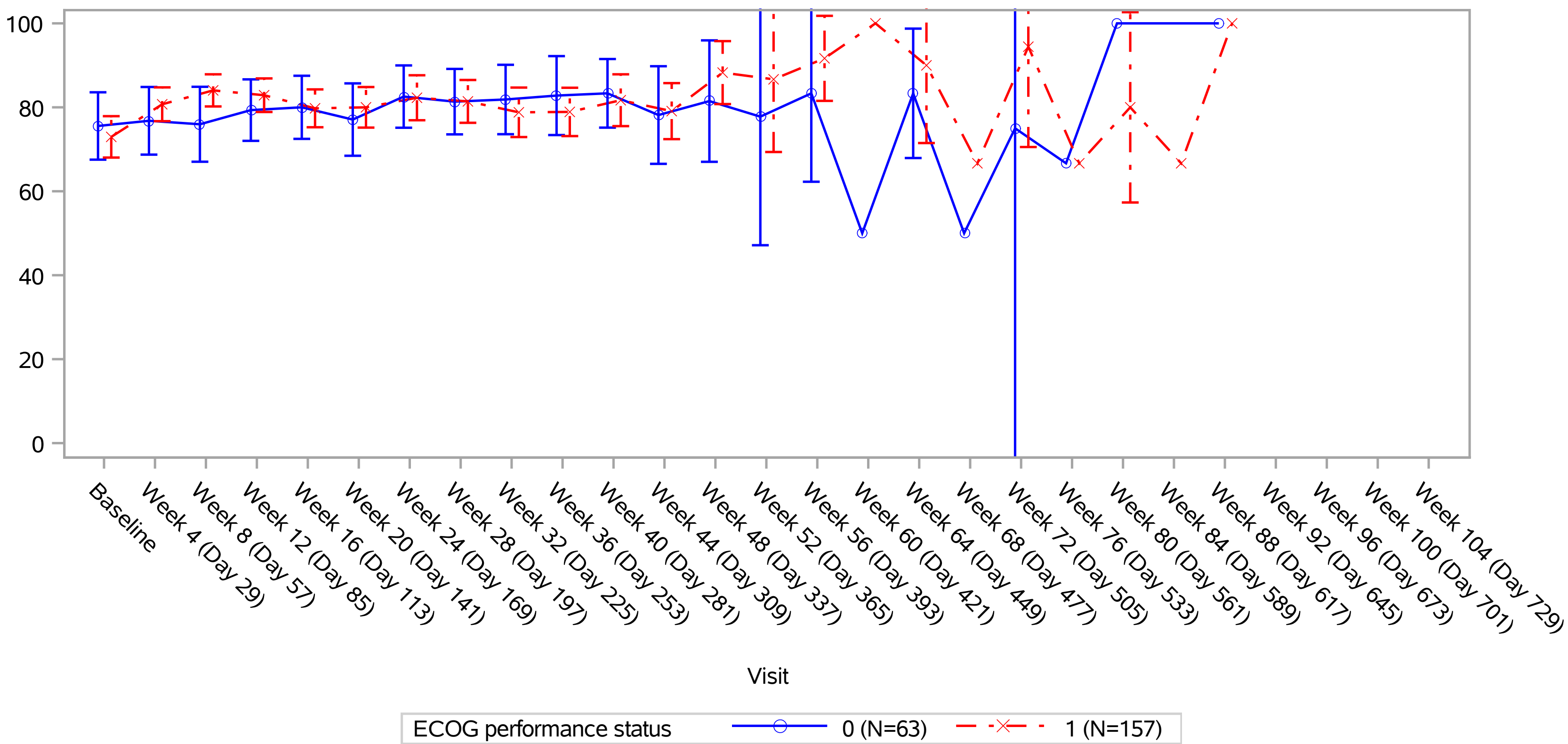
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Role functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30RF_SGAGE65.pdf
15OCT2021 17:39

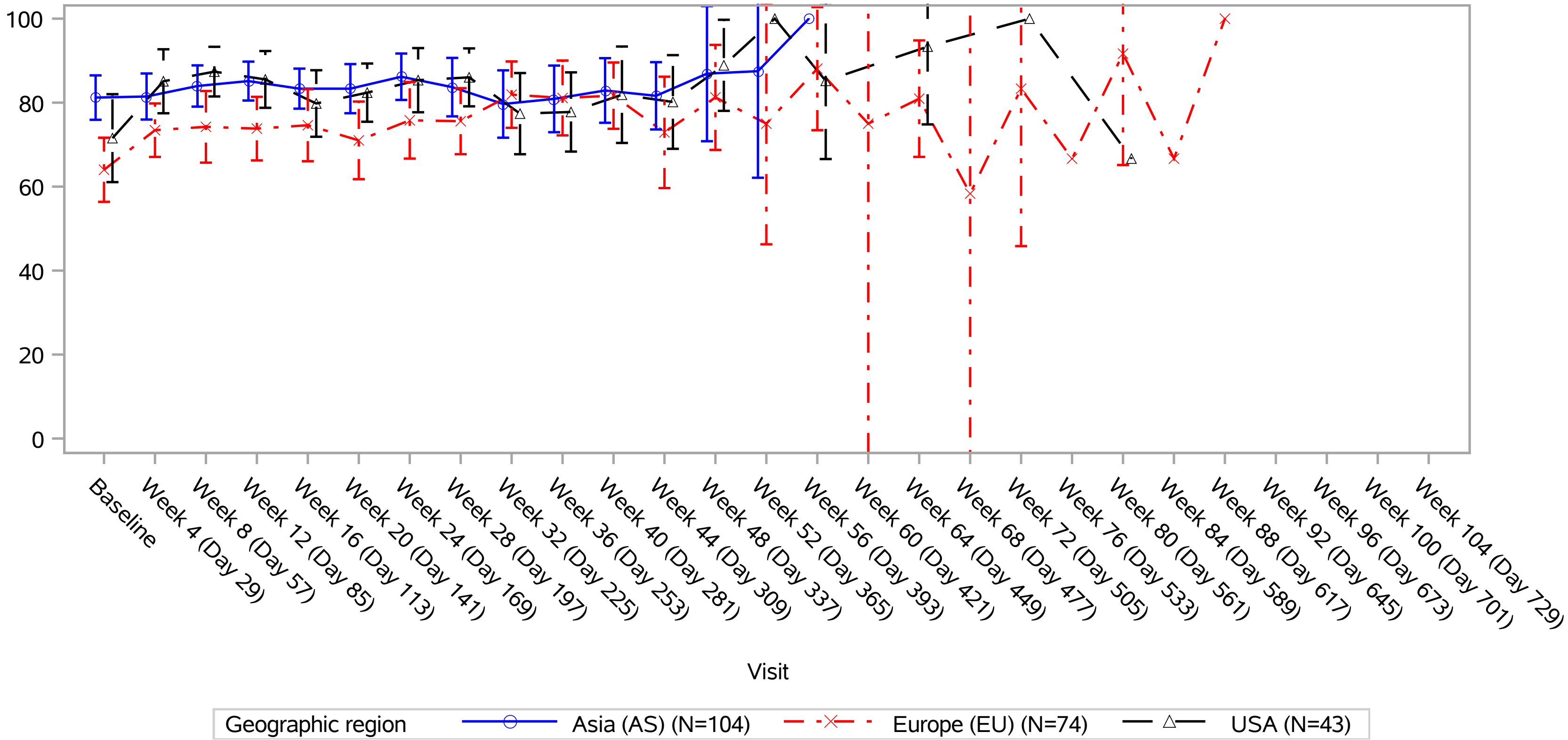
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Role functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30RF_SGECOG.pdf
15OCT2021 18:09

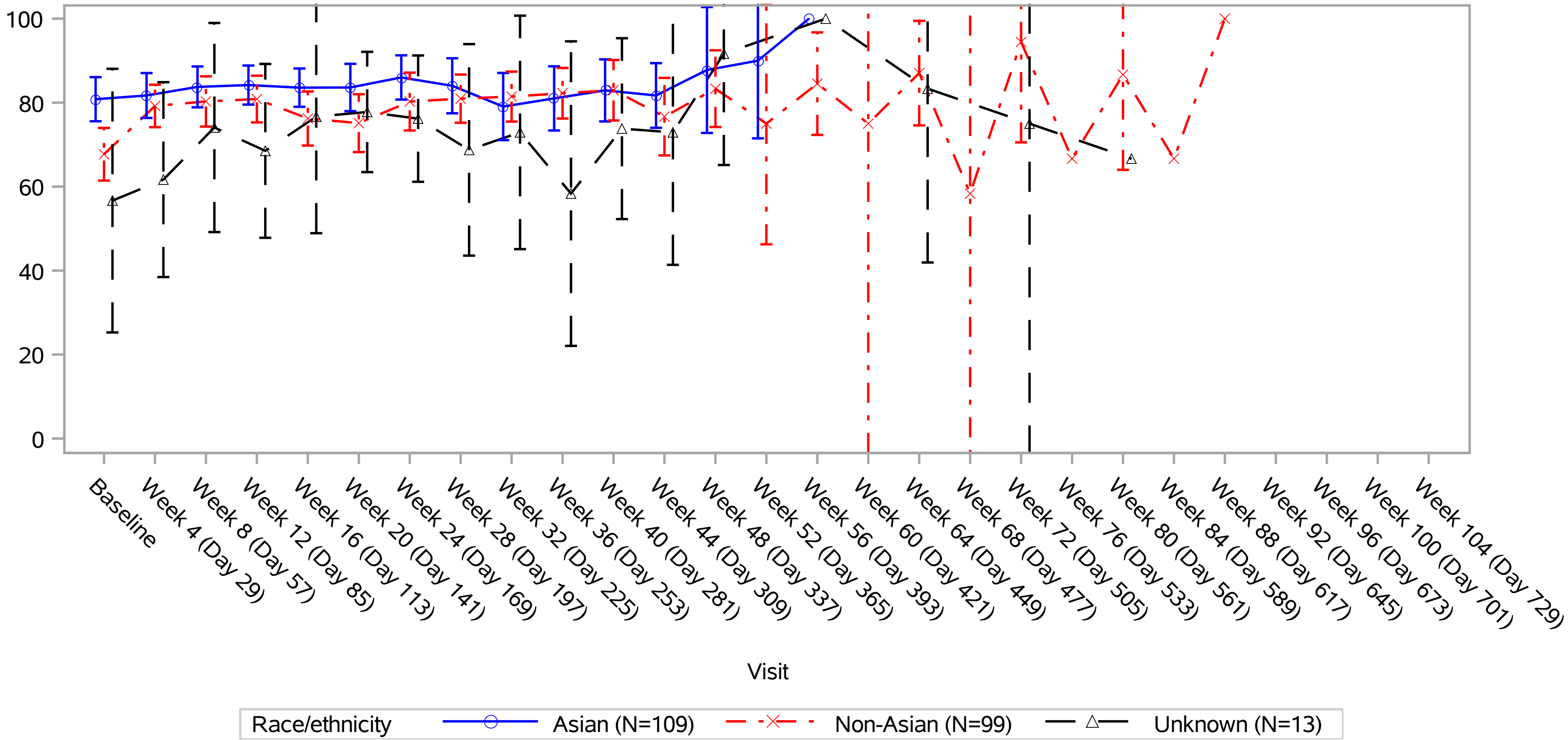
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Role functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30RF_SGGEO.pdf
15OCT2021 18:40

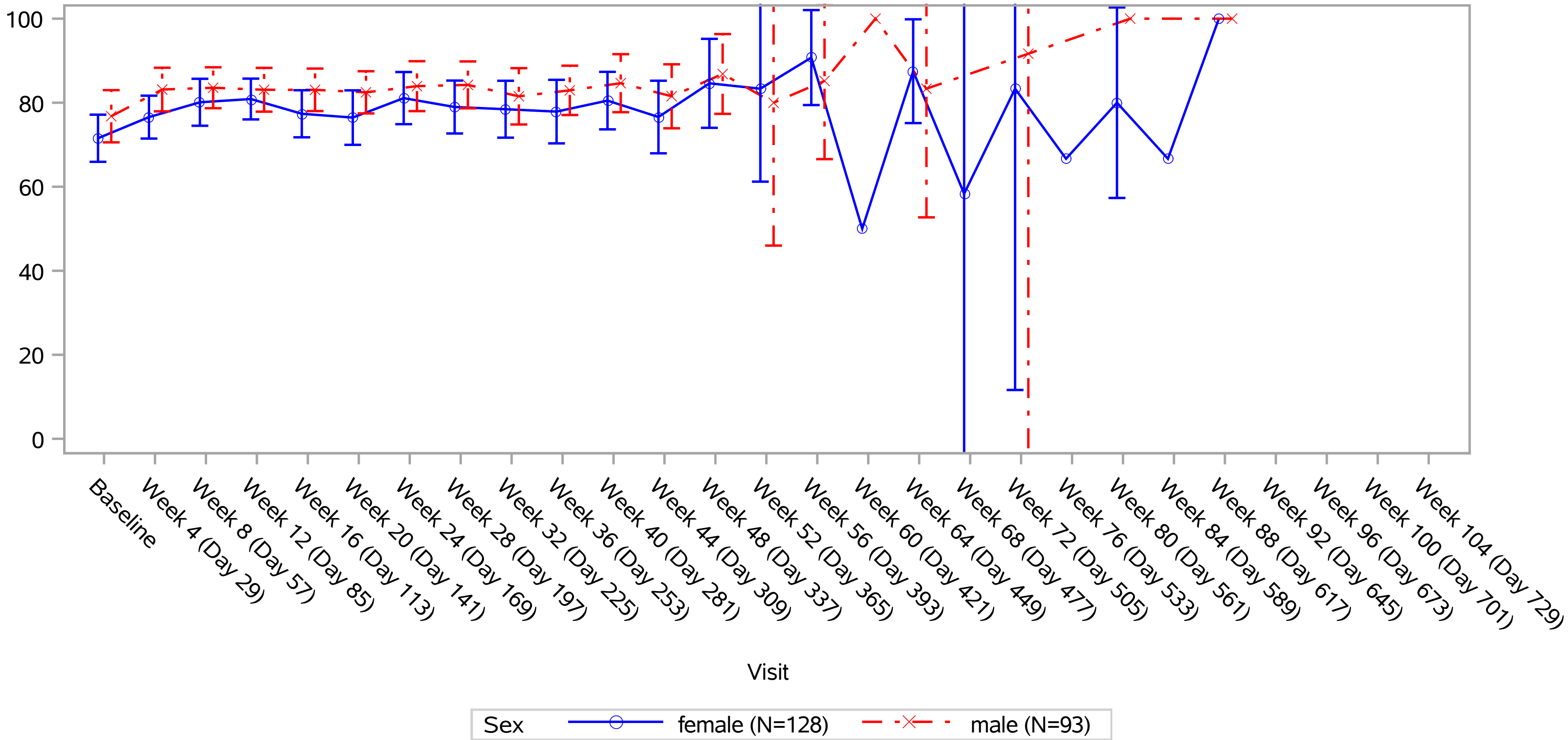
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Role functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30RF_SGRE.pdf
15OCT2021 19:10

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Role functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30RF_SGSEX.pdf
15OCT2021 19:41

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Social functioning
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=221)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	221	100.0	212	95.9	75.55	28.36	71.71	79.39
Week 4 (Day 29)	n/a	221	100.0	191	86.4	80.54	23.65	77.17	83.92
Week 8 (Day 57)	n/a	193	87.3	171	88.6	82.07	21.99	78.75	85.39
Week 12 (Day 85)	n/a	176	79.6	160	90.9	82.71	20.72	79.47	85.94
Week 16 (Day 113)	n/a	164	74.2	142	86.6	82.04	21.66	78.45	85.64
Week 20 (Day 141)	n/a	148	67.0	137	92.6	81.39	26.36	76.93	85.84
Week 24 (Day 169)	n/a	137	62.0	122	89.1	82.38	22.91	78.27	86.48
Week 28 (Day 197)	n/a	129	58.4	120	93.0	82.78	20.38	79.09	86.46
Week 32 (Day 225)	n/a	119	53.8	104	87.4	82.37	22.38	78.02	86.72
Week 36 (Day 253)	n/a	112	50.7	95	84.8	82.28	20.46	78.11	86.45
Week 40 (Day 281)	n/a	104	47.1	91	87.5	82.42	23.09	77.61	87.23
Week 44 (Day 309)	n/a	95	43.0	84	88.4	79.56	27.18	73.67	85.46
Week 48 (Day 337)	n/a	81	36.7	45	55.6	85.56	21.79	79.01	92.10
Week 52 (Day 365)	n/a	64	29.0	11	17.2	87.88	18.40	75.52	100.24
Week 56 (Day 393)	n/a	54	24.4	18	33.3	85.19	17.04	76.71	93.66
Week 60 (Day 421)	n/a	43	19.5	2	4.7	100.00	0.00	NE	NE
Week 64 (Day 449)	n/a	41	18.6	12	29.3	90.28	13.22	81.88	98.67
Week 68 (Day 477)	n/a	34	15.4	2	5.9	83.33	23.57	-128.44	295.10
Week 72 (Day 505)	n/a	34	15.4	5	14.7	100.00	0.00	NE	NE
Week 76 (Day 533)	n/a	31	14.0	3	9.7	83.33	16.67	41.93	124.74
Week 80 (Day 561)	n/a	30	13.6	6	20.0	88.89	27.22	60.33	117.45
Week 84 (Day 589)	n/a	19	8.6	1	5.3	100.00	NE	NE	NE
Week 88 (Day 617)	n/a	15	6.8	2	13.3	100.00	0.00	NE	NE
Week 92 (Day 645)	n/a	8	3.6	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	2.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	1.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	221	100.0	219	99.1	79.60	25.74	76.18	83.03
End of Study (LOCF)	n/a	221	100.0	219	99.1	80.21	24.56	76.94	83.48
Sex									
Baseline	Female	128	100.0	123	96.1	75.34	28.82	70.20	80.48
Week 4 (Day 29)	Female	128	100.0	106	82.8	80.35	23.99	75.73	84.97
Week 8 (Day 57)	Female	112	87.5	98	87.5	79.93	24.52	75.02	84.85
Week 12 (Day 85)	Female	104	81.3	94	90.4	80.50	22.08	75.97	85.02
Week 16 (Day 113)	Female	96	75.0	80	83.3	80.21	23.13	75.06	85.36
Week 20 (Day 141)	Female	86	67.2	79	91.9	79.11	30.01	72.39	85.84
Week 24 (Day 169)	Female	78	60.9	67	85.9	81.09	24.77	75.05	87.14
Week 28 (Day 197)	Female	72	56.3	65	90.3	80.51	22.16	75.02	86.00
Week 32 (Day 225)	Female	69	53.9	58	84.1	81.32	23.79	75.07	87.58
Week 36 (Day 253)	Female	64	50.0	52	81.3	81.09	22.87	74.72	87.46
Week 40 (Day 281)	Female	59	46.1	53	89.8	79.56	25.66	72.49	86.63
Week 44 (Day 309)	Female	56	43.8	47	83.9	77.66	30.15	68.81	86.51
Week 48 (Day 337)	Female	48	37.5	26	54.2	85.90	22.46	76.83	94.97
Week 52 (Day 365)	Female	38	29.7	6	15.8	91.67	13.94	77.03	106.30
Week 56 (Day 393)	Female	31	24.2	9	29.0	85.19	17.57	71.68	98.69
Week 60 (Day 421)	Female	27	21.1	1	3.7	100.00	NE	NE	NE
Week 64 (Day 449)	Female	26	20.3	8	30.8	91.67	12.60	81.13	102.20
Week 68 (Day 477)	Female	23	18.0	2	8.7	83.33	23.57	-128.44	295.10
Week 72 (Day 505)	Female	23	18.0	3	13.0	100.00	0.00	NE	NE
Week 76 (Day 533)	Female	21	16.4	3	14.3	83.33	16.67	41.93	124.74
Week 80 (Day 561)	Female	20	15.6	5	25.0	86.67	29.81	49.65	123.69
Week 84 (Day 589)	Female	12	9.4	1	8.3	100.00	NE	NE	NE
Week 88 (Day 617)	Female	9	7.0	1	11.1	100.00	NE	NE	NE
Week 92 (Day 645)	Female	6	4.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	3.9	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	1.6	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	0.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	128	100.0	127	99.2	79.00	26.83	74.29	83.71
End of Study (LOCF)	Female	128	100.0	127	99.2	80.45	25.47	75.97	84.92
Baseline	Male	93	100.0	89	95.7	75.84	27.87	69.97	81.71
Week 4 (Day 29)	Male	93	100.0	85	91.4	80.78	23.36	75.75	85.82
Week 8 (Day 57)	Male	81	87.1	73	90.1	84.93	17.82	80.77	89.09
Week 12 (Day 85)	Male	72	77.4	66	91.7	85.86	18.31	81.36	90.36
Week 16 (Day 113)	Male	68	73.1	62	91.2	84.41	19.53	79.45	89.37
Week 20 (Day 141)	Male	62	66.7	58	93.5	84.48	20.20	79.17	89.79
Week 24 (Day 169)	Male	59	63.4	55	93.2	83.94	20.53	78.39	89.49
Week 28 (Day 197)	Male	57	61.3	55	96.5	85.45	17.87	80.62	90.29
Week 32 (Day 225)	Male	50	53.8	46	92.0	83.70	20.63	77.57	89.82
Week 36 (Day 253)	Male	48	51.6	43	89.6	83.72	17.25	78.41	89.03
Week 40 (Day 281)	Male	45	48.4	38	84.4	86.40	18.52	80.31	92.49
Week 44 (Day 309)	Male	39	41.9	37	94.9	81.98	23.03	74.30	89.66
Week 48 (Day 337)	Male	33	35.5	19	57.6	85.09	21.44	74.75	95.42
Week 52 (Day 365)	Male	26	28.0	5	19.2	83.33	23.57	54.07	112.60
Week 56 (Day 393)	Male	23	24.7	9	39.1	85.19	17.57	71.68	98.69
Week 60 (Day 421)	Male	16	17.2	1	6.3	100.00	NE	NE	NE
Week 64 (Day 449)	Male	15	16.1	4	26.7	87.50	15.96	62.11	112.89
Week 68 (Day 477)	Male	11	11.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	11	11.8	2	18.2	100.00	0.00	NE	NE
Week 76 (Day 533)	Male	10	10.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	10	10.8	1	10.0	100.00	NE	NE	NE
Week 84 (Day 589)	Male	7	7.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	6	6.5	1	16.7	100.00	NE	NE	NE
Week 92 (Day 645)	Male	2	2.2	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	93	100.0	92	98.9	80.43	24.29	75.41	85.46
End of Study (LOCF)	Male	93	100.0	92	98.9	79.89	23.38	75.05	84.73
Age									

Baseline	< 65	141	100.0	133	94.3	71.55	28.85	66.61	76.50
Week 4 (Day 29)	< 65	141	100.0	123	87.2	78.73	24.36	74.38	83.07
Week 8 (Day 57)	< 65	127	90.1	113	89.0	82.89	19.85	79.19	86.59
Week 12 (Day 85)	< 65	118	83.7	105	89.0	82.22	18.81	78.58	85.86
Week 16 (Day 113)	< 65	108	76.6	92	85.2	82.07	20.11	77.90	86.23
Week 20 (Day 141)	< 65	100	70.9	96	96.0	80.21	26.30	74.88	85.54
Week 24 (Day 169)	< 65	93	66.0	86	92.5	80.62	22.70	75.75	85.49
Week 28 (Day 197)	< 65	88	62.4	83	94.3	82.13	20.95	77.55	86.70
Week 32 (Day 225)	< 65	83	58.9	73	88.0	83.11	21.96	77.98	88.23
Week 36 (Day 253)	< 65	78	55.3	70	89.7	81.90	21.56	76.76	87.05
Week 40 (Day 281)	< 65	75	53.2	69	92.0	81.40	23.66	75.72	87.09
Week 44 (Day 309)	< 65	71	50.4	65	91.5	78.72	27.56	71.89	85.55
Week 48 (Day 337)	< 65	61	43.3	33	54.1	84.85	19.26	78.02	91.68
Week 52 (Day 365)	< 65	48	34.0	6	12.5	88.89	20.18	67.71	110.07
Week 56 (Day 393)	< 65	41	29.1	11	26.8	84.85	18.94	72.13	97.57
Week 60 (Day 421)	< 65	33	23.4	2	6.1	100.00	0.00	NE	NE
Week 64 (Day 449)	< 65	31	22.0	10	32.3	90.00	14.05	79.95	100.05
Week 68 (Day 477)	< 65	26	18.4	2	7.7	83.33	23.57	-128.44	295.10
Week 72 (Day 505)	< 65	26	18.4	5	19.2	100.00	0.00	NE	NE
Week 76 (Day 533)	< 65	25	17.7	3	12.0	83.33	16.67	41.93	124.74
Week 80 (Day 561)	< 65	24	17.0	5	20.8	86.67	29.81	49.65	123.69
Week 84 (Day 589)	< 65	16	11.3	1	6.3	100.00	NE	NE	NE
Week 88 (Day 617)	< 65	13	9.2	2	15.4	100.00	0.00	NE	NE
Week 92 (Day 645)	< 65	7	5.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	3.5	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	2.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	0.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	141	100.0	139	98.6	78.30	25.82	73.97	82.63
End of Study (LOCF)	< 65	141	100.0	139	98.6	79.62	24.25	75.55	83.68
Baseline	>= 65	80	100.0	79	98.8	82.28	26.33	76.38	88.18
Week 4 (Day 29)	>= 65	80	100.0	68	85.0	83.82	22.11	78.47	89.18
Week 8 (Day 57)	>= 65	66	82.5	58	87.9	80.46	25.77	73.68	87.24
Week 12 (Day 85)	>= 65	58	72.5	55	94.8	83.64	24.11	77.12	90.15

Week 16 (Day 113)	>= 65	56	70.0	50	89.3	82.00	24.48	75.04	88.96
Week 20 (Day 141)	>= 65	48	60.0	41	85.4	84.15	26.60	75.75	92.54
Week 24 (Day 169)	>= 65	44	55.0	36	81.8	86.57	23.17	78.73	94.41
Week 28 (Day 197)	>= 65	41	51.3	37	90.2	84.23	19.22	77.82	90.64
Week 32 (Day 225)	>= 65	36	45.0	31	86.1	80.65	23.61	71.99	89.30
Week 36 (Day 253)	>= 65	34	42.5	25	73.5	83.33	17.35	76.17	90.49
Week 40 (Day 281)	>= 65	29	36.3	22	75.9	85.61	21.39	76.12	95.09
Week 44 (Day 309)	>= 65	24	30.0	19	79.2	82.46	26.34	69.76	95.15
Week 48 (Day 337)	>= 65	20	25.0	12	60.0	87.50	28.54	69.37	105.63
Week 52 (Day 365)	>= 65	16	20.0	5	31.3	86.67	18.26	64.00	109.34
Week 56 (Day 393)	>= 65	13	16.3	7	53.8	85.71	15.00	71.85	99.58
Week 60 (Day 421)	>= 65	10	12.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	10	12.5	2	20.0	91.67	11.79	-14.22	197.55
Week 68 (Day 477)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	6	7.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	6	7.5	1	16.7	100.00	NE	NE	NE
Week 84 (Day 589)	>= 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	2.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	80	100.0	80	100.0	81.88	25.60	76.18	87.57
End of Study (LOCF)	>= 65	80	100.0	80	100.0	81.25	25.21	75.64	86.86
ECOG performance status									
Baseline	0	63	100.0	60	95.2	76.94	27.97	69.72	84.17
Week 4 (Day 29)	0	63	100.0	56	88.9	77.98	28.27	70.41	85.55
Week 8 (Day 57)	0	58	92.1	52	89.7	81.41	24.84	74.49	88.33
Week 12 (Day 85)	0	55	87.3	49	89.1	82.31	23.42	75.58	89.04
Week 16 (Day 113)	0	54	85.7	45	83.3	80.00	23.46	72.95	87.05
Week 20 (Day 141)	0	52	82.5	47	90.4	82.98	28.76	74.53	91.42
Week 24 (Day 169)	0	49	77.8	43	87.8	84.11	23.27	76.95	91.27
Week 28 (Day 197)	0	46	73.0	42	91.3	83.73	20.66	77.29	90.17

Week 32 (Day 225)	0	41	65.1	34	82.9	84.80	22.24	77.05	92.56
Week 36 (Day 253)	0	39	61.9	31	79.5	86.56	18.47	79.78	93.33
Week 40 (Day 281)	0	37	58.7	30	81.1	88.33	21.51	80.30	96.36
Week 44 (Day 309)	0	36	57.1	29	80.6	78.74	32.40	66.41	91.06
Week 48 (Day 337)	0	28	44.4	18	64.3	84.26	27.70	70.49	98.03
Week 52 (Day 365)	0	27	42.9	6	22.2	83.33	21.08	61.21	105.46
Week 56 (Day 393)	0	24	38.1	8	33.3	89.58	15.27	76.82	102.35
Week 60 (Day 421)	0	21	33.3	1	4.8	100.00	NE	NE	NE
Week 64 (Day 449)	0	21	33.3	7	33.3	90.48	13.11	78.35	102.60
Week 68 (Day 477)	0	17	27.0	1	5.9	100.00	NE	NE	NE
Week 72 (Day 505)	0	17	27.0	2	11.8	100.00	0.00	NE	NE
Week 76 (Day 533)	0	15	23.8	2	13.3	91.67	11.79	-14.22	197.55
Week 80 (Day 561)	0	14	22.2	1	7.1	100.00	NE	NE	NE
Week 84 (Day 589)	0	11	17.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	10	15.9	1	10.0	100.00	NE	NE	NE
Week 92 (Day 645)	0	5	7.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	6.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	4.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	63	100.0	63	100.0	79.37	30.34	71.72	87.01
End of Study (LOCF)	0	63	100.0	63	100.0	80.42	28.33	73.29	87.56
Baseline	1	157	100.0	151	96.2	74.83	28.60	70.24	79.43
Week 4 (Day 29)	1	157	100.0	134	85.4	81.72	21.52	78.04	85.39
Week 8 (Day 57)	1	134	85.4	119	88.8	82.35	20.73	78.59	86.12
Week 12 (Day 85)	1	121	77.1	111	91.7	82.88	19.52	79.21	86.55
Week 16 (Day 113)	1	110	70.1	97	88.2	82.99	20.83	78.79	87.19
Week 20 (Day 141)	1	96	61.1	90	93.8	80.56	25.14	75.29	85.82
Week 24 (Day 169)	1	88	56.1	79	89.8	81.43	22.80	76.33	86.54
Week 28 (Day 197)	1	83	52.9	78	94.0	82.26	20.34	77.68	86.85
Week 32 (Day 225)	1	78	49.7	70	89.7	81.19	22.51	75.82	86.56
Week 36 (Day 253)	1	73	46.5	64	87.7	80.21	21.18	74.92	85.50
Week 40 (Day 281)	1	67	42.7	61	91.0	79.51	23.45	73.50	85.51

Week 44 (Day 309)	1	59	37.6	55	93.2	80.00	24.30	73.43	86.57
Week 48 (Day 337)	1	53	33.8	27	50.9	86.42	17.32	79.57	93.27
Week 52 (Day 365)	1	37	23.6	5	13.5	93.33	14.91	74.82	111.84
Week 56 (Day 393)	1	30	19.1	10	33.3	81.67	18.34	68.55	94.79
Week 60 (Day 421)	1	22	14.0	1	4.5	100.00	NE	NE	NE
Week 64 (Day 449)	1	20	12.7	5	25.0	90.00	14.91	71.49	108.51
Week 68 (Day 477)	1	17	10.8	1	5.9	66.67	NE	NE	NE
Week 72 (Day 505)	1	17	10.8	3	17.6	100.00	0.00	NE	NE
Week 76 (Day 533)	1	16	10.2	1	6.3	66.67	NE	NE	NE
Week 80 (Day 561)	1	16	10.2	5	31.3	86.67	29.81	49.65	123.69
Week 84 (Day 589)	1	8	5.1	1	12.5	100.00	NE	NE	NE
Week 88 (Day 617)	1	5	3.2	1	20.0	100.00	NE	NE	NE
Week 92 (Day 645)	1	3	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	157	100.0	155	98.7	79.78	23.80	76.01	83.56
End of Study (LOCF)	1	157	100.0	155	98.7	80.22	23.01	76.56	83.87
Baseline	Missing	1	100.0	1	100.0	100.00	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	66.67	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	66.67	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	66.67	NE	NE	NE
Geographic region									
Baseline	USA	43	100.0	41	95.3	81.71	26.30	73.41	90.01
Week 4 (Day 29)	USA	43	100.0	38	88.4	85.09	21.15	78.14	92.04
Week 8 (Day 57)	USA	41	95.3	37	90.2	86.94	17.63	81.06	92.81
Week 12 (Day 85)	USA	41	95.3	37	90.2	87.39	18.17	81.33	93.45
Week 16 (Day 113)	USA	40	93.0	32	80.0	85.42	18.81	78.63	92.20
Week 20 (Day 141)	USA	39	90.7	35	89.7	86.67	19.30	80.04	93.30
Week 24 (Day 169)	USA	36	83.7	33	91.7	87.88	19.66	80.91	94.85
Week 28 (Day 197)	USA	35	81.4	31	88.6	87.63	14.89	82.17	93.10
Week 32 (Day 225)	USA	32	74.4	28	87.5	80.36	21.78	71.91	88.80
Week 36 (Day 253)	USA	32	74.4	24	75.0	81.25	20.45	72.61	89.89
Week 40 (Day 281)	USA	29	67.4	23	79.3	84.06	26.82	72.46	95.65

Week 44 (Day 309)	USA	26	60.5	21	80.8	84.92	21.67	75.06	94.78
Week 48 (Day 337)	USA	21	48.8	15	71.4	87.78	19.38	77.04	98.51
Week 52 (Day 365)	USA	18	41.9	1	5.6	100.00	NE	NE	NE
Week 56 (Day 393)	USA	18	41.9	9	50.0	85.19	19.44	70.24	100.13
Week 60 (Day 421)	USA	17	39.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	15	34.9	5	33.3	93.33	14.91	74.82	111.84
Week 68 (Day 477)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	12	27.9	1	8.3	100.00	NE	NE	NE
Week 76 (Day 533)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	12	27.9	2	16.7	66.67	47.14	-356.87	490.21
Week 84 (Day 589)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	6	14.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	11.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	7.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	43	100.0	43	100.0	87.21	20.52	80.89	93.52
End of Study (LOCF)	USA	43	100.0	43	100.0	86.43	20.66	80.08	92.79
Baseline	Europe (EU)	74	100.0	69	93.2	68.36	30.67	60.99	75.73
Week 4 (Day 29)	Europe (EU)	74	100.0	64	86.5	79.17	25.37	72.83	85.50
Week 8 (Day 57)	Europe (EU)	65	87.8	55	84.6	82.73	22.90	76.54	88.92
Week 12 (Day 85)	Europe (EU)	57	77.0	49	86.0	78.57	23.81	71.73	85.41
Week 16 (Day 113)	Europe (EU)	55	74.3	44	80.0	80.68	22.14	73.95	87.41
Week 20 (Day 141)	Europe (EU)	49	66.2	45	91.8	75.93	31.89	66.34	85.51
Week 24 (Day 169)	Europe (EU)	47	63.5	42	89.4	77.38	25.72	69.37	85.40
Week 28 (Day 197)	Europe (EU)	45	60.8	43	95.6	79.46	22.96	72.39	86.52
Week 32 (Day 225)	Europe (EU)	39	52.7	35	89.7	86.19	19.59	79.46	92.92
Week 36 (Day 253)	Europe (EU)	34	45.9	30	88.2	85.56	18.94	78.48	92.63
Week 40 (Day 281)	Europe (EU)	31	41.9	30	96.8	83.89	22.52	75.48	92.30
Week 44 (Day 309)	Europe (EU)	28	37.8	24	85.7	76.39	33.30	62.33	90.45

Week 48 (Day 337)	Europe (EU)	22	29.7	16	72.7	86.46	15.18	78.37	94.55
Week 52 (Day 365)	Europe (EU)	19	25.7	6	31.6	83.33	21.08	61.21	105.46
Week 56 (Day 393)	Europe (EU)	17	23.0	7	41.2	90.48	13.11	78.35	102.60
Week 60 (Day 421)	Europe (EU)	15	20.3	2	13.3	100.00	0.00	NE	NE
Week 64 (Day 449)	Europe (EU)	15	20.3	7	46.7	88.10	12.60	76.44	99.75
Week 68 (Day 477)	Europe (EU)	13	17.6	2	15.4	83.33	23.57	-128.44	295.10
Week 72 (Day 505)	Europe (EU)	13	17.6	4	30.8	100.00	0.00	NE	NE
Week 76 (Day 533)	Europe (EU)	11	14.9	3	27.3	83.33	16.67	41.93	124.74
Week 80 (Day 561)	Europe (EU)	10	13.5	4	40.0	100.00	0.00	NE	NE
Week 84 (Day 589)	Europe (EU)	6	8.1	1	16.7	100.00	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	4.1	2	66.7	100.00	0.00	NE	NE
Cycle 12 (LOCF)	Europe (EU)	74	100.0	73	98.6	78.08	27.34	71.70	84.46
End of Study (LOCF)	Europe (EU)	74	100.0	73	98.6	80.82	24.32	75.15	86.50
Baseline	Asia (AS)	104	100.0	102	98.1	77.94	26.76	72.69	83.20
Week 4 (Day 29)	Asia (AS)	104	100.0	89	85.6	79.59	23.40	74.66	84.52
Week 8 (Day 57)	Asia (AS)	87	83.7	79	90.8	79.32	22.99	74.18	84.47
Week 12 (Day 85)	Asia (AS)	78	75.0	74	94.9	83.11	19.41	78.61	87.60
Week 16 (Day 113)	Asia (AS)	69	66.3	66	95.7	81.31	22.74	75.72	86.90
Week 20 (Day 141)	Asia (AS)	60	57.7	57	95.0	82.46	24.88	75.85	89.06
Week 24 (Day 169)	Asia (AS)	54	51.9	47	87.0	82.98	21.84	76.57	89.39
Week 28 (Day 197)	Asia (AS)	49	47.1	46	93.9	82.61	20.77	76.44	88.78
Week 32 (Day 225)	Asia (AS)	48	46.2	41	85.4	80.49	24.97	72.61	88.37
Week 36 (Day 253)	Asia (AS)	46	44.2	41	89.1	80.49	21.70	73.64	87.34
Week 40 (Day 281)	Asia (AS)	44	42.3	38	86.4	80.26	21.52	73.19	87.34
Week 44 (Day 309)	Asia (AS)	41	39.4	39	95.1	78.63	25.92	70.23	87.03
Week 48 (Day 337)	Asia (AS)	38	36.5	14	36.8	82.14	30.29	64.66	99.63
Week 52 (Day 365)	Asia (AS)	27	26.0	4	14.8	91.67	16.67	65.15	118.19
Week 56 (Day 393)	Asia (AS)	19	18.3	2	10.5	66.67	0.00	NE	NE
Week 60 (Day 421)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	5.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	104	100.0	103	99.0	77.51	26.17	72.39	82.62
End of Study (LOCF)	Asia (AS)	104	100.0	103	99.0	77.18	25.88	72.13	82.24
Race/ethnicity									
Baseline	Asian	109	100.0	106	97.2	77.52	27.51	72.22	82.81
Week 4 (Day 29)	Asian	109	100.0	92	84.4	79.17	23.65	74.27	84.06
Week 8 (Day 57)	Asian	91	83.5	80	87.9	79.17	22.89	74.07	84.26
Week 12 (Day 85)	Asian	82	75.2	78	95.1	82.69	19.27	78.35	87.04
Week 16 (Day 113)	Asian	73	67.0	69	94.5	81.40	22.42	76.01	86.79
Week 20 (Day 141)	Asian	64	58.7	60	93.8	81.67	25.25	75.14	88.19
Week 24 (Day 169)	Asian	57	52.3	50	87.7	82.67	21.55	76.54	88.79
Week 28 (Day 197)	Asian	52	47.7	49	94.2	82.31	20.53	76.42	88.21
Week 32 (Day 225)	Asian	50	45.9	43	86.0	79.84	24.55	72.29	87.40
Week 36 (Day 253)	Asian	48	44.0	43	89.6	80.23	21.29	73.68	86.78
Week 40 (Day 281)	Asian	46	42.2	40	87.0	80.42	21.31	73.60	87.23
Week 44 (Day 309)	Asian	43	39.4	41	95.3	78.86	25.56	70.80	86.93
Week 48 (Day 337)	Asian	40	36.7	15	37.5	83.33	29.55	66.97	99.70
Week 52 (Day 365)	Asian	29	26.6	5	17.2	93.33	14.91	74.82	111.84
Week 56 (Day 393)	Asian	21	19.3	3	14.3	77.78	19.25	29.97	125.59
Week 60 (Day 421)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	5.5	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	4.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	1.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	109	100.0	107	98.2	77.41	26.23	72.39	82.44
End of Study (LOCF)	Asian	109	100.0	107	98.2	77.10	25.95	72.13	82.08
Baseline	Non-Asian	99	100.0	96	97.0	74.13	27.98	68.46	79.80
Week 4 (Day 29)	Non-Asian	99	100.0	89	89.9	83.15	21.54	78.61	87.68
Week 8 (Day 57)	Non-Asian	91	91.9	82	90.1	84.76	21.15	80.11	89.40
Week 12 (Day 85)	Non-Asian	83	83.8	73	88.0	83.33	22.22	78.15	88.52
Week 16 (Day 113)	Non-Asian	80	80.8	68	85.0	82.11	21.42	76.92	87.29
Week 20 (Day 141)	Non-Asian	74	74.7	68	91.9	80.64	28.59	73.72	87.56
Week 24 (Day 169)	Non-Asian	70	70.7	65	92.9	82.31	24.80	76.16	88.45
Week 28 (Day 197)	Non-Asian	67	67.7	63	94.0	84.39	19.14	79.57	89.21
Week 32 (Day 225)	Non-Asian	60	60.6	53	88.3	84.28	21.03	78.48	90.07
Week 36 (Day 253)	Non-Asian	55	55.6	46	83.6	85.87	18.91	80.25	91.49
Week 40 (Day 281)	Non-Asian	49	49.5	44	89.8	82.95	25.54	75.19	90.72
Week 44 (Day 309)	Non-Asian	43	43.4	35	81.4	80.48	28.15	70.81	90.15
Week 48 (Day 337)	Non-Asian	35	35.4	26	74.3	87.18	17.83	79.98	94.38
Week 52 (Day 365)	Non-Asian	29	29.3	6	20.7	83.33	21.08	61.21	105.46
Week 56 (Day 393)	Non-Asian	27	27.3	14	51.9	85.71	17.12	75.83	95.60
Week 60 (Day 421)	Non-Asian	26	26.3	2	7.7	100.00	0.00	NE	NE
Week 64 (Day 449)	Non-Asian	24	24.2	9	37.5	87.04	13.89	76.36	97.71
Week 68 (Day 477)	Non-Asian	20	20.2	2	10.0	83.33	23.57	-128.44	295.10
Week 72 (Day 505)	Non-Asian	20	20.2	3	15.0	100.00	0.00	NE	NE
Week 76 (Day 533)	Non-Asian	18	18.2	3	16.7	83.33	16.67	41.93	124.74
Week 80 (Day 561)	Non-Asian	17	17.2	5	29.4	86.67	29.81	49.65	123.69
Week 84 (Day 589)	Non-Asian	11	11.1	1	9.1	100.00	NE	NE	NE
Week 88 (Day 617)	Non-Asian	8	8.1	2	25.0	100.00	0.00	NE	NE
Week 92 (Day 645)	Non-Asian	4	4.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	3.0	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	99	100.0	99	100.0	81.99	24.82	77.04	86.94

End of Study (LOCF)	Non-Asian	99	100.0	99	100.0	82.66	23.56	77.96	87.36
Baseline	Unknown	13	100.0	10	76.9	68.33	40.41	39.43	97.24
Week 4 (Day 29)	Unknown	13	100.0	10	76.9	70.00	37.52	43.16	96.84
Week 8 (Day 57)	Unknown	11	84.6	9	81.8	83.33	20.41	67.64	99.02
Week 12 (Day 85)	Unknown	11	84.6	9	81.8	77.78	22.05	60.83	94.73
Week 16 (Day 113)	Unknown	11	84.6	5	45.5	90.00	14.91	71.49	108.51
Week 20 (Day 141)	Unknown	10	76.9	9	90.0	85.19	15.47	73.30	97.07
Week 24 (Day 169)	Unknown	10	76.9	7	70.0	80.95	15.00	67.08	94.82
Week 28 (Day 197)	Unknown	10	76.9	8	80.0	72.92	28.08	49.44	96.40
Week 32 (Day 225)	Unknown	9	69.2	8	88.9	83.33	19.92	66.68	99.99
Week 36 (Day 253)	Unknown	9	69.2	6	66.7	69.44	22.15	46.20	92.69
Week 40 (Day 281)	Unknown	9	69.2	7	77.8	90.48	16.27	75.43	105.52
Week 44 (Day 309)	Unknown	9	69.2	8	88.9	79.17	34.21	50.56	107.77
Week 48 (Day 337)	Unknown	6	46.2	4	66.7	83.33	13.61	61.68	104.99
Week 52 (Day 365)	Unknown	6	46.2	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	6	46.2	1	16.7	100.00	NE	NE	NE
Week 60 (Day 421)	Unknown	5	38.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	5	38.5	3	60.0	100.00	0.00	NE	NE
Week 68 (Day 477)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	4	30.8	2	50.0	100.00	0.00	NE	NE
Week 76 (Day 533)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	4	30.8	1	25.0	100.00	NE	NE	NE
Week 84 (Day 589)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	7.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	13	100.0	13	100.0	79.49	28.99	61.97	97.01
End of Study (LOCF)	Unknown	13	100.0	13	100.0	87.18	16.88	76.98	97.38

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TO_QSC30SF_SG.xls
27OCT2021 7:21

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Social functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	83	39.2	32.8	45.9
	Cycle 12 (LOCF)	n/a	212	95.9	45	21.2	16.3	27.2
	End of Study (LOCF)	n/a	212	95.9	44	20.8	15.8	26.7
Sex	All visits	Female	123	55.7	50	40.7	32.4	49.5
		Male	89	40.3	33	37.1	27.8	47.5
	Cycle 12 (LOCF)	Female	123	55.7	26	21.1	14.9	29.2
		Male	89	40.3	19	21.3	14.1	31.0
	End of Study (LOCF)	Female	123	55.7	25	20.3	14.2	28.3
		Male	89	40.3	19	21.3	14.1	31.0
Age	All visits	< 65	133	60.2	43	32.3	25.0	40.7
		>= 65	79	35.7	40	50.6	39.8	61.4
	Cycle 12 (LOCF)	< 65	133	60.2	26	19.5	13.7	27.1
		>= 65	79	35.7	19	24.1	16.0	34.5
	End of Study (LOCF)	< 65	133	60.2	25	18.8	13.1	26.3
		>= 65	79	35.7	19	24.1	16.0	34.5
ECOG performance status	All visits	0	60	27.1	28	46.7	34.6	59.1
		1	151	68.3	54	35.8	28.6	43.7
		Missing	1	0.5	1	100.0	20.7	100.0
	Cycle 12 (LOCF)	0	60	27.1	13	21.7	13.1	33.6
		1	151	68.3	31	20.5	14.9	27.7
		Missing	1	0.5	1	100.0	20.7	100.0
	End of Study (LOCF)	0	60	27.1	14	23.3	14.4	35.4
		1	151	68.3	29	19.2	13.7	26.2
		Missing	1	0.5	1	100.0	20.7	100.0
Geographic region	All visits	USA	41	18.6	17	41.5	27.8	56.6
		Europe (EU)	69	31.2	27	39.1	28.5	50.9
		Asia (AS)	102	46.2	39	38.2	29.4	47.9
	Cycle 12 (LOCF)	USA	41	18.6	4	9.8	3.9	22.5
		Europe (EU)	69	31.2	14	20.3	12.5	31.2
		Asia (AS)	102	46.2	27	26.5	18.9	35.8
	End of Study (LOCF)	USA	41	18.6	5	12.2	5.3	25.5
		Europe (EU)	69	31.2	12	17.4	10.2	28.0
		Asia (AS)	102	46.2	27	26.5	18.9	35.8
Race/ethnicity	All visits	Asian	106	48.0	41	38.7	30.0	48.2
		Non-Asian	96	43.4	38	39.6	30.4	49.6
		Unknown	10	4.5	4	40.0	16.8	68.7
	Cycle 12 (LOCF)	Asian	106	48.0	28	26.4	19.0	35.5

		Non-Asian	96	43.4	15	15.6	9.7	24.2
		Unknown	10	4.5	2	20.0	5.7	51.0
	End of Study (LOCF)	Asian	106	48.0	28	26.4	19.0	35.5
		Non-Asian	96	43.4	14	14.6	8.9	23.0
		Unknown	10	4.5	2	20.0	5.7	51.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30SF_W10_SG.xls
15OCT2021 12:58

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Social functioning
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

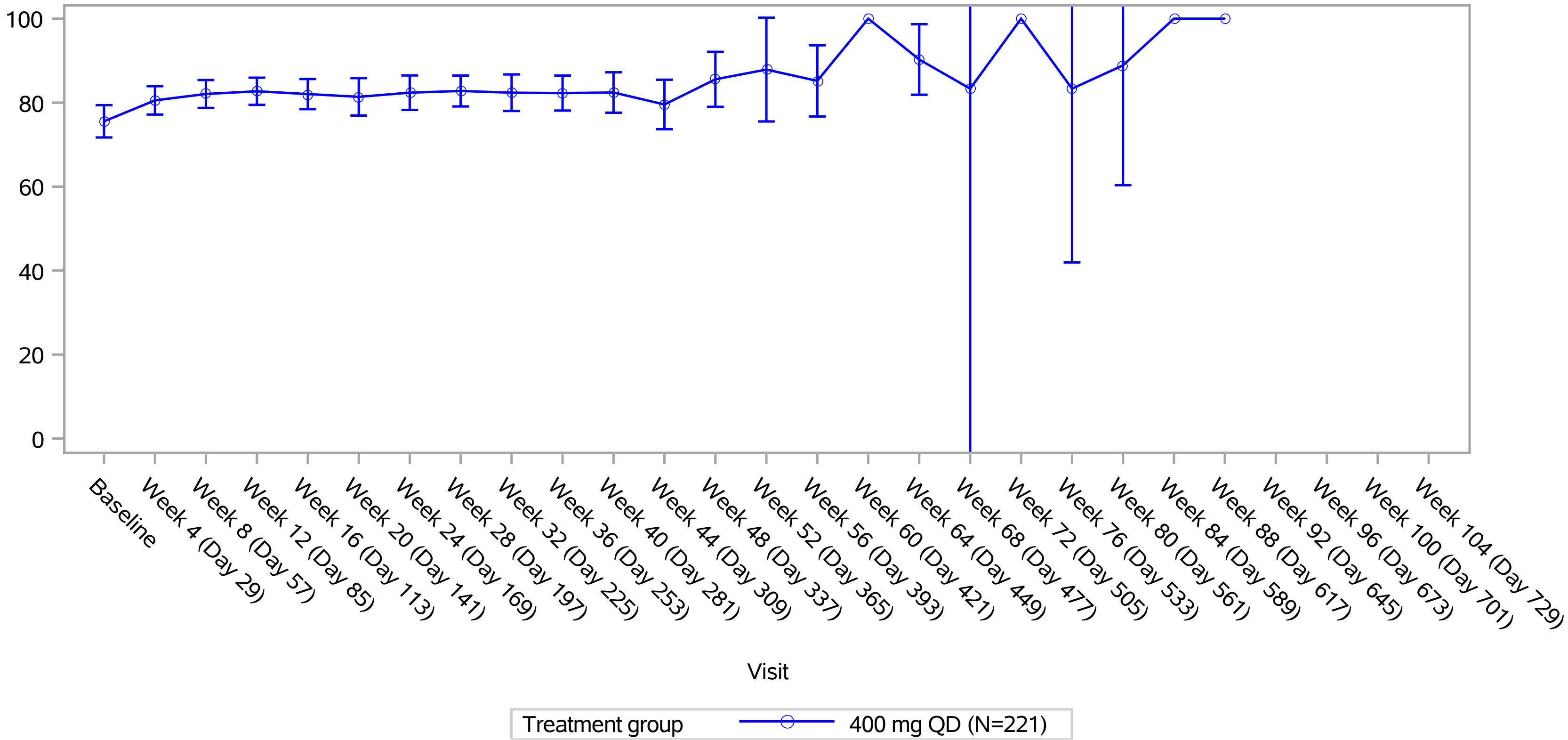
			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	83	39.2	32.8	45.9
	Cycle 12 (LOCF)	n/a	212	95.9	45	21.2	16.3	27.2
	End of Study (LOCF)	n/a	212	95.9	44	20.8	15.8	26.7
Sex	All visits	Female	123	55.7	50	40.7	32.4	49.5
		Male	89	40.3	33	37.1	27.8	47.5
	Cycle 12 (LOCF)	Female	123	55.7	26	21.1	14.9	29.2
		Male	89	40.3	19	21.3	14.1	31.0
	End of Study (LOCF)	Female	123	55.7	25	20.3	14.2	28.3
		Male	89	40.3	19	21.3	14.1	31.0
Age	All visits	< 65	133	60.2	43	32.3	25.0	40.7
		>= 65	79	35.7	40	50.6	39.8	61.4
	Cycle 12 (LOCF)	< 65	133	60.2	26	19.5	13.7	27.1
		>= 65	79	35.7	19	24.1	16.0	34.5
	End of Study (LOCF)	< 65	133	60.2	25	18.8	13.1	26.3
		>= 65	79	35.7	19	24.1	16.0	34.5
ECOG performance status	All visits	0	60	27.1	28	46.7	34.6	59.1
		1	151	68.3	54	35.8	28.6	43.7
		Missing	1	0.5	1	100.0	20.7	100.0
	Cycle 12 (LOCF)	0	60	27.1	13	21.7	13.1	33.6
		1	151	68.3	31	20.5	14.9	27.7
		Missing	1	0.5	1	100.0	20.7	100.0
	End of Study (LOCF)	0	60	27.1	14	23.3	14.4	35.4
		1	151	68.3	29	19.2	13.7	26.2
		Missing	1	0.5	1	100.0	20.7	100.0
Geographic region	All visits	USA	41	18.6	17	41.5	27.8	56.6
		Europe (EU)	69	31.2	27	39.1	28.5	50.9
		Asia (AS)	102	46.2	39	38.2	29.4	47.9
	Cycle 12 (LOCF)	USA	41	18.6	4	9.8	3.9	22.5
		Europe (EU)	69	31.2	14	20.3	12.5	31.2
		Asia (AS)	102	46.2	27	26.5	18.9	35.8
	End of Study (LOCF)	USA	41	18.6	5	12.2	5.3	25.5
		Europe (EU)	69	31.2	12	17.4	10.2	28.0
		Asia (AS)	102	46.2	27	26.5	18.9	35.8
Race/ethnicity	All visits	Asian	106	48.0	41	38.7	30.0	48.2
		Non-Asian	96	43.4	38	39.6	30.4	49.6
		Unknown	10	4.5	4	40.0	16.8	68.7
	Cycle 12 (LOCF)	Asian	106	48.0	28	26.4	19.0	35.5

		Non-Asian	96	43.4	15	15.6	9.7	24.2
		Unknown	10	4.5	2	20.0	5.7	51.0
	End of Study (LOCF)	Asian	106	48.0	28	26.4	19.0	35.5
		Non-Asian	96	43.4	14	14.6	8.9	23.0
		Unknown	10	4.5	2	20.0	5.7	51.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30SF_W15_SG.xls
15OCT2021 12:48

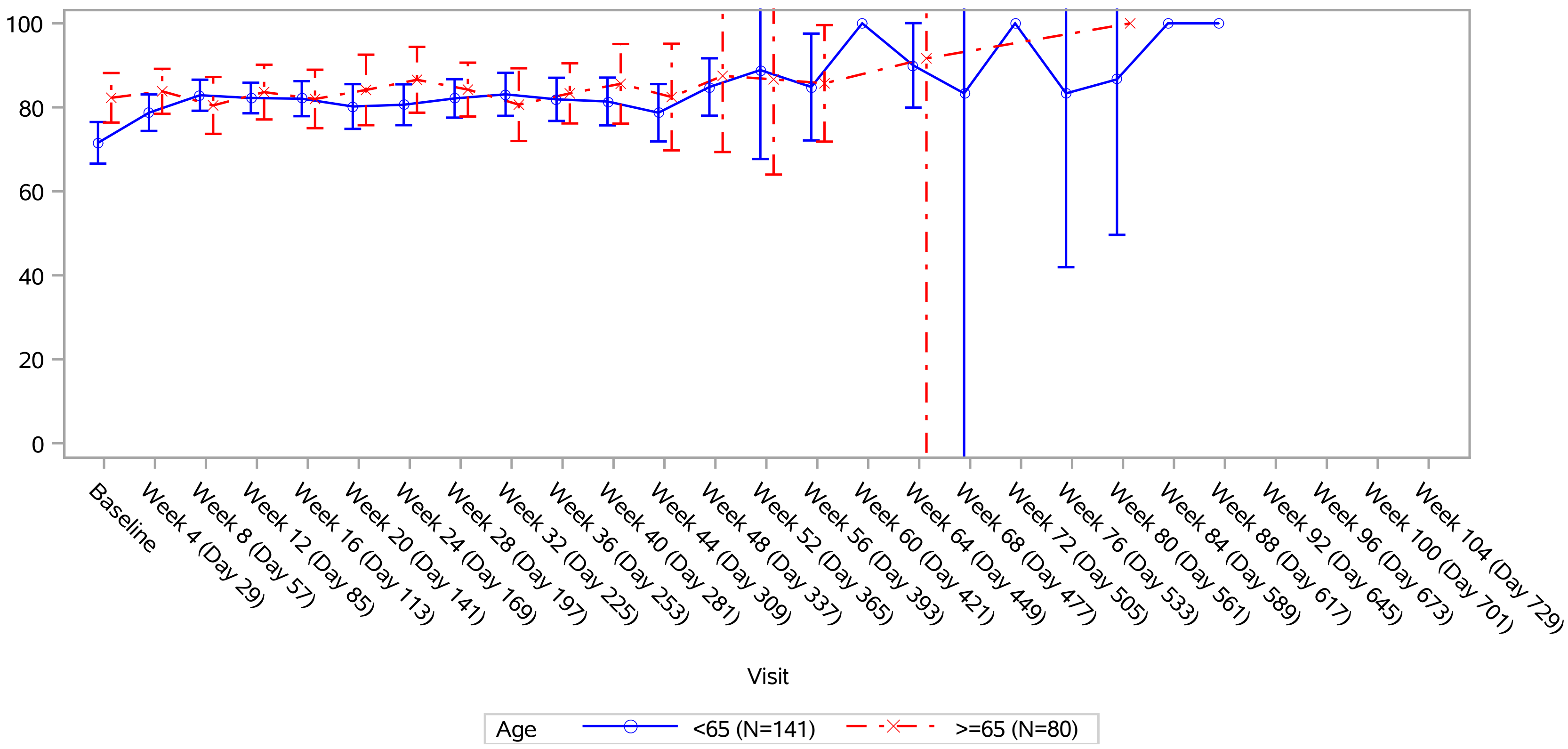
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Social functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30SF.pdf
15OCT2021 17:11

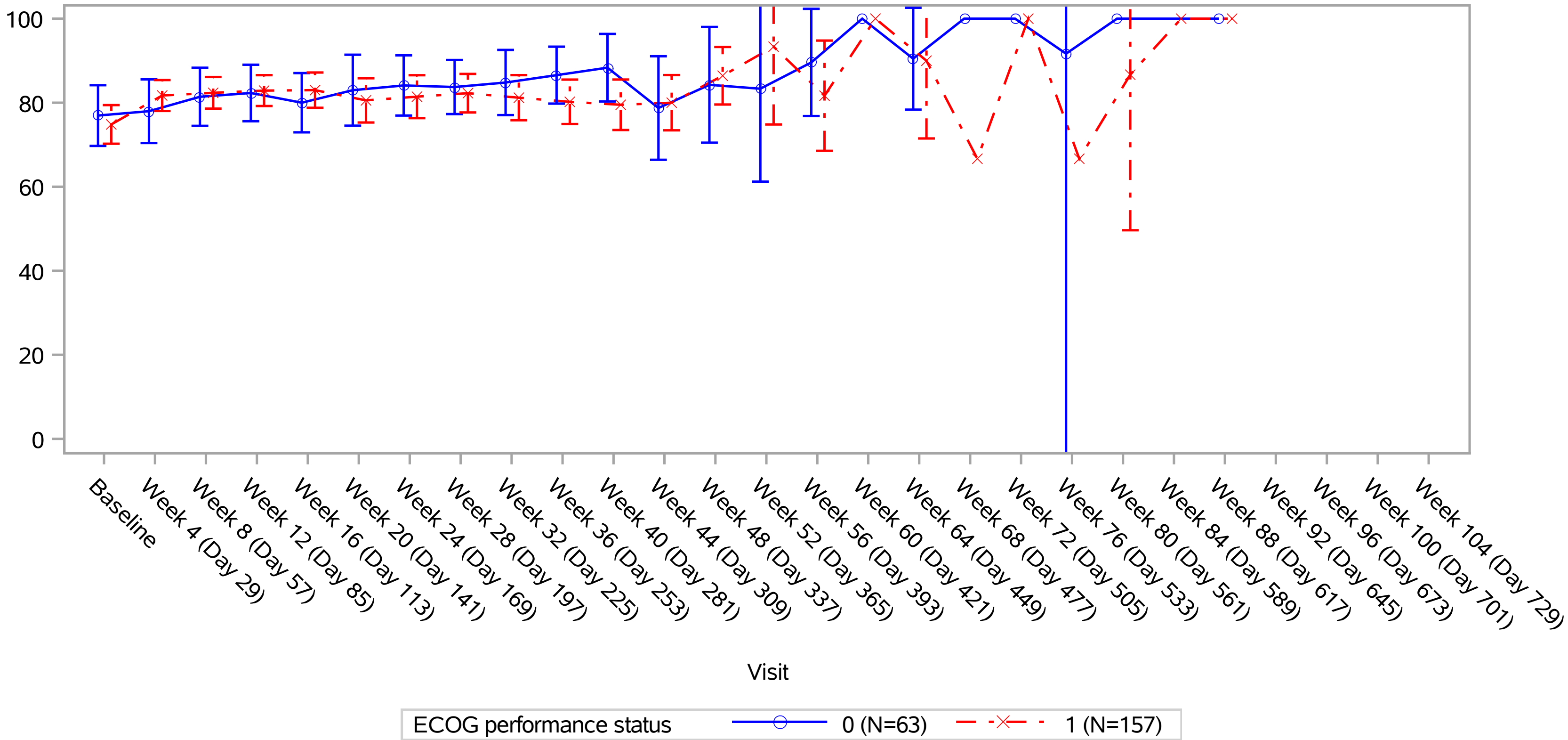
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Social functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30SF_SGAGE65.pdf
15OCT2021 17:40

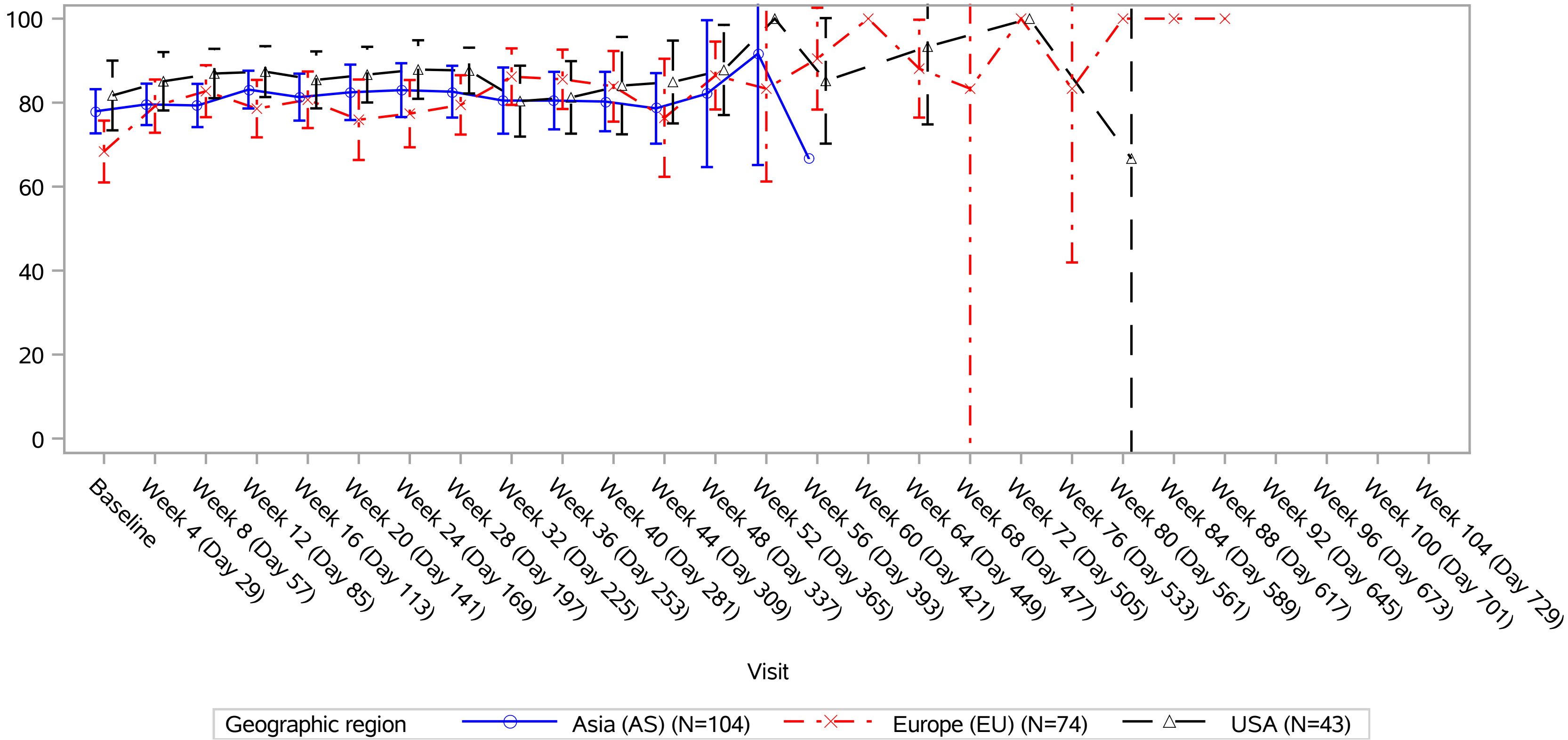
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Social functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30SF_SGECOG.pdf
15OCT2021 18:10

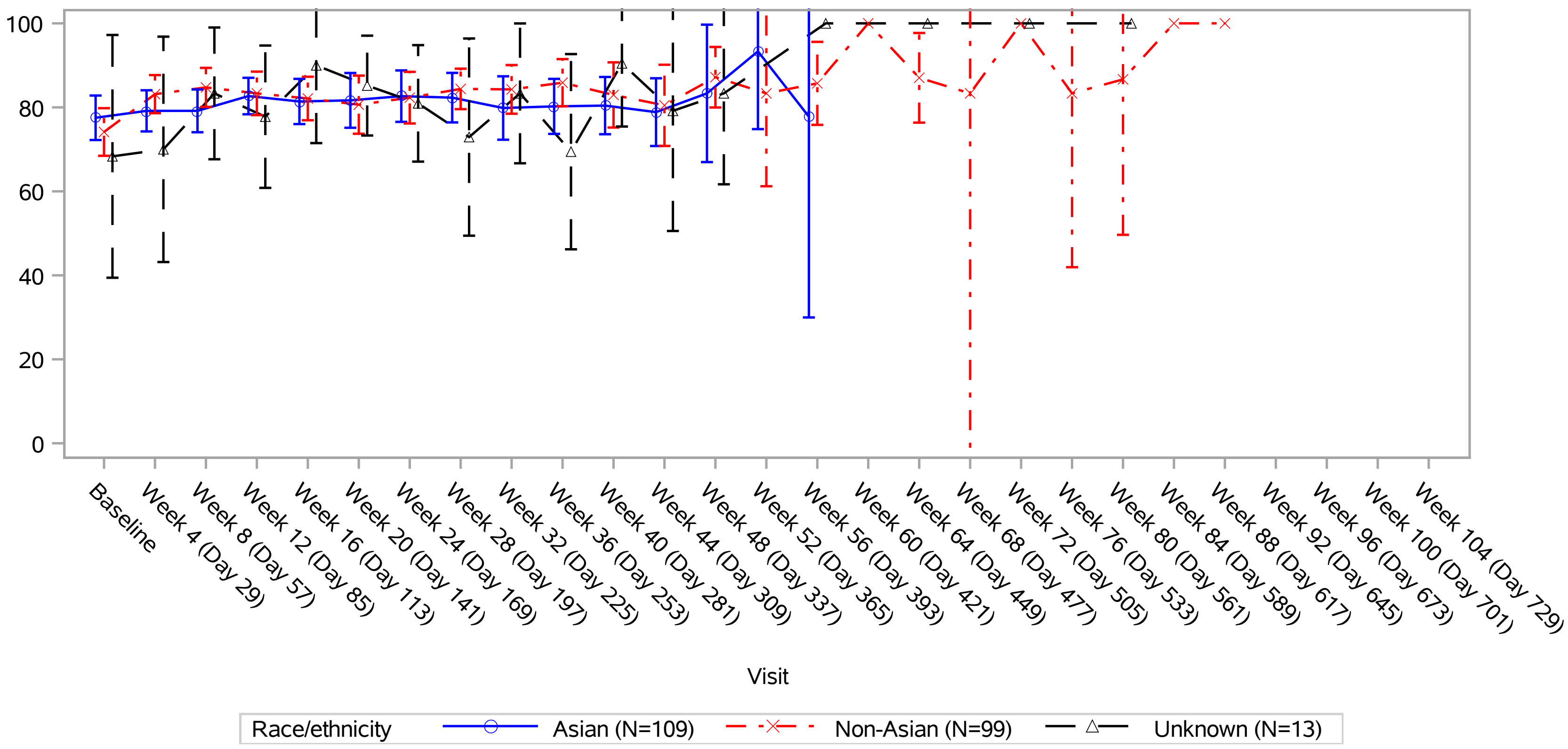
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Social functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30SF_SGGEO.pdf
15OCT2021 18:41

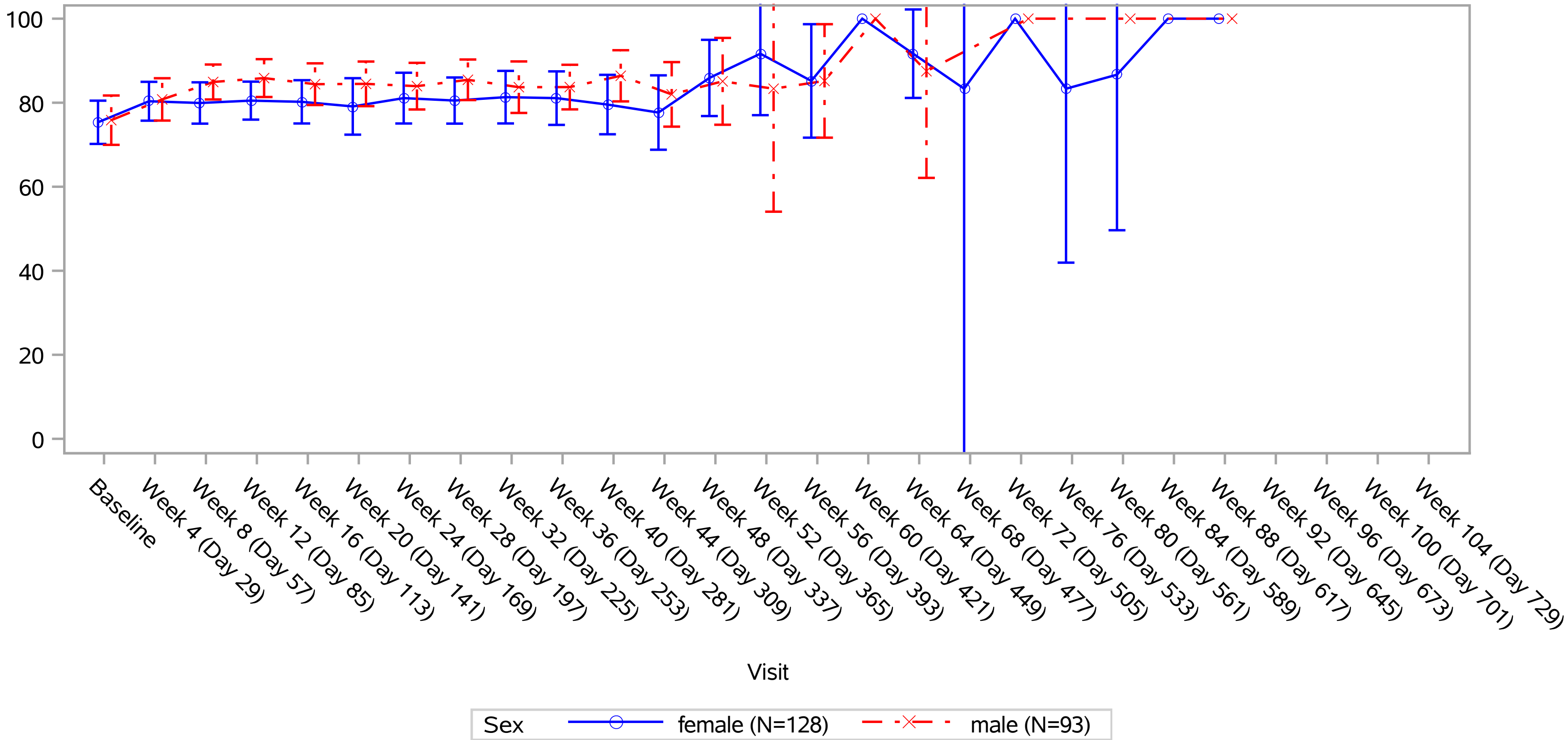
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Social functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30SF_SGRE.pdf
15OCT2021 19:11

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Social functioning
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30SF_SGSEX.pdf
15OCT2021 19:42

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, EORTC QLQ-C30: Insomnia
MODEL: --
STUDY: BO42863
Compliance/Mean

		400 mg QD (N=221)							
		Patients				Statistics			
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	CI LL	CI UL
All									
Baseline	n/a	221	100.0	212	95.9	26.89	30.54	22.75	31.02
Week 4 (Day 29)	n/a	221	100.0	188	85.1	16.31	24.49	12.79	19.84
Week 8 (Day 57)	n/a	193	87.3	171	88.6	13.45	22.16	10.10	16.80
Week 12 (Day 85)	n/a	176	79.6	160	90.9	12.92	20.47	9.72	16.11
Week 16 (Day 113)	n/a	164	74.2	143	87.2	14.69	23.61	10.78	18.59
Week 20 (Day 141)	n/a	148	67.0	138	93.2	17.87	26.76	13.37	22.38
Week 24 (Day 169)	n/a	137	62.0	122	89.1	15.57	26.13	10.89	20.26
Week 28 (Day 197)	n/a	129	58.4	120	93.0	14.44	24.34	10.04	18.84
Week 32 (Day 225)	n/a	119	53.8	104	87.4	15.71	26.26	10.60	20.81
Week 36 (Day 253)	n/a	112	50.7	94	83.9	12.06	22.32	7.48	16.63
Week 40 (Day 281)	n/a	104	47.1	91	87.5	15.75	27.37	10.05	21.45
Week 44 (Day 309)	n/a	95	43.0	84	88.4	19.84	33.18	12.64	27.04
Week 48 (Day 337)	n/a	81	36.7	45	55.6	18.52	27.11	10.37	26.66
Week 52 (Day 365)	n/a	64	29.0	11	17.2	21.21	34.23	-1.78	44.21
Week 56 (Day 393)	n/a	54	24.4	18	33.3	18.52	28.52	4.34	32.70
Week 60 (Day 421)	n/a	43	19.5	2	4.7	50.00	70.71	-585.31	685.31
Week 64 (Day 449)	n/a	41	18.6	12	29.3	8.33	15.08	-1.25	17.91
Week 68 (Day 477)	n/a	34	15.4	2	5.9	50.00	70.71	-585.31	685.31
Week 72 (Day 505)	n/a	34	15.4	5	14.7	13.33	29.81	-23.69	50.35
Week 76 (Day 533)	n/a	31	14.0	3	9.7	33.33	57.74	-110.09	176.76
Week 80 (Day 561)	n/a	30	13.6	6	20.0	11.11	17.21	-6.95	29.18
Week 84 (Day 589)	n/a	19	8.6	1	5.3	33.33	NE	NE	NE
Week 88 (Day 617)	n/a	15	6.8	2	13.3	0.00	0.00	NE	NE
Week 92 (Day 645)	n/a	8	3.6	0	0.0	NE	NE	NE	NE

Week 96 (Day 673)	n/a	6	2.7	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	n/a	3	1.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	n/a	1	0.5	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	n/a	221	100.0	219	99.1	18.57	28.91	14.72	22.42
End of Study (LOCF)	n/a	221	100.0	219	99.1	19.18	27.97	15.45	22.90
Sex									
Baseline	Female	128	100.0	123	96.1	32.25	32.49	26.45	38.05
Week 4 (Day 29)	Female	128	100.0	106	82.8	17.92	26.89	12.75	23.10
Week 8 (Day 57)	Female	112	87.5	98	87.5	15.31	24.95	10.30	20.31
Week 12 (Day 85)	Female	104	81.3	95	91.3	14.39	22.62	9.78	18.99
Week 16 (Day 113)	Female	96	75.0	81	84.4	18.11	25.30	12.51	23.70
Week 20 (Day 141)	Female	86	67.2	80	93.0	20.83	29.71	14.22	27.44
Week 24 (Day 169)	Female	78	60.9	67	85.9	18.41	28.59	11.43	25.38
Week 28 (Day 197)	Female	72	56.3	65	90.3	18.46	27.66	11.61	25.31
Week 32 (Day 225)	Female	69	53.9	58	84.1	19.54	29.97	11.66	27.42
Week 36 (Day 253)	Female	64	50.0	52	81.3	12.82	25.70	5.67	19.97
Week 40 (Day 281)	Female	59	46.1	53	89.8	20.75	30.82	12.26	29.25
Week 44 (Day 309)	Female	56	43.8	47	83.9	21.28	35.73	10.79	31.77
Week 48 (Day 337)	Female	48	37.5	26	54.2	24.36	30.63	11.99	36.73
Week 52 (Day 365)	Female	38	29.7	6	15.8	33.33	42.16	-10.91	77.58
Week 56 (Day 393)	Female	31	24.2	9	29.0	25.93	36.43	-2.08	53.93
Week 60 (Day 421)	Female	27	21.1	1	3.7	100.00	NE	NE	NE
Week 64 (Day 449)	Female	26	20.3	8	30.8	12.50	17.25	-1.92	26.92
Week 68 (Day 477)	Female	23	18.0	2	8.7	50.00	70.71	-585.31	685.31
Week 72 (Day 505)	Female	23	18.0	3	13.0	22.22	38.49	-73.39	117.84
Week 76 (Day 533)	Female	21	16.4	3	14.3	33.33	57.74	-110.09	176.76
Week 80 (Day 561)	Female	20	15.6	5	25.0	13.33	18.26	-9.34	36.00
Week 84 (Day 589)	Female	12	9.4	1	8.3	33.33	NE	NE	NE
Week 88 (Day 617)	Female	9	7.0	1	11.1	0.00	NE	NE	NE
Week 92 (Day 645)	Female	6	4.7	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Female	5	3.9	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Female	2	1.6	0	0.0	NE	NE	NE	NE

Week 104 (Day 729)	Female	1	0.8	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Female	128	100.0	127	99.2	22.57	31.95	16.96	28.18
End of Study (LOCF)	Female	128	100.0	127	99.2	24.41	31.83	18.82	30.00
Baseline	Male	93	100.0	89	95.7	19.48	26.02	13.99	24.96
Week 4 (Day 29)	Male	93	100.0	82	88.2	14.23	20.97	9.62	18.84
Week 8 (Day 57)	Male	81	87.1	73	90.1	10.96	17.62	6.85	15.07
Week 12 (Day 85)	Male	72	77.4	65	90.3	10.77	16.78	6.61	14.93
Week 16 (Day 113)	Male	68	73.1	62	91.2	10.22	20.55	5.00	15.43
Week 20 (Day 141)	Male	62	66.7	58	93.5	13.79	21.66	8.10	19.49
Week 24 (Day 169)	Male	59	63.4	55	93.2	12.12	22.56	6.02	18.22
Week 28 (Day 197)	Male	57	61.3	55	96.5	9.70	18.89	4.59	14.80
Week 32 (Day 225)	Male	50	53.8	46	92.0	10.87	19.94	4.95	16.79
Week 36 (Day 253)	Male	48	51.6	42	87.5	11.11	17.53	5.65	16.57
Week 40 (Day 281)	Male	45	48.4	38	84.4	8.77	20.04	2.19	15.36
Week 44 (Day 309)	Male	39	41.9	37	94.9	18.02	30.02	8.01	28.03
Week 48 (Day 337)	Male	33	35.5	19	57.6	10.53	19.41	1.17	19.88
Week 52 (Day 365)	Male	26	28.0	5	19.2	6.67	14.91	-11.84	25.18
Week 56 (Day 393)	Male	23	24.7	9	39.1	11.11	16.67	-1.70	23.92
Week 60 (Day 421)	Male	16	17.2	1	6.3	0.00	NE	NE	NE
Week 64 (Day 449)	Male	15	16.1	4	26.7	0.00	0.00	NE	NE
Week 68 (Day 477)	Male	11	11.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Male	11	11.8	2	18.2	0.00	0.00	NE	NE
Week 76 (Day 533)	Male	10	10.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Male	10	10.8	1	10.0	0.00	NE	NE	NE
Week 84 (Day 589)	Male	7	7.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Male	6	6.5	1	16.7	0.00	NE	NE	NE
Week 92 (Day 645)	Male	2	2.2	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Male	1	1.1	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Male	93	100.0	92	98.9	13.04	23.16	8.25	17.84
End of Study (LOCF)	Male	93	100.0	92	98.9	11.96	19.51	7.92	16.00
Age									

Baseline	< 65	141	100.0	133	94.3	30.08	32.01	24.58	35.57
Week 4 (Day 29)	< 65	141	100.0	121	85.8	17.91	26.19	13.19	22.62
Week 8 (Day 57)	< 65	127	90.1	113	89.0	12.98	22.02	8.88	17.08
Week 12 (Day 85)	< 65	118	83.7	106	89.8	11.95	20.15	8.07	15.83
Week 16 (Day 113)	< 65	108	76.6	93	86.1	14.70	23.29	9.90	19.49
Week 20 (Day 141)	< 65	100	70.9	97	97.0	19.59	29.56	13.63	25.55
Week 24 (Day 169)	< 65	93	66.0	86	92.5	16.28	26.93	10.50	22.05
Week 28 (Day 197)	< 65	88	62.4	83	94.3	16.47	25.70	10.85	22.08
Week 32 (Day 225)	< 65	83	58.9	73	88.0	16.44	27.29	10.07	22.80
Week 36 (Day 253)	< 65	78	55.3	70	89.7	13.33	24.34	7.53	19.14
Week 40 (Day 281)	< 65	75	53.2	69	92.0	17.39	28.93	10.44	24.34
Week 44 (Day 309)	< 65	71	50.4	65	91.5	21.03	34.65	12.44	29.61
Week 48 (Day 337)	< 65	61	43.3	33	54.1	17.17	25.17	8.25	26.10
Week 52 (Day 365)	< 65	48	34.0	6	12.5	27.78	44.31	-18.72	74.27
Week 56 (Day 393)	< 65	41	29.1	11	26.8	15.15	31.14	-5.77	36.07
Week 60 (Day 421)	< 65	33	23.4	2	6.1	50.00	70.71	-585.31	685.31
Week 64 (Day 449)	< 65	31	22.0	10	32.3	6.67	14.05	-3.39	16.72
Week 68 (Day 477)	< 65	26	18.4	2	7.7	50.00	70.71	-585.31	685.31
Week 72 (Day 505)	< 65	26	18.4	5	19.2	13.33	29.81	-23.69	50.35
Week 76 (Day 533)	< 65	25	17.7	3	12.0	33.33	57.74	-110.09	176.76
Week 80 (Day 561)	< 65	24	17.0	5	20.8	13.33	18.26	-9.34	36.00
Week 84 (Day 589)	< 65	16	11.3	1	6.3	33.33	NE	NE	NE
Week 88 (Day 617)	< 65	13	9.2	2	15.4	0.00	0.00	NE	NE
Week 92 (Day 645)	< 65	7	5.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	< 65	5	3.5	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	< 65	3	2.1	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	< 65	1	0.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	< 65	141	100.0	139	98.6	20.14	30.46	15.04	25.25
End of Study (LOCF)	< 65	141	100.0	139	98.6	20.86	29.29	15.95	25.78
Baseline	>= 65	80	100.0	79	98.8	21.52	27.24	15.42	27.62
Week 4 (Day 29)	>= 65	80	100.0	67	83.8	13.43	20.97	8.32	18.55
Week 8 (Day 57)	>= 65	66	82.5	58	87.9	14.37	22.61	8.42	20.31
Week 12 (Day 85)	>= 65	58	72.5	54	93.1	14.81	21.15	9.04	20.59

Week 16 (Day 113)	>= 65	56	70.0	50	89.3	14.67	24.43	7.72	21.61
Week 20 (Day 141)	>= 65	48	60.0	41	85.4	13.82	18.22	8.07	19.57
Week 24 (Day 169)	>= 65	44	55.0	36	81.8	13.89	24.40	5.63	22.14
Week 28 (Day 197)	>= 65	41	51.3	37	90.2	9.91	20.59	3.05	16.77
Week 32 (Day 225)	>= 65	36	45.0	31	86.1	13.98	24.00	5.18	22.78
Week 36 (Day 253)	>= 65	34	42.5	24	70.6	8.33	14.74	2.11	14.56
Week 40 (Day 281)	>= 65	29	36.3	22	75.9	10.61	21.54	1.05	20.16
Week 44 (Day 309)	>= 65	24	30.0	19	79.2	15.79	28.04	2.27	29.30
Week 48 (Day 337)	>= 65	20	25.0	12	60.0	22.22	32.82	1.37	43.08
Week 52 (Day 365)	>= 65	16	20.0	5	31.3	13.33	18.26	-9.34	36.00
Week 56 (Day 393)	>= 65	13	16.3	7	53.8	23.81	25.20	0.51	47.11
Week 60 (Day 421)	>= 65	10	12.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	>= 65	10	12.5	2	20.0	16.67	23.57	-195.10	228.44
Week 68 (Day 477)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	>= 65	8	10.0	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	>= 65	6	7.5	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	>= 65	6	7.5	1	16.7	0.00	NE	NE	NE
Week 84 (Day 589)	>= 65	3	3.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	>= 65	2	2.5	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	>= 65	1	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	>= 65	80	100.0	80	100.0	15.83	25.97	10.05	21.61
End of Study (LOCF)	>= 65	80	100.0	80	100.0	16.25	25.43	10.59	21.91
ECOG performance status									
Baseline	0	63	100.0	60	95.2	27.22	30.99	19.22	35.23
Week 4 (Day 29)	0	63	100.0	55	87.3	21.82	28.12	14.22	29.42
Week 8 (Day 57)	0	58	92.1	52	89.7	19.23	22.23	13.04	25.42
Week 12 (Day 85)	0	55	87.3	49	89.1	13.61	17.90	8.46	18.75
Week 16 (Day 113)	0	54	85.7	45	83.3	17.78	26.21	9.90	25.65
Week 20 (Day 141)	0	52	82.5	48	92.3	21.53	27.06	13.67	29.39
Week 24 (Day 169)	0	49	77.8	43	87.8	18.60	28.45	9.85	27.36
Week 28 (Day 197)	0	46	73.0	42	91.3	11.90	23.07	4.71	19.09

Week 32 (Day 225)	0	41	65.1	34	82.9	14.71	22.01	7.03	22.38
Week 36 (Day 253)	0	39	61.9	30	76.9	10.00	19.87	2.58	17.42
Week 40 (Day 281)	0	37	58.7	30	81.1	16.67	22.74	8.17	25.16
Week 44 (Day 309)	0	36	57.1	29	80.6	27.59	38.90	12.79	42.38
Week 48 (Day 337)	0	28	44.4	18	64.3	22.22	34.30	5.17	39.28
Week 52 (Day 365)	0	27	42.9	6	22.2	33.33	42.16	-10.91	77.58
Week 56 (Day 393)	0	24	38.1	8	33.3	16.67	25.20	-4.40	37.73
Week 60 (Day 421)	0	21	33.3	1	4.8	100.00	NE	NE	NE
Week 64 (Day 449)	0	21	33.3	7	33.3	9.52	16.27	-5.52	24.57
Week 68 (Day 477)	0	17	27.0	1	5.9	100.00	NE	NE	NE
Week 72 (Day 505)	0	17	27.0	2	11.8	33.33	47.14	-390.21	456.87
Week 76 (Day 533)	0	15	23.8	2	13.3	50.00	70.71	-585.31	685.31
Week 80 (Day 561)	0	14	22.2	1	7.1	0.00	NE	NE	NE
Week 84 (Day 589)	0	11	17.5	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	0	10	15.9	1	10.0	0.00	NE	NE	NE
Week 92 (Day 645)	0	5	7.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	0	4	6.3	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	0	3	4.8	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	0	1	1.6	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	0	63	100.0	63	100.0	23.28	32.59	15.07	31.49
End of Study (LOCF)	0	63	100.0	63	100.0	23.81	31.92	15.77	31.85
Baseline	1	157	100.0	151	96.2	26.71	30.56	21.80	31.62
Week 4 (Day 29)	1	157	100.0	132	84.1	14.14	22.60	10.25	18.03
Week 8 (Day 57)	1	134	85.4	119	88.8	10.92	21.75	6.98	14.87
Week 12 (Day 85)	1	121	77.1	111	91.7	12.61	21.58	8.55	16.67
Week 16 (Day 113)	1	110	70.1	98	89.1	13.27	22.32	8.79	17.74
Week 20 (Day 141)	1	96	61.1	90	93.8	15.93	26.55	10.37	21.49
Week 24 (Day 169)	1	88	56.1	79	89.8	13.92	24.81	8.37	19.48
Week 28 (Day 197)	1	83	52.9	78	94.0	15.81	25.04	10.17	21.46
Week 32 (Day 225)	1	78	49.7	70	89.7	16.19	28.23	9.46	22.92
Week 36 (Day 253)	1	73	46.5	64	87.7	13.02	23.47	7.16	18.88
Week 40 (Day 281)	1	67	42.7	61	91.0	15.30	29.55	7.73	22.87

Week 44 (Day 309)	1	59	37.6	55	93.2	15.76	29.30	7.84	23.68
Week 48 (Day 337)	1	53	33.8	27	50.9	16.05	21.42	7.57	24.52
Week 52 (Day 365)	1	37	23.6	5	13.5	6.67	14.91	-11.84	25.18
Week 56 (Day 393)	1	30	19.1	10	33.3	20.00	32.20	-3.04	43.04
Week 60 (Day 421)	1	22	14.0	1	4.5	0.00	NE	NE	NE
Week 64 (Day 449)	1	20	12.7	5	25.0	6.67	14.91	-11.84	25.18
Week 68 (Day 477)	1	17	10.8	1	5.9	0.00	NE	NE	NE
Week 72 (Day 505)	1	17	10.8	3	17.6	0.00	0.00	NE	NE
Week 76 (Day 533)	1	16	10.2	1	6.3	0.00	NE	NE	NE
Week 80 (Day 561)	1	16	10.2	5	31.3	13.33	18.26	-9.34	36.00
Week 84 (Day 589)	1	8	5.1	1	12.5	33.33	NE	NE	NE
Week 88 (Day 617)	1	5	3.2	1	20.0	0.00	NE	NE	NE
Week 92 (Day 645)	1	3	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	1	2	1.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	1	157	100.0	155	98.7	16.77	27.23	12.45	21.09
End of Study (LOCF)	1	157	100.0	155	98.7	17.42	26.14	13.27	21.57
Baseline	Missing	1	100.0	1	100.0	33.33	NE	NE	NE
Week 4 (Day 29)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Week 8 (Day 57)	Missing	1	100.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
End of Study (LOCF)	Missing	1	100.0	1	100.0	0.00	NE	NE	NE
Geographic region									
Baseline	USA	43	100.0	41	95.3	32.52	28.37	23.57	41.48
Week 4 (Day 29)	USA	43	100.0	37	86.0	16.22	21.69	8.98	23.45
Week 8 (Day 57)	USA	41	95.3	37	90.2	17.12	23.07	9.43	24.81
Week 12 (Day 85)	USA	41	95.3	37	90.2	18.02	24.34	9.90	26.13
Week 16 (Day 113)	USA	40	93.0	33	82.5	20.20	21.95	12.42	27.99
Week 20 (Day 141)	USA	39	90.7	35	89.7	19.05	24.64	10.59	27.51
Week 24 (Day 169)	USA	36	83.7	33	91.7	15.15	20.57	7.86	22.44
Week 28 (Day 197)	USA	35	81.4	31	88.6	11.83	20.27	4.39	19.26
Week 32 (Day 225)	USA	32	74.4	28	87.5	19.05	29.30	7.69	30.41
Week 36 (Day 253)	USA	32	74.4	23	71.9	13.04	26.09	1.76	24.33
Week 40 (Day 281)	USA	29	67.4	23	79.3	15.94	31.57	2.29	29.60

Week 44 (Day 309)	USA	26	60.5	21	80.8	25.40	33.17	10.30	40.50
Week 48 (Day 337)	USA	21	48.8	15	71.4	22.22	24.12	8.86	35.58
Week 52 (Day 365)	USA	18	41.9	1	5.6	0.00	NE	NE	NE
Week 56 (Day 393)	USA	18	41.9	9	50.0	25.93	32.39	1.03	50.83
Week 60 (Day 421)	USA	17	39.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	USA	15	34.9	5	33.3	6.67	14.91	-11.84	25.18
Week 68 (Day 477)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	USA	12	27.9	1	8.3	0.00	NE	NE	NE
Week 76 (Day 533)	USA	12	27.9	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	USA	12	27.9	2	16.7	16.67	23.57	-195.10	228.44
Week 84 (Day 589)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	USA	7	16.3	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	USA	6	14.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	USA	5	11.6	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	USA	3	7.0	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	USA	1	2.3	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	USA	43	100.0	43	100.0	19.38	28.39	10.64	28.12
End of Study (LOCF)	USA	43	100.0	43	100.0	18.60	23.35	11.42	25.79
Baseline	Europe (EU)	74	100.0	69	93.2	28.50	30.93	21.07	35.93
Week 4 (Day 29)	Europe (EU)	74	100.0	62	83.8	18.28	27.45	11.31	25.25
Week 8 (Day 57)	Europe (EU)	65	87.8	55	84.6	16.97	23.89	10.51	23.43
Week 12 (Day 85)	Europe (EU)	57	77.0	49	86.0	12.24	16.24	7.58	16.91
Week 16 (Day 113)	Europe (EU)	55	74.3	44	80.0	18.18	25.37	10.47	25.90
Week 20 (Day 141)	Europe (EU)	49	66.2	46	93.9	21.01	26.63	13.11	28.92
Week 24 (Day 169)	Europe (EU)	47	63.5	42	89.4	19.05	28.65	10.12	27.98
Week 28 (Day 197)	Europe (EU)	45	60.8	43	95.6	17.83	26.58	9.65	26.01
Week 32 (Day 225)	Europe (EU)	39	52.7	35	89.7	11.43	19.71	4.66	18.20
Week 36 (Day 253)	Europe (EU)	34	45.9	30	88.2	13.33	25.67	3.75	22.92
Week 40 (Day 281)	Europe (EU)	31	41.9	30	96.8	18.89	27.24	8.72	29.06
Week 44 (Day 309)	Europe (EU)	28	37.8	24	85.7	19.44	39.22	2.89	36.00

Week 48 (Day 337)	Europe (EU)	22	29.7	16	72.7	20.83	29.50	5.11	36.55
Week 52 (Day 365)	Europe (EU)	19	25.7	6	31.6	33.33	42.16	-10.91	77.58
Week 56 (Day 393)	Europe (EU)	17	23.0	7	41.2	9.52	25.20	-13.78	32.83
Week 60 (Day 421)	Europe (EU)	15	20.3	2	13.3	50.00	70.71	-585.31	685.31
Week 64 (Day 449)	Europe (EU)	15	20.3	7	46.7	9.52	16.27	-5.52	24.57
Week 68 (Day 477)	Europe (EU)	13	17.6	2	15.4	50.00	70.71	-585.31	685.31
Week 72 (Day 505)	Europe (EU)	13	17.6	4	30.8	16.67	33.33	-36.37	69.71
Week 76 (Day 533)	Europe (EU)	11	14.9	3	27.3	33.33	57.74	-110.09	176.76
Week 80 (Day 561)	Europe (EU)	10	13.5	4	40.0	8.33	16.67	-18.19	34.85
Week 84 (Day 589)	Europe (EU)	6	8.1	1	16.7	33.33	NE	NE	NE
Week 88 (Day 617)	Europe (EU)	3	4.1	2	66.7	0.00	0.00	NE	NE
Cycle 12 (LOCF)	Europe (EU)	74	100.0	73	98.6	22.37	30.46	15.27	29.48
End of Study (LOCF)	Europe (EU)	74	100.0	73	98.6	24.20	29.01	17.43	30.97
Baseline	Asia (AS)	104	100.0	102	98.1	23.53	30.97	17.45	29.61
Week 4 (Day 29)	Asia (AS)	104	100.0	89	85.6	14.98	23.58	10.01	19.95
Week 8 (Day 57)	Asia (AS)	87	83.7	79	90.8	9.28	19.93	4.82	13.75
Week 12 (Day 85)	Asia (AS)	78	75.0	74	94.9	10.81	20.72	6.01	15.61
Week 16 (Day 113)	Asia (AS)	69	66.3	66	95.7	9.60	22.47	4.07	15.12
Week 20 (Day 141)	Asia (AS)	60	57.7	57	95.0	14.62	28.18	7.14	22.10
Week 24 (Day 169)	Asia (AS)	54	51.9	47	87.0	12.77	27.41	4.72	20.81
Week 28 (Day 197)	Asia (AS)	49	47.1	46	93.9	13.04	24.82	5.67	20.42
Week 32 (Day 225)	Asia (AS)	48	46.2	41	85.4	17.07	28.98	7.92	26.22
Week 36 (Day 253)	Asia (AS)	46	44.2	41	89.1	10.57	17.38	5.08	16.06
Week 40 (Day 281)	Asia (AS)	44	42.3	38	86.4	13.16	25.16	4.89	21.43
Week 44 (Day 309)	Asia (AS)	41	39.4	39	95.1	17.09	29.49	7.53	26.65
Week 48 (Day 337)	Asia (AS)	38	36.5	14	36.8	11.90	28.06	-4.30	28.11
Week 52 (Day 365)	Asia (AS)	27	26.0	4	14.8	8.33	16.67	-18.19	34.85
Week 56 (Day 393)	Asia (AS)	19	18.3	2	10.5	16.67	23.57	-195.10	228.44
Week 60 (Day 421)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asia (AS)	11	10.6	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE

Week 72 (Day 505)	Asia (AS)	9	8.7	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asia (AS)	8	7.7	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asia (AS)	6	5.8	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Asia (AS)	5	4.8	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asia (AS)	2	1.9	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asia (AS)	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asia (AS)	104	100.0	103	99.0	15.53	27.93	10.07	20.99
End of Study (LOCF)	Asia (AS)	104	100.0	103	99.0	15.86	28.71	10.25	21.47
Race/ethnicity									
Baseline	Asian	109	100.0	106	97.2	23.90	30.43	18.04	29.76
Week 4 (Day 29)	Asian	109	100.0	92	84.4	14.86	23.37	10.02	19.69
Week 8 (Day 57)	Asian	91	83.5	80	87.9	9.17	19.83	4.75	13.58
Week 12 (Day 85)	Asian	82	75.2	77	93.9	10.82	20.55	6.16	15.49
Week 16 (Day 113)	Asian	73	67.0	70	95.9	10.00	22.23	4.70	15.30
Week 20 (Day 141)	Asian	64	58.7	60	93.8	15.56	28.43	8.21	22.90
Week 24 (Day 169)	Asian	57	52.3	50	87.7	12.67	26.84	5.04	20.30
Week 28 (Day 197)	Asian	52	47.7	49	94.2	12.93	24.36	5.93	19.92
Week 32 (Day 225)	Asian	50	45.9	43	86.0	16.28	28.52	7.50	25.06
Week 36 (Day 253)	Asian	48	44.0	43	89.6	10.08	17.11	4.81	15.34
Week 40 (Day 281)	Asian	46	42.2	40	87.0	12.50	24.68	4.61	20.39
Week 44 (Day 309)	Asian	43	39.4	41	95.3	16.26	28.98	7.11	25.41
Week 48 (Day 337)	Asian	40	36.7	15	37.5	11.11	27.22	-3.96	26.18
Week 52 (Day 365)	Asian	29	26.6	5	17.2	6.67	14.91	-11.84	25.18
Week 56 (Day 393)	Asian	21	19.3	3	14.3	11.11	19.25	-36.70	58.92
Week 60 (Day 421)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Asian	12	11.0	0	0.0	NE	NE	NE	NE
Week 68 (Day 477)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Asian	10	9.2	0	0.0	NE	NE	NE	NE
Week 76 (Day 533)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Asian	9	8.3	0	0.0	NE	NE	NE	NE
Week 84 (Day 589)	Asian	6	5.5	0	0.0	NE	NE	NE	NE

Week 88 (Day 617)	Asian	5	4.6	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Asian	2	1.8	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Asian	1	0.9	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Asian	109	100.0	107	98.2	15.89	27.98	10.52	21.25
End of Study (LOCF)	Asian	109	100.0	107	98.2	16.20	28.73	10.69	21.71
Baseline	Non-Asian	99	100.0	96	97.0	30.56	30.84	24.31	36.80
Week 4 (Day 29)	Non-Asian	99	100.0	86	86.9	16.28	23.29	11.29	21.27
Week 8 (Day 57)	Non-Asian	91	91.9	82	90.1	16.67	22.98	11.62	21.72
Week 12 (Day 85)	Non-Asian	83	83.8	74	89.2	14.86	20.75	10.06	19.67
Week 16 (Day 113)	Non-Asian	80	80.8	68	85.0	18.63	24.01	12.82	24.44
Week 20 (Day 141)	Non-Asian	74	74.7	69	93.2	19.32	25.82	13.12	25.53
Week 24 (Day 169)	Non-Asian	70	70.7	65	92.9	17.95	26.40	11.41	24.49
Week 28 (Day 197)	Non-Asian	67	67.7	63	94.0	13.76	22.11	8.19	19.32
Week 32 (Day 225)	Non-Asian	60	60.6	53	88.3	15.09	24.95	8.22	21.97
Week 36 (Day 253)	Non-Asian	55	55.6	45	81.8	14.07	26.10	6.23	21.92
Week 40 (Day 281)	Non-Asian	49	49.5	44	89.8	17.42	30.06	8.28	26.56
Week 44 (Day 309)	Non-Asian	43	43.4	35	81.4	21.90	35.19	9.82	33.99
Week 48 (Day 337)	Non-Asian	35	35.4	26	74.3	24.36	27.58	13.22	35.50
Week 52 (Day 365)	Non-Asian	29	29.3	6	20.7	33.33	42.16	-10.91	77.58
Week 56 (Day 393)	Non-Asian	27	27.3	14	51.9	21.43	30.96	3.55	39.30
Week 60 (Day 421)	Non-Asian	26	26.3	2	7.7	50.00	70.71	-585.31	685.31
Week 64 (Day 449)	Non-Asian	24	24.2	9	37.5	7.41	14.70	-3.89	18.71
Week 68 (Day 477)	Non-Asian	20	20.2	2	10.0	50.00	70.71	-585.31	685.31
Week 72 (Day 505)	Non-Asian	20	20.2	3	15.0	0.00	0.00	NE	NE
Week 76 (Day 533)	Non-Asian	18	18.2	3	16.7	33.33	57.74	-110.09	176.76
Week 80 (Day 561)	Non-Asian	17	17.2	5	29.4	6.67	14.91	-11.84	25.18
Week 84 (Day 589)	Non-Asian	11	11.1	1	9.1	33.33	NE	NE	NE
Week 88 (Day 617)	Non-Asian	8	8.1	2	25.0	0.00	0.00	NE	NE
Week 92 (Day 645)	Non-Asian	4	4.0	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Non-Asian	3	3.0	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Non-Asian	1	1.0	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Non-Asian	99	100.0	99	100.0	20.88	28.80	15.13	26.62

End of Study (LOCF)	Non-Asian	99	100.0	99	100.0	21.89	26.58	16.58	27.19
Baseline	Unknown	13	100.0	10	76.9	23.33	27.44	3.70	42.96
Week 4 (Day 29)	Unknown	13	100.0	10	76.9	30.00	39.91	1.45	58.55
Week 8 (Day 57)	Unknown	11	84.6	9	81.8	22.22	28.87	0.03	44.41
Week 12 (Day 85)	Unknown	11	84.6	9	81.8	14.81	17.57	1.31	28.32
Week 16 (Day 113)	Unknown	11	84.6	5	45.5	26.67	27.89	-7.96	61.30
Week 20 (Day 141)	Unknown	10	76.9	9	90.0	22.22	23.57	4.10	40.34
Week 24 (Day 169)	Unknown	10	76.9	7	70.0	14.29	17.82	-2.19	30.76
Week 28 (Day 197)	Unknown	10	76.9	8	80.0	29.17	37.53	-2.21	60.55
Week 32 (Day 225)	Unknown	9	69.2	8	88.9	16.67	25.20	-4.40	37.73
Week 36 (Day 253)	Unknown	9	69.2	6	66.7	11.11	27.22	-17.45	39.67
Week 40 (Day 281)	Unknown	9	69.2	7	77.8	23.81	25.20	0.51	47.11
Week 44 (Day 309)	Unknown	9	69.2	8	88.9	29.17	45.21	-8.63	66.96
Week 48 (Day 337)	Unknown	6	46.2	4	66.7	8.33	16.67	-18.19	34.85
Week 52 (Day 365)	Unknown	6	46.2	0	0.0	NE	NE	NE	NE
Week 56 (Day 393)	Unknown	6	46.2	1	16.7	0.00	NE	NE	NE
Week 60 (Day 421)	Unknown	5	38.5	0	0.0	NE	NE	NE	NE
Week 64 (Day 449)	Unknown	5	38.5	3	60.0	11.11	19.25	-36.70	58.92
Week 68 (Day 477)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 72 (Day 505)	Unknown	4	30.8	2	50.0	33.33	47.14	-390.21	456.87
Week 76 (Day 533)	Unknown	4	30.8	0	0.0	NE	NE	NE	NE
Week 80 (Day 561)	Unknown	4	30.8	1	25.0	33.33	NE	NE	NE
Week 84 (Day 589)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 88 (Day 617)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 92 (Day 645)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 96 (Day 673)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 100 (Day 701)	Unknown	2	15.4	0	0.0	NE	NE	NE	NE
Week 104 (Day 729)	Unknown	1	7.7	0	0.0	NE	NE	NE	NE
Cycle 12 (LOCF)	Unknown	13	100.0	13	100.0	23.08	36.98	0.73	45.42
End of Study (LOCF)	Unknown	13	100.0	13	100.0	23.08	31.58	3.99	42.16

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The last value per patient collected before or on week 44 is used for the calculation of "Cycle 12 (LOCF)". The last recorded value per patient is used for "End of Study (LOCF)".
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_mean_B63_DCB_SAF_P41_TO_QSC30SL_SG.xls
27OCT2021 7:22

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 10 points, EORTC QLQ-C30: Insomnia
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 10-Point Worsening Compared to Baseline

			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	68	32.1	26.2	38.6
	Cycle 12 (LOCF)	n/a	212	95.9	32	15.1	10.9	20.5
	End of Study (LOCF)	n/a	212	95.9	33	15.6	11.3	21.1
Sex	All visits	Female	123	55.7	37	30.1	22.7	38.7
		Male	89	40.3	31	34.8	25.7	45.2
	Cycle 12 (LOCF)	Female	123	55.7	20	16.3	10.8	23.8
		Male	89	40.3	12	13.5	7.9	22.1
	End of Study (LOCF)	Female	123	55.7	23	18.7	12.8	26.5
		Male	89	40.3	10	11.2	6.2	19.5
Age	All visits	< 65	133	60.2	40	30.1	22.9	38.3
		>= 65	79	35.7	28	35.4	25.8	46.4
	Cycle 12 (LOCF)	< 65	133	60.2	21	15.8	10.6	22.9
		>= 65	79	35.7	11	13.9	8.0	23.2
	End of Study (LOCF)	< 65	133	60.2	22	16.5	11.2	23.8
		>= 65	79	35.7	11	13.9	8.0	23.2
ECOG performance status	All visits	0	60	27.1	21	35.0	24.2	47.6
		1	151	68.3	47	31.1	24.3	38.9
		Missing	1	0.5	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	60	27.1	12	20.0	11.8	31.8
		1	151	68.3	20	13.2	8.7	19.6
		Missing	1	0.5	0	0.0	0.0	79.3
	End of Study (LOCF)	0	60	27.1	13	21.7	13.1	33.6
		1	151	68.3	20	13.2	8.7	19.6
		Missing	1	0.5	0	0.0	0.0	79.3
Geographic region	All visits	USA	41	18.6	13	31.7	19.6	47.0
		Europe (EU)	69	31.2	25	36.2	25.9	48.0
		Asia (AS)	102	46.2	30	29.4	21.4	38.9
	Cycle 12 (LOCF)	USA	41	18.6	6	14.6	6.9	28.4
		Europe (EU)	69	31.2	10	14.5	8.1	24.7
		Asia (AS)	102	46.2	16	15.7	9.9	24.0
	End of Study (LOCF)	USA	41	18.6	5	12.2	5.3	25.5
		Europe (EU)	69	31.2	13	18.8	11.4	29.6
		Asia (AS)	102	46.2	15	14.7	9.1	22.9
Race/ethnicity	All visits	Asian	106	48.0	31	29.2	21.4	38.5
		Non-Asian	96	43.4	33	34.4	25.6	44.3
		Unknown	10	4.5	4	40.0	16.8	68.7
	Cycle 12 (LOCF)	Asian	106	48.0	17	16.0	10.3	24.2

		Non-Asian	96	43.4	14	14.6	8.9	23.0
		Unknown	10	4.5	1	10.0	1.8	40.4
	End of Study (LOCF)	Asian	106	48.0	16	15.1	9.5	23.1
		Non-Asian	96	43.4	15	15.6	9.7	24.2
		Unknown	10	4.5	2	20.0	5.7	51.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30SL_W10_SG.xls
15OCT2021 12:58

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: Subgroup analysis, Worsening of at least 15 points, EORTC QLQ-C30: Insomnia
MODEL: Unstratified analysis
STUDY: BO42863
Responder Analysis: at least 15-Point Worsening Compared to Baseline

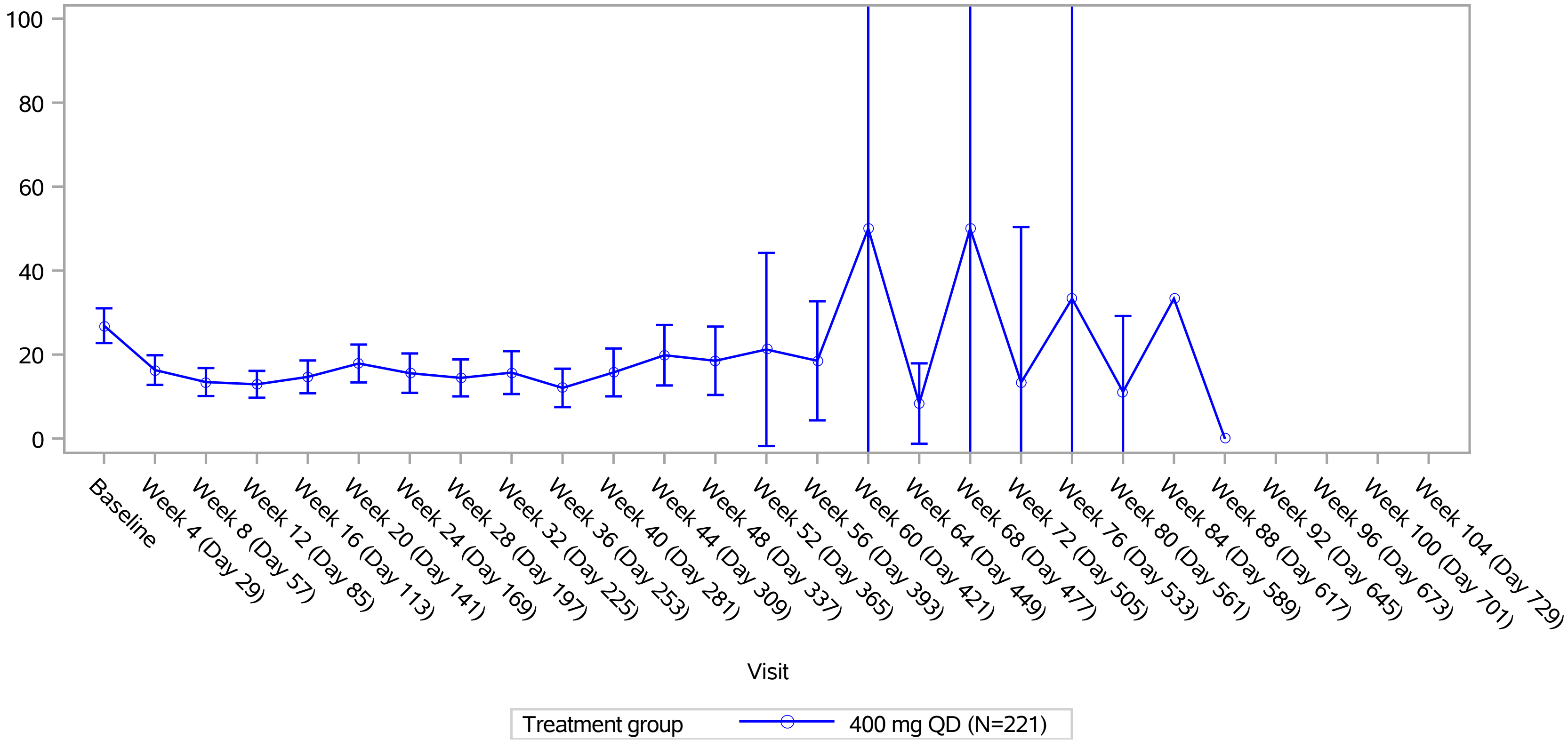
			400 mg QD (N=221)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	All visits	n/a	212	95.9	68	32.1	26.2	38.6
	Cycle 12 (LOCF)	n/a	212	95.9	32	15.1	10.9	20.5
	End of Study (LOCF)	n/a	212	95.9	33	15.6	11.3	21.1
Sex	All visits	Female	123	55.7	37	30.1	22.7	38.7
		Male	89	40.3	31	34.8	25.7	45.2
	Cycle 12 (LOCF)	Female	123	55.7	20	16.3	10.8	23.8
		Male	89	40.3	12	13.5	7.9	22.1
	End of Study (LOCF)	Female	123	55.7	23	18.7	12.8	26.5
		Male	89	40.3	10	11.2	6.2	19.5
Age	All visits	< 65	133	60.2	40	30.1	22.9	38.3
		>= 65	79	35.7	28	35.4	25.8	46.4
	Cycle 12 (LOCF)	< 65	133	60.2	21	15.8	10.6	22.9
		>= 65	79	35.7	11	13.9	8.0	23.2
	End of Study (LOCF)	< 65	133	60.2	22	16.5	11.2	23.8
		>= 65	79	35.7	11	13.9	8.0	23.2
ECOG performance status	All visits	0	60	27.1	21	35.0	24.2	47.6
		1	151	68.3	47	31.1	24.3	38.9
		Missing	1	0.5	0	0.0	0.0	79.3
	Cycle 12 (LOCF)	0	60	27.1	12	20.0	11.8	31.8
		1	151	68.3	20	13.2	8.7	19.6
		Missing	1	0.5	0	0.0	0.0	79.3
	End of Study (LOCF)	0	60	27.1	13	21.7	13.1	33.6
		1	151	68.3	20	13.2	8.7	19.6
		Missing	1	0.5	0	0.0	0.0	79.3
Geographic region	All visits	USA	41	18.6	13	31.7	19.6	47.0
		Europe (EU)	69	31.2	25	36.2	25.9	48.0
		Asia (AS)	102	46.2	30	29.4	21.4	38.9
	Cycle 12 (LOCF)	USA	41	18.6	6	14.6	6.9	28.4
		Europe (EU)	69	31.2	10	14.5	8.1	24.7
		Asia (AS)	102	46.2	16	15.7	9.9	24.0
	End of Study (LOCF)	USA	41	18.6	5	12.2	5.3	25.5
		Europe (EU)	69	31.2	13	18.8	11.4	29.6
		Asia (AS)	102	46.2	15	14.7	9.1	22.9
Race/ethnicity	All visits	Asian	106	48.0	31	29.2	21.4	38.5
		Non-Asian	96	43.4	33	34.4	25.6	44.3
		Unknown	10	4.5	4	40.0	16.8	68.7
	Cycle 12 (LOCF)	Asian	106	48.0	17	16.0	10.3	24.2

		Non-Asian	96	43.4	14	14.6	8.9	23.0
		Unknown	10	4.5	1	10.0	1.8	40.4
	End of Study (LOCF)	Asian	106	48.0	16	15.1	9.5	23.1
		Non-Asian	96	43.4	15	15.6	9.7	24.2
		Unknown	10	4.5	2	20.0	5.7	51.0

Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
95% CI based on Wilson Scores.
Improvement is defined as increase in the functional scale scores or the global health status and as decrease in the symptom scale scores.
Worsening is defined as decrease in the functional scale scores or the global health status and as increase in the symptom scale scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_rsp2_B63_DCB_SAF_P41_TO_QSC30SL_W15_SG.xls
15OCT2021 12:48

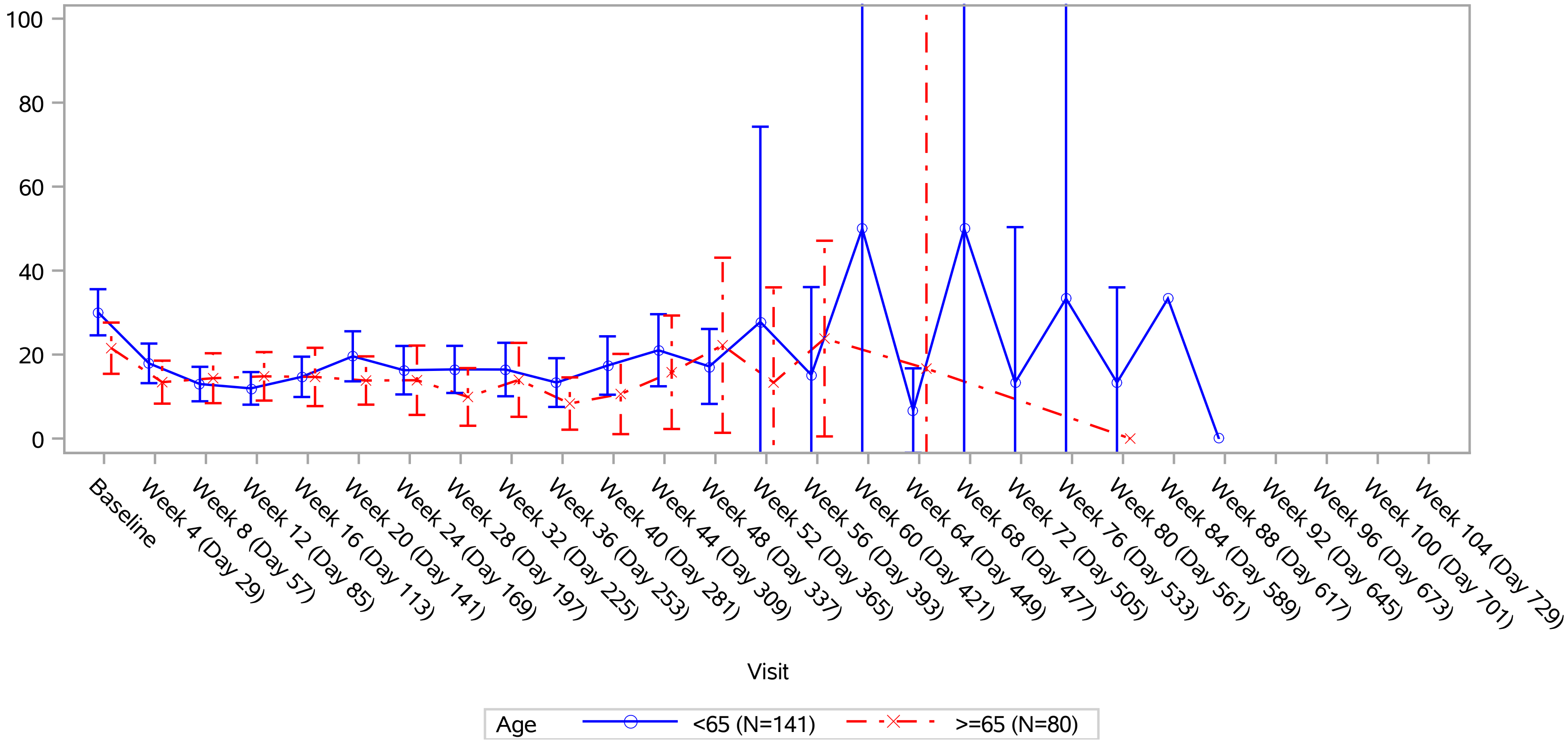
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Insomnia
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30SL.pdf
15OCT2021 17:12

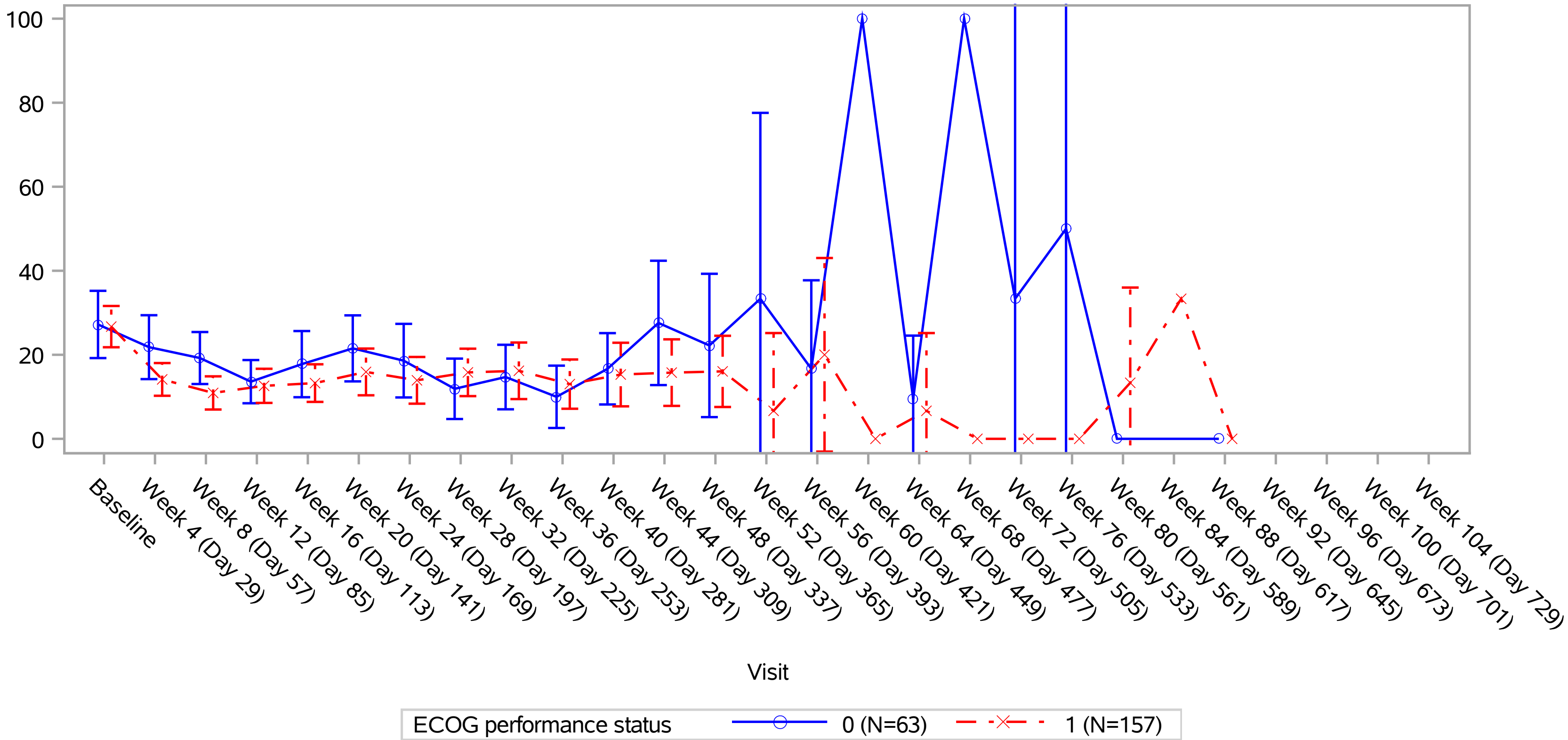
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Insomnia
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30SL_SGAGE65.pdf
15OCT2021 17:40

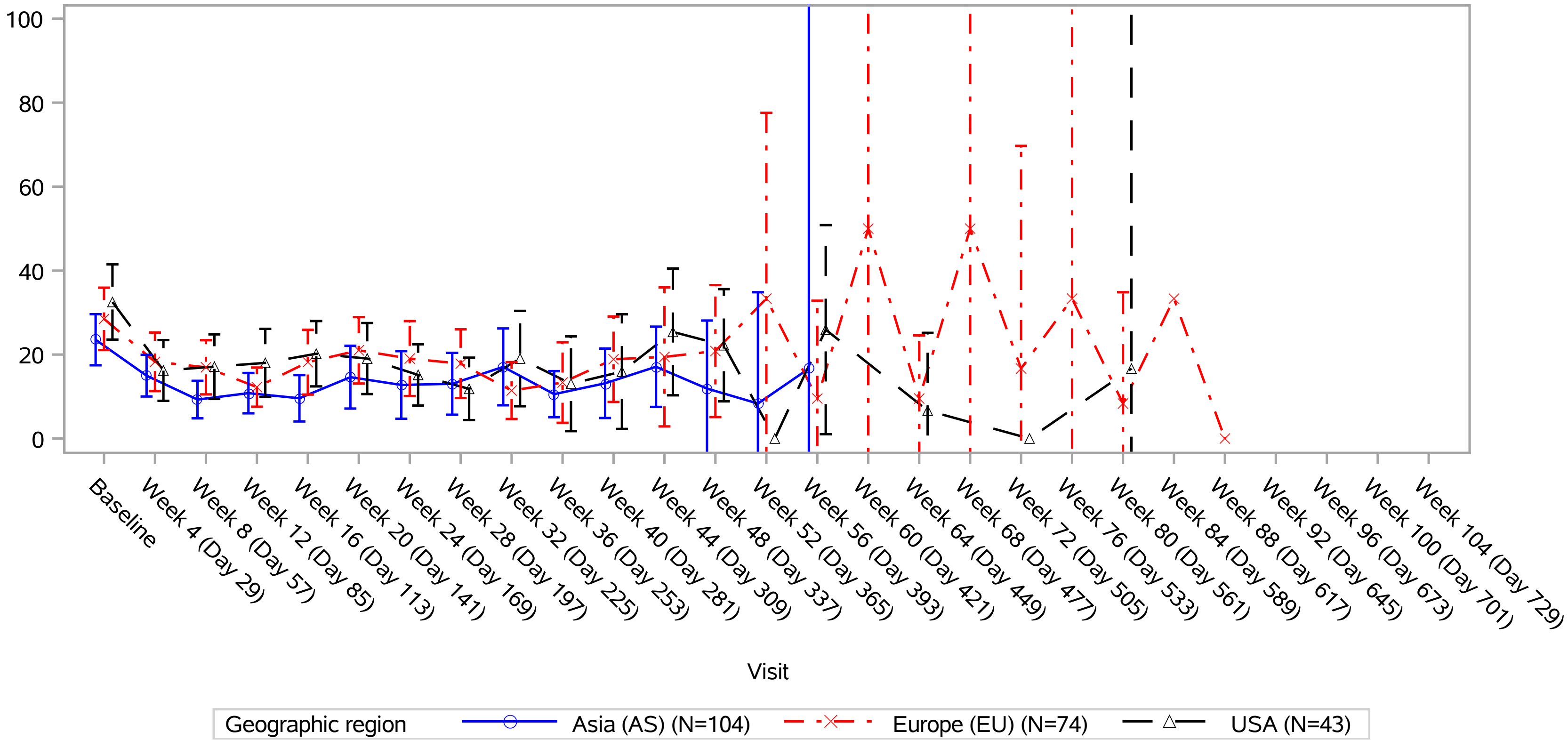
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Insomnia
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30SL_SGECOG.pdf
15OCT2021 18:10

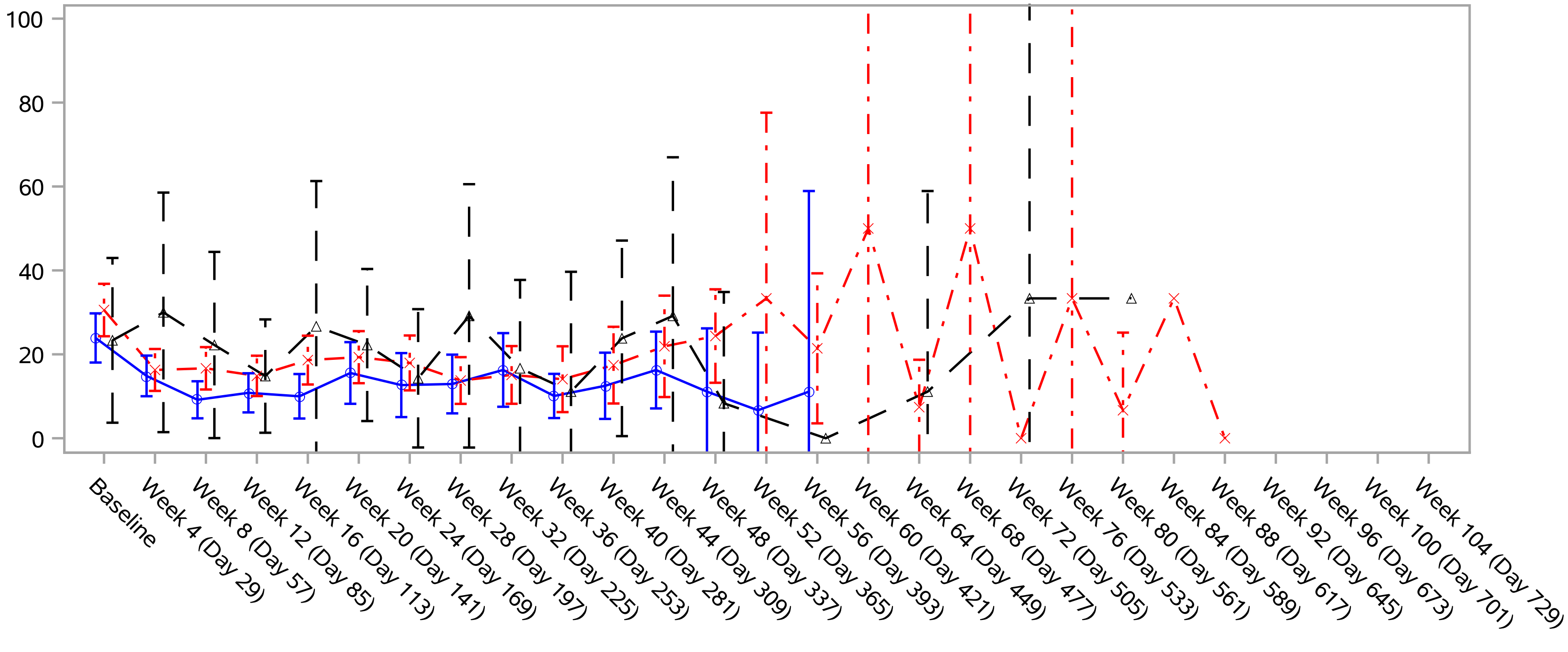
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Insomnia
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30SL_SGGEO.pdf
15OCT2021 18:41

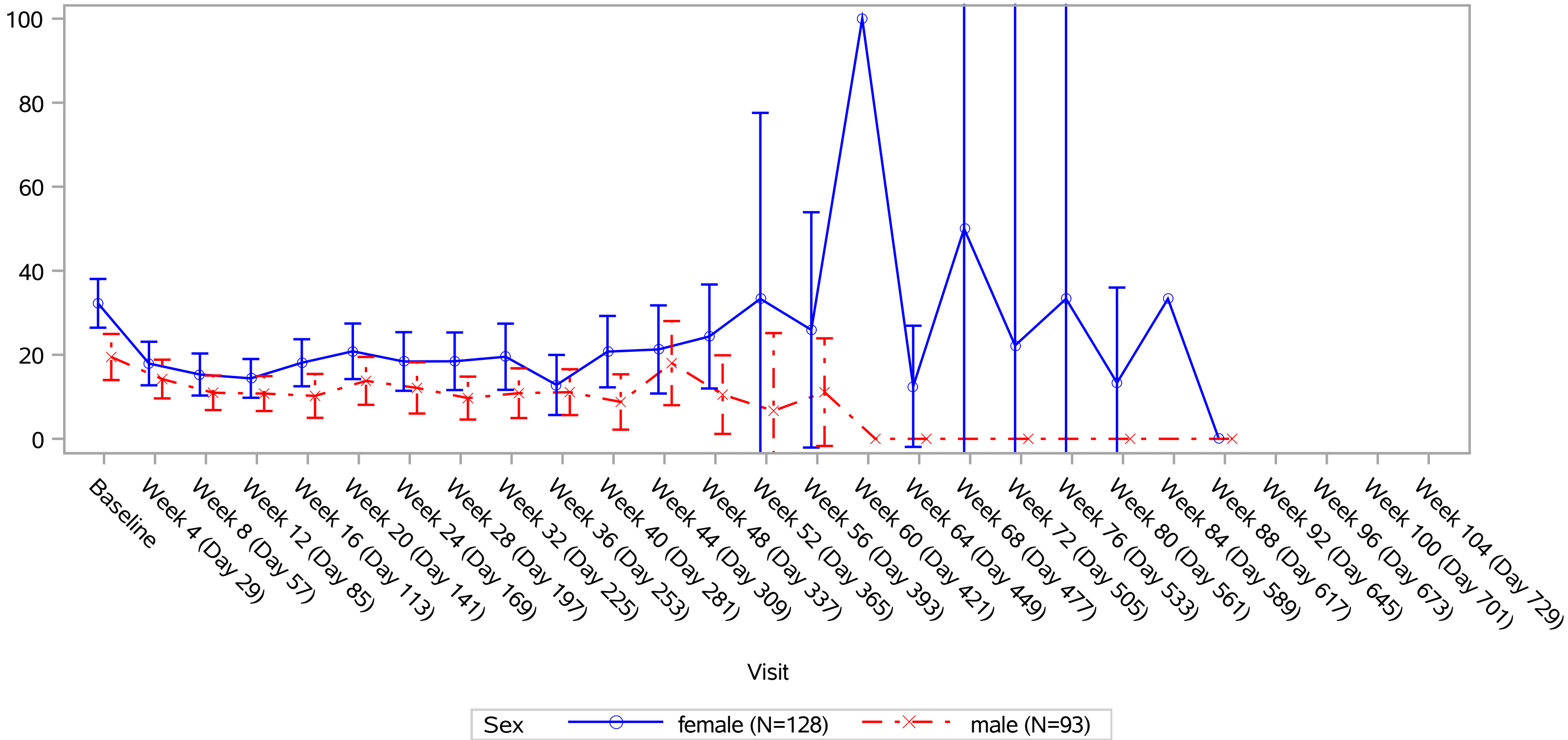
POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Insomnia
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30SL_SGRE.pdf
15OCT2021 19:12

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, PRO population, Safety Population
ENDPOINT: EORTC QLQ-C30: Insomnia
STUDY: BO42863
Plot of Mean and 95% CI by Visit



Patients who signed the informed consent form for protocol amendment 4.1 or later (i.e. protocol amendments 4.1, and 5-13) before the first dosing date are considered in the analysis.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/pro_g_mean.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/pro_g_mean_B63_DCB_SAF_P41_TO_QSC30SL_SGSEX.pdf
15OCT2021 19:42

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	279	99.3	97.4	99.8
Sex	Female	152	54.1	152	100.0	97.5	100.0
	Male	129	45.9	127	98.4	94.5	99.6
Age	< 65	176	62.6	174	98.9	96.0	99.7
	>= 65	105	37.4	105	100.0	96.5	100.0
ECOG performance status	0	84	29.9	83	98.8	93.6	99.8
	1	190	67.6	189	99.5	97.1	99.9
	2	6	2.1	6	100.0	61.0	100.0
	Missing	1	0.4	1	100.0	20.7	100.0
Geographic region	USA	64	22.8	64	100.0	94.3	100.0
	Europe (EU)	95	33.8	93	97.9	92.6	99.4
	Asia (AS)	122	43.4	122	100.0	96.9	100.0
Race/ethnicity	Asian	128	45.6	128	100.0	97.1	100.0
	Non-Asian	135	48.0	133	98.5	94.8	99.6
	Unknown	18	6.4	18	100.0	82.4	100.0
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	115	99.1	95.3	99.8
	1	77	27.4	76	98.7	93.0	99.8
	>= 2	88	31.3	88	100.0	95.8	100.0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AEANY_SG.xls
26MAR2021 10:16

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	279	99.3	97.4	99.8
Sex	Female	152	54.1	152	100.0	97.5	100.0
	Male	129	45.9	127	98.4	94.5	99.6
Age	< 65	176	62.6	174	98.9	96.0	99.7
	>= 65	105	37.4	105	100.0	96.5	100.0
ECOG performance status	0	84	29.9	83	98.8	93.6	99.8
	1	190	67.6	189	99.5	97.1	99.9
	2	6	2.1	6	100.0	61.0	100.0
	Missing	1	0.4	1	100.0	20.7	100.0
Geographic region	USA	64	22.8	64	100.0	94.3	100.0
	Europe (EU)	95	33.8	93	97.9	92.6	99.4
	Asia (AS)	122	43.4	122	100.0	96.9	100.0
Race/ethnicity	Asian	128	45.6	128	100.0	97.1	100.0
	Non-Asian	135	48.0	133	98.5	94.8	99.6
	Unknown	18	6.4	18	100.0	82.4	100.0
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	115	99.1	95.3	99.8
	1	77	27.4	76	98.7	93.0	99.8
	>= 2	88	31.3	88	100.0	95.8	100.0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw_B63_06NOV2020_SE_TO_AEANY_SG.xls
26MAR2021 9:54

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	n/a	281	100.0	169	60.1	54.3	65.7
	Anaemia	n/a	281	100.0	129	45.9	40.2	51.7
	Anaemia macrocytic	n/a	281	100.0	1	0.4	0.1	2.0
	Aplastic anaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Bone marrow oedema	n/a	281	100.0	1	0.4	0.1	2.0
	Cytopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Disseminated intravascular coagulation	n/a	281	100.0	2	0.7	0.2	2.6
	Febrile neutropenia	n/a	281	100.0	5	1.8	0.8	4.1
	Haemorrhagic anaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperfibrinogenaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Leukocytosis	n/a	281	100.0	3	1.1	0.4	3.1
	Leukopenia	n/a	281	100.0	30	10.7	7.6	14.8
	Lymph node pain	n/a	281	100.0	1	0.4	0.1	2.0
	Lymphadenopathy	n/a	281	100.0	2	0.7	0.2	2.6
	Lymphopenia	n/a	281	100.0	23	8.2	5.5	12.0
	Neutropenia	n/a	281	100.0	61	21.7	17.3	26.9
	Neutrophilia	n/a	281	100.0	1	0.4	0.1	2.0
	Pancytopenia	n/a	281	100.0	3	1.1	0.4	3.1
	Thrombocytopenia	n/a	281	100.0	24	8.5	5.8	12.4
	Thrombocytosis	n/a	281	100.0	5	1.8	0.8	4.1
Cardiac disorders	-Total	n/a	281	100.0	39	13.9	10.3	18.4
	Acute coronary syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Acute myocardial infarction	n/a	281	100.0	2	0.7	0.2	2.6
	Angina pectoris	n/a	281	100.0	1	0.4	0.1	2.0
	Aortic valve calcification	n/a	281	100.0	1	0.4	0.1	2.0

	Atrial fibrillation	n/a	281	100.0	1	0.4	0.1	2.0
	Atrial flutter	n/a	281	100.0	2	0.7	0.2	2.6
	Bradycardia	n/a	281	100.0	1	0.4	0.1	2.0
	Bundle branch block right	n/a	281	100.0	1	0.4	0.1	2.0
	Cardiac failure	n/a	281	100.0	2	0.7	0.2	2.6
	Cardio-respiratory arrest	n/a	281	100.0	1	0.4	0.1	2.0
	Extrasystoles	n/a	281	100.0	1	0.4	0.1	2.0
	Myocardial ischaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Nodal arrhythmia	n/a	281	100.0	3	1.1	0.4	3.1
	Palpitations	n/a	281	100.0	4	1.4	0.6	3.6
	Pericardial effusion	n/a	281	100.0	5	1.8	0.8	4.1
	Sinus bradycardia	n/a	281	100.0	4	1.4	0.6	3.6
	Sinus tachycardia	n/a	281	100.0	2	0.7	0.2	2.6
	Stress cardiomyopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Supraventricular tachycardia	n/a	281	100.0	1	0.4	0.1	2.0
	Tachycardia	n/a	281	100.0	7	2.5	1.2	5.1
	Ventricular extrasystoles	n/a	281	100.0	1	0.4	0.1	2.0
	Ventricular pre-excitation	n/a	281	100.0	1	0.4	0.1	2.0
Congenital, familial and genetic disorders	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Gilbert's syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Hydrocele	n/a	281	100.0	1	0.4	0.1	2.0
Ear and labyrinth disorders	-Total	n/a	281	100.0	21	7.5	4.9	11.2
	Ear congestion	n/a	281	100.0	2	0.7	0.2	2.6
	Ear discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Ear pain	n/a	281	100.0	4	1.4	0.6	3.6
	Tinnitus	n/a	281	100.0	4	1.4	0.6	3.6
	Vertigo	n/a	281	100.0	11	3.9	2.2	6.9
Endocrine disorders	-Total	n/a	281	100.0	4	1.4	0.6	3.6
	Adrenal insufficiency	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperthyroidism	n/a	281	100.0	1	0.4	0.1	2.0

	Hypothyroidism	n/a	281	100.0	2	0.7	0.2	2.6
Eye disorders	-Total	n/a	281	100.0	40	14.2	10.6	18.8
	Abnormal sensation in eye	n/a	281	100.0	1	0.4	0.1	2.0
	Blepharitis	n/a	281	100.0	1	0.4	0.1	2.0
	Cataract	n/a	281	100.0	2	0.7	0.2	2.6
	Chalazion	n/a	281	100.0	1	0.4	0.1	2.0
	Conjunctival cyst	n/a	281	100.0	1	0.4	0.1	2.0
	Conjunctival haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Diplopia	n/a	281	100.0	1	0.4	0.1	2.0
	Dry eye	n/a	281	100.0	7	2.5	1.2	5.1
	Eye swelling	n/a	281	100.0	2	0.7	0.2	2.6
	Eyelid oedema	n/a	281	100.0	5	1.8	0.8	4.1
	Eyelid ptosis	n/a	281	100.0	1	0.4	0.1	2.0
	Keratitis	n/a	281	100.0	2	0.7	0.2	2.6
	Ocular discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Periorbital oedema	n/a	281	100.0	6	2.1	1.0	4.6
	Photophobia	n/a	281	100.0	1	0.4	0.1	2.0
	Photopsia	n/a	281	100.0	2	0.7	0.2	2.6
	Ulcerative keratitis	n/a	281	100.0	1	0.4	0.1	2.0
	Vision blurred	n/a	281	100.0	14	5.0	3.0	8.2
	Visual acuity reduced	n/a	281	100.0	1	0.4	0.1	2.0
Gastrointestinal disorders	-Total	n/a	281	100.0	204	72.6	67.1	77.5
	Abdominal discomfort	n/a	281	100.0	5	1.8	0.8	4.1
	Abdominal distension	n/a	281	100.0	8	2.8	1.4	5.5
	Abdominal pain	n/a	281	100.0	18	6.4	4.1	9.9
	Abdominal pain lower	n/a	281	100.0	2	0.7	0.2	2.6
	Abdominal pain upper	n/a	281	100.0	15	5.3	3.3	8.6
	Abdominal symptom	n/a	281	100.0	1	0.4	0.1	2.0
	Anal incontinence	n/a	281	100.0	2	0.7	0.2	2.6
	Aphthous ulcer	n/a	281	100.0	2	0.7	0.2	2.6
	Ascites	n/a	281	100.0	4	1.4	0.6	3.6

	Colitis	n/a	281	100.0	3	1.1	0.4	3.1
	Constipation	n/a	281	100.0	118	42.0	36.4	47.8
	Dental caries	n/a	281	100.0	1	0.4	0.1	2.0
	Dental dysaesthesia	n/a	281	100.0	1	0.4	0.1	2.0
	Diarrhoea	n/a	281	100.0	70	24.9	20.2	30.3
	Diverticular perforation	n/a	281	100.0	1	0.4	0.1	2.0
	Dry mouth	n/a	281	100.0	47	16.7	12.8	21.5
	Dyspepsia	n/a	281	100.0	9	3.2	1.7	6.0
	Dysphagia	n/a	281	100.0	20	7.1	4.7	10.7
	Enteritis	n/a	281	100.0	1	0.4	0.1	2.0
	Epigastric discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Eructation	n/a	281	100.0	1	0.4	0.1	2.0
	Faeces soft	n/a	281	100.0	1	0.4	0.1	2.0
	Flatulence	n/a	281	100.0	2	0.7	0.2	2.6
	Frequent bowel movements	n/a	281	100.0	1	0.4	0.1	2.0
	Gastric ulcer	n/a	281	100.0	1	0.4	0.1	2.0
	Gastritis	n/a	281	100.0	3	1.1	0.4	3.1
	Gastritis erosive	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal haemorrhage	n/a	281	100.0	2	0.7	0.2	2.6
	Gastrointestinal inflammation	n/a	281	100.0	2	0.7	0.2	2.6
	Gastrointestinal oedema	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal wall thickening	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrooesophageal reflux disease	n/a	281	100.0	9	3.2	1.7	6.0
	Gingival bleeding	n/a	281	100.0	3	1.1	0.4	3.1
	Gingival swelling	n/a	281	100.0	1	0.4	0.1	2.0
	Glossitis	n/a	281	100.0	1	0.4	0.1	2.0
	Glossodynia	n/a	281	100.0	1	0.4	0.1	2.0
	Haematochezia	n/a	281	100.0	2	0.7	0.2	2.6
	Haemorrhoids	n/a	281	100.0	7	2.5	1.2	5.1
	Hypoaesthesia oral	n/a	281	100.0	5	1.8	0.8	4.1

	Impaired gastric emptying	n/a	281	100.0	1	0.4	0.1	2.0
	Intestinal obstruction	n/a	281	100.0	1	0.4	0.1	2.0
	Irritable bowel syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Large intestine perforation	n/a	281	100.0	1	0.4	0.1	2.0
	Melaena	n/a	281	100.0	1	0.4	0.1	2.0
	Mouth ulceration	n/a	281	100.0	9	3.2	1.7	6.0
	Nausea	n/a	281	100.0	42	14.9	11.3	19.6
	Odynophagia	n/a	281	100.0	5	1.8	0.8	4.1
	Oesophageal irritation	n/a	281	100.0	1	0.4	0.1	2.0
	Oesophagitis	n/a	281	100.0	4	1.4	0.6	3.6
	Oral disorder	n/a	281	100.0	2	0.7	0.2	2.6
	Oral dysaesthesia	n/a	281	100.0	1	0.4	0.1	2.0
	Oral mucosal erythema	n/a	281	100.0	1	0.4	0.1	2.0
	Oral pain	n/a	281	100.0	7	2.5	1.2	5.1
	Pancreatitis	n/a	281	100.0	1	0.4	0.1	2.0
	Pancreatitis acute	n/a	281	100.0	2	0.7	0.2	2.6
	Paraesthesia oral	n/a	281	100.0	1	0.4	0.1	2.0
	Proctitis ulcerative	n/a	281	100.0	1	0.4	0.1	2.0
	Rectal prolapse	n/a	281	100.0	1	0.4	0.1	2.0
	Regurgitation	n/a	281	100.0	1	0.4	0.1	2.0
	Sensitivity of teeth	n/a	281	100.0	1	0.4	0.1	2.0
	Stomatitis	n/a	281	100.0	13	4.6	2.7	7.8
	Swollen tongue	n/a	281	100.0	1	0.4	0.1	2.0
	Tongue coated	n/a	281	100.0	1	0.4	0.1	2.0
	Tongue discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Tongue ulceration	n/a	281	100.0	1	0.4	0.1	2.0
	Tooth discolouration	n/a	281	100.0	1	0.4	0.1	2.0
	Toothache	n/a	281	100.0	8	2.8	1.4	5.5
	Vomiting	n/a	281	100.0	32	11.4	8.2	15.6
General disorders and administration site conditions	-Total	n/a	281	100.0	197	70.1	64.5	75.2
	Asthenia	n/a	281	100.0	39	13.9	10.3	18.4

	Axillary pain	n/a	281	100.0	1	0.4	0.1	2.0
	Catheter site pain	n/a	281	100.0	1	0.4	0.1	2.0
	Chest discomfort	n/a	281	100.0	10	3.6	1.9	6.4
	Chest pain	n/a	281	100.0	9	3.2	1.7	6.0
	Chills	n/a	281	100.0	4	1.4	0.6	3.6
	Condition aggravated	n/a	281	100.0	1	0.4	0.1	2.0
	Death	n/a	281	100.0	2	0.7	0.2	2.6
	Face oedema	n/a	281	100.0	18	6.4	4.1	9.9
	Facial pain	n/a	281	100.0	1	0.4	0.1	2.0
	Fatigue	n/a	281	100.0	67	23.8	19.2	29.2
	Feeling abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Feeling cold	n/a	281	100.0	1	0.4	0.1	2.0
	Feeling hot	n/a	281	100.0	1	0.4	0.1	2.0
	Gait disturbance	n/a	281	100.0	7	2.5	1.2	5.1
	General physical health deterioration	n/a	281	100.0	5	1.8	0.8	4.1
	Generalised oedema	n/a	281	100.0	3	1.1	0.4	3.1
	Impaired healing	n/a	281	100.0	5	1.8	0.8	4.1
	Influenza like illness	n/a	281	100.0	3	1.1	0.4	3.1
	Injection site bruising	n/a	281	100.0	1	0.4	0.1	2.0
	Localised oedema	n/a	281	100.0	2	0.7	0.2	2.6
	Malaise	n/a	281	100.0	21	7.5	4.9	11.2
	Mucosal dryness	n/a	281	100.0	1	0.4	0.1	2.0
	Mucosal inflammation	n/a	281	100.0	21	7.5	4.9	11.2
	Multiple organ dysfunction syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Non-cardiac chest pain	n/a	281	100.0	12	4.3	2.5	7.3
	Oedema	n/a	281	100.0	4	1.4	0.6	3.6
	Oedema peripheral	n/a	281	100.0	42	14.9	11.3	19.6
	Pain	n/a	281	100.0	7	2.5	1.2	5.1
	Peripheral swelling	n/a	281	100.0	8	2.8	1.4	5.5
	Pyrexia	n/a	281	100.0	72	25.6	20.9	31.0

	Swelling	n/a	281	100.0	1	0.4	0.1	2.0
	Temperature intolerance	n/a	281	100.0	3	1.1	0.4	3.1
	Xerosis	n/a	281	100.0	1	0.4	0.1	2.0
Hepatobiliary disorders	-Total	n/a	281	100.0	26	9.3	6.4	13.2
	Cholecystitis	n/a	281	100.0	4	1.4	0.6	3.6
	Cholelithiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Gallbladder polyp	n/a	281	100.0	1	0.4	0.1	2.0
	Hepatic function abnormal	n/a	281	100.0	3	1.1	0.4	3.1
	Hepatic steatosis	n/a	281	100.0	1	0.4	0.1	2.0
	Hepatocellular injury	n/a	281	100.0	3	1.1	0.4	3.1
	Hyperbilirubinaemia	n/a	281	100.0	7	2.5	1.2	5.1
	Liver disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Liver injury	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumobilia	n/a	281	100.0	1	0.4	0.1	2.0
	Portal vein thrombosis	n/a	281	100.0	4	1.4	0.6	3.6
Immune system disorders	-Total	n/a	281	100.0	6	2.1	1.0	4.6
	Contrast media allergy	n/a	281	100.0	1	0.4	0.1	2.0
	Drug hypersensitivity	n/a	281	100.0	1	0.4	0.1	2.0
	Food allergy	n/a	281	100.0	1	0.4	0.1	2.0
	Hypersensitivity	n/a	281	100.0	1	0.4	0.1	2.0
	Seasonal allergy	n/a	281	100.0	2	0.7	0.2	2.6
Infections and infestations	-Total	n/a	281	100.0	157	55.9	50.0	61.6
	Abdominal abscess	n/a	281	100.0	1	0.4	0.1	2.0
	Acute sinusitis	n/a	281	100.0	1	0.4	0.1	2.0
	Appendicitis	n/a	281	100.0	2	0.7	0.2	2.6
	Arthritis infective	n/a	281	100.0	1	0.4	0.1	2.0
	Atypical pneumonia	n/a	281	100.0	1	0.4	0.1	2.0
	Bacteraemia	n/a	281	100.0	3	1.1	0.4	3.1
	Bacterial disease carrier	n/a	281	100.0	1	0.4	0.1	2.0
	Bacterial infection	n/a	281	100.0	1	0.4	0.1	2.0
	Bacterial vaginosis	n/a	281	100.0	1	0.4	0.1	2.0

	Bronchitis	n/a	281	100.0	7	2.5	1.2	5.1	
	Candida infection	n/a	281	100.0	1	0.4	0.1	2.0	
	Cellulitis	n/a	281	100.0	2	0.7	0.2	2.6	
	Chronic sinusitis	n/a	281	100.0	3	1.1	0.4	3.1	
	Clostridium difficile colitis	n/a	281	100.0	1	0.4	0.1	2.0	
	Conjunctivitis	n/a	281	100.0	1	0.4	0.1	2.0	
	Corona virus infection	n/a	281	100.0	2	0.7	0.2	2.6	
	Cystitis	n/a	281	100.0	3	1.1	0.4	3.1	
	Cystitis escherichia	n/a	281	100.0	1	0.4	0.1	2.0	
	Device related infection	n/a	281	100.0	1	0.4	0.1	2.0	
	Diverticulitis	n/a	281	100.0	2	0.7	0.2	2.6	
	Ear infection	n/a	281	100.0	1	0.4	0.1	2.0	
	Empyema	n/a	281	100.0	1	0.4	0.1	2.0	
	Enterococcal bacteraemia	n/a	281	100.0	1	0.4	0.1	2.0	
	Epididymitis	n/a	281	100.0	1	0.4	0.1	2.0	
	Epstein-Barr virus infection	n/a	281	100.0	1	0.4	0.1	2.0	
	Escherichia bacteraemia	n/a	281	100.0	1	0.4	0.1	2.0	
	Escherichia infection	n/a	281	100.0	1	0.4	0.1	2.0	
	Escherichia urinary tract infection	n/a	281	100.0	1	0.4	0.1	2.0	
	Eye infection	n/a	281	100.0	1	0.4	0.1	2.0	
	Febrile infection	n/a	281	100.0	1	0.4	0.1	2.0	
	Folliculitis	n/a	281	100.0	3	1.1	0.4	3.1	
	Fungal infection	n/a	281	100.0	3	1.1	0.4	3.1	
	Gastroenteritis	n/a	281	100.0	2	0.7	0.2	2.6	
	Genital candidiasis	n/a	281	100.0	1	0.4	0.1	2.0	
	Genital herpes	n/a	281	100.0	2	0.7	0.2	2.6	
	Gingivitis	n/a	281	100.0	1	0.4	0.1	2.0	
	Herpes simplex	n/a	281	100.0	1	0.4	0.1	2.0	
	Herpes virus infection	n/a	281	100.0	3	1.1	0.4	3.1	
	Herpes zoster	n/a	281	100.0	11	3.9	2.2	6.9	

	Infection	n/a	281	100.0	1	0.4	0.1	2.0
	Infectious colitis	n/a	281	100.0	1	0.4	0.1	2.0
	Influenza	n/a	281	100.0	3	1.1	0.4	3.1
	Lower respiratory tract infection	n/a	281	100.0	2	0.7	0.2	2.6
	Lung infection	n/a	281	100.0	4	1.4	0.6	3.6
	Lyme disease	n/a	281	100.0	1	0.4	0.1	2.0
	Lymph node tuberculosis	n/a	281	100.0	2	0.7	0.2	2.6
	Meningitis	n/a	281	100.0	1	0.4	0.1	2.0
	Nasal herpes	n/a	281	100.0	1	0.4	0.1	2.0
	Nasopharyngitis	n/a	281	100.0	9	3.2	1.7	6.0
	Oral candidiasis	n/a	281	100.0	9	3.2	1.7	6.0
	Oral fungal infection	n/a	281	100.0	2	0.7	0.2	2.6
	Oropharyngeal candidiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Otitis externa	n/a	281	100.0	2	0.7	0.2	2.6
	Otitis media	n/a	281	100.0	1	0.4	0.1	2.0
	Paronychia	n/a	281	100.0	7	2.5	1.2	5.1
	Peritonitis	n/a	281	100.0	1	0.4	0.1	2.0
	Pharyngitis	n/a	281	100.0	4	1.4	0.6	3.6
	Pleural infection	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumocystis jirovecii pneumonia	n/a	281	100.0	2	0.7	0.2	2.6
	Pneumonia	n/a	281	100.0	44	15.7	11.9	20.4
	Pneumonia bacterial	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia cytomegaloviral	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia haemophilus	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia influenzal	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia pseudomonal	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia streptococcal	n/a	281	100.0	1	0.4	0.1	2.0
	Pyelonephritis	n/a	281	100.0	2	0.7	0.2	2.6
	Pyelonephritis acute	n/a	281	100.0	1	0.4	0.1	2.0
	Pyuria	n/a	281	100.0	1	0.4	0.1	2.0
	Rectal abscess	n/a	281	100.0	1	0.4	0.1	2.0

	Renal tuberculosis	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory tract infection	n/a	281	100.0	2	0.7	0.2	2.6
	Respiratory tract infection bacterial	n/a	281	100.0	1	0.4	0.1	2.0
	Rhinitis	n/a	281	100.0	5	1.8	0.8	4.1
	Sepsis	n/a	281	100.0	9	3.2	1.7	6.0
	Septic shock	n/a	281	100.0	1	0.4	0.1	2.0
	Sinusitis	n/a	281	100.0	7	2.5	1.2	5.1
	Sinusitis bacterial	n/a	281	100.0	1	0.4	0.1	2.0
	Skin infection	n/a	281	100.0	2	0.7	0.2	2.6
	Staphylococcal infection	n/a	281	100.0	1	0.4	0.1	2.0
	Systemic infection	n/a	281	100.0	1	0.4	0.1	2.0
	Tinea cruris	n/a	281	100.0	1	0.4	0.1	2.0
	Tinea infection	n/a	281	100.0	1	0.4	0.1	2.0
	Tinea pedis	n/a	281	100.0	2	0.7	0.2	2.6
	Tonsillitis	n/a	281	100.0	1	0.4	0.1	2.0
	Tooth infection	n/a	281	100.0	1	0.4	0.1	2.0
	Tracheitis	n/a	281	100.0	1	0.4	0.1	2.0
	Tuberculosis	n/a	281	100.0	1	0.4	0.1	2.0
	Upper respiratory tract infection	n/a	281	100.0	13	4.6	2.7	7.8
	Urethritis	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary tract infection	n/a	281	100.0	38	13.5	10.0	18.0
	Urosepsis	n/a	281	100.0	2	0.7	0.2	2.6
	Varicella	n/a	281	100.0	1	0.4	0.1	2.0
	Varicella zoster virus infection	n/a	281	100.0	1	0.4	0.1	2.0
	Viral hepatitis carrier	n/a	281	100.0	1	0.4	0.1	2.0
	Viral infection	n/a	281	100.0	2	0.7	0.2	2.6
	Vulvovaginal candidiasis	n/a	281	100.0	1	0.4	0.1	2.0
Injury, poisoning and procedural complications	-Total	n/a	281	100.0	27	9.6	6.7	13.6
	Contusion	n/a	281	100.0	5	1.8	0.8	4.1
	Epicondylitis	n/a	281	100.0	1	0.4	0.1	2.0

	Fall	n/a	281	100.0	8	2.8	1.4	5.5
	Fracture	n/a	281	100.0	1	0.4	0.1	2.0
	Heart injury	n/a	281	100.0	1	0.4	0.1	2.0
	Incision site pain	n/a	281	100.0	1	0.4	0.1	2.0
	Injury	n/a	281	100.0	1	0.4	0.1	2.0
	Joint dislocation	n/a	281	100.0	2	0.7	0.2	2.6
	Laceration	n/a	281	100.0	1	0.4	0.1	2.0
	Ligament sprain	n/a	281	100.0	2	0.7	0.2	2.6
	Limb injury	n/a	281	100.0	2	0.7	0.2	2.6
	Muscle rupture	n/a	281	100.0	1	0.4	0.1	2.0
	Muscle strain	n/a	281	100.0	2	0.7	0.2	2.6
	Procedural pain	n/a	281	100.0	2	0.7	0.2	2.6
	Procedural pneumothorax	n/a	281	100.0	1	0.4	0.1	2.0
	Rib fracture	n/a	281	100.0	1	0.4	0.1	2.0
	Scar	n/a	281	100.0	1	0.4	0.1	2.0
	Skin abrasion	n/a	281	100.0	1	0.4	0.1	2.0
	Skin injury	n/a	281	100.0	1	0.4	0.1	2.0
	Subdural haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Tendon rupture	n/a	281	100.0	1	0.4	0.1	2.0
	Thermal burn	n/a	281	100.0	1	0.4	0.1	2.0
	Wound	n/a	281	100.0	2	0.7	0.2	2.6
	Wound complication	n/a	281	100.0	1	0.4	0.1	2.0
	Wrist fracture	n/a	281	100.0	1	0.4	0.1	2.0
Investigations	-Total	n/a	281	100.0	223	79.4	74.2	83.7
	Alanine aminotransferase	n/a	281	100.0	1	0.4	0.1	2.0
	Alanine aminotransferase increased	n/a	281	100.0	92	32.7	27.5	38.4
	Albumin urine present	n/a	281	100.0	1	0.4	0.1	2.0
	Alpha hydroxybutyrate dehydrogenase increased	n/a	281	100.0	3	1.1	0.4	3.1
	Amylase increased	n/a	281	100.0	3	1.1	0.4	3.1
	Aspartate aminotransferase increased	n/a	281	100.0	126	44.8	39.1	50.7
	Bacterial test	n/a	281	100.0	1	0.4	0.1	2.0

	Bilirubin conjugated increased	n/a	281	100.0	20	7.1	4.7	10.7
	Blood albumin decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood alkaline phosphatase	n/a	281	100.0	1	0.4	0.1	2.0
	Blood alkaline phosphatase decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood alkaline phosphatase increased	n/a	281	100.0	35	12.5	9.1	16.8
	Blood bilirubin increased	n/a	281	100.0	27	9.6	6.7	13.6
	Blood bilirubin unconjugated increased	n/a	281	100.0	9	3.2	1.7	6.0
	Blood calcium decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood calcium increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood chloride increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood cholesterol increased	n/a	281	100.0	8	2.8	1.4	5.5
	Blood creatine increased	n/a	281	100.0	3	1.1	0.4	3.1
	Blood creatine phosphokinase MB increased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood creatine phosphokinase increased	n/a	281	100.0	53	18.9	14.7	23.8
	Blood creatinine	n/a	281	100.0	1	0.4	0.1	2.0
	Blood creatinine increased	n/a	281	100.0	62	22.1	17.6	27.3
	Blood fibrinogen increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood glucose increased	n/a	281	100.0	3	1.1	0.4	3.1
	Blood iron decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood ketone body increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood lactate dehydrogenase increased	n/a	281	100.0	11	3.9	2.2	6.9
	Blood magnesium decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood phosphorus increased	n/a	281	100.0	7	2.5	1.2	5.1
	Blood potassium decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood potassium increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood pressure increased	n/a	281	100.0	3	1.1	0.4	3.1
	Blood sodium decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood thyroid stimulating hormone increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood triglycerides increased	n/a	281	100.0	8	2.8	1.4	5.5
	Blood urea increased	n/a	281	100.0	6	2.1	1.0	4.6

	Blood uric acid decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood uric acid increased	n/a	281	100.0	7	2.5	1.2	5.1
	Blood urine	n/a	281	100.0	3	1.1	0.4	3.1
	Blood urine present	n/a	281	100.0	1	0.4	0.1	2.0
	C-reactive protein increased	n/a	281	100.0	4	1.4	0.6	3.6
	Carbon dioxide decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Complement factor C1 decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Computerised tomogram thorax abnormal	n/a	281	100.0	2	0.7	0.2	2.6
	Crystal urine present	n/a	281	100.0	1	0.4	0.1	2.0
	Cystatin C increased	n/a	281	100.0	1	0.4	0.1	2.0
	Electrocardiogram QT prolonged	n/a	281	100.0	15	5.3	3.3	8.6
	Electrocardiogram ST-T change	n/a	281	100.0	2	0.7	0.2	2.6
	Fibrin D dimer increased	n/a	281	100.0	2	0.7	0.2	2.6
	Fibrin degradation products increased	n/a	281	100.0	1	0.4	0.1	2.0
	Free fatty acids increased	n/a	281	100.0	1	0.4	0.1	2.0
	Gamma-glutamyltransferase increased	n/a	281	100.0	20	7.1	4.7	10.7
	Glomerular filtration rate decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Glutamate dehydrogenase increased	n/a	281	100.0	2	0.7	0.2	2.6
	Granulocyte count decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Haematocrit decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Haemoglobin decreased	n/a	281	100.0	7	2.5	1.2	5.1
	Heart rate increased	n/a	281	100.0	6	2.1	1.0	4.6
	Hepatic enzyme increased	n/a	281	100.0	3	1.1	0.4	3.1
	International normalised ratio increased	n/a	281	100.0	2	0.7	0.2	2.6
	Intraocular pressure increased	n/a	281	100.0	1	0.4	0.1	2.0
	Laboratory test abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Lipase increased	n/a	281	100.0	4	1.4	0.6	3.6
	Liver function test increased	n/a	281	100.0	2	0.7	0.2	2.6
	Lymphocyte count decreased	n/a	281	100.0	27	9.6	6.7	13.6
	Lymphocyte count increased	n/a	281	100.0	1	0.4	0.1	2.0
	Mean cell volume increased	n/a	281	100.0	1	0.4	0.1	2.0

	Myoglobin blood increased	n/a	281	100.0	2	0.7	0.2	2.6
	Neutrophil count decreased	n/a	281	100.0	81	28.8	23.8	34.4
	Neutrophil count increased	n/a	281	100.0	2	0.7	0.2	2.6
	Neutrophil percentage increased	n/a	281	100.0	1	0.4	0.1	2.0
	Occult blood positive	n/a	281	100.0	3	1.1	0.4	3.1
	Oxygen saturation decreased	n/a	281	100.0	1	0.4	0.1	2.0
	PO2 decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Platelet count decreased	n/a	281	100.0	33	11.7	8.5	16.0
	Platelet count increased	n/a	281	100.0	5	1.8	0.8	4.1
	Procalcitonin increased	n/a	281	100.0	1	0.4	0.1	2.0
	Protein total decreased	n/a	281	100.0	3	1.1	0.4	3.1
	Protein total increased	n/a	281	100.0	1	0.4	0.1	2.0
	Protein urine present	n/a	281	100.0	2	0.7	0.2	2.6
	Prothrombin time prolonged	n/a	281	100.0	1	0.4	0.1	2.0
	Red blood cell count decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Serum amyloid A protein increased	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombin time prolonged	n/a	281	100.0	1	0.4	0.1	2.0
	Total bile acids increased	n/a	281	100.0	9	3.2	1.7	6.0
	Transaminases increased	n/a	281	100.0	8	2.8	1.4	5.5
	Transferrin increased	n/a	281	100.0	1	0.4	0.1	2.0
	Troponin T increased	n/a	281	100.0	2	0.7	0.2	2.6
	Troponin increased	n/a	281	100.0	2	0.7	0.2	2.6
	Urinary sediment present	n/a	281	100.0	1	0.4	0.1	2.0
	Urine ketone body present	n/a	281	100.0	3	1.1	0.4	3.1
	Urine leukocyte esterase positive	n/a	281	100.0	1	0.4	0.1	2.0
	Urobilinogen urine increased	n/a	281	100.0	2	0.7	0.2	2.6
	Weight decreased	n/a	281	100.0	18	6.4	4.1	9.9
	Weight increased	n/a	281	100.0	26	9.3	6.4	13.2
	White blood cell count decreased	n/a	281	100.0	72	25.6	20.9	31.0
	White blood cells urine positive	n/a	281	100.0	3	1.1	0.4	3.1

Metabolism and nutrition disorders	-Total	n/a	281	100.0	147	52.3	46.5	58.1
	Abnormal loss of weight	n/a	281	100.0	1	0.4	0.1	2.0
	Acidosis	n/a	281	100.0	1	0.4	0.1	2.0
	Alkalosis	n/a	281	100.0	1	0.4	0.1	2.0
	Cell death	n/a	281	100.0	1	0.4	0.1	2.0
	Decreased appetite	n/a	281	100.0	38	13.5	10.0	18.0
	Dehydration	n/a	281	100.0	6	2.1	1.0	4.6
	Electrolyte imbalance	n/a	281	100.0	3	1.1	0.4	3.1
	Failure to thrive	n/a	281	100.0	1	0.4	0.1	2.0
	Fluid retention	n/a	281	100.0	1	0.4	0.1	2.0
	Hypercalcaemia	n/a	281	100.0	7	2.5	1.2	5.1
	Hypercholesterolaemia	n/a	281	100.0	5	1.8	0.8	4.1
	Hyperglycaemia	n/a	281	100.0	18	6.4	4.1	9.9
	Hyperkalaemia	n/a	281	100.0	16	5.7	3.5	9.0
	Hyperlipidaemia	n/a	281	100.0	7	2.5	1.2	5.1
	Hypermagnesaemia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypernatraemia	n/a	281	100.0	4	1.4	0.6	3.6
	Hyperphosphataemia	n/a	281	100.0	32	11.4	8.2	15.6
	Hypertriglyceridaemia	n/a	281	100.0	7	2.5	1.2	5.1
	Hyperuricaemia	n/a	281	100.0	11	3.9	2.2	6.9
	Hypoalbuminaemia	n/a	281	100.0	37	13.2	9.7	17.6
	Hypocalcaemia	n/a	281	100.0	34	12.1	8.8	16.4
	Hypochloraemia	n/a	281	100.0	5	1.8	0.8	4.1
	Hypoglycaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypokalaemia	n/a	281	100.0	38	13.5	10.0	18.0
	Hypomagnesaemia	n/a	281	100.0	21	7.5	4.9	11.2
	Hyponatraemia	n/a	281	100.0	30	10.7	7.6	14.8
	Hypophosphataemia	n/a	281	100.0	35	12.5	9.1	16.8
	Hypoproteinaemia	n/a	281	100.0	6	2.1	1.0	4.6
	Increased appetite	n/a	281	100.0	1	0.4	0.1	2.0
	Vitamin D deficiency	n/a	281	100.0	1	0.4	0.1	2.0

Musculoskeletal and connective tissue disorders	-Total	n/a	281	100.0	124	44.1	38.4	50.0
	Arthralgia	n/a	281	100.0	13	4.6	2.7	7.8
	Arthropathy	n/a	281	100.0	1	0.4	0.1	2.0
	Back pain	n/a	281	100.0	38	13.5	10.0	18.0
	Bone pain	n/a	281	100.0	4	1.4	0.6	3.6
	Bursitis	n/a	281	100.0	1	0.4	0.1	2.0
	Coccydynia	n/a	281	100.0	1	0.4	0.1	2.0
	Costochondritis	n/a	281	100.0	2	0.7	0.2	2.6
	Flank pain	n/a	281	100.0	3	1.1	0.4	3.1
	Groin pain	n/a	281	100.0	1	0.4	0.1	2.0
	Hypercreatinaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Intervertebral disc protrusion	n/a	281	100.0	6	2.1	1.0	4.6
	Joint range of motion decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Joint stiffness	n/a	281	100.0	1	0.4	0.1	2.0
	Joint swelling	n/a	281	100.0	2	0.7	0.2	2.6
	Muscle fatigue	n/a	281	100.0	1	0.4	0.1	2.0
	Muscle haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Muscle spasms	n/a	281	100.0	22	7.8	5.2	11.6
	Muscular weakness	n/a	281	100.0	11	3.9	2.2	6.9
	Musculoskeletal chest pain	n/a	281	100.0	7	2.5	1.2	5.1
	Musculoskeletal pain	n/a	281	100.0	24	8.5	5.8	12.4
	Musculoskeletal stiffness	n/a	281	100.0	1	0.4	0.1	2.0
	Myalgia	n/a	281	100.0	23	8.2	5.5	12.0
	Myopathy	n/a	281	100.0	2	0.7	0.2	2.6
	Neck pain	n/a	281	100.0	14	5.0	3.0	8.2
	Osteopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Pain in extremity	n/a	281	100.0	26	9.3	6.4	13.2
	Pain in jaw	n/a	281	100.0	2	0.7	0.2	2.6
	Rhabdomyolysis	n/a	281	100.0	1	0.4	0.1	2.0
	Rotator cuff syndrome	n/a	281	100.0	1	0.4	0.1	2.0

	Spinal column stenosis	n/a	281	100.0	2	0.7	0.2	2.6
	Spinal osteoarthritis	n/a	281	100.0	1	0.4	0.1	2.0
	Tendon disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Tendon pain	n/a	281	100.0	1	0.4	0.1	2.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	281	100.0	11	3.9	2.2	6.9
	Anogenital warts	n/a	281	100.0	1	0.4	0.1	2.0
	Basal cell carcinoma	n/a	281	100.0	1	0.4	0.1	2.0
	Bowen's disease	n/a	281	100.0	1	0.4	0.1	2.0
	Cancer pain	n/a	281	100.0	1	0.4	0.1	2.0
	Gallbladder cancer	n/a	281	100.0	1	0.4	0.1	2.0
	Metastases to central nervous system	n/a	281	100.0	1	0.4	0.1	2.0
	Renal cell carcinoma	n/a	281	100.0	1	0.4	0.1	2.0
	Squamous cell carcinoma	n/a	281	100.0	1	0.4	0.1	2.0
	Squamous cell carcinoma of skin	n/a	281	100.0	1	0.4	0.1	2.0
	Tumour pain	n/a	281	100.0	2	0.7	0.2	2.6
Nervous system disorders	-Total	n/a	281	100.0	145	51.6	45.8	57.4
	Ageusia	n/a	281	100.0	2	0.7	0.2	2.6
	Aphasia	n/a	281	100.0	1	0.4	0.1	2.0
	Ataxia	n/a	281	100.0	2	0.7	0.2	2.6
	Balance disorder	n/a	281	100.0	2	0.7	0.2	2.6
	Brain oedema	n/a	281	100.0	2	0.7	0.2	2.6
	Cerebellar haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Cerebral haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Cerebral microhaemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Cerebrovascular accident	n/a	281	100.0	1	0.4	0.1	2.0
	Disturbance in attention	n/a	281	100.0	2	0.7	0.2	2.6
	Dizziness	n/a	281	100.0	38	13.5	10.0	18.0
	Dizziness postural	n/a	281	100.0	1	0.4	0.1	2.0
	Dysarthria	n/a	281	100.0	1	0.4	0.1	2.0
	Dysgeusia	n/a	281	100.0	42	14.9	11.3	19.6
	Dyskinesia	n/a	281	100.0	1	0.4	0.1	2.0

	Epilepsy	n/a	281	100.0	1	0.4	0.1	2.0
	Facial paralysis	n/a	281	100.0	1	0.4	0.1	2.0
	Haemorrhage intracranial	n/a	281	100.0	1	0.4	0.1	2.0
	Headache	n/a	281	100.0	34	12.1	8.8	16.4
	Hemiplegia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperaesthesia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypersomnia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypoaesthesia	n/a	281	100.0	18	6.4	4.1	9.9
	Hypotonia	n/a	281	100.0	1	0.4	0.1	2.0
	Lethargy	n/a	281	100.0	1	0.4	0.1	2.0
	Lumbar radiculopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Lumbosacral radiculopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Memory impairment	n/a	281	100.0	2	0.7	0.2	2.6
	Migraine	n/a	281	100.0	1	0.4	0.1	2.0
	Migraine with aura	n/a	281	100.0	1	0.4	0.1	2.0
	Neuralgia	n/a	281	100.0	2	0.7	0.2	2.6
	Neuropathy peripheral	n/a	281	100.0	12	4.3	2.5	7.3
	Paraesthesia	n/a	281	100.0	12	4.3	2.5	7.3
	Paralysis	n/a	281	100.0	1	0.4	0.1	2.0
	Parosmia	n/a	281	100.0	1	0.4	0.1	2.0
	Peripheral sensory neuropathy	n/a	281	100.0	9	3.2	1.7	6.0
	Polyneuropathy chronic	n/a	281	100.0	1	0.4	0.1	2.0
	Post herpetic neuralgia	n/a	281	100.0	1	0.4	0.1	2.0
	Presyncope	n/a	281	100.0	3	1.1	0.4	3.1
	Psychomotor skills impaired	n/a	281	100.0	1	0.4	0.1	2.0
	Restless legs syndrome	n/a	281	100.0	2	0.7	0.2	2.6
	Sciatica	n/a	281	100.0	6	2.1	1.0	4.6
	Seizure	n/a	281	100.0	6	2.1	1.0	4.6
	Sensory disturbance	n/a	281	100.0	1	0.4	0.1	2.0
	Slow speech	n/a	281	100.0	1	0.4	0.1	2.0

	Somnolence	n/a	281	100.0	2	0.7	0.2	2.6
	Spinal cord haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Syncope	n/a	281	100.0	7	2.5	1.2	5.1
	Tension headache	n/a	281	100.0	1	0.4	0.1	2.0
	Tremor	n/a	281	100.0	1	0.4	0.1	2.0
	Visual field defect	n/a	281	100.0	2	0.7	0.2	2.6
Product issues	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Device dislocation	n/a	281	100.0	1	0.4	0.1	2.0
Psychiatric disorders	-Total	n/a	281	100.0	56	19.9	15.7	25.0
	Abnormal behaviour	n/a	281	100.0	1	0.4	0.1	2.0
	Abnormal dreams	n/a	281	100.0	1	0.4	0.1	2.0
	Adjustment disorder with mixed anxiety and depressed mood	n/a	281	100.0	1	0.4	0.1	2.0
	Anxiety	n/a	281	100.0	12	4.3	2.5	7.3
	Bradyphrenia	n/a	281	100.0	1	0.4	0.1	2.0
	Confusional state	n/a	281	100.0	5	1.8	0.8	4.1
	Delirium	n/a	281	100.0	3	1.1	0.4	3.1
	Depressed mood	n/a	281	100.0	1	0.4	0.1	2.0
	Depression	n/a	281	100.0	5	1.8	0.8	4.1
	Fear of falling	n/a	281	100.0	1	0.4	0.1	2.0
	Insomnia	n/a	281	100.0	20	7.1	4.7	10.7
	Irritability	n/a	281	100.0	1	0.4	0.1	2.0
	Libido decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Mental status changes	n/a	281	100.0	4	1.4	0.6	3.6
	Mood altered	n/a	281	100.0	1	0.4	0.1	2.0
	Psychomotor retardation	n/a	281	100.0	2	0.7	0.2	2.6
	Restlessness	n/a	281	100.0	5	1.8	0.8	4.1
	Sleep disorder	n/a	281	100.0	2	0.7	0.2	2.6
Renal and urinary disorders	-Total	n/a	281	100.0	43	15.3	11.6	20.0
	Acute kidney injury	n/a	281	100.0	8	2.8	1.4	5.5
	Azotaemia	n/a	281	100.0	2	0.7	0.2	2.6
	Cystitis haemorrhagic	n/a	281	100.0	1	0.4	0.1	2.0

	Dysuria	n/a	281	100.0	11	3.9	2.2	6.9
	Haematuria	n/a	281	100.0	4	1.4	0.6	3.6
	Haemorrhage urinary tract	n/a	281	100.0	1	0.4	0.1	2.0
	Hydronephrosis	n/a	281	100.0	1	0.4	0.1	2.0
	Micturition urgency	n/a	281	100.0	1	0.4	0.1	2.0
	Nephritis	n/a	281	100.0	1	0.4	0.1	2.0
	Nephrolithiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Nocturia	n/a	281	100.0	3	1.1	0.4	3.1
	Obstructive nephropathy	n/a	281	100.0	1	0.4	0.1	2.0
	Pollakiuria	n/a	281	100.0	2	0.7	0.2	2.6
	Proteinuria	n/a	281	100.0	2	0.7	0.2	2.6
	Renal colic	n/a	281	100.0	1	0.4	0.1	2.0
	Renal disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Renal failure	n/a	281	100.0	2	0.7	0.2	2.6
	Renal impairment	n/a	281	100.0	1	0.4	0.1	2.0
	Strangury	n/a	281	100.0	1	0.4	0.1	2.0
	Urethral stenosis	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary incontinence	n/a	281	100.0	2	0.7	0.2	2.6
	Urinary retention	n/a	281	100.0	7	2.5	1.2	5.1
	Urinary tract pain	n/a	281	100.0	1	0.4	0.1	2.0
	Urine flow decreased	n/a	281	100.0	1	0.4	0.1	2.0
Reproductive system and breast disorders	-Total	n/a	281	100.0	23	8.2	5.5	12.0
	Benign prostatic hyperplasia	n/a	281	100.0	3	1.1	0.4	3.1
	Breast discharge	n/a	281	100.0	1	0.4	0.1	2.0
	Erectile dysfunction	n/a	281	100.0	9	3.2	1.7	6.0
	Galactorrhoea	n/a	281	100.0	1	0.4	0.1	2.0
	Genital ulceration	n/a	281	100.0	1	0.4	0.1	2.0
	Metrorrhagia	n/a	281	100.0	2	0.7	0.2	2.6
	Ovarian cyst	n/a	281	100.0	1	0.4	0.1	2.0
	Pelvic discomfort	n/a	281	100.0	1	0.4	0.1	2.0

	Pelvic fluid collection	n/a	281	100.0	1	0.4	0.1	2.0
	Perineal pain	n/a	281	100.0	1	0.4	0.1	2.0
	Postmenopausal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Prostatitis	n/a	281	100.0	2	0.7	0.2	2.6
	Uterine polyp	n/a	281	100.0	1	0.4	0.1	2.0
	Vaginal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Vulvovaginal dryness	n/a	281	100.0	1	0.4	0.1	2.0
	Vulvovaginal erythema	n/a	281	100.0	1	0.4	0.1	2.0
Respiratory, thoracic and mediastinal disorders	-Total	n/a	281	100.0	167	59.4	53.6	65.0
	Acute respiratory failure	n/a	281	100.0	1	0.4	0.1	2.0
	Aspiration	n/a	281	100.0	1	0.4	0.1	2.0
	Bronchospasm	n/a	281	100.0	1	0.4	0.1	2.0
	Choking	n/a	281	100.0	1	0.4	0.1	2.0
	Cough	n/a	281	100.0	65	23.1	18.6	28.4
	Dry throat	n/a	281	100.0	2	0.7	0.2	2.6
	Dysphonia	n/a	281	100.0	12	4.3	2.5	7.3
	Dyspnoea	n/a	281	100.0	47	16.7	12.8	21.5
	Dyspnoea exertional	n/a	281	100.0	12	4.3	2.5	7.3
	Epistaxis	n/a	281	100.0	14	5.0	3.0	8.2
	Haemoptysis	n/a	281	100.0	11	3.9	2.2	6.9
	Hiccups	n/a	281	100.0	2	0.7	0.2	2.6
	Hypoxia	n/a	281	100.0	5	1.8	0.8	4.1
	Interstitial lung disease	n/a	281	100.0	4	1.4	0.6	3.6
	Laryngeal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Lung consolidation	n/a	281	100.0	1	0.4	0.1	2.0
	Nasal congestion	n/a	281	100.0	4	1.4	0.6	3.6
	Nasal dryness	n/a	281	100.0	4	1.4	0.6	3.6
	Nasal polyps	n/a	281	100.0	1	0.4	0.1	2.0
	Oropharyngeal discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Oropharyngeal pain	n/a	281	100.0	21	7.5	4.9	11.2
	Paranasal sinus discomfort	n/a	281	100.0	1	0.4	0.1	2.0

	Pharyngeal disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Pleural effusion	n/a	281	100.0	12	4.3	2.5	7.3
	Pleural thickening	n/a	281	100.0	2	0.7	0.2	2.6
	Pleuritic pain	n/a	281	100.0	3	1.1	0.4	3.1
	Pneumonitis	n/a	281	100.0	32	11.4	8.2	15.6
	Pneumothorax	n/a	281	100.0	4	1.4	0.6	3.6
	Productive cough	n/a	281	100.0	14	5.0	3.0	8.2
	Pulmonary embolism	n/a	281	100.0	13	4.6	2.7	7.8
	Pulmonary hypertension	n/a	281	100.0	1	0.4	0.1	2.0
	Pulmonary mass	n/a	281	100.0	1	0.4	0.1	2.0
	Pulmonary pain	n/a	281	100.0	1	0.4	0.1	2.0
	Respiration abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory distress	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory failure	n/a	281	100.0	1	0.4	0.1	2.0
	Rhinalgia	n/a	281	100.0	1	0.4	0.1	2.0
	Rhinitis allergic	n/a	281	100.0	2	0.7	0.2	2.6
	Rhinorrhoea	n/a	281	100.0	3	1.1	0.4	3.1
	Sinus congestion	n/a	281	100.0	1	0.4	0.1	2.0
	Sleep apnoea syndrome	n/a	281	100.0	3	1.1	0.4	3.1
	Sputum discoloured	n/a	281	100.0	1	0.4	0.1	2.0
	Throat irritation	n/a	281	100.0	2	0.7	0.2	2.6
	Upper-airway cough syndrome	n/a	281	100.0	2	0.7	0.2	2.6
	Vocal cord leukoplakia	n/a	281	100.0	1	0.4	0.1	2.0
	Wheezing	n/a	281	100.0	2	0.7	0.2	2.6
Skin and subcutaneous tissue disorders	-Total	n/a	281	100.0	100	35.6	30.2	41.3
	Acne	n/a	281	100.0	1	0.4	0.1	2.0
	Alopecia	n/a	281	100.0	14	5.0	3.0	8.2
	Chloasma	n/a	281	100.0	1	0.4	0.1	2.0
	Decubitus ulcer	n/a	281	100.0	1	0.4	0.1	2.0
	Dermal cyst	n/a	281	100.0	1	0.4	0.1	2.0

	Dermatitis	n/a	281	100.0	1	0.4	0.1	2.0
	Dermatitis acneiform	n/a	281	100.0	7	2.5	1.2	5.1
	Dermatitis allergic	n/a	281	100.0	1	0.4	0.1	2.0
	Dermatitis bullous	n/a	281	100.0	2	0.7	0.2	2.6
	Dry skin	n/a	281	100.0	12	4.3	2.5	7.3
	Ecchymosis	n/a	281	100.0	1	0.4	0.1	2.0
	Eczema	n/a	281	100.0	2	0.7	0.2	2.6
	Erythema	n/a	281	100.0	4	1.4	0.6	3.6
	Hair growth abnormal	n/a	281	100.0	6	2.1	1.0	4.6
	Hair texture abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Hirsutism	n/a	281	100.0	7	2.5	1.2	5.1
	Hyperhidrosis	n/a	281	100.0	2	0.7	0.2	2.6
	Hyperkeratosis	n/a	281	100.0	1	0.4	0.1	2.0
	Hypertrichosis	n/a	281	100.0	6	2.1	1.0	4.6
	Madarosis	n/a	281	100.0	1	0.4	0.1	2.0
	Nail discolouration	n/a	281	100.0	1	0.4	0.1	2.0
	Nail disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Night sweats	n/a	281	100.0	2	0.7	0.2	2.6
	Onychalgia	n/a	281	100.0	1	0.4	0.1	2.0
	Onycholysis	n/a	281	100.0	1	0.4	0.1	2.0
	Onychomadesis	n/a	281	100.0	3	1.1	0.4	3.1
	Pain of skin	n/a	281	100.0	1	0.4	0.1	2.0
	Palmar-plantar erythrodysaesthesia syndrome	n/a	281	100.0	5	1.8	0.8	4.1
	Photosensitivity reaction	n/a	281	100.0	1	0.4	0.1	2.0
	Pruritus	n/a	281	100.0	7	2.5	1.2	5.1
	Pruritus generalised	n/a	281	100.0	1	0.4	0.1	2.0
	Purpura	n/a	281	100.0	1	0.4	0.1	2.0
	Rash	n/a	281	100.0	23	8.2	5.5	12.0
	Rash erythematous	n/a	281	100.0	2	0.7	0.2	2.6
	Rash macular	n/a	281	100.0	4	1.4	0.6	3.6
	Rash maculo-papular	n/a	281	100.0	2	0.7	0.2	2.6

	Rash papular	n/a	281	100.0	1	0.4	0.1	2.0
	Scab	n/a	281	100.0	2	0.7	0.2	2.6
	Scar pain	n/a	281	100.0	1	0.4	0.1	2.0
	Skin discolouration	n/a	281	100.0	1	0.4	0.1	2.0
	Skin hyperpigmentation	n/a	281	100.0	1	0.4	0.1	2.0
	Skin lesion	n/a	281	100.0	1	0.4	0.1	2.0
	Swelling face	n/a	281	100.0	6	2.1	1.0	4.6
	Urticaria	n/a	281	100.0	2	0.7	0.2	2.6
Surgical and medical procedures	-Total	n/a	281	100.0	8	2.8	1.4	5.5
	Astringent therapy	n/a	281	100.0	5	1.8	0.8	4.1
	Eye excision	n/a	281	100.0	1	0.4	0.1	2.0
	Hip arthroplasty	n/a	281	100.0	1	0.4	0.1	2.0
	Therapy cessation	n/a	281	100.0	1	0.4	0.1	2.0
Vascular disorders	-Total	n/a	281	100.0	115	40.9	35.3	46.8
	Aortic dissection	n/a	281	100.0	1	0.4	0.1	2.0
	Circulatory collapse	n/a	281	100.0	1	0.4	0.1	2.0
	Deep vein thrombosis	n/a	281	100.0	3	1.1	0.4	3.1
	Embolism	n/a	281	100.0	5	1.8	0.8	4.1
	Embolism venous	n/a	281	100.0	1	0.4	0.1	2.0
	Flushing	n/a	281	100.0	1	0.4	0.1	2.0
	Haematoma	n/a	281	100.0	4	1.4	0.6	3.6
	Hot flush	n/a	281	100.0	3	1.1	0.4	3.1
	Hypertension	n/a	281	100.0	96	34.2	28.9	39.9
	Hypotension	n/a	281	100.0	7	2.5	1.2	5.1
	Lymphoedema	n/a	281	100.0	2	0.7	0.2	2.6
	Orthostatic hypotension	n/a	281	100.0	3	1.1	0.4	3.1
	Pallor	n/a	281	100.0	1	0.4	0.1	2.0
	Phlebitis	n/a	281	100.0	1	0.4	0.1	2.0
	Raynaud's phenomenon	n/a	281	100.0	1	0.4	0.1	2.0
	Shock haemorrhagic	n/a	281	100.0	1	0.4	0.1	2.0

	Superior vena cava syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombophlebitis superficial	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombosis	n/a	281	100.0	2	0.7	0.2	2.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEANY_SG.xls
26MAR2021 14:05

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	< 65	176	62.6	100	56.8	49.4	63.9
		>= 65	105	37.4	69	65.7	56.2	74.1
	Anaemia	< 65	176	62.6	81	46.0	38.8	53.4
		>= 65	105	37.4	48	45.7	36.5	55.2
	Anaemia macrocytic	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Aplastic anaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bone marrow oedema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cytopenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Disseminated intravascular coagulation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Febrile neutropenia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Haemorrhagic anaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperfibrinogenaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Leukocytosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Leukopenia	< 65	176	62.6	21	11.9	7.9	17.6
		>= 65	105	37.4	9	8.6	4.6	15.5
	Lymph node pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lymphadenopathy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymphopenia	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	10	9.5	5.3	16.6
	Neutropenia	< 65	176	62.6	40	22.7	17.2	29.5
		>= 65	105	37.4	21	20.0	13.5	28.6
	Neutrophilia	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Pancytopenia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Thrombocytopenia	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	12	11.4	6.7	18.9
	Thrombocytosis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
Cardiac disorders	-Total	< 65	176	62.6	22	12.5	8.4	18.2
		>= 65	105	37.4	17	16.2	10.4	24.4
	Acute coronary syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Acute myocardial infarction	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Angina pectoris	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Aortic valve calcification	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Atrial fibrillation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Atrial flutter	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bradycardia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bundle branch block right	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cardiac failure	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cardio-respiratory arrest	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Extrasystoles	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Myocardial ischaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nodal arrhythmia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Palpitations	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pericardial effusion	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sinus bradycardia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5

	Sinus tachycardia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Stress cardiomyopathy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Supraventricular tachycardia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tachycardia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Ventricular extrasystoles	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ventricular pre-excitation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Congenital, familial and genetic disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gilbert's syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hydrocele	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Ear and labyrinth disorders	-Total	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	6	5.7	2.6	11.9
	Ear congestion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ear discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ear pain	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tinnitus	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Vertigo	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	3	2.9	1.0	8.1
Endocrine disorders	-Total	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Adrenal insufficiency	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperthyroidism	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypothyroidism	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
Eye disorders	-Total	< 65	176	62.6	29	16.5	11.7	22.7
		>= 65	105	37.4	11	10.5	6.0	17.8

	Abnormal sensation in eye	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blepharitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cataract	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Chalazion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Conjunctival cyst	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Conjunctival haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diplopia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dry eye	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eye swelling	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Eyelid oedema	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Eyelid ptosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Keratitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ocular discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Periorbital oedema	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Photophobia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Photopsia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ulcerative keratitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vision blurred	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Visual acuity reduced	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Gastrointestinal disorders	-Total	< 65	176	62.6	124	70.5	63.3	76.7
		>= 65	105	37.4	80	76.2	67.2	83.3
	Abdominal discomfort	< 65	176	62.6	3	1.7	0.6	4.9

		>= 65	105	37.4	2	1.9	0.5	6.7
	Abdominal distension	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
	Abdominal pain	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	5	4.8	2.1	10.7
	Abdominal pain lower	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Abdominal pain upper	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	5	4.8	2.1	10.7
	Abdominal symptom	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Anal incontinence	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Aphthous ulcer	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Ascites	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Colitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Constipation	< 65	176	62.6	71	40.3	33.4	47.7
		>= 65	105	37.4	47	44.8	35.6	54.3
	Dental caries	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dental dysaesthesia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diarrhoea	< 65	176	62.6	42	23.9	18.2	30.7
		>= 65	105	37.4	28	26.7	19.1	35.8
	Diverticular perforation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dry mouth	< 65	176	62.6	23	13.1	8.9	18.8
		>= 65	105	37.4	24	22.9	15.9	31.8
	Dyspepsia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	3	2.9	1.0	8.1
	Dysphagia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	14	13.3	8.1	21.1
	Enteritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Epigastric discomfort	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eructation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Faeces soft	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Flatulence	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Frequent bowel movements	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastric ulcer	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastritis	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastritis erosive	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastrointestinal haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastrointestinal inflammation	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrointestinal oedema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrointestinal wall thickening	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrooesophageal reflux disease	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	5	4.8	2.1	10.7
	Gingival bleeding	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gingival swelling	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Glossitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Glossodynia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haematochezia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Haemorrhoids	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	4	3.8	1.5	9.4
	Hypoaesthesia oral	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	0	0.0	0.0	3.5
	Impaired gastric emptying	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Intestinal obstruction	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Irritable bowel syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Large intestine perforation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Melaena	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mouth ulceration	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	6	5.7	2.6	11.9
	Nausea	< 65	176	62.6	24	13.6	9.3	19.5
		>= 65	105	37.4	18	17.1	11.1	25.5
	Odynophagia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oesophageal irritation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oesophagitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oral disorder	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oral dysaesthesia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oral mucosal erythema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oral pain	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	3	2.9	1.0	8.1
	Pancreatitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pancreatitis acute	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Paraesthesia oral	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Proctitis ulcerative	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rectal prolapse	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Regurgitation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sensitivity of teeth	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Stomatitis	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	6	5.7	2.6	11.9
	Swollen tongue	< 65	176	62.6	0	0.0	0.0	2.1

		>= 65	105	37.4	1	1.0	0.2	5.2
	Tongue coated	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tongue discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tongue ulceration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tooth discolouration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Toothache	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Vomiting	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	15	14.3	8.9	22.2
General disorders and administration site conditions	-Total	< 65	176	62.6	121	68.8	61.6	75.1
		>= 65	105	37.4	76	72.4	63.2	80.0
	Asthenia	< 65	176	62.6	25	14.2	9.8	20.1
		>= 65	105	37.4	14	13.3	8.1	21.1
	Axillary pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Catheter site pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Chest discomfort	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	4	3.8	1.5	9.4
	Chest pain	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	4	3.8	1.5	9.4
	Chills	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Condition aggravated	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Death	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Face oedema	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	5	4.8	2.1	10.7
	Facial pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fatigue	< 65	176	62.6	33	18.8	13.7	25.2
		>= 65	105	37.4	34	32.4	24.2	41.8
	Feeling abnormal	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Feeling cold	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Feeling hot	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gait disturbance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	6	5.7	2.6	11.9
	General physical health deterioration	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Generalised oedema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Impaired healing	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Influenza like illness	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Injection site bruising	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Localised oedema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Malaise	< 65	176	62.6	18	10.2	6.6	15.6
		>= 65	105	37.4	3	2.9	1.0	8.1
	Mucosal dryness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mucosal inflammation	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	9	8.6	4.6	15.5
	Multiple organ dysfunction syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Non-cardiac chest pain	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	3	2.9	1.0	8.1
	Oedema	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oedema peripheral	< 65	176	62.6	19	10.8	7.0	16.2
		>= 65	105	37.4	23	21.9	15.1	30.7
	Pain	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	3	2.9	1.0	8.1
	Peripheral swelling	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
	Pyrexia	< 65	176	62.6	43	24.4	18.7	31.3
		>= 65	105	37.4	29	27.6	20.0	36.8
	Swelling	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Temperature intolerance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7

	Xerosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Hepatobiliary disorders	-Total	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	14	13.3	8.1	21.1
	Cholecystitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Cholelithiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gallbladder polyp	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hepatic function abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hepatic steatosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hepatocellular injury	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperbilirubinaemia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	4	3.8	1.5	9.4
	Liver disorder	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Liver injury	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumobilia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Portal vein thrombosis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
Immune system disorders	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Contrast media allergy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Drug hypersensitivity	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Food allergy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypersensitivity	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Seasonal allergy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Infections and infestations	-Total	< 65	176	62.6	100	56.8	49.4	63.9
		>= 65	105	37.4	57	54.3	44.8	63.5
	Abdominal abscess	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Acute sinusitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Appendicitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Arthritis infective	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Atypical pneumonia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bacteraemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bacterial disease carrier	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bacterial infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bacterial vaginosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bronchitis	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Candida infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cellulitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Chronic sinusitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Clostridium difficile colitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Conjunctivitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Corona virus infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cystitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Cystitis escherichia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Device related infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diverticulitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ear infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Empyema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Enterococcal bacteraemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Epididymitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Epstein-Barr virus infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Escherichia bacteraemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Escherichia infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Escherichia urinary tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Eye infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Febrile infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Folliculitis	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fungal infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastroenteritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Genital candidiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Genital herpes	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gingivitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Herpes simplex	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Herpes virus infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Herpes zoster	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	2	1.9	0.5	6.7
	Infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Infectious colitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Influenza	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lower respiratory tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lung infection	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lyme disease	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymph node tuberculosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Meningitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nasal herpes	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nasopharyngitis	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oral candidiasis	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	6	5.7	2.6	11.9
	Oral fungal infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oropharyngeal candidiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Otitis externa	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Otitis media	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Paronychia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	1	1.0	0.2	5.2
	Peritonitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pharyngitis	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pleural infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumocystis jirovecii pneumonia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pneumonia	< 65	176	62.6	27	15.3	10.8	21.4
		>= 65	105	37.4	17	16.2	10.4	24.4
	Pneumonia bacterial	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia cytomegaloviral	< 65	176	62.6	0	0.0	0.0	2.1

		>= 65	105	37.4	1	1.0	0.2	5.2
	Pneumonia haemophilus	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia influenzal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia pseudomonal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia streptococcal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyelonephritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pyelonephritis acute	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyuria	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rectal abscess	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Renal tuberculosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory tract infection bacterial	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rhinitis	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sepsis	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	5	4.8	2.1	10.7
	Septic shock	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sinusitis	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sinusitis bacterial	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Skin infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Staphylococcal infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Systemic infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tinea cruris	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Tinea infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tinea pedis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tonsillitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tooth infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tracheitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tuberculosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Upper respiratory tract infection	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Urethritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary tract infection	< 65	176	62.6	19	10.8	7.0	16.2
		>= 65	105	37.4	19	18.1	11.9	26.5
	Urosepsis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Varicella	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Varicella zoster virus infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Viral hepatitis carrier	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Viral infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vulvovaginal candidiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Injury, poisoning and procedural complications	-Total	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	15	14.3	8.9	22.2
	Contusion	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Epicondylitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fall	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	6	5.7	2.6	11.9
	Fracture	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Heart injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Incision site pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Joint dislocation	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Laceration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ligament sprain	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Limb injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Muscle rupture	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscle strain	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Procedural pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Procedural pneumothorax	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rib fracture	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Scar	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Skin abrasion	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Skin injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Subdural haematoma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tendon rupture	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Thermal burn	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Wound	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Wound complication	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Wrist fracture	< 65	176	62.6	0	0.0	0.0	2.1

		>= 65	105	37.4	1	1.0	0.2	5.2
Investigations	-Total	< 65	176	62.6	141	80.1	73.6	85.3
		>= 65	105	37.4	82	78.1	69.3	84.9
	Alanine aminotransferase	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Alanine aminotransferase increased	< 65	176	62.6	63	35.8	29.1	43.1
		>= 65	105	37.4	29	27.6	20.0	36.8
	Albumin urine present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Alpha hydroxybutyrate dehydrogenase increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Amylase increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Aspartate aminotransferase increased	< 65	176	62.6	83	47.2	39.9	54.5
		>= 65	105	37.4	43	41.0	32.0	50.5
	Bacterial test	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bilirubin conjugated increased	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	5	4.8	2.1	10.7
	Blood albumin decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood alkaline phosphatase	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood alkaline phosphatase decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood alkaline phosphatase increased	< 65	176	62.6	24	13.6	9.3	19.5
		>= 65	105	37.4	11	10.5	6.0	17.8
	Blood bilirubin increased	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	12	11.4	6.7	18.9
	Blood bilirubin unconjugated increased	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood calcium decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood calcium increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood chloride increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood cholesterol increased	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood creatine increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2

	Blood creatine phosphokinase MB increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood creatine phosphokinase increased	< 65	176	62.6	39	22.2	16.7	28.9
		>= 65	105	37.4	14	13.3	8.1	21.1
	Blood creatinine	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood creatinine increased	< 65	176	62.6	40	22.7	17.2	29.5
		>= 65	105	37.4	22	21.0	14.3	29.7
	Blood fibrinogen increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood glucose increased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood iron decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood ketone body increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood lactate dehydrogenase increased	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	4	3.8	1.5	9.4
	Blood magnesium decreased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood phosphorus increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood potassium decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood potassium increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood pressure increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood sodium decreased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood thyroid stimulating hormone increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood triglycerides increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood urea increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood uric acid decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood uric acid increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7

	Blood urine	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood urine present	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	C-reactive protein increased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Carbon dioxide decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Complement factor C1 decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Computerised tomogram thorax abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Crystal urine present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cystatin C increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Electrocardiogram QT prolonged	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	6	5.7	2.6	11.9
	Electrocardiogram ST-T change	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Fibrin D dimer increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Fibrin degradation products increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Free fatty acids increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gamma-glutamyltransferase increased	< 65	176	62.6	18	10.2	6.6	15.6
		>= 65	105	37.4	2	1.9	0.5	6.7
	Glomerular filtration rate decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Glutamate dehydrogenase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Granulocyte count decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haematocrit decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haemoglobin decreased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	1	1.0	0.2	5.2
	Heart rate increased	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hepatic enzyme increased	< 65	176	62.6	2	1.1	0.3	4.0

		>= 65	105	37.4	1	1.0	0.2	5.2
	International normalised ratio increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Intraocular pressure increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Laboratory test abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lipase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Liver function test increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymphocyte count decreased	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	10	9.5	5.3	16.6
	Lymphocyte count increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mean cell volume increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Myoglobin blood increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neutrophil count decreased	< 65	176	62.6	61	34.7	28.0	41.9
		>= 65	105	37.4	20	19.0	12.7	27.6
	Neutrophil count increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neutrophil percentage increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Occult blood positive	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oxygen saturation decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	PO2 decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Platelet count decreased	< 65	176	62.6	24	13.6	9.3	19.5
		>= 65	105	37.4	9	8.6	4.6	15.5
	Platelet count increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Procalcitonin increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Protein total decreased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Protein total increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Protein urine present	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Prothrombin time prolonged	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Red blood cell count decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Serum amyloid A protein increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Thrombin time prolonged	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Total bile acids increased	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Transaminases increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	2	1.9	0.5	6.7
	Transferrin increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Troponin T increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Troponin increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary sediment present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urine ketone body present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Urine leukocyte esterase positive	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urobilinogen urine increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Weight decreased	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	10	9.5	5.3	16.6
	Weight increased	< 65	176	62.6	20	11.4	7.5	16.9
		>= 65	105	37.4	6	5.7	2.6	11.9
	White blood cell count decreased	< 65	176	62.6	53	30.1	23.8	37.3
		>= 65	105	37.4	19	18.1	11.9	26.5
	White blood cells urine positive	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
Metabolism and nutrition disorders	-Total	< 65	176	62.6	85	48.3	41.0	55.6
		>= 65	105	37.4	62	59.0	49.5	68.0
	Abnormal loss of weight	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Acidosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Alkalosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cell death	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Decreased appetite	< 65	176	62.6	19	10.8	7.0	16.2
		>= 65	105	37.4	19	18.1	11.9	26.5
	Dehydration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	5	4.8	2.1	10.7
	Electrolyte imbalance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Failure to thrive	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fluid retention	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypercalcaemia	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypercholesterolaemia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperglycaemia	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	8	7.6	3.9	14.3
	Hyperkalaemia	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	8	7.6	3.9	14.3
	Hyperlipidaemia	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypermagnesaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hypernatraemia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperphosphataemia	< 65	176	62.6	23	13.1	8.9	18.8
		>= 65	105	37.4	9	8.6	4.6	15.5
	Hypertriglyceridaemia	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hyperuricaemia	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypoalbuminaemia	< 65	176	62.6	29	16.5	11.7	22.7
		>= 65	105	37.4	8	7.6	3.9	14.3
	Hypocalcaemia	< 65	176	62.6	22	12.5	8.4	18.2
		>= 65	105	37.4	12	11.4	6.7	18.9
	Hypochloraemia	< 65	176	62.6	3	1.7	0.6	4.9

		>= 65	105	37.4	2	1.9	0.5	6.7
	Hypoglycaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypokalaemia	< 65	176	62.6	19	10.8	7.0	16.2
		>= 65	105	37.4	19	18.1	11.9	26.5
	Hypomagnesaemia	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	5	4.8	2.1	10.7
	Hyponatraemia	< 65	176	62.6	19	10.8	7.0	16.2
		>= 65	105	37.4	11	10.5	6.0	17.8
	Hypophosphataemia	< 65	176	62.6	20	11.4	7.5	16.9
		>= 65	105	37.4	15	14.3	8.9	22.2
	Hypoproteinaemia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Increased appetite	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vitamin D deficiency	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Musculoskeletal and connective tissue disorders	-Total	< 65	176	62.6	81	46.0	38.8	53.4
		>= 65	105	37.4	43	41.0	32.0	50.5
	Arthralgia	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	4	3.8	1.5	9.4
	Arthropathy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Back pain	< 65	176	62.6	25	14.2	9.8	20.1
		>= 65	105	37.4	13	12.4	7.4	20.0
	Bone pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Bursitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Coccydynia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Costochondritis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Flank pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Groin pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypercreatinaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Intervertebral disc protrusion	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7

	Joint range of motion decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Joint stiffness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Joint swelling	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Muscle fatigue	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscle haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscle spasms	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	9	8.6	4.6	15.5
	Muscular weakness	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	5	4.8	2.1	10.7
	Musculoskeletal chest pain	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	4	3.8	1.5	9.4
	Musculoskeletal pain	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	7	6.7	3.3	13.1
	Musculoskeletal stiffness	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Myalgia	< 65	176	62.6	18	10.2	6.6	15.6
		>= 65	105	37.4	5	4.8	2.1	10.7
	Myopathy	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neck pain	< 65	176	62.6	11	6.3	3.5	10.8
		>= 65	105	37.4	3	2.9	1.0	8.1
	Osteopenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pain in extremity	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	11	10.5	6.0	17.8
	Pain in jaw	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rhabdomyolysis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rotator cuff syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Spinal column stenosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Spinal osteoarthritis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Tendon disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tendon pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	5	4.8	2.1	10.7
	Anogenital warts	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Basal cell carcinoma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bowen's disease	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cancer pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gallbladder cancer	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Metastases to central nervous system	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Renal cell carcinoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Squamous cell carcinoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Squamous cell carcinoma of skin	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tumour pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Nervous system disorders	-Total	< 65	176	62.6	84	47.7	40.5	55.1
		>= 65	105	37.4	61	58.1	48.5	67.1
	Ageusia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Aphasia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ataxia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Balance disorder	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Brain oedema	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cerebellar haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cerebral haematoma	< 65	176	62.6	0	0.0	0.0	2.1

		>= 65	105	37.4	1	1.0	0.2	5.2
	Cerebral microhaemorrhage	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cerebrovascular accident	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Disturbance in attention	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dizziness	< 65	176	62.6	20	11.4	7.5	16.9
		>= 65	105	37.4	18	17.1	11.1	25.5
	Dizziness postural	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dysarthria	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dysgeusia	< 65	176	62.6	18	10.2	6.6	15.6
		>= 65	105	37.4	24	22.9	15.9	31.8
	Dyskinesia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Epilepsy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Facial paralysis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haemorrhage intracranial	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Headache	< 65	176	62.6	27	15.3	10.8	21.4
		>= 65	105	37.4	7	6.7	3.3	13.1
	Hemiplegia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperaesthesia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypersomnia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypoaesthesia	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	9	8.6	4.6	15.5
	Hypotonia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lethargy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lumbar radiculopathy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lumbosacral radiculopathy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Memory impairment	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Migraine	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Migraine with aura	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neuralgia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neuropathy peripheral	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Paraesthesia	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Paralysis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Parosmia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Peripheral sensory neuropathy	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Polyneuropathy chronic	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Post herpetic neuralgia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Presyncope	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Psychomotor skills impaired	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Restless legs syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sciatica	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Seizure	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Sensory disturbance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Slow speech	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Somnolence	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Spinal cord haematoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Syncope	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	6	5.7	2.6	11.9
	Tension headache	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tremor	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Visual field defect	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
Product issues	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Device dislocation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Psychiatric disorders	-Total	< 65	176	62.6	38	21.6	16.2	28.2
		>= 65	105	37.4	18	17.1	11.1	25.5
	Abnormal behaviour	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Abnormal dreams	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Adjustment disorder with mixed anxiety and depressed mood	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Anxiety	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	3	2.9	1.0	8.1
	Bradyphrenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Confusional state	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Delirium	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Depressed mood	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Depression	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Fear of falling	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Insomnia	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	4	3.8	1.5	9.4
	Irritability	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Libido decreased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mental status changes	< 65	176	62.6	3	1.7	0.6	4.9

		>= 65	105	37.4	1	1.0	0.2	5.2
	Mood altered	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Psychomotor retardation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Restlessness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Sleep disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Renal and urinary disorders	-Total	< 65	176	62.6	22	12.5	8.4	18.2
		>= 65	105	37.4	21	20.0	13.5	28.6
	Acute kidney injury	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Azotaemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cystitis haemorrhagic	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dysuria	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	4	3.8	1.5	9.4
	Haematuria	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Haemorrhage urinary tract	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hydronephrosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Micturition urgency	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nephritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nephrolithiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nocturia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Obstructive nephropathy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pollakiuria	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Proteinuria	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Renal colic	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Renal disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Renal failure	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Renal impairment	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Strangury	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urethral stenosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Urinary incontinence	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Urinary retention	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	4	3.8	1.5	9.4
	Urinary tract pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urine flow decreased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Reproductive system and breast disorders	-Total	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	6	5.7	2.6	11.9
	Benign prostatic hyperplasia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Breast discharge	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Erectile dysfunction	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Galactorrhoea	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Genital ulceration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Metrorrhagia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ovarian cyst	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pelvic discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pelvic fluid collection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Perineal pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Postmenopausal haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Prostatitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Uterine polyp	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vaginal haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vulvovaginal dryness	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Vulvovaginal erythema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Respiratory, thoracic and mediastinal disorders	-Total	< 65	176	62.6	105	59.7	52.3	66.6
		>= 65	105	37.4	62	59.0	49.5	68.0
	Acute respiratory failure	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Aspiration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bronchospasm	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Choking	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cough	< 65	176	62.6	41	23.3	17.7	30.1
		>= 65	105	37.4	24	22.9	15.9	31.8
	Dry throat	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dysphonia	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Dyspnoea	< 65	176	62.6	28	15.9	11.2	22.0
		>= 65	105	37.4	19	18.1	11.9	26.5
	Dyspnoea exertional	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	6	5.7	2.6	11.9
	Epistaxis	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	6	5.7	2.6	11.9
	Haemoptysis	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hiccups	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hypoxia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Interstitial lung disease	< 65	176	62.6	4	2.3	0.9	5.7

		>= 65	105	37.4	0	0.0	0.0	3.5
	Laryngeal haemorrhage	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lung consolidation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nasal congestion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Nasal dryness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Nasal polyps	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oropharyngeal discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oropharyngeal pain	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	6	5.7	2.6	11.9
	Paranasal sinus discomfort	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pharyngeal disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pleural effusion	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	3	2.9	1.0	8.1
	Pleural thickening	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pleuritic pain	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pneumonitis	< 65	176	62.6	19	10.8	7.0	16.2
		>= 65	105	37.4	13	12.4	7.4	20.0
	Pneumothorax	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Productive cough	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	6	5.7	2.6	11.9
	Pulmonary embolism	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	7	6.7	3.3	13.1
	Pulmonary hypertension	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pulmonary mass	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pulmonary pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiration abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Respiratory distress	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory failure	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rhinalgia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rhinitis allergic	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rhinorrhoea	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sinus congestion	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sleep apnoea syndrome	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sputum discoloured	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Throat irritation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Upper-airway cough syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Vocal cord leukoplakia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Wheezing	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
Skin and subcutaneous tissue disorders	-Total	< 65	176	62.6	63	35.8	29.1	43.1
		>= 65	105	37.4	37	35.2	26.8	44.7
	Acne	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Alopecia	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Chloasma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Decubitus ulcer	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermal cyst	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermatitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermatitis acneiform	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	0	0.0	0.0	3.5

	Dermatitis allergic	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dermatitis bullous	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Dry skin	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Ecchymosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eczema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Erythema	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hair growth abnormal	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hair texture abnormal	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hirsutism	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperhidrosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hyperkeratosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypertrichosis	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	0	0.0	0.0	3.5
	Madarosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nail discolouration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nail disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Night sweats	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Onychalgia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Onycholysis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Onychomadesis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pain of skin	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Palmar-plantar erythrodysaesthesia syndrome	< 65	176	62.6	4	2.3	0.9	5.7

		>= 65	105	37.4	1	1.0	0.2	5.2
	Photosensitivity reaction	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pruritus	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	4	3.8	1.5	9.4
	Pruritus generalised	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Purpura	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rash	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	7	6.7	3.3	13.1
	Rash erythematous	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rash macular	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Rash maculo-papular	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rash papular	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Scab	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Scar pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Skin discolouration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Skin hyperpigmentation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Skin lesion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Swelling face	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Urticaria	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Surgical and medical procedures	-Total	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Astringent therapy	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Eye excision	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hip arthroplasty	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Therapy cessation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Vascular disorders	-Total	< 65	176	62.6	58	33.0	26.4	40.2
		>= 65	105	37.4	57	54.3	44.8	63.5
	Aortic dissection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Circulatory collapse	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Deep vein thrombosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Embolism	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Embolism venous	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Flushing	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haematoma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hot flush	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hypertension	< 65	176	62.6	47	26.7	20.7	33.7
		>= 65	105	37.4	49	46.7	37.4	56.2
	Hypotension	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	4	3.8	1.5	9.4
	Lymphoedema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Orthostatic hypotension	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pallor	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Phlebitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Raynaud's phenomenon	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Shock haemorrhagic	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Superior vena cava syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Thrombophlebitis superficial	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Thrombosis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEANY_SG.xls
26MAR2021 14:05

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	84	29.9	46	54.8	44.1	65.0
		1	190	67.6	118	62.1	55.0	68.7
		2	6	2.1	5	83.3	43.6	97.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia	0	84	29.9	31	36.9	27.4	47.6
		1	190	67.6	94	49.5	42.4	56.5
		2	6	2.1	4	66.7	30.0	90.3
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia macrocytic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aplastic anaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bone marrow oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disseminated intravascular coagulation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Febrile neutropenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhagic anaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperfibrinogenaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Leukocytosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Leukopenia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	22	11.6	7.8	16.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymph node pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphadenopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphopenia	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutropenia	0	84	29.9	25	29.8	21.0	40.2
		1	190	67.6	35	18.4	13.6	24.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophilia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytopenia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	16	8.4	5.2	13.2
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytosis	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Cardiac disorders	-Total	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	30	15.8	11.3	21.6
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute coronary syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Acute myocardial infarction	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Angina pectoris	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aortic valve calcification	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Atrial fibrillation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Atrial flutter	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bradycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bundle branch block right	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cardiac failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cardio-respiratory arrest	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Extrasystoles	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myocardial ischaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nodal arrhythmia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Palpitations	0	84	29.9	3	3.6	1.2	10.0

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pericardial effusion	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinus bradycardia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinus tachycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Stress cardiomyopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Supraventricular tachycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tachycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Ventricular extrasystoles	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ventricular pre-excitation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Congenital, familial and genetic disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gilbert's syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hydrocele	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Ear and labyrinth disorders	-Total	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	13	6.8	4.0	11.4

		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear congestion	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear pain	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tinnitus	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Vertigo	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Endocrine disorders	-Total	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Adrenal insufficiency	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperthyroidism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypothyroidism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Eye disorders	-Total	0	84	29.9	15	17.9	11.1	27.4
		1	190	67.6	24	12.6	8.6	18.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal sensation in eye	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blepharitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Cataract	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chalazion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Conjunctival cyst	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Conjunctival haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diplopia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry eye	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eye swelling	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eyelid oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eyelid ptosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Keratitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ocular discomfort	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Periorbital oedema	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Photophobia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Photopsia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ulcerative keratitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vision blurred	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Visual acuity reduced	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Gastrointestinal disorders	-Total	0	84	29.9	66	78.6	68.7	86.0
		1	190	67.6	132	69.5	62.6	75.6
		2	6	2.1	5	83.3	43.6	97.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Abdominal discomfort	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal distension	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain lower	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain upper	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal symptom	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Anal incontinence	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aphthous ulcer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ascites	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Colitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Constipation	0	84	29.9	42	50.0	39.5	60.5
		1	190	67.6	72	37.9	31.3	45.0
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	1	100.0	20.7	100.0
	Dental caries	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dental dysaesthesia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diarrhoea	0	84	29.9	23	27.4	19.0	37.7
		1	190	67.6	44	23.2	17.7	29.7
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Diverticular perforation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry mouth	0	84	29.9	20	23.8	16.0	33.9
		1	190	67.6	26	13.7	9.5	19.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspepsia	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysphagia	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Enteritis	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epigastric discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eructation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Faeces soft	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Flatulence	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Frequent bowel movements	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastric ulcer	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastritis erosive	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal inflammation	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal wall thickening	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrooesophageal reflux disease	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gingival bleeding	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gingival swelling	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glossitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glossodynia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematochezia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhoids	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoaesthesia oral	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Impaired gastric emptying	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intestinal obstruction	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Irritable bowel syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Large intestine perforation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Melaena	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Mouth ulceration	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nausea	0	84	29.9	13	15.5	9.3	24.7
		1	190	67.6	27	14.2	10.0	19.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	1	100.0	20.7	100.0
	Odynophagia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oesophageal irritation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oesophagitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral dysaesthesia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral mucosal erythema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancreatitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancreatitis acute	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Paraesthesia oral	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Proctitis ulcerative	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rectal prolapse	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Regurgitation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sensitivity of teeth	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Stomatitis	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Swollen tongue	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tongue coated	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tongue discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tongue ulceration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tooth discolouration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Toothache	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Vomiting	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	20	10.5	6.9	15.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
General disorders and administration site conditions	-Total	0	84	29.9	57	67.9	57.3	76.9
		1	190	67.6	133	70.0	63.1	76.1
		2	6	2.1	6	100.0	61.0	100.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Asthenia	0	84	29.9	15	17.9	11.1	27.4
		1	190	67.6	23	12.1	8.2	17.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Axillary pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Catheter site pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest discomfort	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chills	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Condition aggravated	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Death	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Face oedema	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Facial pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fatigue	0	84	29.9	19	22.6	15.0	32.6

		1	190	67.6	44	23.2	17.7	29.7
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	1	100.0	20.7	100.0
	Feeling abnormal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Feeling cold	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Feeling hot	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gait disturbance	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	General physical health deterioration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Generalised oedema	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Impaired healing	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Influenza like illness	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Injection site bruising	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Localised oedema	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Malaise	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	20	10.5	6.9	15.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mucosal dryness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mucosal inflammation	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Multiple organ dysfunction syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Non-cardiac chest pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oedema peripheral	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	30	15.8	11.3	21.6
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Peripheral swelling	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyrexia	0	84	29.9	25	29.8	21.0	40.2
		1	190	67.6	43	22.6	17.3	29.1
		2	6	2.1	4	66.7	30.0	90.3
		Missing	1	0.4	0	0.0	0.0	79.3
	Swelling	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Temperature intolerance	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Xerosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Hepatobiliary disorders	-Total	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	1	16.7	3.0	56.4

		Missing	1	0.4	0	0.0	0.0	79.3
	Cholecystitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Cholelithiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gallbladder polyp	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic function abnormal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic steatosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatocellular injury	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperbilirubinaemia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Liver disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Liver injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumobilia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Portal vein thrombosis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
Immune system disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Contrast media allergy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Drug hypersensitivity	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Food allergy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypersensitivity	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Seasonal allergy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Infections and infestations	-Total	0	84	29.9	52	61.9	51.2	71.6
		1	190	67.6	101	53.2	46.1	60.1
		2	6	2.1	4	66.7	30.0	90.3
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal abscess	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute sinusitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Appendicitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Arthritis infective	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Atypical pneumonia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Bacterial disease carrier	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacterial infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacterial vaginosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bronchitis	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Candida infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cellulitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chronic sinusitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Clostridium difficile colitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Conjunctivitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Corona virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis escherichia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Device related infection	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diverticulitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Empyema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Enterococcal bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epididymitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epstein-Barr virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Escherichia bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Escherichia infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Escherichia urinary tract infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eye infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Febrile infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Folliculitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fungal infection	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastroenteritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Genital candidiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Genital herpes	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gingivitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Herpes simplex	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Herpes virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Herpes zoster	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Infectious colitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Influenza	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lower respiratory tract infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Lung infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lyme disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymph node tuberculosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Meningitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasal herpes	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasopharyngitis	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral candidiasis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral fungal infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oropharyngeal candidiasis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Otitis externa	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Otitis media	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paronychia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Peritonitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Pharyngitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumocystis jirovecii pneumonia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia	0	84	29.9	16	19.0	12.1	28.7
		1	190	67.6	26	13.7	9.5	19.3
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia bacterial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia cytomegaloviral	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia haemophilus	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia influenzal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia pseudomonal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia streptococcal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyelonephritis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Pyelonephritis acute	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rectal abscess	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal tuberculosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory tract infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory tract infection bacterial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinitis	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sepsis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Septic shock	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinusitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinusitis bacterial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Staphylococcal infection	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Systemic infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tinea cruris	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tinea infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tinea pedis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tonsillitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tooth infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tracheitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tuberculosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Upper respiratory tract infection	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urethritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary tract infection	0	84	29.9	13	15.5	9.3	24.7
		1	190	67.6	24	12.6	8.6	18.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Urosepsis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Varicella	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Varicella zoster virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Viral hepatitis carrier	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Viral infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vulvovaginal candidiasis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Injury, poisoning and procedural complications	-Total	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	20	10.5	6.9	15.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Contusion	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epicondylitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fall	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Fracture	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Heart injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Incision site pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint dislocation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Laceration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ligament sprain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Limb injury	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle rupture	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle strain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Procedural pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Procedural pneumothorax	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rib fracture	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Scar	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin abrasion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Skin injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Subdural haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Tendon rupture	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thermal burn	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wound	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wound complication	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wrist fracture	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Investigations	-Total	0	84	29.9	64	76.2	66.1	84.0
		1	190	67.6	154	81.1	74.9	86.0
		2	6	2.1	4	66.7	30.0	90.3
		Missing	1	0.4	1	100.0	20.7	100.0
	Alanine aminotransferase	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alanine aminotransferase increased	0	84	29.9	24	28.6	20.0	39.0
		1	190	67.6	66	34.7	28.3	41.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	1	100.0	20.7	100.0
	Albumin urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alpha hydroxybutyrate dehydrogenase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Amylase increased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aspartate aminotransferase increased	0	84	29.9	30	35.7	26.3	46.4
		1	190	67.6	92	48.4	41.4	55.5
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	1	100.0	20.7	100.0
	Bacterial test	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bilirubin conjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	20	10.5	6.9	15.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood albumin decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase increased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	32	16.8	12.2	22.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin increased	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	21	11.1	7.3	16.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin unconjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood calcium decreased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood calcium increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood chloride increased	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood cholesterol increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine increased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase MB increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase increased	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	42	22.1	16.8	28.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatinine	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatinine increased	0	84	29.9	18	21.4	14.0	31.3
		1	190	67.6	43	22.6	17.3	29.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood fibrinogen increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood glucose increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood iron decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood ketone body increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood lactate dehydrogenase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood magnesium decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood phosphorus increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood potassium decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood potassium increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood pressure increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood sodium decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood thyroid stimulating hormone increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood triglycerides increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood urea increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood uric acid decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood uric acid increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood urine	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	C-reactive protein increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Carbon dioxide decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Complement factor C1 decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Computerised tomogram thorax abnormal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Crystal urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystatin C increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrocardiogram QT prolonged	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrocardiogram ST-T change	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fibrin D dimer increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fibrin degradation products increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Free fatty acids increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gamma-glutamyltransferase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	20	10.5	6.9	15.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Glomerular filtration rate decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glutamate dehydrogenase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Granulocyte count decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematocrit decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemoglobin decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Heart rate increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic enzyme increased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	International normalised ratio increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intraocular pressure increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Laboratory test abnormal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lipase increased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Liver function test increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Lymphocyte count decreased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	22	11.6	7.8	16.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphocyte count increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mean cell volume increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myoglobin blood increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil count decreased	0	84	29.9	19	22.6	15.0	32.6
		1	190	67.6	61	32.1	25.9	39.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil count increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil percentage increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Occult blood positive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oxygen saturation decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	PO2 decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count decreased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	29	15.3	10.8	21.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Procalcitonin increased	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Protein total decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Protein total increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Protein urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Prothrombin time prolonged	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Red blood cell count decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Serum amyloid A protein increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombin time prolonged	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Total bile acids increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Transaminases increased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Transferrin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Troponin T increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Troponin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary sediment present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urine ketone body present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urine leukocyte esterase positive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urobilinogen urine increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Weight decreased	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Weight increased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	21	11.1	7.3	16.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	White blood cell count decreased	0	84	29.9	12	14.3	8.4	23.3
		1	190	67.6	59	31.1	24.9	38.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	White blood cells urine positive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Metabolism and nutrition disorders	-Total	0	84	29.9	41	48.8	38.4	59.3
		1	190	67.6	103	54.2	47.1	61.1
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal loss of weight	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Acidosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alkalosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Cell death	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Decreased appetite	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	29	15.3	10.8	21.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dehydration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrolyte imbalance	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Failure to thrive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fluid retention	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercalcaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercholesterolaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperglycaemia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperkalaemia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperlipidaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypermagnesaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Hypernatraemia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperphosphataemia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	25	13.2	9.1	18.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertriglyceridaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperuricaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoalbuminaemia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	29	15.3	10.8	21.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypocalcaemia	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	29	15.3	10.8	21.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypochloraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoglycaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypokalaemia	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	27	14.2	10.0	19.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypomagnesaemia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyponatraemia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	22	11.6	7.8	16.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypophosphataemia	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	25	13.2	9.1	18.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Hypoproteinaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Increased appetite	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vitamin D deficiency	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Musculoskeletal and connective tissue disorders	-Total	0	84	29.9	43	51.2	40.7	61.6
		1	190	67.6	78	41.1	34.3	48.2
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Arthralgia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Arthropathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Back pain	0	84	29.9	15	17.9	11.1	27.4
		1	190	67.6	21	11.1	7.3	16.3
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bone pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bursitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Coccydynia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Costochondritis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Flank pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Groin pain	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercreatinaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intervertebral disc protrusion	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint range of motion decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint stiffness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint swelling	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle fatigue	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle haemorrhage	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle spasms	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	16	8.4	5.2	13.2
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscular weakness	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal chest pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal pain	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	16	8.4	5.2	13.2
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal stiffness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myalgia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neck pain	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Osteopenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain in extremity	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain in jaw	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhabdomyolysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rotator cuff syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Spinal column stenosis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Spinal osteoarthritis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tendon disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tendon pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anogenital warts	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Basal cell carcinoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bowen's disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cancer pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gallbladder cancer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Metastases to central nervous system	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal cell carcinoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Squamous cell carcinoma	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Squamous cell carcinoma of skin	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tumour pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Nervous system disorders	-Total	0	84	29.9	39	46.4	36.2	57.0
		1	190	67.6	102	53.7	46.6	60.6
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	1	100.0	20.7	100.0

	Ageusia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aphasia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ataxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Balance disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Brain oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebellar haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebral haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebral microhaemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebrovascular accident	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disturbance in attention	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dizziness	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	29	15.3	10.8	21.1
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dizziness postural	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Dysarthria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysgeusia	0	84	29.9	13	15.5	9.3	24.7
		1	190	67.6	28	14.7	10.4	20.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyskinesia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epilepsy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Facial paralysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhage intracranial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Headache	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	23	12.1	8.2	17.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	1	100.0	20.7	100.0
	Hemiplegia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperaesthesia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypersomnia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoaesthesia	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypotonia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lethargy	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lumbar radiculopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lumbosacral radiculopathy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Memory impairment	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Migraine	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Migraine with aura	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neuralgia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neuropathy peripheral	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paraesthesia	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paralysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Parosmia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Peripheral sensory neuropathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Polyneuropathy chronic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Post herpetic neuralgia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Presyncope	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Psychomotor skills impaired	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Restless legs syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sciatica	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Seizure	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Sensory disturbance	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Slow speech	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Somnolence	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Spinal cord haematoma	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Syncope	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tension headache	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Tremor	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Visual field defect	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Product issues	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Device dislocation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Psychiatric disorders	-Total	0	84	29.9	18	21.4	14.0	31.3
		1	190	67.6	36	18.9	14.0	25.1
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal behaviour	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal dreams	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Adjustment disorder with mixed anxiety and depressed mood	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anxiety	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Bradyphrenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Confusional state	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Delirium	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Depressed mood	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Depression	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fear of falling	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Insomnia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	18	9.5	6.1	14.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Irritability	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Libido decreased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mental status changes	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mood altered	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Psychomotor retardation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Restlessness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sleep disorder	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Renal and urinary disorders	-Total	0	84	29.9	14	16.7	10.2	26.1
		1	190	67.6	26	13.7	9.5	19.3
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3

	Acute kidney injury	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Azotaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis haemorrhagic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysuria	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhage urinary tract	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hydronephrosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Micturition urgency	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Nephritis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nephrolithiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nocturia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Obstructive nephropathy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pollakiuria	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Proteinuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal colic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal disorder	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal failure	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal impairment	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Strangury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urethral stenosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary incontinence	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary retention	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary tract pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urine flow decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Reproductive system and breast disorders	-Total	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	13	6.8	4.0	11.4

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Benign prostatic hyperplasia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Breast discharge	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Erectile dysfunction	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Galactorrhoea	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Genital ulceration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Metrorrhagia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ovarian cyst	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pelvic discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pelvic fluid collection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Perineal pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Postmenopausal haemorrhage	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Prostatitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Uterine polyp	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vaginal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vulvovaginal dryness	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vulvovaginal erythema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Respiratory, thoracic and mediastinal disorders	-Total	0	84	29.9	55	65.5	54.8	74.8
		1	190	67.6	109	57.4	50.3	64.2
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute respiratory failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aspiration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bronchospasm	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Choking	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cough	0	84	29.9	24	28.6	20.0	39.0
		1	190	67.6	39	20.5	15.4	26.8
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry throat	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysphonia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Dyspnoea	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	35	18.4	13.6	24.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea exertional	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epistaxis	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemoptysis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hiccups	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Interstitial lung disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Laryngeal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lung consolidation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasal congestion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasal dryness	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasal polyps	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Oropharyngeal discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oropharyngeal pain	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paranasal sinus discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pharyngeal disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural effusion	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural thickening	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleuritic pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonitis	0	84	29.9	15	17.9	11.1	27.4
		1	190	67.6	16	8.4	5.2	13.2
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumothorax	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Productive cough	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary embolism	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary hypertension	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary mass	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiration abnormal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory distress	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinalgia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinitis allergic	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinorrhoea	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinus congestion	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sleep apnoea syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sputum discoloured	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Throat irritation	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Upper-airway cough syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vocal cord leukoplakia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wheezing	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Skin and subcutaneous tissue disorders	-Total	0	84	29.9	37	44.0	33.9	54.7
		1	190	67.6	59	31.1	24.9	38.0
		2	6	2.1	4	66.7	30.0	90.3
		Missing	1	0.4	0	0.0	0.0	79.3
	Acne	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alopecia	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chloasma	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Decubitus ulcer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermal cyst	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis acneiform	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis allergic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis bullous	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Dry skin	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Ecchymosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eczema	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Erythema	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hair growth abnormal	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hair texture abnormal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hirsutism	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperhidrosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperkeratosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertrichosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Madarosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nail discolouration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Nail disorder	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Night sweats	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Onychalgia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Onycholysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Onychomadesis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain of skin	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Palmar-plantar erythrodysaesthesia syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Photosensitivity reaction	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pruritus	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pruritus generalised	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Purpura	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Rash erythematous	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash macular	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash maculo-papular	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash papular	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Scab	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Scar pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin discolouration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin hyperpigmentation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin lesion	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Swelling face	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urticaria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Surgical and medical procedures	-Total	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Astringent therapy	0	84	29.9	3	3.6	1.2	10.0

		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eye excision	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hip arthroplasty	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Therapy cessation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Vascular disorders	-Total	0	84	29.9	33	39.3	29.5	50.0
		1	190	67.6	80	42.1	35.3	49.2
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aortic dissection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Circulatory collapse	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Deep vein thrombosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism venous	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Flushing	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hot flush	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertension	0	84	29.9	29	34.5	25.2	45.2
		1	190	67.6	65	34.2	27.8	41.2
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypotension	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphoedema	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Orthostatic hypotension	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pallor	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Phlebitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Raynaud's phenomenon	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Shock haemorrhagic	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Superior vena cava syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombophlebitis superficial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEANY_SG.xls
26MAR2021 14:05

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	USA	64	22.8	40	62.5	50.3	73.3
		Europe (EU)	95	33.8	48	50.5	40.6	60.4
		Asia (AS)	122	43.4	81	66.4	57.6	74.2
	Anaemia	USA	64	22.8	31	48.4	36.6	60.4
		Europe (EU)	95	33.8	39	41.1	31.7	51.1
		Asia (AS)	122	43.4	59	48.4	39.7	57.1
	Anaemia macrocytic	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aplastic anaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bone marrow oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cytopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Disseminated intravascular coagulation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Febrile neutropenia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Haemorrhagic anaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperfibrinogenaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Leukocytosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Leukopenia	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	14	14.7	9.0	23.2
		Asia (AS)	122	43.4	12	9.8	5.7	16.4
	Lymph node pain	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lymphadenopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lymphopenia	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	14	14.7	9.0	23.2
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neutropenia	USA	64	22.8	19	29.7	19.9	41.8
		Europe (EU)	95	33.8	20	21.1	14.1	30.3
		Asia (AS)	122	43.4	22	18.0	12.2	25.8
	Neutrophilia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pancytopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thrombocytopenia	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Thrombocytosis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Cardiac disorders	-Total	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	12	12.6	7.4	20.8
		Asia (AS)	122	43.4	19	15.6	10.2	23.0
	Acute coronary syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Acute myocardial infarction	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Angina pectoris	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aortic valve calcification	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Atrial fibrillation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Atrial flutter	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Bradycardia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bundle branch block right	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cardiac failure	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Cardio-respiratory arrest	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Extrasystoles	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Myocardial ischaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nodal arrhythmia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Palpitations	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pericardial effusion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinus bradycardia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinus tachycardia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Stress cardiomyopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Supraventricular tachycardia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tachycardia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Ventricular extrasystoles	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Ventricular pre-excitation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

Congenital, familial and genetic disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gilbert's syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hydrocele	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Ear and labyrinth disorders	-Total	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Ear congestion	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ear discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ear pain	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tinnitus	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Vertigo	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
Endocrine disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Adrenal insufficiency	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperthyroidism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypothyroidism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Eye disorders	-Total	USA	64	22.8	17	26.6	17.3	38.5
		Europe (EU)	95	33.8	13	13.7	8.2	22.0
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Abnormal sensation in eye	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Blepharitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cataract	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Chalazion	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Conjunctival cyst	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Conjunctival haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Diplopia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dry eye	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eye swelling	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eyelid oedema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Eyelid ptosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Keratitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ocular discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Periorbital oedema	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Photophobia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Photopsia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ulcerative keratitis	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vision blurred	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Visual acuity reduced	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Gastrointestinal disorders	-Total	USA	64	22.8	54	84.4	73.6	91.3
		Europe (EU)	95	33.8	71	74.7	65.2	82.4
		Asia (AS)	122	43.4	79	64.8	55.9	72.7
	Abdominal discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Abdominal distension	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Abdominal pain	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Abdominal pain lower	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Abdominal pain upper	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Abdominal symptom	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Anal incontinence	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Aphthous ulcer	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ascites	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Colitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Constipation	USA	64	22.8	25	39.1	28.1	51.3
		Europe (EU)	95	33.8	40	42.1	32.7	52.2
		Asia (AS)	122	43.4	53	43.4	35.0	52.3
	Dental caries	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dental dysaesthesia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Diarrhoea	USA	64	22.8	19	29.7	19.9	41.8
		Europe (EU)	95	33.8	27	28.4	20.3	38.2
		Asia (AS)	122	43.4	24	19.7	13.6	27.6
	Diverticular perforation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dry mouth	USA	64	22.8	19	29.7	19.9	41.8
		Europe (EU)	95	33.8	18	18.9	12.3	28.0
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Dyspepsia	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Dysphagia	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Enteritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epigastric discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eructation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Faeces soft	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Flatulence	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Frequent bowel movements	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastric ulcer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastritis erosive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Gastrointestinal haemorrhage	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastrointestinal inflammation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal wall thickening	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrooesophageal reflux disease	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gingival bleeding	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Gingival swelling	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Glossitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Glossodynia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haematochezia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haemorrhoids	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hypoaesthesia oral	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Impaired gastric emptying	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Intestinal obstruction	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Irritable bowel syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Large intestine perforation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Melaena	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Mouth ulceration	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Nausea	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	17	17.9	11.5	26.8
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Odynophagia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oesophageal irritation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oesophagitis	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oral disorder	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oral dysaesthesia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oral mucosal erythema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oral pain	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pancreatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pancreatitis acute	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Paraesthesia oral	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Proctitis ulcerative	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rectal prolapse	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Regurgitation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sensitivity of teeth	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Stomatitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Swollen tongue	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tongue coated	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tongue discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tongue ulceration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tooth discolouration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Toothache	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Vomiting	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	13	13.7	8.2	22.0
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
General disorders and administration site conditions	-Total	USA	64	22.8	49	76.6	64.9	85.3
		Europe (EU)	95	33.8	67	70.5	60.7	78.8
		Asia (AS)	122	43.4	81	66.4	57.6	74.2
	Asthenia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	26	27.4	19.4	37.1
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Axillary pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Catheter site pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Chest discomfort	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Chest pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Chills	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Condition aggravated	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Death	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Face oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	17	13.9	8.9	21.2
	Facial pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fatigue	USA	64	22.8	27	42.2	30.9	54.4
		Europe (EU)	95	33.8	23	24.2	16.7	33.7
		Asia (AS)	122	43.4	17	13.9	8.9	21.2
	Feeling abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Feeling cold	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Feeling hot	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gait disturbance	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	General physical health deterioration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Generalised oedema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Impaired healing	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Influenza like illness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Injection site bruising	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Localised oedema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Malaise	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	18	14.8	9.5	22.1
	Mucosal dryness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Mucosal inflammation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	18	18.9	12.3	28.0
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Multiple organ dysfunction syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Non-cardiac chest pain	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Oedema	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oedema peripheral	USA	64	22.8	19	29.7	19.9	41.8
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Pain	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Peripheral swelling	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Pyrexia	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	27	28.4	20.3	38.2
		Asia (AS)	122	43.4	34	27.9	20.7	36.4
	Swelling	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Temperature intolerance	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Xerosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

Hepatobiliary disorders	-Total	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Cholecystitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Cholelithiasis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gallbladder polyp	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hepatic function abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Hepatic steatosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hepatocellular injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperbilirubinaemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Liver disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Liver injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumobilia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Portal vein thrombosis	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Immune system disorders	-Total	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Contrast media allergy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Drug hypersensitivity	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Food allergy	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypersensitivity	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Seasonal allergy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Infections and infestations	-Total	USA	64	22.8	41	64.1	51.8	74.7
		Europe (EU)	95	33.8	61	64.2	54.2	73.1
		Asia (AS)	122	43.4	55	45.1	36.5	53.9
	Abdominal abscess	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Acute sinusitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Appendicitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Arthritis infective	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Atypical pneumonia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacteraemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacterial disease carrier	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacterial infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacterial vaginosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bronchitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Candida infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cellulitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Chronic sinusitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Clostridium difficile colitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Conjunctivitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Corona virus infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cystitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cystitis escherichia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Device related infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Diverticulitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ear infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Empyema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Enterococcal bacteraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epididymitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epstein-Barr virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Escherichia bacteraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Escherichia infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Escherichia urinary tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eye infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Febrile infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Folliculitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fungal infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Gastroenteritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Genital candidiasis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Genital herpes	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gingivitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Herpes simplex	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Herpes virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Herpes zoster	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Infectious colitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Influenza	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Lower respiratory tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lung infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Lyme disease	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymph node tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Meningitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasal herpes	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasopharyngitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Oral candidiasis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oral fungal infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oropharyngeal candidiasis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Otitis externa	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Otitis media	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Paronychia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Peritonitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pharyngitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pleural infection	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumocystis jirovecii pneumonia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonia	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	15	15.8	9.8	24.4
		Asia (AS)	122	43.4	22	18.0	12.2	25.8
	Pneumonia bacterial	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonia cytomegaloviral	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonia haemophilus	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonia influenzal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonia pseudomonal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonia streptococcal	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pyelonephritis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pyelonephritis acute	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pyuria	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rectal abscess	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory tract infection bacterial	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhinitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Sepsis	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Septic shock	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinusitis	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Sinusitis bacterial	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Staphylococcal infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Systemic infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tinea cruris	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tinea infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tinea pedis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tonsillitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tooth infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tracheitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Upper respiratory tract infection	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Urethritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary tract infection	USA	64	22.8	14	21.9	13.5	33.4
		Europe (EU)	95	33.8	14	14.7	9.0	23.2
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Urosepsis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Varicella	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Varicella zoster virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Viral hepatitis carrier	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Viral infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vulvovaginal candidiasis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Injury, poisoning and procedural complications	-Total	USA	64	22.8	13	20.3	12.3	31.7
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Contusion	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epicondylitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fall	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Fracture	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Heart injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Incision site pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Joint dislocation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Laceration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ligament sprain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Limb injury	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle rupture	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle strain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Procedural pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Procedural pneumothorax	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rib fracture	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Scar	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin abrasion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Subdural haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tendon rupture	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thermal burn	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Wound	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Wound complication	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Wrist fracture	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Investigations	-Total	USA	64	22.8	51	79.7	68.3	87.7
		Europe (EU)	95	33.8	68	71.6	61.8	79.7
		Asia (AS)	122	43.4	104	85.2	77.9	90.5
	Alanine aminotransferase	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Alanine aminotransferase increased	USA	64	22.8	20	31.3	21.2	43.4
		Europe (EU)	95	33.8	20	21.1	14.1	30.3
		Asia (AS)	122	43.4	52	42.6	34.2	51.5
	Albumin urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Alpha hydroxybutyrate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Amylase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Aspartate aminotransferase increased	USA	64	22.8	28	43.8	32.3	55.9
		Europe (EU)	95	33.8	29	30.5	22.2	40.4
		Asia (AS)	122	43.4	69	56.6	47.7	65.0
	Bacterial test	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bilirubin conjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	20	16.4	10.9	24.0
	Blood albumin decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood alkaline phosphatase	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood alkaline phosphatase decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood alkaline phosphatase increased	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	25	20.5	14.3	28.5
	Blood bilirubin increased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	19	15.6	10.2	23.0
	Blood bilirubin unconjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Blood calcium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood calcium increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood chloride increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood cholesterol increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Blood creatine increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood creatine phosphokinase MB increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Blood creatine phosphokinase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	16	16.8	10.6	25.6
		Asia (AS)	122	43.4	37	30.3	22.9	39.0
	Blood creatinine	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood creatinine increased	USA	64	22.8	17	26.6	17.3	38.5
		Europe (EU)	95	33.8	21	22.1	14.9	31.4
		Asia (AS)	122	43.4	24	19.7	13.6	27.6
	Blood fibrinogen increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood glucose increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

	Blood iron decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood ketone body increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood lactate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Blood magnesium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood phosphorus increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Blood potassium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood potassium increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood pressure increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Blood sodium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood thyroid stimulating hormone increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood triglycerides increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Blood urea increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Blood uric acid decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood uric acid increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Blood urine	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0

	Blood urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	C-reactive protein increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Carbon dioxide decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Complement factor C1 decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Computerised tomogram thorax abnormal	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Crystal urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cystatin C increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Electrocardiogram QT prolonged	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Electrocardiogram ST-T change	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Fibrin D dimer increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Fibrin degradation products increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Free fatty acids increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gamma-glutamyltransferase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	19	15.6	10.2	23.0
	Glomerular filtration rate decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Glutamate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Granulocyte count decreased	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haematocrit decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haemoglobin decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Heart rate increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Hepatic enzyme increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	International normalised ratio increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Intraocular pressure increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Laboratory test abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lipase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Liver function test increased	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymphocyte count decreased	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	12	9.8	5.7	16.4
	Lymphocyte count increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Mean cell volume increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Myoglobin blood increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Neutrophil count decreased	USA	64	22.8	10	15.6	8.7	26.4
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	64	52.5	43.7	61.1
	Neutrophil count increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Neutrophil percentage increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Occult blood positive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Oxygen saturation decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	PO2 decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Platelet count decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	26	21.3	15.0	29.4
	Platelet count increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Procalcitonin increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Protein total decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Protein total increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Protein urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Prothrombin time prolonged	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Red blood cell count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Serum amyloid A protein increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Thrombin time prolonged	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Total bile acids increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	9	7.4	3.9	13.4

	Transaminases increased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Transferrin increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Troponin T increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Troponin increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary sediment present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urine ketone body present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Urine leukocyte esterase positive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urobilinogen urine increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Weight decreased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
	Weight increased	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	19	15.6	10.2	23.0
	White blood cell count decreased	USA	64	22.8	18	28.1	18.6	40.1
		Europe (EU)	95	33.8	12	12.6	7.4	20.8
		Asia (AS)	122	43.4	42	34.4	26.6	43.2
	White blood cells urine positive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
Metabolism and nutrition disorders	-Total	USA	64	22.8	30	46.9	35.2	58.9
		Europe (EU)	95	33.8	44	46.3	36.6	56.3
		Asia (AS)	122	43.4	73	59.8	51.0	68.1
	Abnormal loss of weight	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Acidosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Alkalosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cell death	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Decreased appetite	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	24	19.7	13.6	27.6
	Dehydration	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Electrolyte imbalance	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Failure to thrive	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fluid retention	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypercalcaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Hypercholesterolaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hyperglycaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
	Hyperkalaemia	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Hyperlipidaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Hypermagnesaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hypernatraemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hyperphosphataemia	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Hypertriglyceridaemia	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Hyperuricaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Hypoalbuminaemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	32	26.2	19.2	34.7
	Hypocalcaemia	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	19	15.6	10.2	23.0
	Hypochloraemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Hypoglycaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypokalaemia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	14	14.7	9.0	23.2
		Asia (AS)	122	43.4	21	17.2	11.5	24.9
	Hypomagnesaemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Hyponatraemia	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	19	15.6	10.2	23.0
	Hypophosphataemia	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	10	10.5	5.8	18.3
		Asia (AS)	122	43.4	20	16.4	10.9	24.0
	Hypoproteinaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Increased appetite	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vitamin D deficiency	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Musculoskeletal and connective tissue disorders	-Total	USA	64	22.8	41	64.1	51.8	74.7
		Europe (EU)	95	33.8	40	42.1	32.7	52.2
		Asia (AS)	122	43.4	43	35.2	27.3	44.1
	Arthralgia	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Arthropathy	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Back pain	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	12	9.8	5.7	16.4
	Bone pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Bursitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Coccydynia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Costochondritis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Flank pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Groin pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypercreatinaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Intervertebral disc protrusion	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Joint range of motion decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Joint stiffness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Joint swelling	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle fatigue	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Muscle haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle spasms	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1

	Muscular weakness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Musculoskeletal chest pain	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Musculoskeletal pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	12	12.6	7.4	20.8
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Musculoskeletal stiffness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Myalgia	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Myopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neck pain	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Osteopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pain in extremity	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Pain in jaw	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhabdomyolysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rotator cuff syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Spinal column stenosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Spinal osteoarthritis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tendon disorder	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Tendon pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Anogenital warts	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Basal cell carcinoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bowen's disease	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cancer pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gallbladder cancer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Metastases to central nervous system	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal cell carcinoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Squamous cell carcinoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Squamous cell carcinoma of skin	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tumour pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Nervous system disorders	-Total	USA	64	22.8	43	67.2	55.0	77.4
		Europe (EU)	95	33.8	47	49.5	39.6	59.4
		Asia (AS)	122	43.4	55	45.1	36.5	53.9
	Ageusia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aphasia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ataxia	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Balance disorder	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Brain oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebellar haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebral haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebral microhaemorrhage	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebrovascular accident	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Disturbance in attention	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dizziness	USA	64	22.8	14	21.9	13.5	33.4
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Dizziness postural	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dysarthria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dysgeusia	USA	64	22.8	14	21.9	13.5	33.4
		Europe (EU)	95	33.8	20	21.1	14.1	30.3
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Dyskinesia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Epilepsy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Facial paralysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haemorrhage intracranial	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Headache	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	13	13.7	8.2	22.0
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Hemiplegia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyperaesthesia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypersomnia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypoaesthesia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	16	13.1	8.2	20.2
	Hypotonia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lethargy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lumbar radiculopathy	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lumbosacral radiculopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Memory impairment	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Migraine	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Migraine with aura	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neuralgia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neuropathy peripheral	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Paraesthesia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	8	6.6	3.4	12.4

	Paralysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Parosmia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Peripheral sensory neuropathy	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Polyneuropathy chronic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Post herpetic neuralgia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Presyncope	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Psychomotor skills impaired	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Restless legs syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sciatica	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Seizure	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Sensory disturbance	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Slow speech	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Somnolence	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Spinal cord haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Syncope	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Tension headache	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tremor	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Visual field defect	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Product issues	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Device dislocation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Psychiatric disorders	-Total	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	17	17.9	11.5	26.8
		Asia (AS)	122	43.4	24	19.7	13.6	27.6
	Abnormal behaviour	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Abnormal dreams	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Adjustment disorder with mixed anxiety and depressed mood	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Anxiety	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Bradyphrenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Confusional state	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Delirium	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Depressed mood	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Depression	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fear of falling	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Insomnia	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Irritability	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Libido decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Mental status changes	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Mood altered	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Psychomotor retardation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Restlessness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Sleep disorder	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Renal and urinary disorders	-Total	USA	64	22.8	19	29.7	19.9	41.8
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Acute kidney injury	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Azotaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Cystitis haemorrhagic	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dysuria	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Haematuria	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Haemorrhage urinary tract	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hydronephrosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Micturition urgency	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nephritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nephrolithiasis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nocturia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Obstructive nephropathy	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pollakiuria	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Proteinuria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Renal colic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal failure	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal impairment	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Strangury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urethral stenosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary incontinence	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Urinary retention	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urinary tract pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urine flow decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Reproductive system and breast disorders	-Total	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Benign prostatic hyperplasia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Breast discharge	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Erectile dysfunction	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Galactorrhoea	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Genital ulceration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Metrorrhagia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ovarian cyst	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pelvic discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pelvic fluid collection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Perineal pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Postmenopausal haemorrhage	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Prostatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Uterine polyp	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vaginal haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vulvovaginal dryness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vulvovaginal erythema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Respiratory, thoracic and mediastinal disorders	-Total	USA	64	22.8	39	60.9	48.7	71.9
		Europe (EU)	95	33.8	59	62.1	52.1	71.2
		Asia (AS)	122	43.4	69	56.6	47.7	65.0
	Acute respiratory failure	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aspiration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bronchospasm	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Choking	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cough	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	23	24.2	16.7	33.7
		Asia (AS)	122	43.4	27	22.1	15.7	30.3
	Dry throat	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dysphonia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Dyspnoea	USA	64	22.8	10	15.6	8.7	26.4
		Europe (EU)	95	33.8	18	18.9	12.3	28.0
		Asia (AS)	122	43.4	19	15.6	10.2	23.0
	Dyspnoea exertional	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Epistaxis	USA	64	22.8	7	10.9	5.4	20.9

		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Haemoptysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Hiccups	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypoxia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Interstitial lung disease	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Laryngeal haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lung consolidation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasal congestion	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasal dryness	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasal polyps	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oropharyngeal discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oropharyngeal pain	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Paranasal sinus discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pharyngeal disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pleural effusion	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Pleural thickening	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pleuritic pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonitis	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	10	10.5	5.8	18.3
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Pneumothorax	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Productive cough	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Pulmonary embolism	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pulmonary hypertension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pulmonary mass	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pulmonary pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiration abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Respiratory distress	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory failure	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhinalgia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhinitis allergic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rhinorrhoea	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinus congestion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Sleep apnoea syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Sputum discoloured	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Throat irritation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Upper-airway cough syndrome	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vocal cord leukoplakia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Wheezing	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Skin and subcutaneous tissue disorders	-Total	USA	64	22.8	32	50.0	38.1	61.9
		Europe (EU)	95	33.8	29	30.5	22.2	40.4
		Asia (AS)	122	43.4	39	32.0	24.4	40.7
	Acne	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Alopecia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Chloasma	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Decubitus ulcer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dermal cyst	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dermatitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dermatitis acneiform	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Dermatitis allergic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Dermatitis bullous	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dry skin	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Ecchymosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Eczema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Erythema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hair growth abnormal	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hair texture abnormal	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hirsutism	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperhidrosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperkeratosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypertrichosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Madarosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nail discolouration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nail disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Night sweats	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Onychalgia	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Onycholysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Onychomadesis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Pain of skin	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Palmar-plantar erythrodysaesthesia syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Photosensitivity reaction	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pruritus	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Pruritus generalised	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Purpura	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rash	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Rash erythematous	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rash macular	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rash maculo-papular	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rash papular	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Scab	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Scar pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Skin discolouration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin hyperpigmentation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin lesion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Swelling face	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Urticaria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Surgical and medical procedures	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Astringent therapy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eye excision	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hip arthroplasty	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Therapy cessation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Vascular disorders	-Total	USA	64	22.8	32	50.0	38.1	61.9
		Europe (EU)	95	33.8	32	33.7	25.0	43.7
		Asia (AS)	122	43.4	51	41.8	33.4	50.7
	Aortic dissection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Circulatory collapse	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Deep vein thrombosis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Embolism	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Embolism venous	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Flushing	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hot flush	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypertension	USA	64	22.8	24	37.5	26.7	49.7
		Europe (EU)	95	33.8	24	25.3	17.6	34.8
		Asia (AS)	122	43.4	48	39.3	31.1	48.2
	Hypotension	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Lymphoedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Orthostatic hypotension	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pallor	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Phlebitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Raynaud's phenomenon	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Shock haemorrhagic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Superior vena cava syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Thrombophlebitis superficial	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thrombosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEANY_SG.xls
26MAR2021 14:05

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	116	41.3	61	52.6	43.6	61.4
		1	77	27.4	46	59.7	48.6	70.0
		>= 2	88	31.3	62	70.5	60.2	79.0
	Anaemia	0	116	41.3	43	37.1	28.8	46.1
		1	77	27.4	39	50.6	39.7	61.5
		>= 2	88	31.3	47	53.4	43.1	63.5
	Anaemia macrocytic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Aplastic anaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bone marrow oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cytopenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Disseminated intravascular coagulation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Febrile neutropenia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Haemorrhagic anaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperfibrinogenaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Leukocytosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Leukopenia	0	116	41.3	15	12.9	8.0	20.2
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	8	9.1	4.7	16.9
	Lymph node pain	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymphadenopathy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymphopenia	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	6	6.8	3.2	14.1
	Neutropenia	0	116	41.3	19	16.4	10.7	24.2
		1	77	27.4	19	24.7	16.4	35.4
		>= 2	88	31.3	23	26.1	18.1	36.2
	Neutrophilia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pancytopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Thrombocytopenia	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	9	10.2	5.5	18.3
	Thrombocytosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
Cardiac disorders	-Total	0	116	41.3	15	12.9	8.0	20.2
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	17	19.3	12.4	28.8
	Acute coronary syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Acute myocardial infarction	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Angina pectoris	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Aortic valve calcification	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Atrial fibrillation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Atrial flutter	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bradycardia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	0	0.0	0.0	4.2
	Bundle branch block right	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cardiac failure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cardio-respiratory arrest	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Extrasystoles	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Myocardial ischaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nodal arrhythmia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Palpitations	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pericardial effusion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Sinus bradycardia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Sinus tachycardia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Stress cardiomyopathy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Supraventricular tachycardia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tachycardia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Ventricular extrasystoles	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ventricular pre-excitation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

Congenital, familial and genetic disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gilbert's syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hydrocele	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Ear and labyrinth disorders	-Total	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	9	10.2	5.5	18.3
	Ear congestion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ear discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ear pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Tinnitus	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vertigo	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	6	6.8	3.2	14.1
Endocrine disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Adrenal insufficiency	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperthyroidism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypothyroidism	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
Eye disorders	-Total	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	17	22.1	14.3	32.5
		>= 2	88	31.3	14	15.9	9.7	25.0
	Abnormal sensation in eye	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Blepharitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cataract	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Chalazion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Conjunctival cyst	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Conjunctival haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Diplopia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dry eye	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Eye swelling	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eyelid oedema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Eyelid ptosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Keratitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ocular discomfort	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Periorbital oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	1	1.1	0.2	6.2
	Photophobia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Photopsia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ulcerative keratitis	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vision blurred	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	5	5.7	2.5	12.6
	Visual acuity reduced	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Gastrointestinal disorders	-Total	0	116	41.3	81	69.8	60.9	77.4
		1	77	27.4	56	72.7	61.9	81.4
		>= 2	88	31.3	67	76.1	66.3	83.8
	Abdominal discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Abdominal distension	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Abdominal pain	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Abdominal pain lower	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Abdominal pain upper	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Abdominal symptom	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Anal incontinence	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Aphthous ulcer	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ascites	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Colitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Constipation	0	116	41.3	51	44.0	35.3	53.0
		1	77	27.4	33	42.9	32.4	54.0
		>= 2	88	31.3	34	38.6	29.1	49.1
	Dental caries	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Dental dysaesthesia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Diarrhoea	0	116	41.3	25	21.6	15.0	29.9
		1	77	27.4	22	28.6	19.7	39.5
		>= 2	88	31.3	23	26.1	18.1	36.2
	Diverticular perforation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dry mouth	0	116	41.3	14	12.1	7.3	19.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	20	22.7	15.2	32.5
	Dyspepsia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Dysphagia	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	9	10.2	5.5	18.3
	Enteritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Epigastric discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Eructation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Faeces soft	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Flatulence	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Frequent bowel movements	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastric ulcer	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastritis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Gastritis erosive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Gastrointestinal haemorrhage	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastrointestinal inflammation	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrointestinal oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastrointestinal wall thickening	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrooesophageal reflux disease	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Gingival bleeding	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Gingival swelling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Glossitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Glossodynia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haematochezia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemorrhoids	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypoaesthesia oral	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Impaired gastric emptying	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intestinal obstruction	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Irritable bowel syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Large intestine perforation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Melaena	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Mouth ulceration	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Nausea	0	116	41.3	18	15.5	10.0	23.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	11	12.5	7.1	21.0
	Odynophagia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oesophageal irritation	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oesophagitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oral disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Oral dysaesthesia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oral mucosal erythema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Oral pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Pancreatitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pancreatitis acute	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Paraesthesia oral	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Proctitis ulcerative	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rectal prolapse	0	116	41.3	1	0.9	0.2	4.7

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Regurgitation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sensitivity of teeth	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Stomatitis	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	6	6.8	3.2	14.1
	Swollen tongue	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tongue coated	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tongue discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tongue ulceration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tooth discolouration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Toothache	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Vomiting	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	12	15.6	9.1	25.3
		>= 2	88	31.3	10	11.4	6.3	19.7
General disorders and administration site conditions	-Total	0	116	41.3	74	63.8	54.7	72.0
		1	77	27.4	54	70.1	59.2	79.2
		>= 2	88	31.3	69	78.4	68.7	85.7
	Asthenia	0	116	41.3	19	16.4	10.7	24.2
		1	77	27.4	11	14.3	8.2	23.8
		>= 2	88	31.3	9	10.2	5.5	18.3
	Axillary pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Catheter site pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Chest discomfort	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	5	5.7	2.5	12.6
	Chest pain	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Chills	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Condition aggravated	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Death	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Face oedema	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	8	9.1	4.7	16.9
	Facial pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fatigue	0	116	41.3	25	21.6	15.0	29.9
		1	77	27.4	16	20.8	13.2	31.1
		>= 2	88	31.3	26	29.5	21.0	39.8
	Feeling abnormal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Feeling cold	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Feeling hot	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gait disturbance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	General physical health deterioration	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Generalised oedema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Impaired healing	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Influenza like illness	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2

	Injection site bruising	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Localised oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Malaise	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	6	6.8	3.2	14.1
	Mucosal dryness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Mucosal inflammation	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Multiple organ dysfunction syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Non-cardiac chest pain	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oedema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oedema peripheral	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	19	21.6	14.3	31.3
	Pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Peripheral swelling	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pyrexia	0	116	41.3	23	19.8	13.6	28.0
		1	77	27.4	23	29.9	20.8	40.8
		>= 2	88	31.3	26	29.5	21.0	39.8
	Swelling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Temperature intolerance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Xerosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

Hepatobiliary disorders	-Total	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	7	8.0	3.9	15.5
	Cholecystitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cholelithiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gallbladder polyp	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hepatic function abnormal	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hepatic steatosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hepatocellular injury	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hyperbilirubinaemia	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Liver disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Liver injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumobilia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Portal vein thrombosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Immune system disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Contrast media allergy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Drug hypersensitivity	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Food allergy	0	116	41.3	1	0.9	0.2	4.7

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypersensitivity	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Seasonal allergy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
Infections and infestations	-Total	0	116	41.3	52	44.8	36.1	53.9
		1	77	27.4	46	59.7	48.6	70.0
		>= 2	88	31.3	59	67.0	56.7	76.0
	Abdominal abscess	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Acute sinusitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Appendicitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Arthritis infective	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Atypical pneumonia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bacteraemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Bacterial disease carrier	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bacterial infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bacterial vaginosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bronchitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	2	2.3	0.6	7.9
	Candida infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cellulitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	1	1.1	0.2	6.2
	Chronic sinusitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Clostridium difficile colitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Conjunctivitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Corona virus infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cystitis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cystitis escherichia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Device related infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Diverticulitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ear infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Empyema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Enterococcal bacteraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Epididymitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Epstein-Barr virus infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Escherichia bacteraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Escherichia infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Escherichia urinary tract infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eye infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Febrile infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Folliculitis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fungal infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastroenteritis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Genital candidiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Genital herpes	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gingivitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Herpes simplex	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Herpes virus infection	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Herpes zoster	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Infectious colitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Influenza	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Lower respiratory tract infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lung infection	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Lyme disease	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lymph node tuberculosis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Meningitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasal herpes	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasopharyngitis	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Oral candidiasis	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Oral fungal infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oropharyngeal candidiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Otitis externa	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Otitis media	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Paronychia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Peritonitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pharyngitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pleural infection	0	116	41.3	1	0.9	0.2	4.7

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumocystis jirovecii pneumonia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	18	20.5	13.3	30.0
	Pneumonia bacterial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia cytomegaloviral	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia haemophilus	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonia influenzal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonia pseudomonal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia streptococcal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pyelonephritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pyelonephritis acute	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pyuria	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rectal abscess	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Renal tuberculosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiratory tract infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiratory tract infection bacterial	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Sepsis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	5	5.7	2.5	12.6
	Septic shock	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sinusitis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Sinusitis bacterial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Skin infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Staphylococcal infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Systemic infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tinea cruris	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tinea infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tinea pedis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Tonsillitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tooth infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tracheitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tuberculosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Upper respiratory tract infection	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	7	8.0	3.9	15.5
	Urethritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urinary tract infection	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	16	18.2	11.5	27.5
	Urosepsis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Varicella	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Varicella zoster virus infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Viral hepatitis carrier	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Viral infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vulvovaginal candidiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Injury, poisoning and procedural complications	-Total	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	15	17.0	10.6	26.2
	Contusion	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Epicondylitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Fall	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Fracture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Heart injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Incision site pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Joint dislocation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Laceration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ligament sprain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Limb injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Muscle rupture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Muscle strain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Procedural pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Procedural pneumothorax	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rib fracture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Scar	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Skin abrasion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Skin injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Subdural haematoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tendon rupture	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Thermal burn	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Wound	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Wound complication	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Wrist fracture	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Investigations	-Total	0	116	41.3	90	77.6	69.2	84.2
		1	77	27.4	62	80.5	70.3	87.8
		>= 2	88	31.3	71	80.7	71.2	87.6
	Alanine aminotransferase	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Alanine aminotransferase increased	0	116	41.3	41	35.3	27.2	44.4
		1	77	27.4	20	26.0	17.5	36.7
		>= 2	88	31.3	31	35.2	26.1	45.6
	Albumin urine present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Alpha hydroxybutyrate dehydrogenase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Amylase increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Aspartate aminotransferase increased	0	116	41.3	49	42.2	33.6	51.3
		1	77	27.4	33	42.9	32.4	54.0
		>= 2	88	31.3	44	50.0	39.8	60.2
	Bacterial test	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bilirubin conjugated increased	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	6	6.8	3.2	14.1
	Blood albumin decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood alkaline phosphatase	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood alkaline phosphatase decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood alkaline phosphatase increased	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	12	15.6	9.1	25.3
		>= 2	88	31.3	14	15.9	9.7	25.0
	Blood bilirubin increased	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	8	9.1	4.7	16.9
	Blood bilirubin unconjugated increased	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood calcium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood calcium increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood chloride increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood cholesterol increased	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Blood creatine increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood creatine phosphokinase MB increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood creatine phosphokinase increased	0	116	41.3	27	23.3	16.5	31.7
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	18	20.5	13.3	30.0
	Blood creatinine	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood creatinine increased	0	116	41.3	18	15.5	10.0	23.2
		1	77	27.4	19	24.7	16.4	35.4
		>= 2	88	31.3	25	28.4	20.0	38.6
	Blood fibrinogen increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood glucose increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5

	Blood iron decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood ketone body increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood lactate dehydrogenase increased	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood magnesium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood phosphorus increased	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood potassium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood potassium increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood pressure increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood sodium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood thyroid stimulating hormone increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood triglycerides increased	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood urea increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood uric acid decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood uric acid increased	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Blood urine	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5

	Blood urine present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	C-reactive protein increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Carbon dioxide decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Complement factor C1 decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Computerised tomogram thorax abnormal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Crystal urine present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cystatin C increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Electrocardiogram QT prolonged	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	7	8.0	3.9	15.5
	Electrocardiogram ST-T change	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Fibrin D dimer increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Fibrin degradation products increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Free fatty acids increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gamma-glutamyltransferase increased	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	9	10.2	5.5	18.3
	Glomerular filtration rate decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Glutamate dehydrogenase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Granulocyte count decreased	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haematocrit decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemoglobin decreased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Heart rate increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hepatic enzyme increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	International normalised ratio increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intraocular pressure increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Laboratory test abnormal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lipase increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Liver function test increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lymphocyte count decreased	0	116	41.3	12	10.3	6.0	17.2
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	8	9.1	4.7	16.9
	Lymphocyte count increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Mean cell volume increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Myoglobin blood increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neutrophil count decreased	0	116	41.3	36	31.0	23.3	39.9
		1	77	27.4	18	23.4	15.3	34.0
		>= 2	88	31.3	27	30.7	22.0	41.0
	Neutrophil count increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	1	1.1	0.2	6.2
	Neutrophil percentage increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Occult blood positive	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oxygen saturation decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	PO2 decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Platelet count decreased	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	11	14.3	8.2	23.8
		>= 2	88	31.3	11	12.5	7.1	21.0
	Platelet count increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Procalcitonin increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Protein total decreased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Protein total increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Protein urine present	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Prothrombin time prolonged	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Red blood cell count decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Serum amyloid A protein increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Thrombin time prolonged	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Total bile acids increased	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2

	Transaminases increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	1	1.1	0.2	6.2
	Transferrin increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Troponin T increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Troponin increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Urinary sediment present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urine ketone body present	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Urine leukocyte esterase positive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urobilinogen urine increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Weight decreased	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	7	8.0	3.9	15.5
	Weight increased	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	10	11.4	6.3	19.7
	White blood cell count decreased	0	116	41.3	31	26.7	19.5	35.4
		1	77	27.4	17	22.1	14.3	32.5
		>= 2	88	31.3	24	27.3	19.1	37.4
	White blood cells urine positive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
Metabolism and nutrition disorders	-Total	0	116	41.3	59	50.9	41.9	59.8
		1	77	27.4	36	46.8	36.0	57.8
		>= 2	88	31.3	52	59.1	48.6	68.8
	Abnormal loss of weight	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Acidosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Alkalosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cell death	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Decreased appetite	0	116	41.3	12	10.3	6.0	17.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	13	14.8	8.8	23.7
	Dehydration	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Electrolyte imbalance	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Failure to thrive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fluid retention	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypercalcaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Hypercholesterolaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperglycaemia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	7	8.0	3.9	15.5
	Hyperkalaemia	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Hyperlipidaemia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypermagnesaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypernatraemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperphosphataemia	0	116	41.3	15	12.9	8.0	20.2
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	11	12.5	7.1	21.0
	Hypertriglyceridaemia	0	116	41.3	1	0.9	0.2	4.7

		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Hyperuricaemia	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hypoalbuminaemia	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	17	19.3	12.4	28.8
	Hypocalcaemia	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	13	14.8	8.8	23.7
	Hypochloraemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hypoglycaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypokalaemia	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	14	15.9	9.7	25.0
	Hypomagnesaemia	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	10	11.4	6.3	19.7
	Hyponatraemia	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	8	9.1	4.7	16.9
	Hypophosphataemia	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	14	18.2	11.2	28.2
		>= 2	88	31.3	15	17.0	10.6	26.2
	Hypoproteinaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Increased appetite	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vitamin D deficiency	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Musculoskeletal and connective tissue disorders	-Total	0	116	41.3	46	39.7	31.2	48.8
		1	77	27.4	37	48.1	37.3	59.0
		>= 2	88	31.3	41	46.6	36.5	56.9
	Arthralgia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	3	3.4	1.2	9.5
	Arthropathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Back pain	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	15	17.0	10.6	26.2
	Bone pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bursitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Coccydynia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Costochondritis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Flank pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Groin pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypercreatinaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intervertebral disc protrusion	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Joint range of motion decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Joint stiffness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Joint swelling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Muscle fatigue	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Muscle haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Muscle spasms	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	10	11.4	6.3	19.7

	Muscular weakness	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Musculoskeletal chest pain	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Musculoskeletal pain	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	8	9.1	4.7	16.9
	Musculoskeletal stiffness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Myalgia	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	3	3.4	1.2	9.5
	Myopathy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neck pain	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	6	6.8	3.2	14.1
	Osteopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pain in extremity	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	11	12.5	7.1	21.0
	Pain in jaw	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rhabdomyolysis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rotator cuff syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Spinal column stenosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Spinal osteoarthritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tendon disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Tendon pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Anogenital warts	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Basal cell carcinoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bowen's disease	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cancer pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gallbladder cancer	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Metastases to central nervous system	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal cell carcinoma	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Squamous cell carcinoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Squamous cell carcinoma of skin	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tumour pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
Nervous system disorders	-Total	0	116	41.3	54	46.6	37.7	55.6
		1	77	27.4	45	58.4	47.3	68.8
		>= 2	88	31.3	46	52.3	42.0	62.4
	Ageusia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Aphasia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ataxia	0	116	41.3	1	0.9	0.2	4.7

		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Balance disorder	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Brain oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Cerebellar haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cerebral haematoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cerebral microhaemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cerebrovascular accident	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Disturbance in attention	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dizziness	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	12	13.6	8.0	22.3
	Dizziness postural	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dysarthria	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dysgeusia	0	116	41.3	20	17.2	11.4	25.1
		1	77	27.4	14	18.2	11.2	28.2
		>= 2	88	31.3	8	9.1	4.7	16.9
	Dyskinesia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Epilepsy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Facial paralysis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haemorrhage intracranial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Headache	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	14	18.2	11.2	28.2
		>= 2	88	31.3	9	10.2	5.5	18.3
	Hemiplegia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperaesthesia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypersomnia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypoaesthesia	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	7	8.0	3.9	15.5
	Hypotonia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lethargy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lumbar radiculopathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lumbosacral radiculopathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Memory impairment	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Migraine	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Migraine with aura	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Neuralgia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neuropathy peripheral	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	3	3.4	1.2	9.5
	Paraesthesia	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	4	4.5	1.8	11.1

	Paralysis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Parosmia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Peripheral sensory neuropathy	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Polyneuropathy chronic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Post herpetic neuralgia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Presyncope	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Psychomotor skills impaired	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Restless legs syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sciatica	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Seizure	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Sensory disturbance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Slow speech	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Somnolence	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Spinal cord haematoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Syncope	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5

	Tension headache	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tremor	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Visual field defect	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Product issues	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Device dislocation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Psychiatric disorders	-Total	0	116	41.3	20	17.2	11.4	25.1
		1	77	27.4	15	19.5	12.2	29.7
		>= 2	88	31.3	21	23.9	16.2	33.7
	Abnormal behaviour	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Abnormal dreams	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Adjustment disorder with mixed anxiety and depressed mood	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Anxiety	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Bradyphrenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Confusional state	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Delirium	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Depressed mood	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Depression	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fear of falling	0	116	41.3	1	0.9	0.2	4.7

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Insomnia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	9	10.2	5.5	18.3
	Irritability	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Libido decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Mental status changes	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Mood altered	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Psychomotor retardation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Restlessness	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sleep disorder	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Renal and urinary disorders	-Total	0	116	41.3	15	12.9	8.0	20.2
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	18	20.5	13.3	30.0
	Acute kidney injury	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Azotaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Cystitis haemorrhagic	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dysuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	8	9.1	4.7	16.9
	Haematuria	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemorrhage urinary tract	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1	0.2	6.2
	Hydronephrosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Micturition urgency	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Nephritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nephrolithiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Nocturia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Obstructive nephropathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pollakiuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Proteinuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Renal colic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal failure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal impairment	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Strangury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Urethral stenosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urinary incontinence	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Urinary retention	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Urinary tract pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urine flow decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Reproductive system and breast disorders	-Total	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	8	9.1	4.7	16.9
	Benign prostatic hyperplasia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Breast discharge	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Erectile dysfunction	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Galactorrhoea	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Genital ulceration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Metrorrhagia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ovarian cyst	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pelvic discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pelvic fluid collection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Perineal pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Postmenopausal haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Prostatitis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Uterine polyp	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vaginal haemorrhage	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vulvovaginal dryness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vulvovaginal erythema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Respiratory, thoracic and mediastinal disorders	-Total	0	116	41.3	63	54.3	45.3	63.1
		1	77	27.4	50	64.9	53.8	74.7
		>= 2	88	31.3	54	61.4	50.9	70.9
	Acute respiratory failure	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Aspiration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bronchospasm	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Choking	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cough	0	116	41.3	19	16.4	10.7	24.2
		1	77	27.4	26	33.8	24.2	44.9
		>= 2	88	31.3	20	22.7	15.2	32.5
	Dry throat	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dysphonia	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Dyspnoea	0	116	41.3	15	12.9	8.0	20.2
		1	77	27.4	14	18.2	11.2	28.2
		>= 2	88	31.3	18	20.5	13.3	30.0
	Dyspnoea exertional	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Epistaxis	0	116	41.3	6	5.2	2.4	10.8

		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	3	3.4	1.2	9.5
	Haemoptysis	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Hiccups	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypoxia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Interstitial lung disease	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Laryngeal haemorrhage	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lung consolidation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasal congestion	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Nasal dryness	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasal polyps	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oropharyngeal discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oropharyngeal pain	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	5	5.7	2.5	12.6
	Paranasal sinus discomfort	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pharyngeal disorder	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pleural effusion	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Pleural thickening	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1	0.2	6.2
	Pleuritic pain	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonitis	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	11	14.3	8.2	23.8
		>= 2	88	31.3	12	13.6	8.0	22.3
	Pneumothorax	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Productive cough	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	6	6.8	3.2	14.1
	Pulmonary embolism	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Pulmonary hypertension	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pulmonary mass	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pulmonary pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiration abnormal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiratory distress	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Respiratory failure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinalgia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinitis allergic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinorrhoea	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sinus congestion	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Sleep apnoea syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sputum discoloured	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Throat irritation	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Upper-airway cough syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Vocal cord leukoplakia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Wheezing	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Skin and subcutaneous tissue disorders	-Total	0	116	41.3	32	27.6	20.3	36.3
		1	77	27.4	35	45.5	34.8	56.5
		>= 2	88	31.3	33	37.5	28.1	47.9
	Acne	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Alopecia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	4	4.5	1.8	11.1
	Chloasma	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Decubitus ulcer	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dermal cyst	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dermatitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dermatitis acneiform	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Dermatitis allergic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Dermatitis bullous	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dry skin	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Ecchymosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eczema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Erythema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hair growth abnormal	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Hair texture abnormal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hirsutism	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hyperhidrosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperkeratosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypertrichosis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	0	0.0	0.0	4.2
	Madarosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Nail discolouration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nail disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Night sweats	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Onychalgia	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Onycholysis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Onychomadesis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pain of skin	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Palmar-plantar erythrodysaesthesia syndrome	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Photosensitivity reaction	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pruritus	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Pruritus generalised	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Purpura	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rash	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	10	11.4	6.3	19.7
	Rash erythematous	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Rash macular	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Rash maculo-papular	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rash papular	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Scab	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Scar pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1	0.2	6.2
	Skin discolouration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Skin hyperpigmentation	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Skin lesion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Swelling face	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urticaria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Surgical and medical procedures	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	2	2.3	0.6	7.9
	Astringent therapy	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eye excision	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hip arthroplasty	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Therapy cessation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Vascular disorders	-Total	0	116	41.3	37	31.9	24.1	40.8
		1	77	27.4	31	40.3	30.0	51.4
		>= 2	88	31.3	47	53.4	43.1	63.5
	Aortic dissection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Circulatory collapse	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Deep vein thrombosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Embolism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9

	Embolism venous	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Flushing	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haematoma	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hot flush	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypertension	0	116	41.3	33	28.4	21.0	37.2
		1	77	27.4	27	35.1	25.3	46.2
		>= 2	88	31.3	36	40.9	31.2	51.4
	Hypotension	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Lymphoedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Orthostatic hypotension	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pallor	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Phlebitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Raynaud's phenomenon	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Shock haemorrhagic	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Superior vena cava syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Thrombophlebitis superficial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Thrombosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEANY_SG.xls
26MAR2021 14:05

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Asian	128	45.6	85	66.4	57.9	74.0
		Non-Asian	135	48.0	75	55.6	47.1	63.7
		Unknown	18	6.4	9	50.0	29.0	71.0
	Anaemia	Asian	128	45.6	61	47.7	39.2	56.3
		Non-Asian	135	48.0	61	45.2	37.0	53.6
		Unknown	18	6.4	7	38.9	20.3	61.4
	Anaemia macrocytic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aplastic anaemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bone marrow oedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cytopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Disseminated intravascular coagulation	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Febrile neutropenia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhagic anaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperfibrinogenaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Leukocytosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Leukopenia	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	18	13.3	8.6	20.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymph node pain	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphadenopathy	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	23	17.0	11.6	24.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutropenia	Asian	128	45.6	24	18.8	12.9	26.4
		Non-Asian	135	48.0	34	25.2	18.6	33.1
		Unknown	18	6.4	3	16.7	5.8	39.2
	Neutrophilia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancytopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytopenia	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	13	9.6	5.7	15.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
Cardiac disorders	-Total	Asian	128	45.6	20	15.6	10.3	22.9
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	Acute coronary syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Acute myocardial infarction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Angina pectoris	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aortic valve calcification	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Atrial fibrillation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Atrial flutter	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bradycardia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Bundle branch block right	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cardiac failure	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cardio-respiratory arrest	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Extrasystoles	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Myocardial ischaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nodal arrhythmia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Palpitations	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pericardial effusion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinus bradycardia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Sinus tachycardia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Stress cardiomyopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Supraventricular tachycardia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tachycardia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ventricular extrasystoles	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ventricular pre-excitation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

Congenital, familial and genetic disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gilbert's syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hydrocele	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Ear and labyrinth disorders	-Total	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	2	11.1	3.1	32.8
	Ear congestion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ear discomfort	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ear pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinnitus	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vertigo	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	2	11.1	3.1	32.8
Endocrine disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Adrenal insufficiency	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperthyroidism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypothyroidism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Eye disorders	-Total	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	26	19.3	13.5	26.7
		Unknown	18	6.4	3	16.7	5.8	39.2
	Abnormal sensation in eye	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Blepharitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cataract	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chalazion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Conjunctival cyst	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Conjunctival haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diplopia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dry eye	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Eye swelling	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eyelid oedema	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eyelid ptosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Keratitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ocular discomfort	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Periorbital oedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Photophobia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Photopsia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ulcerative keratitis	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vision blurred	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Visual acuity reduced	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Gastrointestinal disorders	-Total	Asian	128	45.6	84	65.6	57.0	73.3
		Non-Asian	135	48.0	106	78.5	70.9	84.6
		Unknown	18	6.4	14	77.8	54.8	91.0
	Abdominal discomfort	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal distension	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal pain	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	1	5.6	1.0	25.8
	Abdominal pain lower	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal pain upper	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Abdominal symptom	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anal incontinence	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aphthous ulcer	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ascites	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Constipation	Asian	128	45.6	55	43.0	34.7	51.6
		Non-Asian	135	48.0	55	40.7	32.8	49.2
		Unknown	18	6.4	8	44.4	24.6	66.3
	Dental caries	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Dental dysaesthesia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diarrhoea	Asian	128	45.6	25	19.5	13.6	27.2
		Non-Asian	135	48.0	41	30.4	23.2	38.6
		Unknown	18	6.4	4	22.2	9.0	45.2
	Diverticular perforation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dry mouth	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	32	23.7	17.3	31.5
		Unknown	18	6.4	4	22.2	9.0	45.2
	Dyspepsia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	3	16.7	5.8	39.2
	Dysphagia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	15	11.1	6.9	17.5
		Unknown	18	6.4	1	5.6	1.0	25.8
	Enteritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epigastric discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eructation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Faeces soft	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Flatulence	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Frequent bowel movements	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastric ulcer	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastritis erosive	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Gastrointestinal haemorrhage	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal inflammation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal oedema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal wall thickening	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrooesophageal reflux disease	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Gingival bleeding	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gingival swelling	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Glossitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Glossodynia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematochezia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhoids	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoaesthesia oral	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Impaired gastric emptying	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intestinal obstruction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Irritable bowel syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Large intestine perforation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Melaena	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mouth ulceration	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nausea	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	23	17.0	11.6	24.3
		Unknown	18	6.4	3	16.7	5.8	39.2
	Odynophagia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oesophageal irritation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oesophagitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral dysaesthesia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral mucosal erythema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancreatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancreatitis acute	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Paraesthesia oral	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Proctitis ulcerative	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rectal prolapse	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Regurgitation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sensitivity of teeth	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Stomatitis	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Swollen tongue	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tongue coated	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tongue discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tongue ulceration	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tooth discolouration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Toothache	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vomiting	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	2	11.1	3.1	32.8
General disorders and administration site conditions	-Total	Asian	128	45.6	85	66.4	57.9	74.0
		Non-Asian	135	48.0	101	74.8	66.9	81.4
		Unknown	18	6.4	11	61.1	38.6	79.7
	Asthenia	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	23	17.0	11.6	24.3
		Unknown	18	6.4	5	27.8	12.5	50.9
	Axillary pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Catheter site pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chest discomfort	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3

		Unknown	18	6.4	0	0.0	0.0	17.6
	Chest pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chills	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Condition aggravated	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Death	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Face oedema	Asian	128	45.6	17	13.3	8.5	20.2
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Facial pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fatigue	Asian	128	45.6	19	14.8	9.7	22.0
		Non-Asian	135	48.0	44	32.6	25.3	40.9
		Unknown	18	6.4	4	22.2	9.0	45.2
	Feeling abnormal	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Feeling cold	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Feeling hot	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gait disturbance	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	General physical health deterioration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Generalised oedema	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Impaired healing	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Influenza like illness	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

	Injection site bruising	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Localised oedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Malaise	Asian	128	45.6	19	14.8	9.7	22.0
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Mucosal dryness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mucosal inflammation	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Multiple organ dysfunction syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Non-cardiac chest pain	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Oedema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oedema peripheral	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	25	18.5	12.9	25.9
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pain	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Peripheral swelling	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pyrexia	Asian	128	45.6	36	28.1	21.1	36.5
		Non-Asian	135	48.0	32	23.7	17.3	31.5
		Unknown	18	6.4	4	22.2	9.0	45.2
	Swelling	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Temperature intolerance	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Xerosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

Hepatobiliary disorders	-Total	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	13	9.6	5.7	15.8
		Unknown	18	6.4	3	16.7	5.8	39.2
	Cholecystitis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cholelithiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gallbladder polyp	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatic function abnormal	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatic steatosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatocellular injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	3	16.7	5.8	39.2
	Hyperbilirubinaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Liver disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Liver injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumobilia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Portal vein thrombosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
Immune system disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Contrast media allergy	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Drug hypersensitivity	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Food allergy	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypersensitivity	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Seasonal allergy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Infections and infestations	-Total	Asian	128	45.6	59	46.1	37.7	54.7
		Non-Asian	135	48.0	90	66.7	58.4	74.1
		Unknown	18	6.4	8	44.4	24.6	66.3
	Abdominal abscess	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Acute sinusitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Appendicitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Arthritis infective	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Atypical pneumonia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Bacterial disease carrier	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bacterial infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Bacterial vaginosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bronchitis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Candida infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cellulitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2

		Unknown	18	6.4	0	0.0	0.0	17.6
	Chronic sinusitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Clostridium difficile colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Conjunctivitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Corona virus infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis escherichia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Device related infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diverticulitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ear infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Empyema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Enterococcal bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epididymitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epstein-Barr virus infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Escherichia bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Escherichia infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Escherichia urinary tract infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eye infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Febrile infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Folliculitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fungal infection	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastroenteritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Genital candidiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Genital herpes	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gingivitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Herpes simplex	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Herpes virus infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Herpes zoster	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Infectious colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Influenza	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

	Lower respiratory tract infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lung infection	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Lyme disease	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymph node tuberculosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Meningitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal herpes	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasopharyngitis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral candidiasis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral fungal infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oropharyngeal candidiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Otitis externa	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Otitis media	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Paronychia	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Peritonitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pharyngitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleural infection	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumocystis jirovecii pneumonia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia	Asian	128	45.6	23	18.0	12.3	25.5
		Non-Asian	135	48.0	20	14.8	9.8	21.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumonia bacterial	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia cytomegaloviral	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia haemophilus	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia influenzal	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia pseudomonal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumonia streptococcal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyelonephritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyelonephritis acute	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyuria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rectal abscess	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal tuberculosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory tract infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory tract infection bacterial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sepsis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Septic shock	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinusitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Sinusitis bacterial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Staphylococcal infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Systemic infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinea cruris	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinea infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinea pedis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tonsillitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tooth infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tracheitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tuberculosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Upper respiratory tract infection	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urethritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary tract infection	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	27	20.0	14.1	27.5
		Unknown	18	6.4	1	5.6	1.0	25.8
	Urosepsis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Varicella	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Varicella zoster virus infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Viral hepatitis carrier	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Viral infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vulvovaginal candidiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Injury, poisoning and procedural complications	-Total	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	18	13.3	8.6	20.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Contusion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epicondylitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fall	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fracture	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Heart injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Incision site pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint dislocation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Laceration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ligament sprain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Limb injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle rupture	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle strain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Procedural pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Procedural pneumothorax	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rib fracture	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Scar	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin abrasion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Subdural haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tendon rupture	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thermal burn	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wound	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wound complication	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wrist fracture	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Investigations	-Total	Asian	128	45.6	109	85.2	78.0	90.3
		Non-Asian	135	48.0	101	74.8	66.9	81.4
		Unknown	18	6.4	13	72.2	49.1	87.5
	Alanine aminotransferase	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alanine aminotransferase increased	Asian	128	45.6	52	40.6	32.5	49.3
		Non-Asian	135	48.0	37	27.4	20.6	35.5
		Unknown	18	6.4	3	16.7	5.8	39.2
	Albumin urine present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alpha hydroxybutyrate dehydrogenase increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Amylase increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aspartate aminotransferase increased	Asian	128	45.6	71	55.5	46.8	63.8
		Non-Asian	135	48.0	51	37.8	30.0	46.2
		Unknown	18	6.4	4	22.2	9.0	45.2
	Bacterial test	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bilirubin conjugated increased	Asian	128	45.6	20	15.6	10.3	22.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood albumin decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood alkaline phosphatase	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood alkaline phosphatase decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood alkaline phosphatase increased	Asian	128	45.6	25	19.5	13.6	27.2
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood bilirubin increased	Asian	128	45.6	19	14.8	9.7	22.0
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Blood bilirubin unconjugated increased	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood calcium decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood calcium increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood chloride increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood cholesterol increased	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine phosphokinase MB increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine phosphokinase increased	Asian	128	45.6	37	28.9	21.8	37.3
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	5	27.8	12.5	50.9
	Blood creatinine	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatinine increased	Asian	128	45.6	24	18.8	12.9	26.4
		Non-Asian	135	48.0	34	25.2	18.6	33.1
		Unknown	18	6.4	4	22.2	9.0	45.2
	Blood fibrinogen increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood glucose increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Blood iron decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood ketone body increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood lactate dehydrogenase increased	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood magnesium decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood phosphorus increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood potassium decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood potassium increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood pressure increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood sodium decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood thyroid stimulating hormone increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood triglycerides increased	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood urea increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood uric acid decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood uric acid increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood urine	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Blood urine present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	C-reactive protein increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Carbon dioxide decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Complement factor C1 decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Computerised tomogram thorax abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Crystal urine present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystatin C increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrocardiogram QT prolonged	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrocardiogram ST-T change	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fibrin D dimer increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fibrin degradation products increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Free fatty acids increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gamma-glutamyltransferase increased	Asian	128	45.6	19	14.8	9.7	22.0
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Glomerular filtration rate decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Glutamate dehydrogenase increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Granulocyte count decreased	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematocrit decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemoglobin decreased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Heart rate increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatic enzyme increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	International normalised ratio increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intraocular pressure increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Laboratory test abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Lipase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Liver function test increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphocyte count decreased	Asian	128	45.6	14	10.9	6.6	17.5
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	2	11.1	3.1	32.8
	Lymphocyte count increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mean cell volume increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Myoglobin blood increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutrophil count decreased	Asian	128	45.6	66	51.6	43.0	60.0
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	1	5.6	1.0	25.8
	Neutrophil count increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutrophil percentage increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Occult blood positive	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oxygen saturation decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	PO2 decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Platelet count decreased	Asian	128	45.6	26	20.3	14.3	28.1
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Platelet count increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Procalcitonin increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Protein total decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Protein total increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Protein urine present	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Prothrombin time prolonged	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Red blood cell count decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Serum amyloid A protein increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombin time prolonged	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Total bile acids increased	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Transaminases increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Transferrin increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Troponin T increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Troponin increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary sediment present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urine ketone body present	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urine leukocyte esterase positive	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urobilinogen urine increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Weight decreased	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Weight increased	Asian	128	45.6	19	14.8	9.7	22.0
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	White blood cell count decreased	Asian	128	45.6	45	35.2	27.4	43.8
		Non-Asian	135	48.0	23	17.0	11.6	24.3
		Unknown	18	6.4	4	22.2	9.0	45.2
	White blood cells urine positive	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Metabolism and nutrition disorders	-Total	Asian	128	45.6	77	60.2	51.5	68.2
		Non-Asian	135	48.0	63	46.7	38.5	55.1
		Unknown	18	6.4	7	38.9	20.3	61.4
	Abnormal loss of weight	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Acidosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Alkalosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cell death	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Decreased appetite	Asian	128	45.6	25	19.5	13.6	27.2
		Non-Asian	135	48.0	12	8.9	5.2	14.9
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dehydration	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Electrolyte imbalance	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Failure to thrive	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fluid retention	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercalcaemia	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercholesterolaemia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperglycaemia	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperkalaemia	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyperlipidaemia	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypermagnesaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypernatraemia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperphosphataemia	Asian	128	45.6	15	11.7	7.2	18.4
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypertriglyceridaemia	Asian	128	45.6	6	4.7	2.2	9.8

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperuricaemia	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoalbuminaemia	Asian	128	45.6	32	25.0	18.3	33.2
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypocalcaemia	Asian	128	45.6	20	15.6	10.3	22.9
		Non-Asian	135	48.0	13	9.6	5.7	15.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypochloraemia	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoglycaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypokalaemia	Asian	128	45.6	21	16.4	11.0	23.8
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypomagnesaemia	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyponatraemia	Asian	128	45.6	19	14.8	9.7	22.0
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypophosphataemia	Asian	128	45.6	21	16.4	11.0	23.8
		Non-Asian	135	48.0	12	8.9	5.2	14.9
		Unknown	18	6.4	2	11.1	3.1	32.8
	Hypoproteinaemia	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Increased appetite	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vitamin D deficiency	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Musculoskeletal and connective tissue disorders	-Total	Asian	128	45.6	47	36.7	28.9	45.3
		Non-Asian	135	48.0	67	49.6	41.3	58.0
		Unknown	18	6.4	10	55.6	33.7	75.4
	Arthralgia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	1	5.6	1.0	25.8
	Arthropathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Back pain	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	24	17.8	12.2	25.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Bone pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bursitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Coccydynia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Costochondritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Flank pain	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Groin pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercreatinaemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intervertebral disc protrusion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint range of motion decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint stiffness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint swelling	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Muscle fatigue	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle spasms	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	3	16.7	5.8	39.2

	Muscular weakness	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Musculoskeletal chest pain	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Musculoskeletal pain	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	2	11.1	3.1	32.8
	Musculoskeletal stiffness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Myalgia	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	2	11.1	3.1	32.8
	Myopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neck pain	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Osteopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain in extremity	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	18	13.3	8.6	20.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain in jaw	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Rhabdomyolysis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rotator cuff syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Spinal column stenosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Spinal osteoarthritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tendon disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Tendon pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Anogenital warts	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Basal cell carcinoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bowen's disease	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cancer pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gallbladder cancer	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Metastases to central nervous system	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal cell carcinoma	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Squamous cell carcinoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Squamous cell carcinoma of skin	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tumour pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
Nervous system disorders	-Total	Asian	128	45.6	59	46.1	37.7	54.7
		Non-Asian	135	48.0	78	57.8	49.3	65.8
		Unknown	18	6.4	8	44.4	24.6	66.3
	Ageusia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aphasia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ataxia	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Balance disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Brain oedema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebellar haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebral haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebral microhaemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebrovascular accident	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Disturbance in attention	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dizziness	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	20	14.8	9.8	21.8
		Unknown	18	6.4	2	11.1	3.1	32.8
	Dizziness postural	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysarthria	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysgeusia	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	29	21.5	15.4	29.1
		Unknown	18	6.4	3	16.7	5.8	39.2
	Dyskinesia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epilepsy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Facial paralysis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Haemorrhage intracranial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Headache	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	21	15.6	10.4	22.6
		Unknown	18	6.4	4	22.2	9.0	45.2
	Hemiplegia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperaesthesia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Hypersomnia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoaesthesia	Asian	128	45.6	17	13.3	8.5	20.2
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypotonia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lethargy	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lumbar radiculopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lumbosacral radiculopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Memory impairment	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Migraine	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Migraine with aura	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Neuralgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Neuropathy peripheral	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Paraesthesia	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	2	11.1	3.1	32.8

	Paralysis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Parosmia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Peripheral sensory neuropathy	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Polyneuropathy chronic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Post herpetic neuralgia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Presyncope	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Psychomotor skills impaired	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Restless legs syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sciatica	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Seizure	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sensory disturbance	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Slow speech	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Somnolence	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Spinal cord haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Syncope	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6

	Tension headache	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tremor	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Visual field defect	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Product issues	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Device dislocation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Psychiatric disorders	-Total	Asian	128	45.6	27	21.1	14.9	29.0
		Non-Asian	135	48.0	25	18.5	12.9	25.9
		Unknown	18	6.4	4	22.2	9.0	45.2
	Abnormal behaviour	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abnormal dreams	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Adjustment disorder with mixed anxiety and depressed mood	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anxiety	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bradyphrenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Confusional state	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Delirium	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Depressed mood	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Depression	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Fear of falling	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Insomnia	Asian	128	45.6	17	13.3	8.5	20.2
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Irritability	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Libido decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mental status changes	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mood altered	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Psychomotor retardation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Restlessness	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sleep disorder	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Renal and urinary disorders	-Total	Asian	128	45.6	17	13.3	8.5	20.2
		Non-Asian	135	48.0	25	18.5	12.9	25.9
		Unknown	18	6.4	1	5.6	1.0	25.8
	Acute kidney injury	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Azotaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis haemorrhagic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysuria	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematuria	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhage urinary tract	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Hydronephrosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Micturition urgency	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nephritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nephrolithiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nocturia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Obstructive nephropathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pollakiuria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Proteinuria	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal colic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal impairment	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Strangury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urethral stenosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary incontinence	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Urinary retention	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Urinary tract pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urine flow decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Reproductive system and breast disorders	-Total	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	3	16.7	5.8	39.2
	Benign prostatic hyperplasia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Breast discharge	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Erectile dysfunction	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Galactorrhoea	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Genital ulceration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Metrorrhagia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Ovarian cyst	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pelvic discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pelvic fluid collection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Perineal pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Postmenopausal haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Prostatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Uterine polyp	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vaginal haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vulvovaginal dryness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vulvovaginal erythema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Respiratory, thoracic and mediastinal disorders	-Total	Asian	128	45.6	73	57.0	48.4	65.3
		Non-Asian	135	48.0	85	63.0	54.6	70.6
		Unknown	18	6.4	9	50.0	29.0	71.0
	Acute respiratory failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aspiration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bronchospasm	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Choking	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cough	Asian	128	45.6	30	23.4	16.9	31.5
		Non-Asian	135	48.0	31	23.0	16.7	30.7
		Unknown	18	6.4	4	22.2	9.0	45.2
	Dry throat	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysphonia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dyspnoea	Asian	128	45.6	19	14.8	9.7	22.0
		Non-Asian	135	48.0	25	18.5	12.9	25.9
		Unknown	18	6.4	3	16.7	5.8	39.2
	Dyspnoea exertional	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epistaxis	Asian	128	45.6	4	3.1	1.2	7.8

		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Haemoptysis	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hiccups	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoxia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Interstitial lung disease	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Laryngeal haemorrhage	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lung consolidation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal congestion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal dryness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal polyps	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oropharyngeal discomfort	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oropharyngeal pain	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	0	0.0	0.0	17.6
	Paranasal sinus discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pharyngeal disorder	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleural effusion	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pleural thickening	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2

		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleuritic pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonitis	Asian	128	45.6	14	10.9	6.6	17.5
		Non-Asian	135	48.0	16	11.9	7.4	18.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Pneumothorax	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Productive cough	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary embolism	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	Pulmonary hypertension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary mass	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiration abnormal	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory distress	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Respiratory failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinalgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinitis allergic	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinorrhoea	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinus congestion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Sleep apnoea syndrome	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sputum discoloured	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Throat irritation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Upper-airway cough syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Vocal cord leukoplakia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wheezing	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Skin and subcutaneous tissue disorders	-Total	Asian	128	45.6	42	32.8	25.3	41.3
		Non-Asian	135	48.0	50	37.0	29.4	45.4
		Unknown	18	6.4	8	44.4	24.6	66.3
	Acne	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alopecia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chloasma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Decubitus ulcer	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermal cyst	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermatitis acneiform	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dermatitis allergic	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Dermatitis bullous	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dry skin	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Ecchymosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eczema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Erythema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hair growth abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hair texture abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hirsutism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyperhidrosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyperkeratosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypertrichosis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Madarosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nail discolouration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nail disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Night sweats	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Onychalgia	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Onycholysis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Onychomadesis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain of skin	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Palmar-plantar erythrodysaesthesia syndrome	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Photosensitivity reaction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pruritus	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pruritus generalised	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Purpura	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rash	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Rash erythematous	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rash macular	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Rash maculo-papular	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rash papular	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Scab	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Scar pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin discolouration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin hyperpigmentation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin lesion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Swelling face	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Urticaria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Surgical and medical procedures	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Astringent therapy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eye excision	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hip arthroplasty	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Therapy cessation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Vascular disorders	-Total	Asian	128	45.6	54	42.2	34.0	50.8
		Non-Asian	135	48.0	54	40.0	32.1	48.4
		Unknown	18	6.4	7	38.9	20.3	61.4
	Aortic dissection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Circulatory collapse	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Deep vein thrombosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Embolism	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8

	Embolism venous	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Flushing	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematoma	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hot flush	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypertension	Asian	128	45.6	51	39.8	31.8	48.5
		Non-Asian	135	48.0	42	31.1	23.9	39.4
		Unknown	18	6.4	3	16.7	5.8	39.2
	Hypotension	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphoedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Orthostatic hypotension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Pallor	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Phlebitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Raynaud's phenomenon	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Shock haemorrhagic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Superior vena cava syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombophlebitis superficial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEANY_SG.xls
26MAR2021 14:05

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Female	152	54.1	101	66.4	58.6	73.5
		Male	129	45.9	68	52.7	44.1	61.1
	Anaemia	Female	152	54.1	81	53.3	45.4	61.0
		Male	129	45.9	48	37.2	29.4	45.8
	Anaemia macrocytic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Aplastic anaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bone marrow oedema	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cytopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Disseminated intravascular coagulation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Febrile neutropenia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Haemorrhagic anaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperfibrinogenaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Leukocytosis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Leukopenia	Female	152	54.1	19	12.5	8.2	18.7
		Male	129	45.9	11	8.5	4.8	14.6
	Lymph node pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lymphadenopathy	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Lymphopenia	Female	152	54.1	15	9.9	6.1	15.6
		Male	129	45.9	8	6.2	3.2	11.8
	Neutropenia	Female	152	54.1	40	26.3	20.0	33.8
		Male	129	45.9	21	16.3	10.9	23.6
	Neutrophilia	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Pancytopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Thrombocytopenia	Female	152	54.1	17	11.2	7.1	17.2
		Male	129	45.9	7	5.4	2.7	10.8
	Thrombocytosis	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	0	0.0	0.0	2.9
Cardiac disorders	-Total	Female	152	54.1	18	11.8	7.6	17.9
		Male	129	45.9	21	16.3	10.9	23.6
	Acute coronary syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Acute myocardial infarction	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Angina pectoris	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Aortic valve calcification	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Atrial fibrillation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Atrial flutter	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Bradycardia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Bundle branch block right	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cardiac failure	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cardio-respiratory arrest	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Extrasystoles	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Myocardial ischaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Nodal arrhythmia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Palpitations	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Pericardial effusion	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Sinus bradycardia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5

	Sinus tachycardia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Stress cardiomyopathy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Supraventricular tachycardia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tachycardia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Ventricular extrasystoles	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Ventricular pre-excitation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Congenital, familial and genetic disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Gilbert's syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hydrocele	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Ear and labyrinth disorders	-Total	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	10	7.8	4.3	13.7
	Ear congestion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Ear discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Ear pain	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Tinnitus	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Vertigo	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	4	3.1	1.2	7.7
Endocrine disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Adrenal insufficiency	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hyperthyroidism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypothyroidism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Eye disorders	-Total	Female	152	54.1	30	19.7	14.2	26.8
		Male	129	45.9	10	7.8	4.3	13.7

	Abnormal sensation in eye	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blepharitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cataract	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Chalazion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Conjunctival cyst	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Conjunctival haemorrhage	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Diplopia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dry eye	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Eye swelling	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Eyelid oedema	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	0	0.0	0.0	2.9
	Eyelid ptosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Keratitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Ocular discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Periorbital oedema	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Photophobia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Photopsia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Ulcerative keratitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vision blurred	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	1	0.8	0.1	4.3
	Visual acuity reduced	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Gastrointestinal disorders	-Total	Female	152	54.1	119	78.3	71.1	84.1
		Male	129	45.9	85	65.9	57.4	73.5
	Abdominal discomfort	Female	152	54.1	2	1.3	0.4	4.7

		Male	129	45.9	3	2.3	0.8	6.6
	Abdominal distension	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	2	1.6	0.4	5.5
	Abdominal pain	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	5	3.9	1.7	8.8
	Abdominal pain lower	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Abdominal pain upper	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	8	6.2	3.2	11.8
	Abdominal symptom	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Anal incontinence	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Aphthous ulcer	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Ascites	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Constipation	Female	152	54.1	71	46.7	39.0	54.6
		Male	129	45.9	47	36.4	28.6	45.0
	Dental caries	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dental dysaesthesia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Diarrhoea	Female	152	54.1	42	27.6	21.1	35.2
		Male	129	45.9	28	21.7	15.5	29.6
	Diverticular perforation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dry mouth	Female	152	54.1	28	18.4	13.1	25.3
		Male	129	45.9	19	14.7	9.6	21.9
	Dyspepsia	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	3	2.3	0.8	6.6
	Dysphagia	Female	152	54.1	15	9.9	6.1	15.6
		Male	129	45.9	5	3.9	1.7	8.8
	Enteritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Epigastric discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Eructation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Faeces soft	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Flatulence	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Frequent bowel movements	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastric ulcer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastritis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastritis erosive	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrointestinal haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Gastrointestinal inflammation	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrointestinal oedema	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gastrointestinal wall thickening	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrooesophageal reflux disease	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	4	3.1	1.2	7.7
	Gingival bleeding	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Gingival swelling	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Glossitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Glossodynia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haematochezia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Haemorrhoids	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hypoaesthesia oral	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Impaired gastric emptying	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Intestinal obstruction	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Irritable bowel syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Large intestine perforation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Melaena	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Mouth ulceration	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	3	2.3	0.8	6.6
	Nausea	Female	152	54.1	31	20.4	14.8	27.5
		Male	129	45.9	11	8.5	4.8	14.6
	Odynophagia	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	0	0.0	0.0	2.9
	Oesophageal irritation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oesophagitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Oral disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Oral dysaesthesia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oral mucosal erythema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Oral pain	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	1	0.8	0.1	4.3
	Pancreatitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pancreatitis acute	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Paraesthesia oral	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Proctitis ulcerative	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rectal prolapse	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Regurgitation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Sensitivity of teeth	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Stomatitis	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	4	3.1	1.2	7.7
	Swollen tongue	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Tongue coated	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tongue discomfort	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tongue ulceration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tooth discolouration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Toothache	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	5	3.9	1.7	8.8
	Vomiting	Female	152	54.1	22	14.5	9.8	20.9
		Male	129	45.9	10	7.8	4.3	13.7
General disorders and administration site conditions	-Total	Female	152	54.1	113	74.3	66.9	80.6
		Male	129	45.9	84	65.1	56.6	72.8
	Asthenia	Female	152	54.1	25	16.4	11.4	23.2
		Male	129	45.9	14	10.9	6.6	17.4
	Axillary pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Catheter site pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Chest discomfort	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	3	2.3	0.8	6.6
	Chest pain	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	6	4.7	2.1	9.8
	Chills	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Condition aggravated	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Death	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Face oedema	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	5	3.9	1.7	8.8
	Facial pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Fatigue	Female	152	54.1	34	22.4	16.5	29.6
		Male	129	45.9	33	25.6	18.8	33.7
	Feeling abnormal	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Feeling cold	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Feeling hot	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gait disturbance	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	General physical health deterioration	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Generalised oedema	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Impaired healing	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Influenza like illness	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Injection site bruising	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Localised oedema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Malaise	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	9	7.0	3.7	12.7
	Mucosal dryness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Mucosal inflammation	Female	152	54.1	18	11.8	7.6	17.9
		Male	129	45.9	3	2.3	0.8	6.6
	Multiple organ dysfunction syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Non-cardiac chest pain	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	4	3.1	1.2	7.7
	Oedema	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Oedema peripheral	Female	152	54.1	26	17.1	11.9	23.9
		Male	129	45.9	16	12.4	7.8	19.2
	Pain	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Peripheral swelling	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Pyrexia	Female	152	54.1	42	27.6	21.1	35.2
		Male	129	45.9	30	23.3	16.8	31.3
	Swelling	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Temperature intolerance	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6

	Xerosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Hepatobiliary disorders	-Total	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	16	12.4	7.8	19.2
	Cholecystitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cholelithiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gallbladder polyp	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hepatic function abnormal	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hepatic steatosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hepatocellular injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Hyperbilirubinaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	6	4.7	2.1	9.8
	Liver disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Liver injury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pneumobilia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Portal vein thrombosis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
Immune system disorders	-Total	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Contrast media allergy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Drug hypersensitivity	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Food allergy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypersensitivity	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Seasonal allergy	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
Infections and infestations	-Total	Female	152	54.1	87	57.2	49.3	64.8
		Male	129	45.9	70	54.3	45.7	62.6
	Abdominal abscess	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Acute sinusitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Appendicitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Arthritis infective	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Atypical pneumonia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bacteraemia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Bacterial disease carrier	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Bacterial infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bacterial vaginosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bronchitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	Candida infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cellulitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Chronic sinusitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Clostridium difficile colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Conjunctivitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Corona virus infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Cystitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Cystitis escherichia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Device related infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Diverticulitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Ear infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Empyema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Enterococcal bacteraemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Epididymitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Epstein-Barr virus infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Escherichia bacteraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Escherichia infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Escherichia urinary tract infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Eye infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Febrile infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Folliculitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Fungal infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Gastroenteritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Genital candidiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Genital herpes	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Gingivitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Herpes simplex	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Herpes virus infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Herpes zoster	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	4	3.1	1.2	7.7
	Infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Infectious colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Influenza	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lower respiratory tract infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Lung infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Lyme disease	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lymph node tuberculosis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Meningitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nasal herpes	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nasopharyngitis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	5	3.9	1.7	8.8
	Oral candidiasis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	5	3.9	1.7	8.8
	Oral fungal infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Oropharyngeal candidiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Otitis externa	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Otitis media	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Paronychia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Peritonitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pharyngitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Pleural infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumocystis jirovecii pneumonia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Pneumonia	Female	152	54.1	22	14.5	9.8	20.9
		Male	129	45.9	22	17.1	11.5	24.5
	Pneumonia bacterial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonia cytomegaloviral	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Pneumonia haemophilus	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonia influenzal	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonia pseudomonal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pneumonia streptococcal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pyelonephritis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Pyelonephritis acute	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pyuria	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rectal abscess	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Renal tuberculosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Respiratory tract infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Respiratory tract infection bacterial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rhinitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Sepsis	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	4	3.1	1.2	7.7
	Septic shock	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sinusitis	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	1	0.8	0.1	4.3
	Sinusitis bacterial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Skin infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Staphylococcal infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Systemic infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tinea cruris	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Tinea infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tinea pedis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Tonsillitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tooth infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tracheitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tuberculosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Upper respiratory tract infection	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	4	3.1	1.2	7.7
	Urethritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urinary tract infection	Female	152	54.1	26	17.1	11.9	23.9
		Male	129	45.9	12	9.3	5.4	15.6
	Urosepsis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Varicella	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Varicella zoster virus infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Viral hepatitis carrier	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Viral infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Vulvovaginal candidiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Injury, poisoning and procedural complications	-Total	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	15	11.6	7.2	18.3
	Contusion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	4	3.1	1.2	7.7
	Epicondylitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Fall	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	6	4.7	2.1	9.8
	Fracture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Heart injury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Incision site pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Joint dislocation	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Laceration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ligament sprain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Limb injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Muscle rupture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Muscle strain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Procedural pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Procedural pneumothorax	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rib fracture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Scar	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin abrasion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Subdural haematoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tendon rupture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Thermal burn	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Wound	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Wound complication	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Wrist fracture	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
Investigations	-Total	Female	152	54.1	127	83.6	76.8	88.6
		Male	129	45.9	96	74.4	66.3	81.2
	Alanine aminotransferase	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Alanine aminotransferase increased	Female	152	54.1	57	37.5	30.2	45.4
		Male	129	45.9	35	27.1	20.2	35.4
	Albumin urine present	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Alpha hydroxybutyrate dehydrogenase increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Amylase increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Aspartate aminotransferase increased	Female	152	54.1	73	48.0	40.2	55.9
		Male	129	45.9	53	41.1	33.0	49.7
	Bacterial test	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bilirubin conjugated increased	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	7	5.4	2.7	10.8
	Blood albumin decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood alkaline phosphatase	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood alkaline phosphatase decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood alkaline phosphatase increased	Female	152	54.1	22	14.5	9.8	20.9
		Male	129	45.9	13	10.1	6.0	16.5
	Blood bilirubin increased	Female	152	54.1	18	11.8	7.6	17.9
		Male	129	45.9	9	7.0	3.7	12.7
	Blood bilirubin unconjugated increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	5	3.9	1.7	8.8
	Blood calcium decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Blood calcium increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood chloride increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood cholesterol increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	4	3.1	1.2	7.7
	Blood creatine increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3

	Blood creatine phosphokinase MB increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Blood creatine phosphokinase increased	Female	152	54.1	33	21.7	15.9	28.9
		Male	129	45.9	20	15.5	10.3	22.7
	Blood creatinine	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood creatinine increased	Female	152	54.1	27	17.8	12.5	24.6
		Male	129	45.9	35	27.1	20.2	35.4
	Blood fibrinogen increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood glucose increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Blood iron decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood ketone body increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood lactate dehydrogenase increased	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	3	2.3	0.8	6.6
	Blood magnesium decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood phosphorus increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Blood potassium decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood potassium increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood pressure increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Blood sodium decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Blood thyroid stimulating hormone increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood triglycerides increased	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Blood urea increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Blood uric acid decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood uric acid increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6

	Blood urine	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Blood urine present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	C-reactive protein increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Carbon dioxide decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Complement factor C1 decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Computerised tomogram thorax abnormal	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Crystal urine present	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cystatin C increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Electrocardiogram QT prolonged	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	2	1.6	0.4	5.5
	Electrocardiogram ST-T change	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Fibrin D dimer increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Fibrin degradation products increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Free fatty acids increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gamma-glutamyltransferase increased	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	7	5.4	2.7	10.8
	Glomerular filtration rate decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Glutamate dehydrogenase increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Granulocyte count decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haematocrit decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haemoglobin decreased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Heart rate increased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hepatic enzyme increased	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	2	1.6	0.4	5.5
	International normalised ratio increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Intraocular pressure increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Laboratory test abnormal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lipase increased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Liver function test increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Lymphocyte count decreased	Female	152	54.1	15	9.9	6.1	15.6
		Male	129	45.9	12	9.3	5.4	15.6
	Lymphocyte count increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Mean cell volume increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Myoglobin blood increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Neutrophil count decreased	Female	152	54.1	54	35.5	28.4	43.4
		Male	129	45.9	27	20.9	14.8	28.7
	Neutrophil count increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Neutrophil percentage increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Occult blood positive	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Oxygen saturation decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	PO2 decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Platelet count decreased	Female	152	54.1	25	16.4	11.4	23.2
		Male	129	45.9	8	6.2	3.2	11.8
	Platelet count increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Procalcitonin increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Protein total decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Protein total increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Protein urine present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Prothrombin time prolonged	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Red blood cell count decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Serum amyloid A protein increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombin time prolonged	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Total bile acids increased	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	4	3.1	1.2	7.7
	Transaminases increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	4	3.1	1.2	7.7
	Transferrin increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Troponin T increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Troponin increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Urinary sediment present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urine ketone body present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Urine leukocyte esterase positive	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urobilinogen urine increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Weight decreased	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	4	3.1	1.2	7.7
	Weight increased	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	10	7.8	4.3	13.7
	White blood cell count decreased	Female	152	54.1	46	30.3	23.5	38.0
		Male	129	45.9	26	20.2	14.1	27.9
	White blood cells urine positive	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
Metabolism and nutrition disorders	-Total	Female	152	54.1	88	57.9	49.9	65.5
		Male	129	45.9	59	45.7	37.4	54.3
	Abnormal loss of weight	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Acidosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Alkalosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cell death	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Decreased appetite	Female	152	54.1	20	13.2	8.7	19.5
		Male	129	45.9	18	14.0	9.0	21.0
	Dehydration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	5	3.9	1.7	8.8
	Electrolyte imbalance	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Failure to thrive	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Fluid retention	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypercalcaemia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hypercholesterolaemia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Hyperglycaemia	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	7	5.4	2.7	10.8
	Hyperkalaemia	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	8	6.2	3.2	11.8
	Hyperlipidaemia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hypermagnesaemia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hypernatraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hyperphosphataemia	Female	152	54.1	23	15.1	10.3	21.7
		Male	129	45.9	9	7.0	3.7	12.7
	Hypertriglyceridaemia	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Hyperuricaemia	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	5	3.9	1.7	8.8
	Hypoalbuminaemia	Female	152	54.1	25	16.4	11.4	23.2
		Male	129	45.9	12	9.3	5.4	15.6
	Hypocalcaemia	Female	152	54.1	23	15.1	10.3	21.7
		Male	129	45.9	11	8.5	4.8	14.6
	Hypochloraemia	Female	152	54.1	3	2.0	0.7	5.6

		Male	129	45.9	2	1.6	0.4	5.5
	Hypoglycaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypokalaemia	Female	152	54.1	25	16.4	11.4	23.2
		Male	129	45.9	13	10.1	6.0	16.5
	Hypomagnesaemia	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	8	6.2	3.2	11.8
	Hyponatraemia	Female	152	54.1	15	9.9	6.1	15.6
		Male	129	45.9	15	11.6	7.2	18.3
	Hypophosphataemia	Female	152	54.1	21	13.8	9.2	20.2
		Male	129	45.9	14	10.9	6.6	17.4
	Hypoproteinaemia	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	1	0.8	0.1	4.3
	Increased appetite	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Vitamin D deficiency	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Musculoskeletal and connective tissue disorders	-Total	Female	152	54.1	70	46.1	38.3	54.0
		Male	129	45.9	54	41.9	33.7	50.5
	Arthralgia	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	6	4.7	2.1	9.8
	Arthropathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Back pain	Female	152	54.1	19	12.5	8.2	18.7
		Male	129	45.9	19	14.7	9.6	21.9
	Bone pain	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Bursitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Coccydynia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Costochondritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Flank pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Groin pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypercreatinaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Intervertebral disc protrusion	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	4	3.1	1.2	7.7

	Joint range of motion decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Joint stiffness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Joint swelling	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Muscle fatigue	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Muscle haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Muscle spasms	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	8	6.2	3.2	11.8
	Muscular weakness	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	4	3.1	1.2	7.7
	Musculoskeletal chest pain	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	5	3.9	1.7	8.8
	Musculoskeletal pain	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	11	8.5	4.8	14.6
	Musculoskeletal stiffness	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Myalgia	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	7	5.4	2.7	10.8
	Myopathy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Neck pain	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	5	3.9	1.7	8.8
	Osteopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pain in extremity	Female	152	54.1	18	11.8	7.6	17.9
		Male	129	45.9	8	6.2	3.2	11.8
	Pain in jaw	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Rhabdomyolysis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rotator cuff syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Spinal column stenosis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Spinal osteoarthritis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Tendon disorder	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tendon pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	5	3.9	1.7	8.8
	Anogenital warts	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Basal cell carcinoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Bowen's disease	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cancer pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gallbladder cancer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Metastases to central nervous system	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Renal cell carcinoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Squamous cell carcinoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Squamous cell carcinoma of skin	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tumour pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Nervous system disorders	-Total	Female	152	54.1	80	52.6	44.7	60.4
		Male	129	45.9	65	50.4	41.9	58.9
	Ageusia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Aphasia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Ataxia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Balance disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Brain oedema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cerebellar haemorrhage	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cerebral haematoma	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Cerebral microhaemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cerebrovascular accident	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Disturbance in attention	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Dizziness	Female	152	54.1	20	13.2	8.7	19.5
		Male	129	45.9	18	14.0	9.0	21.0
	Dizziness postural	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dysarthria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dysgeusia	Female	152	54.1	24	15.8	10.8	22.4
		Male	129	45.9	18	14.0	9.0	21.0
	Dyskinesia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Epilepsy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Facial paralysis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Haemorrhage intracranial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Headache	Female	152	54.1	17	11.2	7.1	17.2
		Male	129	45.9	17	13.2	8.4	20.1
	Hemiplegia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperaesthesia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypersomnia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypoaesthesia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	6	4.7	2.1	9.8
	Hypotonia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lethargy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lumbar radiculopathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lumbosacral radiculopathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Memory impairment	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Migraine	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Migraine with aura	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neuralgia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Neuropathy peripheral	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	5	3.9	1.7	8.8
	Paraesthesia	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	6	4.7	2.1	9.8
	Paralysis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Parosmia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Peripheral sensory neuropathy	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	3	2.3	0.8	6.6
	Polyneuropathy chronic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Post herpetic neuralgia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Presyncope	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Psychomotor skills impaired	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Restless legs syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Sciatica	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Seizure	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Sensory disturbance	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Slow speech	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Somnolence	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Spinal cord haematoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Syncope	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	Tension headache	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tremor	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Visual field defect	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
Product issues	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Device dislocation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Psychiatric disorders	-Total	Female	152	54.1	30	19.7	14.2	26.8
		Male	129	45.9	26	20.2	14.1	27.9
	Abnormal behaviour	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Abnormal dreams	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Adjustment disorder with mixed anxiety and depressed mood	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Anxiety	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	4	3.1	1.2	7.7
	Bradyphrenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Confusional state	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	4	3.1	1.2	7.7
	Delirium	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Depressed mood	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Depression	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Fear of falling	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Insomnia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	8	6.2	3.2	11.8
	Irritability	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Libido decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Mental status changes	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	3	2.3	0.8	6.6
	Mood altered	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Psychomotor retardation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Restlessness	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Sleep disorder	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Renal and urinary disorders	-Total	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	27	20.9	14.8	28.7
	Acute kidney injury	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	5	3.9	1.7	8.8
	Azotaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cystitis haemorrhagic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dysuria	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	6	4.7	2.1	9.8
	Haematuria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	4	3.1	1.2	7.7
	Haemorrhage urinary tract	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hydronephrosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Micturition urgency	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Nephritis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Nephrolithiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nocturia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Obstructive nephropathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pollakiuria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Proteinuria	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Renal colic	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Renal disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Renal failure	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Renal impairment	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Strangury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urethral stenosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urinary incontinence	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Urinary retention	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	5	3.9	1.7	8.8
	Urinary tract pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urine flow decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Reproductive system and breast disorders	-Total	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	14	10.9	6.6	17.4
	Benign prostatic hyperplasia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Breast discharge	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Erectile dysfunction	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	9	7.0	3.7	12.7
	Galactorrhoea	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Genital ulceration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Metrorrhagia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Ovarian cyst	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pelvic discomfort	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pelvic fluid collection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Perineal pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Postmenopausal haemorrhage	Female	152	54.1	1	0.7		0.1	3.6
		Male	129	45.9	0	0.0		0.0	2.9
	Prostatitis	Female	152	54.1	0	0.0		0.0	2.5
		Male	129	45.9	2	1.6		0.4	5.5
	Uterine polyp	Female	152	54.1	1	0.7		0.1	3.6
		Male	129	45.9	0	0.0		0.0	2.9
	Vaginal haemorrhage	Female	152	54.1	1	0.7		0.1	3.6
		Male	129	45.9	0	0.0		0.0	2.9
	Vulvovaginal dryness	Female	152	54.1	1	0.7		0.1	3.6
		Male	129	45.9	0	0.0		0.0	2.9
	Vulvovaginal erythema	Female	152	54.1	1	0.7		0.1	3.6
		Male	129	45.9	0	0.0		0.0	2.9
Respiratory, thoracic and mediastinal disorders	-Total	Female	152	54.1	91	59.9		51.9	67.3
		Male	129	45.9	76	58.9		50.3	67.0
	Acute respiratory failure	Female	152	54.1	1	0.7		0.1	3.6
		Male	129	45.9	0	0.0		0.0	2.9
	Aspiration	Female	152	54.1	0	0.0		0.0	2.5
		Male	129	45.9	1	0.8		0.1	4.3
	Bronchospasm	Female	152	54.1	1	0.7		0.1	3.6
		Male	129	45.9	0	0.0		0.0	2.9
	Choking	Female	152	54.1	0	0.0		0.0	2.5
		Male	129	45.9	1	0.8		0.1	4.3
	Cough	Female	152	54.1	35	23.0		17.0	30.3
		Male	129	45.9	30	23.3		16.8	31.3
	Dry throat	Female	152	54.1	1	0.7		0.1	3.6
		Male	129	45.9	1	0.8		0.1	4.3
	Dysphonia	Female	152	54.1	7	4.6		2.2	9.2
		Male	129	45.9	5	3.9		1.7	8.8
	Dyspnoea	Female	152	54.1	26	17.1		11.9	23.9
		Male	129	45.9	21	16.3		10.9	23.6
	Dyspnoea exertional	Female	152	54.1	4	2.6		1.0	6.6
		Male	129	45.9	8	6.2		3.2	11.8
	Epistaxis	Female	152	54.1	8	5.3		2.7	10.0
		Male	129	45.9	6	4.7		2.1	9.8
	Haemoptysis	Female	152	54.1	6	3.9		1.8	8.3
		Male	129	45.9	5	3.9		1.7	8.8
	Hiccups	Female	152	54.1	1	0.7		0.1	3.6
		Male	129	45.9	1	0.8		0.1	4.3
	Hypoxia	Female	152	54.1	1	0.7		0.1	3.6
		Male	129	45.9	4	3.1		1.2	7.7
	Interstitial lung disease	Female	152	54.1	2	1.3		0.4	4.7

		Male	129	45.9	2	1.6	0.4	5.5
	Laryngeal haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lung consolidation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nasal congestion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Nasal dryness	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Nasal polyps	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oropharyngeal discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oropharyngeal pain	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	5	3.9	1.7	8.8
	Paranasal sinus discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pharyngeal disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pleural effusion	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	4	3.1	1.2	7.7
	Pleural thickening	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pleuritic pain	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonitis	Female	152	54.1	20	13.2	8.7	19.5
		Male	129	45.9	12	9.3	5.4	15.6
	Pneumothorax	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Productive cough	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	7	5.4	2.7	10.8
	Pulmonary embolism	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	7	5.4	2.7	10.8
	Pulmonary hypertension	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pulmonary mass	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pulmonary pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Respiration abnormal	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Respiratory distress	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Respiratory failure	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rhinalgia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rhinitis allergic	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Rhinorrhoea	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Sinus congestion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sleep apnoea syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Sputum discoloured	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Throat irritation	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Upper-airway cough syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Vocal cord leukoplakia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Wheezing	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
Skin and subcutaneous tissue disorders	-Total	Female	152	54.1	63	41.4	33.9	49.4
		Male	129	45.9	37	28.7	21.6	37.0
	Acne	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Alopecia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	2	1.6	0.4	5.5
	Chloasma	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Decubitus ulcer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dermal cyst	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dermatitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dermatitis acneiform	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6

	Dermatitis allergic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dermatitis bullous	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Dry skin	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	6	4.7	2.1	9.8
	Ecchymosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Eczema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Erythema	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Hair growth abnormal	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hair texture abnormal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hirsutism	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Hyperhidrosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Hyperkeratosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypertrichosis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Madarosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nail discolouration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nail disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Night sweats	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Onychalgia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Onycholysis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Onychomadesis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Pain of skin	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Palmar-plantar erythrodysaesthesia syndrome	Female	152	54.1	5	3.3	1.4	7.5

		Male	129	45.9	0	0.0	0.0	2.9
	Photosensitivity reaction	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pruritus	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	Pruritus generalised	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Purpura	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rash	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	7	5.4	2.7	10.8
	Rash erythematous	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Rash macular	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Rash maculo-papular	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Rash papular	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Scab	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Scar pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin discolouration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin hyperpigmentation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Skin lesion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Swelling face	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urticaria	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Surgical and medical procedures	-Total	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Astringent therapy	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Eye excision	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hip arthroplasty	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Therapy cessation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Vascular disorders	-Total	Female	152	54.1	63	41.4	33.9	49.4
		Male	129	45.9	52	40.3	32.2	48.9
	Aortic dissection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Circulatory collapse	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Deep vein thrombosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Embolism	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Embolism venous	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Flushing	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Haematoma	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Hot flush	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hypertension	Female	152	54.1	51	33.6	26.5	41.4
		Male	129	45.9	45	34.9	27.2	43.4
	Hypotension	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Lymphoedema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Orthostatic hypotension	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Pallor	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Phlebitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Raynaud's phenomenon	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Shock haemorrhagic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Superior vena cava syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombophlebitis superficial	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Thrombosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEANY_SG.xls
26MAR2021 14:05

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	n/a	281	100.0	169	60.1	54.3	65.7
	Anaemia	n/a	281	100.0	129	45.9	40.2	51.7
	Anaemia macrocytic	n/a	281	100.0	1	0.4	0.1	2.0
	Aplastic anaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Bone marrow oedema	n/a	281	100.0	1	0.4	0.1	2.0
	Cytopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Disseminated intravascular coagulation	n/a	281	100.0	2	0.7	0.2	2.6
	Febrile neutropenia	n/a	281	100.0	5	1.8	0.8	4.1
	Haemorrhagic anaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperfibrinogenaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Leukocytosis	n/a	281	100.0	3	1.1	0.4	3.1
	Leukopenia	n/a	281	100.0	30	10.7	7.6	14.8
	Lymph node pain	n/a	281	100.0	1	0.4	0.1	2.0
	Lymphadenopathy	n/a	281	100.0	2	0.7	0.2	2.6
	Lymphopenia	n/a	281	100.0	23	8.2	5.5	12.0
	Neutropenia	n/a	281	100.0	61	21.7	17.3	26.9
	Neutrophilia	n/a	281	100.0	1	0.4	0.1	2.0
	Pancytopenia	n/a	281	100.0	3	1.1	0.4	3.1
	Thrombocytopenia	n/a	281	100.0	24	8.5	5.8	12.4
	Thrombocytosis	n/a	281	100.0	5	1.8	0.8	4.1
Cardiac disorders	-Total	n/a	281	100.0	39	13.9	10.3	18.4
	Acute coronary syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Acute myocardial infarction	n/a	281	100.0	2	0.7	0.2	2.6
	Angina pectoris	n/a	281	100.0	1	0.4	0.1	2.0
	Aortic valve calcification	n/a	281	100.0	1	0.4	0.1	2.0

	Atrial fibrillation	n/a	281	100.0	1	0.4	0.1	2.0
	Atrial flutter	n/a	281	100.0	2	0.7	0.2	2.6
	Bradycardia	n/a	281	100.0	1	0.4	0.1	2.0
	Bundle branch block right	n/a	281	100.0	1	0.4	0.1	2.0
	Cardiac failure	n/a	281	100.0	2	0.7	0.2	2.6
	Cardio-respiratory arrest	n/a	281	100.0	1	0.4	0.1	2.0
	Extrasystoles	n/a	281	100.0	1	0.4	0.1	2.0
	Myocardial ischaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Nodal arrhythmia	n/a	281	100.0	3	1.1	0.4	3.1
	Palpitations	n/a	281	100.0	4	1.4	0.6	3.6
	Pericardial effusion	n/a	281	100.0	5	1.8	0.8	4.1
	Sinus bradycardia	n/a	281	100.0	4	1.4	0.6	3.6
	Sinus tachycardia	n/a	281	100.0	2	0.7	0.2	2.6
	Stress cardiomyopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Supraventricular tachycardia	n/a	281	100.0	1	0.4	0.1	2.0
	Tachycardia	n/a	281	100.0	7	2.5	1.2	5.1
	Ventricular extrasystoles	n/a	281	100.0	1	0.4	0.1	2.0
	Ventricular pre-excitation	n/a	281	100.0	1	0.4	0.1	2.0
Congenital, familial and genetic disorders	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Gilbert's syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Hydrocele	n/a	281	100.0	1	0.4	0.1	2.0
Ear and labyrinth disorders	-Total	n/a	281	100.0	21	7.5	4.9	11.2
	Ear congestion	n/a	281	100.0	2	0.7	0.2	2.6
	Ear discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Ear pain	n/a	281	100.0	4	1.4	0.6	3.6
	Tinnitus	n/a	281	100.0	4	1.4	0.6	3.6
	Vertigo	n/a	281	100.0	11	3.9	2.2	6.9
Endocrine disorders	-Total	n/a	281	100.0	4	1.4	0.6	3.6
	Adrenal insufficiency	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperthyroidism	n/a	281	100.0	1	0.4	0.1	2.0

	Hypothyroidism	n/a	281	100.0	2	0.7	0.2	2.6
Eye disorders	-Total	n/a	281	100.0	40	14.2	10.6	18.8
	Abnormal sensation in eye	n/a	281	100.0	1	0.4	0.1	2.0
	Blepharitis	n/a	281	100.0	1	0.4	0.1	2.0
	Cataract	n/a	281	100.0	2	0.7	0.2	2.6
	Chalazion	n/a	281	100.0	1	0.4	0.1	2.0
	Conjunctival cyst	n/a	281	100.0	1	0.4	0.1	2.0
	Conjunctival haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Diplopia	n/a	281	100.0	1	0.4	0.1	2.0
	Dry eye	n/a	281	100.0	7	2.5	1.2	5.1
	Eye swelling	n/a	281	100.0	2	0.7	0.2	2.6
	Eyelid oedema	n/a	281	100.0	5	1.8	0.8	4.1
	Eyelid ptosis	n/a	281	100.0	1	0.4	0.1	2.0
	Keratitis	n/a	281	100.0	2	0.7	0.2	2.6
	Ocular discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Periorbital oedema	n/a	281	100.0	6	2.1	1.0	4.6
	Photophobia	n/a	281	100.0	1	0.4	0.1	2.0
	Photopsia	n/a	281	100.0	2	0.7	0.2	2.6
	Ulcerative keratitis	n/a	281	100.0	1	0.4	0.1	2.0
	Vision blurred	n/a	281	100.0	14	5.0	3.0	8.2
	Visual acuity reduced	n/a	281	100.0	1	0.4	0.1	2.0
Gastrointestinal disorders	-Total	n/a	281	100.0	204	72.6	67.1	77.5
	Abdominal discomfort	n/a	281	100.0	5	1.8	0.8	4.1
	Abdominal distension	n/a	281	100.0	8	2.8	1.4	5.5
	Abdominal pain	n/a	281	100.0	18	6.4	4.1	9.9
	Abdominal pain lower	n/a	281	100.0	2	0.7	0.2	2.6
	Abdominal pain upper	n/a	281	100.0	15	5.3	3.3	8.6
	Abdominal symptom	n/a	281	100.0	1	0.4	0.1	2.0
	Anal incontinence	n/a	281	100.0	2	0.7	0.2	2.6
	Aphthous ulcer	n/a	281	100.0	2	0.7	0.2	2.6
	Ascites	n/a	281	100.0	4	1.4	0.6	3.6

	Colitis	n/a	281	100.0	3	1.1	0.4	3.1
	Constipation	n/a	281	100.0	118	42.0	36.4	47.8
	Dental caries	n/a	281	100.0	1	0.4	0.1	2.0
	Dental dysaesthesia	n/a	281	100.0	1	0.4	0.1	2.0
	Diarrhoea	n/a	281	100.0	70	24.9	20.2	30.3
	Diverticular perforation	n/a	281	100.0	1	0.4	0.1	2.0
	Dry mouth	n/a	281	100.0	47	16.7	12.8	21.5
	Dyspepsia	n/a	281	100.0	9	3.2	1.7	6.0
	Dysphagia	n/a	281	100.0	20	7.1	4.7	10.7
	Enteritis	n/a	281	100.0	1	0.4	0.1	2.0
	Epigastric discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Eructation	n/a	281	100.0	1	0.4	0.1	2.0
	Faeces soft	n/a	281	100.0	1	0.4	0.1	2.0
	Flatulence	n/a	281	100.0	2	0.7	0.2	2.6
	Frequent bowel movements	n/a	281	100.0	1	0.4	0.1	2.0
	Gastric ulcer	n/a	281	100.0	1	0.4	0.1	2.0
	Gastritis	n/a	281	100.0	3	1.1	0.4	3.1
	Gastritis erosive	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal haemorrhage	n/a	281	100.0	2	0.7	0.2	2.6
	Gastrointestinal inflammation	n/a	281	100.0	2	0.7	0.2	2.6
	Gastrointestinal oedema	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal wall thickening	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrooesophageal reflux disease	n/a	281	100.0	9	3.2	1.7	6.0
	Gingival bleeding	n/a	281	100.0	3	1.1	0.4	3.1
	Gingival swelling	n/a	281	100.0	1	0.4	0.1	2.0
	Glossitis	n/a	281	100.0	1	0.4	0.1	2.0
	Glossodynia	n/a	281	100.0	1	0.4	0.1	2.0
	Haematochezia	n/a	281	100.0	2	0.7	0.2	2.6
	Haemorrhoids	n/a	281	100.0	7	2.5	1.2	5.1
	Hypoaesthesia oral	n/a	281	100.0	5	1.8	0.8	4.1

	Impaired gastric emptying	n/a	281	100.0	1	0.4	0.1	2.0
	Intestinal obstruction	n/a	281	100.0	1	0.4	0.1	2.0
	Irritable bowel syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Large intestine perforation	n/a	281	100.0	1	0.4	0.1	2.0
	Melaena	n/a	281	100.0	1	0.4	0.1	2.0
	Mouth ulceration	n/a	281	100.0	9	3.2	1.7	6.0
	Nausea	n/a	281	100.0	42	14.9	11.3	19.6
	Odynophagia	n/a	281	100.0	5	1.8	0.8	4.1
	Oesophageal irritation	n/a	281	100.0	1	0.4	0.1	2.0
	Oesophagitis	n/a	281	100.0	4	1.4	0.6	3.6
	Oral disorder	n/a	281	100.0	2	0.7	0.2	2.6
	Oral dysaesthesia	n/a	281	100.0	1	0.4	0.1	2.0
	Oral mucosal erythema	n/a	281	100.0	1	0.4	0.1	2.0
	Oral pain	n/a	281	100.0	7	2.5	1.2	5.1
	Pancreatitis	n/a	281	100.0	1	0.4	0.1	2.0
	Pancreatitis acute	n/a	281	100.0	2	0.7	0.2	2.6
	Paraesthesia oral	n/a	281	100.0	1	0.4	0.1	2.0
	Proctitis ulcerative	n/a	281	100.0	1	0.4	0.1	2.0
	Rectal prolapse	n/a	281	100.0	1	0.4	0.1	2.0
	Regurgitation	n/a	281	100.0	1	0.4	0.1	2.0
	Sensitivity of teeth	n/a	281	100.0	1	0.4	0.1	2.0
	Stomatitis	n/a	281	100.0	13	4.6	2.7	7.8
	Swollen tongue	n/a	281	100.0	1	0.4	0.1	2.0
	Tongue coated	n/a	281	100.0	1	0.4	0.1	2.0
	Tongue discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Tongue ulceration	n/a	281	100.0	1	0.4	0.1	2.0
	Tooth discolouration	n/a	281	100.0	1	0.4	0.1	2.0
	Toothache	n/a	281	100.0	8	2.8	1.4	5.5
	Vomiting	n/a	281	100.0	32	11.4	8.2	15.6
General disorders and administration site conditions	-Total	n/a	281	100.0	202	71.9	66.4	76.8
	Asthenia	n/a	281	100.0	39	13.9	10.3	18.4

	Axillary pain	n/a	281	100.0	1	0.4	0.1	2.0
	Catheter site pain	n/a	281	100.0	1	0.4	0.1	2.0
	Chest discomfort	n/a	281	100.0	10	3.6	1.9	6.4
	Chest pain	n/a	281	100.0	9	3.2	1.7	6.0
	Chills	n/a	281	100.0	4	1.4	0.6	3.6
	Condition aggravated	n/a	281	100.0	1	0.4	0.1	2.0
	Death	n/a	281	100.0	2	0.7	0.2	2.6
	Disease progression	n/a	281	100.0	23	8.2	5.5	12.0
	Face oedema	n/a	281	100.0	18	6.4	4.1	9.9
	Facial pain	n/a	281	100.0	1	0.4	0.1	2.0
	Fatigue	n/a	281	100.0	67	23.8	19.2	29.2
	Feeling abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Feeling cold	n/a	281	100.0	1	0.4	0.1	2.0
	Feeling hot	n/a	281	100.0	1	0.4	0.1	2.0
	Gait disturbance	n/a	281	100.0	7	2.5	1.2	5.1
	General physical health deterioration	n/a	281	100.0	5	1.8	0.8	4.1
	Generalised oedema	n/a	281	100.0	3	1.1	0.4	3.1
	Impaired healing	n/a	281	100.0	5	1.8	0.8	4.1
	Influenza like illness	n/a	281	100.0	3	1.1	0.4	3.1
	Injection site bruising	n/a	281	100.0	1	0.4	0.1	2.0
	Localised oedema	n/a	281	100.0	2	0.7	0.2	2.6
	Malaise	n/a	281	100.0	21	7.5	4.9	11.2
	Mucosal dryness	n/a	281	100.0	1	0.4	0.1	2.0
	Mucosal inflammation	n/a	281	100.0	21	7.5	4.9	11.2
	Multiple organ dysfunction syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Non-cardiac chest pain	n/a	281	100.0	12	4.3	2.5	7.3
	Oedema	n/a	281	100.0	4	1.4	0.6	3.6
	Oedema peripheral	n/a	281	100.0	42	14.9	11.3	19.6
	Pain	n/a	281	100.0	7	2.5	1.2	5.1
	Peripheral swelling	n/a	281	100.0	8	2.8	1.4	5.5

	Pyrexia	n/a	281	100.0	72	25.6	20.9	31.0
	Swelling	n/a	281	100.0	1	0.4	0.1	2.0
	Temperature intolerance	n/a	281	100.0	3	1.1	0.4	3.1
	Xerosis	n/a	281	100.0	1	0.4	0.1	2.0
Hepatobiliary disorders	-Total	n/a	281	100.0	26	9.3	6.4	13.2
	Cholecystitis	n/a	281	100.0	4	1.4	0.6	3.6
	Cholelithiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Gallbladder polyp	n/a	281	100.0	1	0.4	0.1	2.0
	Hepatic function abnormal	n/a	281	100.0	3	1.1	0.4	3.1
	Hepatic steatosis	n/a	281	100.0	1	0.4	0.1	2.0
	Hepatocellular injury	n/a	281	100.0	3	1.1	0.4	3.1
	Hyperbilirubinaemia	n/a	281	100.0	7	2.5	1.2	5.1
	Liver disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Liver injury	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumobilia	n/a	281	100.0	1	0.4	0.1	2.0
	Portal vein thrombosis	n/a	281	100.0	4	1.4	0.6	3.6
Immune system disorders	-Total	n/a	281	100.0	6	2.1	1.0	4.6
	Contrast media allergy	n/a	281	100.0	1	0.4	0.1	2.0
	Drug hypersensitivity	n/a	281	100.0	1	0.4	0.1	2.0
	Food allergy	n/a	281	100.0	1	0.4	0.1	2.0
	Hypersensitivity	n/a	281	100.0	1	0.4	0.1	2.0
	Seasonal allergy	n/a	281	100.0	2	0.7	0.2	2.6
Infections and infestations	-Total	n/a	281	100.0	157	55.9	50.0	61.6
	Abdominal abscess	n/a	281	100.0	1	0.4	0.1	2.0
	Acute sinusitis	n/a	281	100.0	1	0.4	0.1	2.0
	Appendicitis	n/a	281	100.0	2	0.7	0.2	2.6
	Arthritis infective	n/a	281	100.0	1	0.4	0.1	2.0
	Atypical pneumonia	n/a	281	100.0	1	0.4	0.1	2.0
	Bacteraemia	n/a	281	100.0	3	1.1	0.4	3.1
	Bacterial disease carrier	n/a	281	100.0	1	0.4	0.1	2.0
	Bacterial infection	n/a	281	100.0	1	0.4	0.1	2.0

	Bacterial vaginosis	n/a	281	100.0	1	0.4	0.1	2.0
	Bronchitis	n/a	281	100.0	7	2.5	1.2	5.1
	Candida infection	n/a	281	100.0	1	0.4	0.1	2.0
	Cellulitis	n/a	281	100.0	2	0.7	0.2	2.6
	Chronic sinusitis	n/a	281	100.0	3	1.1	0.4	3.1
	Clostridium difficile colitis	n/a	281	100.0	1	0.4	0.1	2.0
	Conjunctivitis	n/a	281	100.0	1	0.4	0.1	2.0
	Corona virus infection	n/a	281	100.0	2	0.7	0.2	2.6
	Cystitis	n/a	281	100.0	3	1.1	0.4	3.1
	Cystitis escherichia	n/a	281	100.0	1	0.4	0.1	2.0
	Device related infection	n/a	281	100.0	1	0.4	0.1	2.0
	Diverticulitis	n/a	281	100.0	2	0.7	0.2	2.6
	Ear infection	n/a	281	100.0	1	0.4	0.1	2.0
	Empyema	n/a	281	100.0	1	0.4	0.1	2.0
	Enterococcal bacteraemia	n/a	281	100.0	1	0.4	0.1	2.0
	Epididymitis	n/a	281	100.0	1	0.4	0.1	2.0
	Epstein-Barr virus infection	n/a	281	100.0	1	0.4	0.1	2.0
	Escherichia bacteraemia	n/a	281	100.0	1	0.4	0.1	2.0
	Escherichia infection	n/a	281	100.0	1	0.4	0.1	2.0
	Escherichia urinary tract infection	n/a	281	100.0	1	0.4	0.1	2.0
	Eye infection	n/a	281	100.0	1	0.4	0.1	2.0
	Febrile infection	n/a	281	100.0	1	0.4	0.1	2.0
	Folliculitis	n/a	281	100.0	3	1.1	0.4	3.1
	Fungal infection	n/a	281	100.0	3	1.1	0.4	3.1
	Gastroenteritis	n/a	281	100.0	2	0.7	0.2	2.6
	Genital candidiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Genital herpes	n/a	281	100.0	2	0.7	0.2	2.6
	Gingivitis	n/a	281	100.0	1	0.4	0.1	2.0
	Herpes simplex	n/a	281	100.0	1	0.4	0.1	2.0
	Herpes virus infection	n/a	281	100.0	3	1.1	0.4	3.1

	Herpes zoster	n/a	281	100.0	11	3.9	2.2	6.9
	Infection	n/a	281	100.0	1	0.4	0.1	2.0
	Infectious colitis	n/a	281	100.0	1	0.4	0.1	2.0
	Influenza	n/a	281	100.0	3	1.1	0.4	3.1
	Lower respiratory tract infection	n/a	281	100.0	2	0.7	0.2	2.6
	Lung infection	n/a	281	100.0	4	1.4	0.6	3.6
	Lyme disease	n/a	281	100.0	1	0.4	0.1	2.0
	Lymph node tuberculosis	n/a	281	100.0	2	0.7	0.2	2.6
	Meningitis	n/a	281	100.0	1	0.4	0.1	2.0
	Nasal herpes	n/a	281	100.0	1	0.4	0.1	2.0
	Nasopharyngitis	n/a	281	100.0	9	3.2	1.7	6.0
	Oral candidiasis	n/a	281	100.0	9	3.2	1.7	6.0
	Oral fungal infection	n/a	281	100.0	2	0.7	0.2	2.6
	Oropharyngeal candidiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Otitis externa	n/a	281	100.0	2	0.7	0.2	2.6
	Otitis media	n/a	281	100.0	1	0.4	0.1	2.0
	Paronychia	n/a	281	100.0	7	2.5	1.2	5.1
	Peritonitis	n/a	281	100.0	1	0.4	0.1	2.0
	Pharyngitis	n/a	281	100.0	4	1.4	0.6	3.6
	Pleural infection	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumocystis jirovecii pneumonia	n/a	281	100.0	2	0.7	0.2	2.6
	Pneumonia	n/a	281	100.0	44	15.7	11.9	20.4
	Pneumonia bacterial	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia cytomegaloviral	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia haemophilus	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia influenzal	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia pseudomonal	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia streptococcal	n/a	281	100.0	1	0.4	0.1	2.0
	Pyelonephritis	n/a	281	100.0	2	0.7	0.2	2.6
	Pyelonephritis acute	n/a	281	100.0	1	0.4	0.1	2.0
	Pyuria	n/a	281	100.0	1	0.4	0.1	2.0

	Rectal abscess	n/a	281	100.0	1	0.4	0.1	2.0
	Renal tuberculosis	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory tract infection	n/a	281	100.0	2	0.7	0.2	2.6
	Respiratory tract infection bacterial	n/a	281	100.0	1	0.4	0.1	2.0
	Rhinitis	n/a	281	100.0	5	1.8	0.8	4.1
	Sepsis	n/a	281	100.0	9	3.2	1.7	6.0
	Septic shock	n/a	281	100.0	1	0.4	0.1	2.0
	Sinusitis	n/a	281	100.0	7	2.5	1.2	5.1
	Sinusitis bacterial	n/a	281	100.0	1	0.4	0.1	2.0
	Skin infection	n/a	281	100.0	2	0.7	0.2	2.6
	Staphylococcal infection	n/a	281	100.0	1	0.4	0.1	2.0
	Systemic infection	n/a	281	100.0	1	0.4	0.1	2.0
	Tinea cruris	n/a	281	100.0	1	0.4	0.1	2.0
	Tinea infection	n/a	281	100.0	1	0.4	0.1	2.0
	Tinea pedis	n/a	281	100.0	2	0.7	0.2	2.6
	Tonsillitis	n/a	281	100.0	1	0.4	0.1	2.0
	Tooth infection	n/a	281	100.0	1	0.4	0.1	2.0
	Tracheitis	n/a	281	100.0	1	0.4	0.1	2.0
	Tuberculosis	n/a	281	100.0	1	0.4	0.1	2.0
	Upper respiratory tract infection	n/a	281	100.0	13	4.6	2.7	7.8
	Urethritis	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary tract infection	n/a	281	100.0	38	13.5	10.0	18.0
	Urosepsis	n/a	281	100.0	2	0.7	0.2	2.6
	Varicella	n/a	281	100.0	1	0.4	0.1	2.0
	Varicella zoster virus infection	n/a	281	100.0	1	0.4	0.1	2.0
	Viral hepatitis carrier	n/a	281	100.0	1	0.4	0.1	2.0
	Viral infection	n/a	281	100.0	2	0.7	0.2	2.6
	Vulvovaginal candidiasis	n/a	281	100.0	1	0.4	0.1	2.0
Injury, poisoning and procedural complications	-Total	n/a	281	100.0	27	9.6	6.7	13.6
	Contusion	n/a	281	100.0	5	1.8	0.8	4.1

	Epicondylitis	n/a	281	100.0	1	0.4	0.1	2.0
	Fall	n/a	281	100.0	8	2.8	1.4	5.5
	Fracture	n/a	281	100.0	1	0.4	0.1	2.0
	Heart injury	n/a	281	100.0	1	0.4	0.1	2.0
	Incision site pain	n/a	281	100.0	1	0.4	0.1	2.0
	Injury	n/a	281	100.0	1	0.4	0.1	2.0
	Joint dislocation	n/a	281	100.0	2	0.7	0.2	2.6
	Laceration	n/a	281	100.0	1	0.4	0.1	2.0
	Ligament sprain	n/a	281	100.0	2	0.7	0.2	2.6
	Limb injury	n/a	281	100.0	2	0.7	0.2	2.6
	Muscle rupture	n/a	281	100.0	1	0.4	0.1	2.0
	Muscle strain	n/a	281	100.0	2	0.7	0.2	2.6
	Procedural pain	n/a	281	100.0	2	0.7	0.2	2.6
	Procedural pneumothorax	n/a	281	100.0	1	0.4	0.1	2.0
	Rib fracture	n/a	281	100.0	1	0.4	0.1	2.0
	Scar	n/a	281	100.0	1	0.4	0.1	2.0
	Skin abrasion	n/a	281	100.0	1	0.4	0.1	2.0
	Skin injury	n/a	281	100.0	1	0.4	0.1	2.0
	Subdural haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Tendon rupture	n/a	281	100.0	1	0.4	0.1	2.0
	Thermal burn	n/a	281	100.0	1	0.4	0.1	2.0
	Wound	n/a	281	100.0	2	0.7	0.2	2.6
	Wound complication	n/a	281	100.0	1	0.4	0.1	2.0
	Wrist fracture	n/a	281	100.0	1	0.4	0.1	2.0
Investigations	-Total	n/a	281	100.0	223	79.4	74.2	83.7
	Alanine aminotransferase	n/a	281	100.0	1	0.4	0.1	2.0
	Alanine aminotransferase increased	n/a	281	100.0	92	32.7	27.5	38.4
	Albumin urine present	n/a	281	100.0	1	0.4	0.1	2.0
	Alpha hydroxybutyrate dehydrogenase increased	n/a	281	100.0	3	1.1	0.4	3.1
	Amylase increased	n/a	281	100.0	3	1.1	0.4	3.1
	Aspartate aminotransferase increased	n/a	281	100.0	126	44.8	39.1	50.7

	Bacterial test	n/a	281	100.0	1	0.4	0.1	2.0
	Bilirubin conjugated increased	n/a	281	100.0	20	7.1	4.7	10.7
	Blood albumin decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood alkaline phosphatase	n/a	281	100.0	1	0.4	0.1	2.0
	Blood alkaline phosphatase decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood alkaline phosphatase increased	n/a	281	100.0	35	12.5	9.1	16.8
	Blood bilirubin increased	n/a	281	100.0	27	9.6	6.7	13.6
	Blood bilirubin unconjugated increased	n/a	281	100.0	9	3.2	1.7	6.0
	Blood calcium decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood calcium increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood chloride increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood cholesterol increased	n/a	281	100.0	8	2.8	1.4	5.5
	Blood creatine increased	n/a	281	100.0	3	1.1	0.4	3.1
	Blood creatine phosphokinase MB increased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood creatine phosphokinase increased	n/a	281	100.0	53	18.9	14.7	23.8
	Blood creatinine	n/a	281	100.0	1	0.4	0.1	2.0
	Blood creatinine increased	n/a	281	100.0	62	22.1	17.6	27.3
	Blood fibrinogen increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood glucose increased	n/a	281	100.0	3	1.1	0.4	3.1
	Blood iron decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood ketone body increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood lactate dehydrogenase increased	n/a	281	100.0	11	3.9	2.2	6.9
	Blood magnesium decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood phosphorus increased	n/a	281	100.0	7	2.5	1.2	5.1
	Blood potassium decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood potassium increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood pressure increased	n/a	281	100.0	3	1.1	0.4	3.1
	Blood sodium decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood thyroid stimulating hormone increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood triglycerides increased	n/a	281	100.0	8	2.8	1.4	5.5

	Blood urea increased	n/a	281	100.0	6	2.1	1.0	4.6
	Blood uric acid decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood uric acid increased	n/a	281	100.0	7	2.5	1.2	5.1
	Blood urine	n/a	281	100.0	3	1.1	0.4	3.1
	Blood urine present	n/a	281	100.0	1	0.4	0.1	2.0
	C-reactive protein increased	n/a	281	100.0	4	1.4	0.6	3.6
	Carbon dioxide decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Complement factor C1 decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Computerised tomogram thorax abnormal	n/a	281	100.0	2	0.7	0.2	2.6
	Crystal urine present	n/a	281	100.0	1	0.4	0.1	2.0
	Cystatin C increased	n/a	281	100.0	1	0.4	0.1	2.0
	Electrocardiogram QT prolonged	n/a	281	100.0	15	5.3	3.3	8.6
	Electrocardiogram ST-T change	n/a	281	100.0	2	0.7	0.2	2.6
	Fibrin D dimer increased	n/a	281	100.0	2	0.7	0.2	2.6
	Fibrin degradation products increased	n/a	281	100.0	1	0.4	0.1	2.0
	Free fatty acids increased	n/a	281	100.0	1	0.4	0.1	2.0
	Gamma-glutamyltransferase increased	n/a	281	100.0	20	7.1	4.7	10.7
	Glomerular filtration rate decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Glutamate dehydrogenase increased	n/a	281	100.0	2	0.7	0.2	2.6
	Granulocyte count decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Haematocrit decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Haemoglobin decreased	n/a	281	100.0	7	2.5	1.2	5.1
	Heart rate increased	n/a	281	100.0	6	2.1	1.0	4.6
	Hepatic enzyme increased	n/a	281	100.0	3	1.1	0.4	3.1
	International normalised ratio increased	n/a	281	100.0	2	0.7	0.2	2.6
	Intraocular pressure increased	n/a	281	100.0	1	0.4	0.1	2.0
	Laboratory test abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Lipase increased	n/a	281	100.0	4	1.4	0.6	3.6
	Liver function test increased	n/a	281	100.0	2	0.7	0.2	2.6
	Lymphocyte count decreased	n/a	281	100.0	27	9.6	6.7	13.6
	Lymphocyte count increased	n/a	281	100.0	1	0.4	0.1	2.0

	Mean cell volume increased	n/a	281	100.0	1	0.4	0.1	2.0
	Myoglobin blood increased	n/a	281	100.0	2	0.7	0.2	2.6
	Neutrophil count decreased	n/a	281	100.0	81	28.8	23.8	34.4
	Neutrophil count increased	n/a	281	100.0	2	0.7	0.2	2.6
	Neutrophil percentage increased	n/a	281	100.0	1	0.4	0.1	2.0
	Occult blood positive	n/a	281	100.0	3	1.1	0.4	3.1
	Oxygen saturation decreased	n/a	281	100.0	1	0.4	0.1	2.0
	PO2 decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Platelet count decreased	n/a	281	100.0	33	11.7	8.5	16.0
	Platelet count increased	n/a	281	100.0	5	1.8	0.8	4.1
	Procalcitonin increased	n/a	281	100.0	1	0.4	0.1	2.0
	Protein total decreased	n/a	281	100.0	3	1.1	0.4	3.1
	Protein total increased	n/a	281	100.0	1	0.4	0.1	2.0
	Protein urine present	n/a	281	100.0	2	0.7	0.2	2.6
	Prothrombin time prolonged	n/a	281	100.0	1	0.4	0.1	2.0
	Red blood cell count decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Serum amyloid A protein increased	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombin time prolonged	n/a	281	100.0	1	0.4	0.1	2.0
	Total bile acids increased	n/a	281	100.0	9	3.2	1.7	6.0
	Transaminases increased	n/a	281	100.0	8	2.8	1.4	5.5
	Transferrin increased	n/a	281	100.0	1	0.4	0.1	2.0
	Troponin T increased	n/a	281	100.0	2	0.7	0.2	2.6
	Troponin increased	n/a	281	100.0	2	0.7	0.2	2.6
	Urinary sediment present	n/a	281	100.0	1	0.4	0.1	2.0
	Urine ketone body present	n/a	281	100.0	3	1.1	0.4	3.1
	Urine leukocyte esterase positive	n/a	281	100.0	1	0.4	0.1	2.0
	Urobilinogen urine increased	n/a	281	100.0	2	0.7	0.2	2.6
	Weight decreased	n/a	281	100.0	18	6.4	4.1	9.9
	Weight increased	n/a	281	100.0	26	9.3	6.4	13.2
	White blood cell count decreased	n/a	281	100.0	72	25.6	20.9	31.0

	White blood cells urine positive	n/a	281	100.0	3	1.1	0.4	3.1
Metabolism and nutrition disorders	-Total	n/a	281	100.0	147	52.3	46.5	58.1
	Abnormal loss of weight	n/a	281	100.0	1	0.4	0.1	2.0
	Acidosis	n/a	281	100.0	1	0.4	0.1	2.0
	Alkalosis	n/a	281	100.0	1	0.4	0.1	2.0
	Cell death	n/a	281	100.0	1	0.4	0.1	2.0
	Decreased appetite	n/a	281	100.0	38	13.5	10.0	18.0
	Dehydration	n/a	281	100.0	6	2.1	1.0	4.6
	Electrolyte imbalance	n/a	281	100.0	3	1.1	0.4	3.1
	Failure to thrive	n/a	281	100.0	1	0.4	0.1	2.0
	Fluid retention	n/a	281	100.0	1	0.4	0.1	2.0
	Hypercalcaemia	n/a	281	100.0	7	2.5	1.2	5.1
	Hypercholesterolaemia	n/a	281	100.0	5	1.8	0.8	4.1
	Hyperglycaemia	n/a	281	100.0	18	6.4	4.1	9.9
	Hyperkalaemia	n/a	281	100.0	16	5.7	3.5	9.0
	Hyperlipidaemia	n/a	281	100.0	7	2.5	1.2	5.1
	Hypermagnesaemia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypernatraemia	n/a	281	100.0	4	1.4	0.6	3.6
	Hyperphosphataemia	n/a	281	100.0	32	11.4	8.2	15.6
	Hypertriglyceridaemia	n/a	281	100.0	7	2.5	1.2	5.1
	Hyperuricaemia	n/a	281	100.0	11	3.9	2.2	6.9
	Hypoalbuminaemia	n/a	281	100.0	37	13.2	9.7	17.6
	Hypocalcaemia	n/a	281	100.0	34	12.1	8.8	16.4
	Hypochloraemia	n/a	281	100.0	5	1.8	0.8	4.1
	Hypoglycaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypokalaemia	n/a	281	100.0	38	13.5	10.0	18.0
	Hypomagnesaemia	n/a	281	100.0	21	7.5	4.9	11.2
	Hyponatraemia	n/a	281	100.0	30	10.7	7.6	14.8
	Hypophosphataemia	n/a	281	100.0	35	12.5	9.1	16.8
	Hypoproteinaemia	n/a	281	100.0	6	2.1	1.0	4.6
	Increased appetite	n/a	281	100.0	1	0.4	0.1	2.0

	Vitamin D deficiency	n/a	281	100.0	1	0.4	0.1	2.0
Musculoskeletal and connective tissue disorders	-Total	n/a	281	100.0	124	44.1	38.4	50.0
	Arthralgia	n/a	281	100.0	13	4.6	2.7	7.8
	Arthropathy	n/a	281	100.0	1	0.4	0.1	2.0
	Back pain	n/a	281	100.0	38	13.5	10.0	18.0
	Bone pain	n/a	281	100.0	4	1.4	0.6	3.6
	Bursitis	n/a	281	100.0	1	0.4	0.1	2.0
	Coccydynia	n/a	281	100.0	1	0.4	0.1	2.0
	Costochondritis	n/a	281	100.0	2	0.7	0.2	2.6
	Flank pain	n/a	281	100.0	3	1.1	0.4	3.1
	Groin pain	n/a	281	100.0	1	0.4	0.1	2.0
	Hypercreatinaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Intervertebral disc protrusion	n/a	281	100.0	6	2.1	1.0	4.6
	Joint range of motion decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Joint stiffness	n/a	281	100.0	1	0.4	0.1	2.0
	Joint swelling	n/a	281	100.0	2	0.7	0.2	2.6
	Muscle fatigue	n/a	281	100.0	1	0.4	0.1	2.0
	Muscle haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Muscle spasms	n/a	281	100.0	22	7.8	5.2	11.6
	Muscular weakness	n/a	281	100.0	11	3.9	2.2	6.9
	Musculoskeletal chest pain	n/a	281	100.0	7	2.5	1.2	5.1
	Musculoskeletal pain	n/a	281	100.0	24	8.5	5.8	12.4
	Musculoskeletal stiffness	n/a	281	100.0	1	0.4	0.1	2.0
	Myalgia	n/a	281	100.0	23	8.2	5.5	12.0
	Myopathy	n/a	281	100.0	2	0.7	0.2	2.6
	Neck pain	n/a	281	100.0	14	5.0	3.0	8.2
	Osteopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Pain in extremity	n/a	281	100.0	26	9.3	6.4	13.2
	Pain in jaw	n/a	281	100.0	2	0.7	0.2	2.6
	Rhabdomyolysis	n/a	281	100.0	1	0.4	0.1	2.0

	Rotator cuff syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Spinal column stenosis	n/a	281	100.0	2	0.7	0.2	2.6
	Spinal osteoarthritis	n/a	281	100.0	1	0.4	0.1	2.0
	Tendon disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Tendon pain	n/a	281	100.0	1	0.4	0.1	2.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	281	100.0	11	3.9	2.2	6.9
	Anogenital warts	n/a	281	100.0	1	0.4	0.1	2.0
	Basal cell carcinoma	n/a	281	100.0	1	0.4	0.1	2.0
	Bowen's disease	n/a	281	100.0	1	0.4	0.1	2.0
	Cancer pain	n/a	281	100.0	1	0.4	0.1	2.0
	Gallbladder cancer	n/a	281	100.0	1	0.4	0.1	2.0
	Metastases to central nervous system	n/a	281	100.0	1	0.4	0.1	2.0
	Renal cell carcinoma	n/a	281	100.0	1	0.4	0.1	2.0
	Squamous cell carcinoma	n/a	281	100.0	1	0.4	0.1	2.0
	Squamous cell carcinoma of skin	n/a	281	100.0	1	0.4	0.1	2.0
	Tumour pain	n/a	281	100.0	2	0.7	0.2	2.6
Nervous system disorders	-Total	n/a	281	100.0	145	51.6	45.8	57.4
	Ageusia	n/a	281	100.0	2	0.7	0.2	2.6
	Aphasia	n/a	281	100.0	1	0.4	0.1	2.0
	Ataxia	n/a	281	100.0	2	0.7	0.2	2.6
	Balance disorder	n/a	281	100.0	2	0.7	0.2	2.6
	Brain oedema	n/a	281	100.0	2	0.7	0.2	2.6
	Cerebellar haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Cerebral haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Cerebral microhaemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Cerebrovascular accident	n/a	281	100.0	1	0.4	0.1	2.0
	Disturbance in attention	n/a	281	100.0	2	0.7	0.2	2.6
	Dizziness	n/a	281	100.0	38	13.5	10.0	18.0
	Dizziness postural	n/a	281	100.0	1	0.4	0.1	2.0
	Dysarthria	n/a	281	100.0	1	0.4	0.1	2.0
	Dysgeusia	n/a	281	100.0	42	14.9	11.3	19.6

	Dyskinesia	n/a	281	100.0	1	0.4	0.1	2.0
	Epilepsy	n/a	281	100.0	1	0.4	0.1	2.0
	Facial paralysis	n/a	281	100.0	1	0.4	0.1	2.0
	Haemorrhage intracranial	n/a	281	100.0	1	0.4	0.1	2.0
	Headache	n/a	281	100.0	34	12.1	8.8	16.4
	Hemiplegia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperaesthesia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypersomnia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypoaesthesia	n/a	281	100.0	18	6.4	4.1	9.9
	Hypotonia	n/a	281	100.0	1	0.4	0.1	2.0
	Lethargy	n/a	281	100.0	1	0.4	0.1	2.0
	Lumbar radiculopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Lumbosacral radiculopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Memory impairment	n/a	281	100.0	2	0.7	0.2	2.6
	Migraine	n/a	281	100.0	1	0.4	0.1	2.0
	Migraine with aura	n/a	281	100.0	1	0.4	0.1	2.0
	Neuralgia	n/a	281	100.0	2	0.7	0.2	2.6
	Neuropathy peripheral	n/a	281	100.0	12	4.3	2.5	7.3
	Paraesthesia	n/a	281	100.0	12	4.3	2.5	7.3
	Paralysis	n/a	281	100.0	1	0.4	0.1	2.0
	Parosmia	n/a	281	100.0	1	0.4	0.1	2.0
	Peripheral sensory neuropathy	n/a	281	100.0	9	3.2	1.7	6.0
	Polyneuropathy chronic	n/a	281	100.0	1	0.4	0.1	2.0
	Post herpetic neuralgia	n/a	281	100.0	1	0.4	0.1	2.0
	Presyncope	n/a	281	100.0	3	1.1	0.4	3.1
	Psychomotor skills impaired	n/a	281	100.0	1	0.4	0.1	2.0
	Restless legs syndrome	n/a	281	100.0	2	0.7	0.2	2.6
	Sciatica	n/a	281	100.0	6	2.1	1.0	4.6
	Seizure	n/a	281	100.0	6	2.1	1.0	4.6
	Sensory disturbance	n/a	281	100.0	1	0.4	0.1	2.0

	Slow speech	n/a	281	100.0	1	0.4	0.1	2.0
	Somnolence	n/a	281	100.0	2	0.7	0.2	2.6
	Spinal cord haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Syncope	n/a	281	100.0	7	2.5	1.2	5.1
	Tension headache	n/a	281	100.0	1	0.4	0.1	2.0
	Tremor	n/a	281	100.0	1	0.4	0.1	2.0
	Visual field defect	n/a	281	100.0	2	0.7	0.2	2.6
Product issues	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Device dislocation	n/a	281	100.0	1	0.4	0.1	2.0
Psychiatric disorders	-Total	n/a	281	100.0	56	19.9	15.7	25.0
	Abnormal behaviour	n/a	281	100.0	1	0.4	0.1	2.0
	Abnormal dreams	n/a	281	100.0	1	0.4	0.1	2.0
	Adjustment disorder with mixed anxiety and depressed mood	n/a	281	100.0	1	0.4	0.1	2.0
	Anxiety	n/a	281	100.0	12	4.3	2.5	7.3
	Bradyphrenia	n/a	281	100.0	1	0.4	0.1	2.0
	Confusional state	n/a	281	100.0	5	1.8	0.8	4.1
	Delirium	n/a	281	100.0	3	1.1	0.4	3.1
	Depressed mood	n/a	281	100.0	1	0.4	0.1	2.0
	Depression	n/a	281	100.0	5	1.8	0.8	4.1
	Fear of falling	n/a	281	100.0	1	0.4	0.1	2.0
	Insomnia	n/a	281	100.0	20	7.1	4.7	10.7
	Irritability	n/a	281	100.0	1	0.4	0.1	2.0
	Libido decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Mental status changes	n/a	281	100.0	4	1.4	0.6	3.6
	Mood altered	n/a	281	100.0	1	0.4	0.1	2.0
	Psychomotor retardation	n/a	281	100.0	2	0.7	0.2	2.6
	Restlessness	n/a	281	100.0	5	1.8	0.8	4.1
	Sleep disorder	n/a	281	100.0	2	0.7	0.2	2.6
Renal and urinary disorders	-Total	n/a	281	100.0	43	15.3	11.6	20.0
	Acute kidney injury	n/a	281	100.0	8	2.8	1.4	5.5
	Azotaemia	n/a	281	100.0	2	0.7	0.2	2.6

	Cystitis haemorrhagic	n/a	281	100.0	1	0.4	0.1	2.0
	Dysuria	n/a	281	100.0	11	3.9	2.2	6.9
	Haematuria	n/a	281	100.0	4	1.4	0.6	3.6
	Haemorrhage urinary tract	n/a	281	100.0	1	0.4	0.1	2.0
	Hydronephrosis	n/a	281	100.0	1	0.4	0.1	2.0
	Micturition urgency	n/a	281	100.0	1	0.4	0.1	2.0
	Nephritis	n/a	281	100.0	1	0.4	0.1	2.0
	Nephrolithiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Nocturia	n/a	281	100.0	3	1.1	0.4	3.1
	Obstructive nephropathy	n/a	281	100.0	1	0.4	0.1	2.0
	Pollakiuria	n/a	281	100.0	2	0.7	0.2	2.6
	Proteinuria	n/a	281	100.0	2	0.7	0.2	2.6
	Renal colic	n/a	281	100.0	1	0.4	0.1	2.0
	Renal disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Renal failure	n/a	281	100.0	2	0.7	0.2	2.6
	Renal impairment	n/a	281	100.0	1	0.4	0.1	2.0
	Strangury	n/a	281	100.0	1	0.4	0.1	2.0
	Urethral stenosis	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary incontinence	n/a	281	100.0	2	0.7	0.2	2.6
	Urinary retention	n/a	281	100.0	7	2.5	1.2	5.1
	Urinary tract pain	n/a	281	100.0	1	0.4	0.1	2.0
	Urine flow decreased	n/a	281	100.0	1	0.4	0.1	2.0
Reproductive system and breast disorders	-Total	n/a	281	100.0	23	8.2	5.5	12.0
	Benign prostatic hyperplasia	n/a	281	100.0	3	1.1	0.4	3.1
	Breast discharge	n/a	281	100.0	1	0.4	0.1	2.0
	Erectile dysfunction	n/a	281	100.0	9	3.2	1.7	6.0
	Galactorrhoea	n/a	281	100.0	1	0.4	0.1	2.0
	Genital ulceration	n/a	281	100.0	1	0.4	0.1	2.0
	Metrorrhagia	n/a	281	100.0	2	0.7	0.2	2.6
	Ovarian cyst	n/a	281	100.0	1	0.4	0.1	2.0

	Pelvic discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Pelvic fluid collection	n/a	281	100.0	1	0.4	0.1	2.0
	Perineal pain	n/a	281	100.0	1	0.4	0.1	2.0
	Postmenopausal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Prostatitis	n/a	281	100.0	2	0.7	0.2	2.6
	Uterine polyp	n/a	281	100.0	1	0.4	0.1	2.0
	Vaginal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Vulvovaginal dryness	n/a	281	100.0	1	0.4	0.1	2.0
	Vulvovaginal erythema	n/a	281	100.0	1	0.4	0.1	2.0
Respiratory, thoracic and mediastinal disorders	-Total	n/a	281	100.0	167	59.4	53.6	65.0
	Acute respiratory failure	n/a	281	100.0	1	0.4	0.1	2.0
	Aspiration	n/a	281	100.0	1	0.4	0.1	2.0
	Bronchospasm	n/a	281	100.0	1	0.4	0.1	2.0
	Choking	n/a	281	100.0	1	0.4	0.1	2.0
	Cough	n/a	281	100.0	65	23.1	18.6	28.4
	Dry throat	n/a	281	100.0	2	0.7	0.2	2.6
	Dysphonia	n/a	281	100.0	12	4.3	2.5	7.3
	Dyspnoea	n/a	281	100.0	47	16.7	12.8	21.5
	Dyspnoea exertional	n/a	281	100.0	12	4.3	2.5	7.3
	Epistaxis	n/a	281	100.0	14	5.0	3.0	8.2
	Haemoptysis	n/a	281	100.0	11	3.9	2.2	6.9
	Hiccups	n/a	281	100.0	2	0.7	0.2	2.6
	Hypoxia	n/a	281	100.0	5	1.8	0.8	4.1
	Interstitial lung disease	n/a	281	100.0	4	1.4	0.6	3.6
	Laryngeal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Lung consolidation	n/a	281	100.0	1	0.4	0.1	2.0
	Nasal congestion	n/a	281	100.0	4	1.4	0.6	3.6
	Nasal dryness	n/a	281	100.0	4	1.4	0.6	3.6
	Nasal polyps	n/a	281	100.0	1	0.4	0.1	2.0
	Oropharyngeal discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Oropharyngeal pain	n/a	281	100.0	21	7.5	4.9	11.2

	Paranasal sinus discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Pharyngeal disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Pleural effusion	n/a	281	100.0	12	4.3	2.5	7.3
	Pleural thickening	n/a	281	100.0	2	0.7	0.2	2.6
	Pleuritic pain	n/a	281	100.0	3	1.1	0.4	3.1
	Pneumonitis	n/a	281	100.0	32	11.4	8.2	15.6
	Pneumothorax	n/a	281	100.0	4	1.4	0.6	3.6
	Productive cough	n/a	281	100.0	14	5.0	3.0	8.2
	Pulmonary embolism	n/a	281	100.0	13	4.6	2.7	7.8
	Pulmonary hypertension	n/a	281	100.0	1	0.4	0.1	2.0
	Pulmonary mass	n/a	281	100.0	1	0.4	0.1	2.0
	Pulmonary pain	n/a	281	100.0	1	0.4	0.1	2.0
	Respiration abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory distress	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory failure	n/a	281	100.0	1	0.4	0.1	2.0
	Rhinalgia	n/a	281	100.0	1	0.4	0.1	2.0
	Rhinitis allergic	n/a	281	100.0	2	0.7	0.2	2.6
	Rhinorrhoea	n/a	281	100.0	3	1.1	0.4	3.1
	Sinus congestion	n/a	281	100.0	1	0.4	0.1	2.0
	Sleep apnoea syndrome	n/a	281	100.0	3	1.1	0.4	3.1
	Sputum discoloured	n/a	281	100.0	1	0.4	0.1	2.0
	Throat irritation	n/a	281	100.0	2	0.7	0.2	2.6
	Upper-airway cough syndrome	n/a	281	100.0	2	0.7	0.2	2.6
	Vocal cord leukoplakia	n/a	281	100.0	1	0.4	0.1	2.0
	Wheezing	n/a	281	100.0	2	0.7	0.2	2.6
Skin and subcutaneous tissue disorders	-Total	n/a	281	100.0	100	35.6	30.2	41.3
	Acne	n/a	281	100.0	1	0.4	0.1	2.0
	Alopecia	n/a	281	100.0	14	5.0	3.0	8.2
	Chloasma	n/a	281	100.0	1	0.4	0.1	2.0
	Decubitus ulcer	n/a	281	100.0	1	0.4	0.1	2.0

	Dermal cyst	n/a	281	100.0	1	0.4	0.1	2.0
	Dermatitis	n/a	281	100.0	1	0.4	0.1	2.0
	Dermatitis acneiform	n/a	281	100.0	7	2.5	1.2	5.1
	Dermatitis allergic	n/a	281	100.0	1	0.4	0.1	2.0
	Dermatitis bullous	n/a	281	100.0	2	0.7	0.2	2.6
	Dry skin	n/a	281	100.0	12	4.3	2.5	7.3
	Ecchymosis	n/a	281	100.0	1	0.4	0.1	2.0
	Eczema	n/a	281	100.0	2	0.7	0.2	2.6
	Erythema	n/a	281	100.0	4	1.4	0.6	3.6
	Hair growth abnormal	n/a	281	100.0	6	2.1	1.0	4.6
	Hair texture abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Hirsutism	n/a	281	100.0	7	2.5	1.2	5.1
	Hyperhidrosis	n/a	281	100.0	2	0.7	0.2	2.6
	Hyperkeratosis	n/a	281	100.0	1	0.4	0.1	2.0
	Hypertrichosis	n/a	281	100.0	6	2.1	1.0	4.6
	Madarosis	n/a	281	100.0	1	0.4	0.1	2.0
	Nail discolouration	n/a	281	100.0	1	0.4	0.1	2.0
	Nail disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Night sweats	n/a	281	100.0	2	0.7	0.2	2.6
	Onychalgia	n/a	281	100.0	1	0.4	0.1	2.0
	Onycholysis	n/a	281	100.0	1	0.4	0.1	2.0
	Onychomadesis	n/a	281	100.0	3	1.1	0.4	3.1
	Pain of skin	n/a	281	100.0	1	0.4	0.1	2.0
	Palmar-plantar erythrodysaesthesia syndrome	n/a	281	100.0	5	1.8	0.8	4.1
	Photosensitivity reaction	n/a	281	100.0	1	0.4	0.1	2.0
	Pruritus	n/a	281	100.0	7	2.5	1.2	5.1
	Pruritus generalised	n/a	281	100.0	1	0.4	0.1	2.0
	Purpura	n/a	281	100.0	1	0.4	0.1	2.0
	Rash	n/a	281	100.0	23	8.2	5.5	12.0
	Rash erythematous	n/a	281	100.0	2	0.7	0.2	2.6
	Rash macular	n/a	281	100.0	4	1.4	0.6	3.6

	Rash maculo-papular	n/a	281	100.0	2	0.7	0.2	2.6
	Rash papular	n/a	281	100.0	1	0.4	0.1	2.0
	Scab	n/a	281	100.0	2	0.7	0.2	2.6
	Scar pain	n/a	281	100.0	1	0.4	0.1	2.0
	Skin discolouration	n/a	281	100.0	1	0.4	0.1	2.0
	Skin hyperpigmentation	n/a	281	100.0	1	0.4	0.1	2.0
	Skin lesion	n/a	281	100.0	1	0.4	0.1	2.0
	Swelling face	n/a	281	100.0	6	2.1	1.0	4.6
	Urticaria	n/a	281	100.0	2	0.7	0.2	2.6
Surgical and medical procedures	-Total	n/a	281	100.0	8	2.8	1.4	5.5
	Astringent therapy	n/a	281	100.0	5	1.8	0.8	4.1
	Eye excision	n/a	281	100.0	1	0.4	0.1	2.0
	Hip arthroplasty	n/a	281	100.0	1	0.4	0.1	2.0
	Therapy cessation	n/a	281	100.0	1	0.4	0.1	2.0
Vascular disorders	-Total	n/a	281	100.0	115	40.9	35.3	46.8
	Aortic dissection	n/a	281	100.0	1	0.4	0.1	2.0
	Circulatory collapse	n/a	281	100.0	1	0.4	0.1	2.0
	Deep vein thrombosis	n/a	281	100.0	3	1.1	0.4	3.1
	Embolism	n/a	281	100.0	5	1.8	0.8	4.1
	Embolism venous	n/a	281	100.0	1	0.4	0.1	2.0
	Flushing	n/a	281	100.0	1	0.4	0.1	2.0
	Haematoma	n/a	281	100.0	4	1.4	0.6	3.6
	Hot flush	n/a	281	100.0	3	1.1	0.4	3.1
	Hypertension	n/a	281	100.0	96	34.2	28.9	39.9
	Hypotension	n/a	281	100.0	7	2.5	1.2	5.1
	Lymphoedema	n/a	281	100.0	2	0.7	0.2	2.6
	Orthostatic hypotension	n/a	281	100.0	3	1.1	0.4	3.1
	Pallor	n/a	281	100.0	1	0.4	0.1	2.0
	Phlebitis	n/a	281	100.0	1	0.4	0.1	2.0
	Raynaud's phenomenon	n/a	281	100.0	1	0.4	0.1	2.0

	Shock haemorrhagic	n/a	281	100.0	1	0.4	0.1	2.0
	Superior vena cava syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombophlebitis superficial	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombosis	n/a	281	100.0	2	0.7	0.2	2.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEANY_SG.xls
26MAR2021 13:27

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	< 65	176	62.6	100	56.8	49.4	63.9
		>= 65	105	37.4	69	65.7	56.2	74.1
	Anaemia	< 65	176	62.6	81	46.0	38.8	53.4
		>= 65	105	37.4	48	45.7	36.5	55.2
	Anaemia macrocytic	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Aplastic anaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bone marrow oedema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cytopenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Disseminated intravascular coagulation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Febrile neutropenia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Haemorrhagic anaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperfibrinogenaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Leukocytosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Leukopenia	< 65	176	62.6	21	11.9	7.9	17.6
		>= 65	105	37.4	9	8.6	4.6	15.5
	Lymph node pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lymphadenopathy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymphopenia	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	10	9.5	5.3	16.6
	Neutropenia	< 65	176	62.6	40	22.7	17.2	29.5
		>= 65	105	37.4	21	20.0	13.5	28.6
	Neutrophilia	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Pancytopenia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Thrombocytopenia	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	12	11.4	6.7	18.9
	Thrombocytosis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
Cardiac disorders	-Total	< 65	176	62.6	22	12.5	8.4	18.2
		>= 65	105	37.4	17	16.2	10.4	24.4
	Acute coronary syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Acute myocardial infarction	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Angina pectoris	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Aortic valve calcification	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Atrial fibrillation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Atrial flutter	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bradycardia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bundle branch block right	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cardiac failure	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cardio-respiratory arrest	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Extrasystoles	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Myocardial ischaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nodal arrhythmia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Palpitations	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pericardial effusion	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sinus bradycardia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5

	Sinus tachycardia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Stress cardiomyopathy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Supraventricular tachycardia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tachycardia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Ventricular extrasystoles	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ventricular pre-excitation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Congenital, familial and genetic disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gilbert's syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hydrocele	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Ear and labyrinth disorders	-Total	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	6	5.7	2.6	11.9
	Ear congestion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ear discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ear pain	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tinnitus	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Vertigo	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	3	2.9	1.0	8.1
Endocrine disorders	-Total	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Adrenal insufficiency	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperthyroidism	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypothyroidism	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
Eye disorders	-Total	< 65	176	62.6	29	16.5	11.7	22.7
		>= 65	105	37.4	11	10.5	6.0	17.8

	Abnormal sensation in eye	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blepharitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cataract	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Chalazion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Conjunctival cyst	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Conjunctival haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diplopia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dry eye	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eye swelling	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Eyelid oedema	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Eyelid ptosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Keratitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ocular discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Periorbital oedema	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Photophobia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Photopsia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ulcerative keratitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vision blurred	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Visual acuity reduced	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Gastrointestinal disorders	-Total	< 65	176	62.6	124	70.5	63.3	76.7
		>= 65	105	37.4	80	76.2	67.2	83.3
	Abdominal discomfort	< 65	176	62.6	3	1.7	0.6	4.9

		>= 65	105	37.4	2	1.9	0.5	6.7
	Abdominal distension	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
	Abdominal pain	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	5	4.8	2.1	10.7
	Abdominal pain lower	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Abdominal pain upper	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	5	4.8	2.1	10.7
	Abdominal symptom	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Anal incontinence	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Aphthous ulcer	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Ascites	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Colitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Constipation	< 65	176	62.6	71	40.3	33.4	47.7
		>= 65	105	37.4	47	44.8	35.6	54.3
	Dental caries	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dental dysaesthesia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diarrhoea	< 65	176	62.6	42	23.9	18.2	30.7
		>= 65	105	37.4	28	26.7	19.1	35.8
	Diverticular perforation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dry mouth	< 65	176	62.6	23	13.1	8.9	18.8
		>= 65	105	37.4	24	22.9	15.9	31.8
	Dyspepsia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	3	2.9	1.0	8.1
	Dysphagia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	14	13.3	8.1	21.1
	Enteritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Epigastric discomfort	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eructation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Faeces soft	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Flatulence	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Frequent bowel movements	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastric ulcer	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastritis	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastritis erosive	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastrointestinal haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastrointestinal inflammation	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrointestinal oedema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrointestinal wall thickening	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrooesophageal reflux disease	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	5	4.8	2.1	10.7
	Gingival bleeding	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gingival swelling	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Glossitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Glossodynia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haematochezia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Haemorrhoids	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	4	3.8	1.5	9.4
	Hypoaesthesia oral	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	0	0.0	0.0	3.5
	Impaired gastric emptying	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Intestinal obstruction	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Irritable bowel syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Large intestine perforation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Melaena	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mouth ulceration	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	6	5.7	2.6	11.9
	Nausea	< 65	176	62.6	24	13.6	9.3	19.5
		>= 65	105	37.4	18	17.1	11.1	25.5
	Odynophagia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oesophageal irritation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oesophagitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oral disorder	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oral dysaesthesia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oral mucosal erythema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oral pain	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	3	2.9	1.0	8.1
	Pancreatitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pancreatitis acute	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Paraesthesia oral	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Proctitis ulcerative	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rectal prolapse	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Regurgitation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sensitivity of teeth	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Stomatitis	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	6	5.7	2.6	11.9
	Swollen tongue	< 65	176	62.6	0	0.0	0.0	2.1

		>= 65	105	37.4	1	1.0	0.2	5.2
	Tongue coated	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tongue discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tongue ulceration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tooth discolouration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Toothache	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Vomiting	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	15	14.3	8.9	22.2
General disorders and administration site conditions	-Total	< 65	176	62.6	125	71.0	63.9	77.2
		>= 65	105	37.4	77	73.3	64.2	80.9
	Asthenia	< 65	176	62.6	25	14.2	9.8	20.1
		>= 65	105	37.4	14	13.3	8.1	21.1
	Axillary pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Catheter site pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Chest discomfort	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	4	3.8	1.5	9.4
	Chest pain	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	4	3.8	1.5	9.4
	Chills	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Condition aggravated	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Death	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Disease progression	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	8	7.6	3.9	14.3
	Face oedema	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	5	4.8	2.1	10.7
	Facial pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fatigue	< 65	176	62.6	33	18.8	13.7	25.2
		>= 65	105	37.4	34	32.4	24.2	41.8
	Feeling abnormal	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Feeling cold	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Feeling hot	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gait disturbance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	6	5.7	2.6	11.9
	General physical health deterioration	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Generalised oedema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Impaired healing	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Influenza like illness	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Injection site bruising	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Localised oedema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Malaise	< 65	176	62.6	18	10.2	6.6	15.6
		>= 65	105	37.4	3	2.9	1.0	8.1
	Mucosal dryness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mucosal inflammation	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	9	8.6	4.6	15.5
	Multiple organ dysfunction syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Non-cardiac chest pain	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	3	2.9	1.0	8.1
	Oedema	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oedema peripheral	< 65	176	62.6	19	10.8	7.0	16.2
		>= 65	105	37.4	23	21.9	15.1	30.7
	Pain	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	3	2.9	1.0	8.1
	Peripheral swelling	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
	Pyrexia	< 65	176	62.6	43	24.4	18.7	31.3
		>= 65	105	37.4	29	27.6	20.0	36.8
	Swelling	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Temperature intolerance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Xerosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Hepatobiliary disorders	-Total	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	14	13.3	8.1	21.1
	Cholecystitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Cholelithiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gallbladder polyp	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hepatic function abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hepatic steatosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hepatocellular injury	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperbilirubinaemia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	4	3.8	1.5	9.4
	Liver disorder	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Liver injury	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumobilia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Portal vein thrombosis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
Immune system disorders	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Contrast media allergy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Drug hypersensitivity	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Food allergy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypersensitivity	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Seasonal allergy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Infections and infestations	-Total	< 65	176	62.6	100	56.8	49.4	63.9

		>= 65	105	37.4	57	54.3	44.8	63.5
	Abdominal abscess	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Acute sinusitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Appendicitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Arthritis infective	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Atypical pneumonia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bacteraemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bacterial disease carrier	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bacterial infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bacterial vaginosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bronchitis	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Candida infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cellulitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Chronic sinusitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Clostridium difficile colitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Conjunctivitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Corona virus infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cystitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Cystitis escherichia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Device related infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diverticulitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Ear infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Empyema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Enterococcal bacteraemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Epididymitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Epstein-Barr virus infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Escherichia bacteraemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Escherichia infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Escherichia urinary tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Eye infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Febrile infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Folliculitis	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fungal infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastroenteritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Genital candidiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Genital herpes	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gingivitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Herpes simplex	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Herpes virus infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Herpes zoster	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	2	1.9	0.5	6.7
	Infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Infectious colitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Influenza	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lower respiratory tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lung infection	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lyme disease	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymph node tuberculosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Meningitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nasal herpes	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nasopharyngitis	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oral candidiasis	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	6	5.7	2.6	11.9
	Oral fungal infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oropharyngeal candidiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Otitis externa	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Otitis media	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Paronychia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	1	1.0	0.2	5.2
	Peritonitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pharyngitis	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pleural infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumocystis jirovecii pneumonia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pneumonia	< 65	176	62.6	27	15.3	10.8	21.4
		>= 65	105	37.4	17	16.2	10.4	24.4
	Pneumonia bacterial	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia cytomegaloviral	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pneumonia haemophilus	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia influenzal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia pseudomonal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia streptococcal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyelonephritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pyelonephritis acute	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyuria	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rectal abscess	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Renal tuberculosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory tract infection bacterial	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rhinitis	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sepsis	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	5	4.8	2.1	10.7
	Septic shock	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sinusitis	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sinusitis bacterial	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Skin infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Staphylococcal infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Systemic infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Tinea cruris	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tinea infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tinea pedis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tonsillitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tooth infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tracheitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tuberculosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Upper respiratory tract infection	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Urethritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary tract infection	< 65	176	62.6	19	10.8	7.0	16.2
		>= 65	105	37.4	19	18.1	11.9	26.5
	Urosepsis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Varicella	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Varicella zoster virus infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Viral hepatitis carrier	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Viral infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vulvovaginal candidiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Injury, poisoning and procedural complications	-Total	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	15	14.3	8.9	22.2
	Contusion	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Epicondylitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fall	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	6	5.7	2.6	11.9

	Fracture	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Heart injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Incision site pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Joint dislocation	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Laceration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ligament sprain	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Limb injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Muscle rupture	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscle strain	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Procedural pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Procedural pneumothorax	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rib fracture	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Scar	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Skin abrasion	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Skin injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Subdural haematoma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tendon rupture	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Thermal burn	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Wound	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Wound complication	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Wrist fracture	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Investigations	-Total	< 65	176	62.6	141	80.1	73.6	85.3
		>= 65	105	37.4	82	78.1	69.3	84.9
	Alanine aminotransferase	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Alanine aminotransferase increased	< 65	176	62.6	63	35.8	29.1	43.1
		>= 65	105	37.4	29	27.6	20.0	36.8
	Albumin urine present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Alpha hydroxybutyrate dehydrogenase increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Amylase increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Aspartate aminotransferase increased	< 65	176	62.6	83	47.2	39.9	54.5
		>= 65	105	37.4	43	41.0	32.0	50.5
	Bacterial test	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bilirubin conjugated increased	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	5	4.8	2.1	10.7
	Blood albumin decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood alkaline phosphatase	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood alkaline phosphatase decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood alkaline phosphatase increased	< 65	176	62.6	24	13.6	9.3	19.5
		>= 65	105	37.4	11	10.5	6.0	17.8
	Blood bilirubin increased	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	12	11.4	6.7	18.9
	Blood bilirubin unconjugated increased	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood calcium decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood calcium increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood chloride increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood cholesterol increased	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	0	0.0	0.0	3.5

	Blood creatine increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood creatine phosphokinase MB increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood creatine phosphokinase increased	< 65	176	62.6	39	22.2	16.7	28.9
		>= 65	105	37.4	14	13.3	8.1	21.1
	Blood creatinine	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood creatinine increased	< 65	176	62.6	40	22.7	17.2	29.5
		>= 65	105	37.4	22	21.0	14.3	29.7
	Blood fibrinogen increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood glucose increased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood iron decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood ketone body increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood lactate dehydrogenase increased	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	4	3.8	1.5	9.4
	Blood magnesium decreased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood phosphorus increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood potassium decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood potassium increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood pressure increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood sodium decreased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood thyroid stimulating hormone increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood triglycerides increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood urea increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood uric acid decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Blood uric acid increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood urine	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood urine present	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	C-reactive protein increased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Carbon dioxide decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Complement factor C1 decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Computerised tomogram thorax abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Crystal urine present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cystatin C increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Electrocardiogram QT prolonged	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	6	5.7	2.6	11.9
	Electrocardiogram ST-T change	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Fibrin D dimer increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Fibrin degradation products increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Free fatty acids increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gamma-glutamyltransferase increased	< 65	176	62.6	18	10.2	6.6	15.6
		>= 65	105	37.4	2	1.9	0.5	6.7
	Glomerular filtration rate decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Glutamate dehydrogenase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Granulocyte count decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haematocrit decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haemoglobin decreased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	1	1.0	0.2	5.2
	Heart rate increased	< 65	176	62.6	4	2.3	0.9	5.7

		>= 65	105	37.4	2	1.9	0.5	6.7
	Hepatic enzyme increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	International normalised ratio increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Intraocular pressure increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Laboratory test abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lipase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Liver function test increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymphocyte count decreased	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	10	9.5	5.3	16.6
	Lymphocyte count increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mean cell volume increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Myoglobin blood increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neutrophil count decreased	< 65	176	62.6	61	34.7	28.0	41.9
		>= 65	105	37.4	20	19.0	12.7	27.6
	Neutrophil count increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neutrophil percentage increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Occult blood positive	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oxygen saturation decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	PO2 decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Platelet count decreased	< 65	176	62.6	24	13.6	9.3	19.5
		>= 65	105	37.4	9	8.6	4.6	15.5
	Platelet count increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Procalcitonin increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Protein total decreased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5

	Protein total increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Protein urine present	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Prothrombin time prolonged	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Red blood cell count decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Serum amyloid A protein increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Thrombin time prolonged	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Total bile acids increased	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Transaminases increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	2	1.9	0.5	6.7
	Transferrin increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Troponin T increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Troponin increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary sediment present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urine ketone body present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Urine leukocyte esterase positive	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urobilinogen urine increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Weight decreased	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	10	9.5	5.3	16.6
	Weight increased	< 65	176	62.6	20	11.4	7.5	16.9
		>= 65	105	37.4	6	5.7	2.6	11.9
	White blood cell count decreased	< 65	176	62.6	53	30.1	23.8	37.3
		>= 65	105	37.4	19	18.1	11.9	26.5
	White blood cells urine positive	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
Metabolism and nutrition disorders	-Total	< 65	176	62.6	85	48.3	41.0	55.6
		>= 65	105	37.4	62	59.0	49.5	68.0

	Abnormal loss of weight	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Acidosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Alkalosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cell death	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Decreased appetite	< 65	176	62.6	19	10.8	7.0	16.2
		>= 65	105	37.4	19	18.1	11.9	26.5
	Dehydration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	5	4.8	2.1	10.7
	Electrolyte imbalance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Failure to thrive	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fluid retention	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypercalcaemia	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypercholesterolaemia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperglycaemia	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	8	7.6	3.9	14.3
	Hyperkalaemia	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	8	7.6	3.9	14.3
	Hyperlipidaemia	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypermagnesaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hypernatraemia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperphosphataemia	< 65	176	62.6	23	13.1	8.9	18.8
		>= 65	105	37.4	9	8.6	4.6	15.5
	Hypertriglyceridaemia	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hyperuricaemia	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypoalbuminaemia	< 65	176	62.6	29	16.5	11.7	22.7
		>= 65	105	37.4	8	7.6	3.9	14.3
	Hypocalcaemia	< 65	176	62.6	22	12.5	8.4	18.2

		>= 65	105	37.4	12	11.4	6.7	18.9
	Hypochloraemia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hypoglycaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypokalaemia	< 65	176	62.6	19	10.8	7.0	16.2
		>= 65	105	37.4	19	18.1	11.9	26.5
	Hypomagnesaemia	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	5	4.8	2.1	10.7
	Hyponatraemia	< 65	176	62.6	19	10.8	7.0	16.2
		>= 65	105	37.4	11	10.5	6.0	17.8
	Hypophosphataemia	< 65	176	62.6	20	11.4	7.5	16.9
		>= 65	105	37.4	15	14.3	8.9	22.2
	Hypoproteinaemia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Increased appetite	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vitamin D deficiency	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Musculoskeletal and connective tissue disorders	-Total	< 65	176	62.6	81	46.0	38.8	53.4
		>= 65	105	37.4	43	41.0	32.0	50.5
	Arthralgia	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	4	3.8	1.5	9.4
	Arthropathy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Back pain	< 65	176	62.6	25	14.2	9.8	20.1
		>= 65	105	37.4	13	12.4	7.4	20.0
	Bone pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Bursitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Coccydynia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Costochondritis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Flank pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Groin pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypercreatinaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Intervertebral disc protrusion	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Joint range of motion decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Joint stiffness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Joint swelling	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Muscle fatigue	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscle haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscle spasms	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	9	8.6	4.6	15.5
	Muscular weakness	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	5	4.8	2.1	10.7
	Musculoskeletal chest pain	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	4	3.8	1.5	9.4
	Musculoskeletal pain	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	7	6.7	3.3	13.1
	Musculoskeletal stiffness	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Myalgia	< 65	176	62.6	18	10.2	6.6	15.6
		>= 65	105	37.4	5	4.8	2.1	10.7
	Myopathy	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neck pain	< 65	176	62.6	11	6.3	3.5	10.8
		>= 65	105	37.4	3	2.9	1.0	8.1
	Osteopenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pain in extremity	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	11	10.5	6.0	17.8
	Pain in jaw	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rhabdomyolysis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rotator cuff syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Spinal column stenosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Spinal osteoarthritis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tendon disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tendon pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	5	4.8	2.1	10.7
	Anogenital warts	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Basal cell carcinoma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bowen's disease	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cancer pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gallbladder cancer	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Metastases to central nervous system	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Renal cell carcinoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Squamous cell carcinoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Squamous cell carcinoma of skin	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tumour pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Nervous system disorders	-Total	< 65	176	62.6	84	47.7	40.5	55.1
		>= 65	105	37.4	61	58.1	48.5	67.1
	Ageusia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Aphasia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ataxia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Balance disorder	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Brain oedema	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cerebellar haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Cerebral haematoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cerebral microhaemorrhage	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cerebrovascular accident	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Disturbance in attention	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dizziness	< 65	176	62.6	20	11.4	7.5	16.9
		>= 65	105	37.4	18	17.1	11.1	25.5
	Dizziness postural	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dysarthria	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dysgeusia	< 65	176	62.6	18	10.2	6.6	15.6
		>= 65	105	37.4	24	22.9	15.9	31.8
	Dyskinesia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Epilepsy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Facial paralysis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haemorrhage intracranial	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Headache	< 65	176	62.6	27	15.3	10.8	21.4
		>= 65	105	37.4	7	6.7	3.3	13.1
	Hemiplegia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperaesthesia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypersomnia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypoaesthesia	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	9	8.6	4.6	15.5
	Hypotonia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lethargy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lumbar radiculopathy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Lumbosacral radiculopathy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Memory impairment	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Migraine	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Migraine with aura	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neuralgia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neuropathy peripheral	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Paraesthesia	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Paralysis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Parosmia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Peripheral sensory neuropathy	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Polyneuropathy chronic	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Post herpetic neuralgia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Presyncope	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Psychomotor skills impaired	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Restless legs syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sciatica	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Seizure	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Sensory disturbance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Slow speech	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Somnolence	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Spinal cord haematoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Syncope	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	6	5.7	2.6	11.9
	Tension headache	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tremor	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Visual field defect	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
Product issues	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Device dislocation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Psychiatric disorders	-Total	< 65	176	62.6	38	21.6	16.2	28.2
		>= 65	105	37.4	18	17.1	11.1	25.5
	Abnormal behaviour	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Abnormal dreams	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Adjustment disorder with mixed anxiety and depressed mood	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Anxiety	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	3	2.9	1.0	8.1
	Bradyphrenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Confusional state	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Delirium	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Depressed mood	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Depression	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Fear of falling	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Insomnia	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	4	3.8	1.5	9.4
	Irritability	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Libido decreased	< 65	176	62.6	2	1.1	0.3	4.0

		>= 65	105	37.4	0	0.0	0.0	3.5
	Mental status changes	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Mood altered	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Psychomotor retardation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Restlessness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Sleep disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Renal and urinary disorders	-Total	< 65	176	62.6	22	12.5	8.4	18.2
		>= 65	105	37.4	21	20.0	13.5	28.6
	Acute kidney injury	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Azotaemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cystitis haemorrhagic	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dysuria	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	4	3.8	1.5	9.4
	Haematuria	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Haemorrhage urinary tract	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hydronephrosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Micturition urgency	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nephritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nephrolithiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nocturia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Obstructive nephropathy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pollakiuria	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Proteinuria	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Renal colic	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Renal disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Renal failure	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Renal impairment	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Strangury	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urethral stenosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Urinary incontinence	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Urinary retention	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	4	3.8	1.5	9.4
	Urinary tract pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urine flow decreased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Reproductive system and breast disorders	-Total	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	6	5.7	2.6	11.9
	Benign prostatic hyperplasia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Breast discharge	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Erectile dysfunction	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Galactorrhoea	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Genital ulceration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Metrorrhagia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ovarian cyst	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pelvic discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pelvic fluid collection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Perineal pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Postmenopausal haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Prostatitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Uterine polyp	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vaginal haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vulvovaginal dryness	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Vulvovaginal erythema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Respiratory, thoracic and mediastinal disorders	-Total	< 65	176	62.6	105	59.7	52.3	66.6
		>= 65	105	37.4	62	59.0	49.5	68.0
	Acute respiratory failure	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Aspiration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bronchospasm	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Choking	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cough	< 65	176	62.6	41	23.3	17.7	30.1
		>= 65	105	37.4	24	22.9	15.9	31.8
	Dry throat	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dysphonia	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Dyspnoea	< 65	176	62.6	28	15.9	11.2	22.0
		>= 65	105	37.4	19	18.1	11.9	26.5
	Dyspnoea exertional	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	6	5.7	2.6	11.9
	Epistaxis	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	6	5.7	2.6	11.9
	Haemoptysis	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hiccups	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hypoxia	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	4	3.8	1.5	9.4
	Interstitial lung disease	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Laryngeal haemorrhage	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lung consolidation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nasal congestion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Nasal dryness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Nasal polyps	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oropharyngeal discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oropharyngeal pain	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	6	5.7	2.6	11.9
	Paranasal sinus discomfort	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pharyngeal disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pleural effusion	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	3	2.9	1.0	8.1
	Pleural thickening	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pleuritic pain	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pneumonitis	< 65	176	62.6	19	10.8	7.0	16.2
		>= 65	105	37.4	13	12.4	7.4	20.0
	Pneumothorax	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Productive cough	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	6	5.7	2.6	11.9
	Pulmonary embolism	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	7	6.7	3.3	13.1
	Pulmonary hypertension	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pulmonary mass	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pulmonary pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Respiration abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Respiratory distress	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory failure	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rhinalgia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rhinitis allergic	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rhinorrhoea	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sinus congestion	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sleep apnoea syndrome	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sputum discoloured	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Throat irritation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Upper-airway cough syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Vocal cord leukoplakia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Wheezing	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
Skin and subcutaneous tissue disorders	-Total	< 65	176	62.6	63	35.8	29.1	43.1
		>= 65	105	37.4	37	35.2	26.8	44.7
	Acne	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Alopecia	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Chloasma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Decubitus ulcer	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermal cyst	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermatitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Dermatitis acneiform	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermatitis allergic	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dermatitis bullous	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Dry skin	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Ecchymosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eczema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Erythema	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hair growth abnormal	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hair texture abnormal	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hirsutism	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperhidrosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hyperkeratosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypertrichosis	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	0	0.0	0.0	3.5
	Madarosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nail discolouration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nail disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Night sweats	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Onychalgia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Onycholysis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Onychomadesis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pain of skin	< 65	176	62.6	0	0.0	0.0	2.1

		>= 65	105	37.4	1	1.0	0.2	5.2
	Palmar-plantar erythrodysaesthesia syndrome	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Photosensitivity reaction	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pruritus	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	4	3.8	1.5	9.4
	Pruritus generalised	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Purpura	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rash	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	7	6.7	3.3	13.1
	Rash erythematous	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rash macular	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Rash maculo-papular	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rash papular	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Scab	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Scar pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Skin discolouration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Skin hyperpigmentation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Skin lesion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Swelling face	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Urticaria	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Surgical and medical procedures	-Total	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Astringent therapy	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Eye excision	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Hip arthroplasty	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Therapy cessation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Vascular disorders	-Total	< 65	176	62.6	58	33.0	26.4	40.2
		>= 65	105	37.4	57	54.3	44.8	63.5
	Aortic dissection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Circulatory collapse	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Deep vein thrombosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Embolism	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Embolism venous	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Flushing	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haematoma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hot flush	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hypertension	< 65	176	62.6	47	26.7	20.7	33.7
		>= 65	105	37.4	49	46.7	37.4	56.2
	Hypotension	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	4	3.8	1.5	9.4
	Lymphoedema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Orthostatic hypotension	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pallor	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Phlebitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Raynaud's phenomenon	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Shock haemorrhagic	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Superior vena cava syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Thrombophlebitis superficial	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Thrombosis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEANY_SG.xls
26MAR2021 13:27

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	84	29.9	46	54.8	44.1	65.0
		1	190	67.6	118	62.1	55.0	68.7
		2	6	2.1	5	83.3	43.6	97.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia	0	84	29.9	31	36.9	27.4	47.6
		1	190	67.6	94	49.5	42.4	56.5
		2	6	2.1	4	66.7	30.0	90.3
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia macrocytic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aplastic anaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bone marrow oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disseminated intravascular coagulation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Febrile neutropenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhagic anaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperfibrinogenaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Leukocytosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Leukopenia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	22	11.6	7.8	16.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymph node pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphadenopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphopenia	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutropenia	0	84	29.9	25	29.8	21.0	40.2
		1	190	67.6	35	18.4	13.6	24.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophilia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytopenia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	16	8.4	5.2	13.2
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytosis	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Cardiac disorders	-Total	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	30	15.8	11.3	21.6
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute coronary syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Acute myocardial infarction	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Angina pectoris	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aortic valve calcification	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Atrial fibrillation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Atrial flutter	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bradycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bundle branch block right	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cardiac failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cardio-respiratory arrest	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Extrasystoles	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myocardial ischaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nodal arrhythmia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Palpitations	0	84	29.9	3	3.6	1.2	10.0

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pericardial effusion	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinus bradycardia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinus tachycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Stress cardiomyopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Supraventricular tachycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tachycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Ventricular extrasystoles	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ventricular pre-excitation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Congenital, familial and genetic disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gilbert's syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hydrocele	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Ear and labyrinth disorders	-Total	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	13	6.8	4.0	11.4

		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear congestion	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear pain	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tinnitus	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Vertigo	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Endocrine disorders	-Total	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Adrenal insufficiency	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperthyroidism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypothyroidism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Eye disorders	-Total	0	84	29.9	15	17.9	11.1	27.4
		1	190	67.6	24	12.6	8.6	18.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal sensation in eye	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blepharitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Cataract	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chalazion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Conjunctival cyst	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Conjunctival haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diplopia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry eye	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eye swelling	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eyelid oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eyelid ptosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Keratitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ocular discomfort	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Periorbital oedema	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Photophobia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Photopsia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ulcerative keratitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vision blurred	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Visual acuity reduced	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Gastrointestinal disorders	-Total	0	84	29.9	66	78.6	68.7	86.0
		1	190	67.6	132	69.5	62.6	75.6
		2	6	2.1	5	83.3	43.6	97.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Abdominal discomfort	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal distension	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain lower	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain upper	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal symptom	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Anal incontinence	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aphthous ulcer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ascites	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Colitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Constipation	0	84	29.9	42	50.0	39.5	60.5
		1	190	67.6	72	37.9	31.3	45.0
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	1	100.0	20.7	100.0
	Dental caries	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dental dysaesthesia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diarrhoea	0	84	29.9	23	27.4	19.0	37.7
		1	190	67.6	44	23.2	17.7	29.7
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Diverticular perforation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry mouth	0	84	29.9	20	23.8	16.0	33.9
		1	190	67.6	26	13.7	9.5	19.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspepsia	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysphagia	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Enteritis	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epigastric discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eructation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Faeces soft	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Flatulence	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Frequent bowel movements	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastric ulcer	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastritis erosive	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal inflammation	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal wall thickening	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrooesophageal reflux disease	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gingival bleeding	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gingival swelling	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glossitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glossodynia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematochezia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhoids	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoaesthesia oral	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Impaired gastric emptying	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intestinal obstruction	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Irritable bowel syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Large intestine perforation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Melaena	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Mouth ulceration	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nausea	0	84	29.9	13	15.5	9.3	24.7
		1	190	67.6	27	14.2	10.0	19.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	1	100.0	20.7	100.0
	Odynophagia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oesophageal irritation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oesophagitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral dysaesthesia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral mucosal erythema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancreatitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancreatitis acute	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Paraesthesia oral	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Proctitis ulcerative	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rectal prolapse	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Regurgitation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sensitivity of teeth	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Stomatitis	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Swollen tongue	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tongue coated	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tongue discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tongue ulceration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tooth discolouration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Toothache	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Vomiting	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	20	10.5	6.9	15.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
General disorders and administration site conditions	-Total	0	84	29.9	58	69.0	58.5	77.9
		1	190	67.6	137	72.1	65.3	78.0
		2	6	2.1	6	100.0	61.0	100.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Asthenia	0	84	29.9	15	17.9	11.1	27.4
		1	190	67.6	23	12.1	8.2	17.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Axillary pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Catheter site pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest discomfort	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chills	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Condition aggravated	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Death	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disease progression	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	18	9.5	6.1	14.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Face oedema	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Facial pain	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fatigue	0	84	29.9	19	22.6	15.0	32.6
		1	190	67.6	44	23.2	17.7	29.7
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	1	100.0	20.7	100.0
	Feeling abnormal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Feeling cold	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Feeling hot	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gait disturbance	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	General physical health deterioration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Generalised oedema	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Impaired healing	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Influenza like illness	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Injection site bruising	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Localised oedema	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Malaise	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	20	10.5	6.9	15.7

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mucosal dryness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mucosal inflammation	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Multiple organ dysfunction syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Non-cardiac chest pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oedema peripheral	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	30	15.8	11.3	21.6
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Peripheral swelling	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyrexia	0	84	29.9	25	29.8	21.0	40.2
		1	190	67.6	43	22.6	17.3	29.1
		2	6	2.1	4	66.7	30.0	90.3
		Missing	1	0.4	0	0.0	0.0	79.3
	Swelling	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Temperature intolerance	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Xerosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
Hepatobiliary disorders	-Total	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Cholecystitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Cholelithiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gallbladder polyp	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic function abnormal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic steatosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatocellular injury	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperbilirubinaemia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Liver disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Liver injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumobilia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Portal vein thrombosis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

Immune system disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Contrast media allergy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Drug hypersensitivity	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Food allergy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypersensitivity	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Seasonal allergy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Infections and infestations	-Total	0	84	29.9	52	61.9	51.2	71.6
		1	190	67.6	101	53.2	46.1	60.1
		2	6	2.1	4	66.7	30.0	90.3
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal abscess	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute sinusitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Appendicitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Arthritis infective	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Atypical pneumonia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacterial disease carrier	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacterial infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacterial vaginosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bronchitis	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Candida infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cellulitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chronic sinusitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Clostridium difficile colitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Conjunctivitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Corona virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis escherichia	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Device related infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diverticulitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Empyema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Enterococcal bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epididymitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epstein-Barr virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Escherichia bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Escherichia infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Escherichia urinary tract infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eye infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Febrile infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Folliculitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fungal infection	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastroenteritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Genital candidiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Genital herpes	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gingivitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Herpes simplex	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Herpes virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Herpes zoster	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Infectious colitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Influenza	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Lower respiratory tract infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lung infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lyme disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymph node tuberculosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Meningitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasal herpes	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasopharyngitis	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral candidiasis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral fungal infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oropharyngeal candidiasis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Otitis externa	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Otitis media	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Paronychia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Peritonitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Pharyngitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumocystis jirovecii pneumonia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia	0	84	29.9	16	19.0	12.1	28.7
		1	190	67.6	26	13.7	9.5	19.3
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia bacterial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia cytomegaloviral	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia haemophilus	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia influenzal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia pseudomonal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia streptococcal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Pyelonephritis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyelonephritis acute	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rectal abscess	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal tuberculosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory tract infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory tract infection bacterial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinitis	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sepsis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Septic shock	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinusitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinusitis bacterial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin infection	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Staphylococcal infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Systemic infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tinea cruris	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tinea infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tinea pedis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tonsillitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tooth infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tracheitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tuberculosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Upper respiratory tract infection	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urethritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary tract infection	0	84	29.9	13	15.5	9.3	24.7
		1	190	67.6	24	12.6	8.6	18.1

		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Urosepsis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Varicella	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Varicella zoster virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Viral hepatitis carrier	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Viral infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vulvovaginal candidiasis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Injury, poisoning and procedural complications	-Total	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	20	10.5	6.9	15.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Contusion	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epicondylitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fall	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Fracture	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Heart injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Incision site pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint dislocation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Laceration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ligament sprain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Limb injury	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle rupture	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle strain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Procedural pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Procedural pneumothorax	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rib fracture	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Scar	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Skin abrasion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Subdural haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Tendon rupture	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thermal burn	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wound	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wound complication	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wrist fracture	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Investigations	-Total	0	84	29.9	64	76.2	66.1	84.0
		1	190	67.6	154	81.1	74.9	86.0
		2	6	2.1	4	66.7	30.0	90.3
		Missing	1	0.4	1	100.0	20.7	100.0
	Alanine aminotransferase	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alanine aminotransferase increased	0	84	29.9	24	28.6	20.0	39.0
		1	190	67.6	66	34.7	28.3	41.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	1	100.0	20.7	100.0
	Albumin urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Alpha hydroxybutyrate dehydrogenase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Amylase increased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aspartate aminotransferase increased	0	84	29.9	30	35.7	26.3	46.4
		1	190	67.6	92	48.4	41.4	55.5
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	1	100.0	20.7	100.0
	Bacterial test	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bilirubin conjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	20	10.5	6.9	15.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood albumin decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase increased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	32	16.8	12.2	22.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin increased	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	21	11.1	7.3	16.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin unconjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood calcium decreased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood calcium increased	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood chloride increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood cholesterol increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine increased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase MB increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase increased	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	42	22.1	16.8	28.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatinine	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatinine increased	0	84	29.9	18	21.4	14.0	31.3
		1	190	67.6	43	22.6	17.3	29.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood fibrinogen increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood glucose increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood iron decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood ketone body increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood lactate dehydrogenase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	10	5.3	2.9	9.4

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood magnesium decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood phosphorus increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood potassium decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood potassium increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood pressure increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood sodium decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood thyroid stimulating hormone increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood triglycerides increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood urea increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood uric acid decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood uric acid increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood urine	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Blood urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	C-reactive protein increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Carbon dioxide decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Complement factor C1 decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Computerised tomogram thorax abnormal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Crystal urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystatin C increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrocardiogram QT prolonged	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrocardiogram ST-T change	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fibrin D dimer increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fibrin degradation products increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Free fatty acids increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Gamma-glutamyltransferase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	20	10.5	6.9	15.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glomerular filtration rate decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glutamate dehydrogenase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Granulocyte count decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematocrit decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemoglobin decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Heart rate increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic enzyme increased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	International normalised ratio increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intraocular pressure increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Laboratory test abnormal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lipase increased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Liver function test increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphocyte count decreased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	22	11.6	7.8	16.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphocyte count increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mean cell volume increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myoglobin blood increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil count decreased	0	84	29.9	19	22.6	15.0	32.6
		1	190	67.6	61	32.1	25.9	39.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil count increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil percentage increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Occult blood positive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oxygen saturation decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	PO2 decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count decreased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	29	15.3	10.8	21.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count increased	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Procalcitonin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Protein total decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Protein total increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Protein urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Prothrombin time prolonged	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Red blood cell count decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Serum amyloid A protein increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombin time prolonged	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Total bile acids increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Transaminases increased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Transferrin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Troponin T increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Troponin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary sediment present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urine ketone body present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urine leukocyte esterase positive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urobilinogen urine increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Weight decreased	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Weight increased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	21	11.1	7.3	16.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	White blood cell count decreased	0	84	29.9	12	14.3	8.4	23.3
		1	190	67.6	59	31.1	24.9	38.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	White blood cells urine positive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Metabolism and nutrition disorders	-Total	0	84	29.9	41	48.8	38.4	59.3
		1	190	67.6	103	54.2	47.1	61.1
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal loss of weight	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Acidosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Alkalosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cell death	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Decreased appetite	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	29	15.3	10.8	21.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dehydration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrolyte imbalance	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Failure to thrive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fluid retention	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercalcaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercholesterolaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperglycaemia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperkalaemia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperlipidaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Hypermagnesaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypernatraemia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperphosphataemia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	25	13.2	9.1	18.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertriglyceridaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperuricaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoalbuminaemia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	29	15.3	10.8	21.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypocalcaemia	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	29	15.3	10.8	21.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypochloraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoglycaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypokalaemia	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	27	14.2	10.0	19.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypomagnesaemia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyponatraemia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	22	11.6	7.8	16.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Hypophosphataemia	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	25	13.2	9.1	18.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoproteinaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Increased appetite	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vitamin D deficiency	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Musculoskeletal and connective tissue disorders	-Total	0	84	29.9	43	51.2	40.7	61.6
		1	190	67.6	78	41.1	34.3	48.2
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Arthralgia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Arthropathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Back pain	0	84	29.9	15	17.9	11.1	27.4
		1	190	67.6	21	11.1	7.3	16.3
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bone pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bursitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Coccydynia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Costochondritis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Flank pain	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Groin pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercreatinaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intervertebral disc protrusion	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint range of motion decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint stiffness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint swelling	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle fatigue	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle haemorrhage	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle spasms	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	16	8.4	5.2	13.2
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscular weakness	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal chest pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal pain	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	16	8.4	5.2	13.2

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal stiffness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myalgia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neck pain	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Osteopenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain in extremity	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain in jaw	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhabdomyolysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rotator cuff syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Spinal column stenosis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Spinal osteoarthritis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tendon disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Tendon pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anogenital warts	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Basal cell carcinoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bowen's disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cancer pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gallbladder cancer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Metastases to central nervous system	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal cell carcinoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Squamous cell carcinoma	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Squamous cell carcinoma of skin	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tumour pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

Nervous system disorders	-Total	0	84	29.9	39	46.4	36.2	57.0
		1	190	67.6	102	53.7	46.6	60.6
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	1	100.0	20.7	100.0
	Ageusia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aphasia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ataxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Balance disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Brain oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebellar haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebral haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebral microhaemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebrovascular accident	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disturbance in attention	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dizziness	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	29	15.3	10.8	21.1
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Dizziness postural	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysarthria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysgeusia	0	84	29.9	13	15.5	9.3	24.7
		1	190	67.6	28	14.7	10.4	20.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyskinesia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epilepsy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Facial paralysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhage intracranial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Headache	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	23	12.1	8.2	17.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	1	100.0	20.7	100.0
	Hemiplegia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperaesthesia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypersomnia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoaesthesia	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypotonia	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lethargy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lumbar radiculopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lumbosacral radiculopathy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Memory impairment	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Migraine	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Migraine with aura	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neuralgia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neuropathy peripheral	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paraesthesia	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paralysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Parosmia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Peripheral sensory neuropathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	8	4.2	2.1	8.1

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Polyneuropathy chronic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Post herpetic neuralgia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Presyncope	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Psychomotor skills impaired	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Restless legs syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sciatica	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Seizure	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Sensory disturbance	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Slow speech	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Somnolence	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Spinal cord haematoma	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Syncope	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Tension headache	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tremor	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Visual field defect	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Product issues	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Device dislocation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Psychiatric disorders	-Total	0	84	29.9	18	21.4	14.0	31.3
		1	190	67.6	36	18.9	14.0	25.1
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal behaviour	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal dreams	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Adjustment disorder with mixed anxiety and depressed mood	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anxiety	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Bradyphrenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Confusional state	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Delirium	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Depressed mood	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Depression	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fear of falling	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Insomnia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	18	9.5	6.1	14.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Irritability	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Libido decreased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mental status changes	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mood altered	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Psychomotor retardation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Restlessness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sleep disorder	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

Renal and urinary disorders	-Total	0	84	29.9	14	16.7	10.2	26.1
		1	190	67.6	26	13.7	9.5	19.3
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute kidney injury	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Azotaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis haemorrhagic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysuria	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhage urinary tract	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hydronephrosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Micturition urgency	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Nephritis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nephrolithiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nocturia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Obstructive nephropathy	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pollakiuria	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Proteinuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal colic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal disorder	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal failure	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal impairment	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Strangury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urethral stenosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary incontinence	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary retention	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary tract pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urine flow decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Reproductive system and breast disorders	-Total	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Benign prostatic hyperplasia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Breast discharge	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Erectile dysfunction	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Galactorrhoea	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Genital ulceration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Metrorrhagia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ovarian cyst	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pelvic discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pelvic fluid collection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Perineal pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Postmenopausal haemorrhage	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Prostatitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Uterine polyp	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vaginal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vulvovaginal dryness	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vulvovaginal erythema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Respiratory, thoracic and mediastinal disorders	-Total	0	84	29.9	55	65.5	54.8	74.8
		1	190	67.6	109	57.4	50.3	64.2
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute respiratory failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aspiration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bronchospasm	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Choking	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cough	0	84	29.9	24	28.6	20.0	39.0
		1	190	67.6	39	20.5	15.4	26.8
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry throat	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Dysphonia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	35	18.4	13.6	24.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea exertional	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epistaxis	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemoptysis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hiccups	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Interstitial lung disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Laryngeal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lung consolidation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasal congestion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasal dryness	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Nasal polyps	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oropharyngeal discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oropharyngeal pain	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paranasal sinus discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pharyngeal disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural effusion	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural thickening	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleuritic pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonitis	0	84	29.9	15	17.9	11.1	27.4
		1	190	67.6	16	8.4	5.2	13.2
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumothorax	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Productive cough	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary embolism	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary hypertension	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary mass	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiration abnormal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory distress	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinalgia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinitis allergic	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinorrhoea	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinus congestion	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sleep apnoea syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sputum discoloured	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Throat irritation	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Upper-airway cough syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vocal cord leukoplakia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wheezing	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Skin and subcutaneous tissue disorders	-Total	0	84	29.9	37	44.0	33.9	54.7
		1	190	67.6	59	31.1	24.9	38.0
		2	6	2.1	4	66.7	30.0	90.3
		Missing	1	0.4	0	0.0	0.0	79.3
	Acne	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alopecia	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chloasma	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Decubitus ulcer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermal cyst	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis acneiform	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis allergic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis bullous	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry skin	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Ecchymosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eczema	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Erythema	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hair growth abnormal	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hair texture abnormal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hirsutism	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperhidrosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperkeratosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertrichosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Madarosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Nail discolouration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nail disorder	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Night sweats	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Onychalgia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Onycholysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Onychomadesis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain of skin	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Palmar-plantar erythrodysaesthesia syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Photosensitivity reaction	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pruritus	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pruritus generalised	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Purpura	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Rash	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash erythematous	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash macular	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash maculo-papular	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash papular	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Scab	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Scar pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin discolouration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin hyperpigmentation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin lesion	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Swelling face	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urticaria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Surgical and medical procedures	-Total	0	84	29.9	6	7.1	3.3	14.7

		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Astringent therapy	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eye excision	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hip arthroplasty	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Therapy cessation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Vascular disorders	-Total	0	84	29.9	33	39.3	29.5	50.0
		1	190	67.6	80	42.1	35.3	49.2
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aortic dissection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Circulatory collapse	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Deep vein thrombosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism venous	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Flushing	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hot flush	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertension	0	84	29.9	29	34.5	25.2	45.2
		1	190	67.6	65	34.2	27.8	41.2
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypotension	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphoedema	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Orthostatic hypotension	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pallor	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Phlebitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Raynaud's phenomenon	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Shock haemorrhagic	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Superior vena cava syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombophlebitis superficial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEANY_SG.xls
26MAR2021 13:27

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	USA	64	22.8	40	62.5	50.3	73.3
		Europe (EU)	95	33.8	48	50.5	40.6	60.4
		Asia (AS)	122	43.4	81	66.4	57.6	74.2
	Anaemia	USA	64	22.8	31	48.4	36.6	60.4
		Europe (EU)	95	33.8	39	41.1	31.7	51.1
		Asia (AS)	122	43.4	59	48.4	39.7	57.1
	Anaemia macrocytic	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aplastic anaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bone marrow oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cytopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Disseminated intravascular coagulation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Febrile neutropenia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Haemorrhagic anaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperfibrinogenaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Leukocytosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Leukopenia	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	14	14.7	9.0	23.2
		Asia (AS)	122	43.4	12	9.8	5.7	16.4
	Lymph node pain	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lymphadenopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lymphopenia	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	14	14.7	9.0	23.2
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neutropenia	USA	64	22.8	19	29.7	19.9	41.8
		Europe (EU)	95	33.8	20	21.1	14.1	30.3
		Asia (AS)	122	43.4	22	18.0	12.2	25.8
	Neutrophilia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pancytopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thrombocytopenia	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Thrombocytosis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Cardiac disorders	-Total	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	12	12.6	7.4	20.8
		Asia (AS)	122	43.4	19	15.6	10.2	23.0
	Acute coronary syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Acute myocardial infarction	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Angina pectoris	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aortic valve calcification	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Atrial fibrillation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Atrial flutter	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Bradycardia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bundle branch block right	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cardiac failure	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Cardio-respiratory arrest	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Extrasystoles	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Myocardial ischaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nodal arrhythmia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Palpitations	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pericardial effusion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinus bradycardia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinus tachycardia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Stress cardiomyopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Supraventricular tachycardia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tachycardia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Ventricular extrasystoles	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Ventricular pre-excitation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

Congenital, familial and genetic disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gilbert's syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hydrocele	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Ear and labyrinth disorders	-Total	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Ear congestion	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ear discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ear pain	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tinnitus	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Vertigo	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
Endocrine disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Adrenal insufficiency	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperthyroidism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypothyroidism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Eye disorders	-Total	USA	64	22.8	17	26.6	17.3	38.5
		Europe (EU)	95	33.8	13	13.7	8.2	22.0
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Abnormal sensation in eye	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Blepharitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cataract	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Chalazion	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Conjunctival cyst	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Conjunctival haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Diplopia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dry eye	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eye swelling	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eyelid oedema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Eyelid ptosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Keratitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ocular discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Periorbital oedema	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Photophobia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Photopsia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ulcerative keratitis	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vision blurred	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Visual acuity reduced	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Gastrointestinal disorders	-Total	USA	64	22.8	54	84.4	73.6	91.3
		Europe (EU)	95	33.8	71	74.7	65.2	82.4
		Asia (AS)	122	43.4	79	64.8	55.9	72.7
	Abdominal discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Abdominal distension	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Abdominal pain	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Abdominal pain lower	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Abdominal pain upper	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Abdominal symptom	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Anal incontinence	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Aphthous ulcer	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ascites	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Colitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Constipation	USA	64	22.8	25	39.1	28.1	51.3
		Europe (EU)	95	33.8	40	42.1	32.7	52.2
		Asia (AS)	122	43.4	53	43.4	35.0	52.3
	Dental caries	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dental dysaesthesia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Diarrhoea	USA	64	22.8	19	29.7	19.9	41.8
		Europe (EU)	95	33.8	27	28.4	20.3	38.2
		Asia (AS)	122	43.4	24	19.7	13.6	27.6
	Diverticular perforation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dry mouth	USA	64	22.8	19	29.7	19.9	41.8
		Europe (EU)	95	33.8	18	18.9	12.3	28.0
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Dyspepsia	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Dysphagia	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Enteritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epigastric discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eructation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Faeces soft	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Flatulence	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Frequent bowel movements	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastric ulcer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastritis erosive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Gastrointestinal haemorrhage	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastrointestinal inflammation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal wall thickening	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrooesophageal reflux disease	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gingival bleeding	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Gingival swelling	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Glossitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Glossodynia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haematochezia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haemorrhoids	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hypoaesthesia oral	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Impaired gastric emptying	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Intestinal obstruction	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Irritable bowel syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Large intestine perforation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Melaena	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Mouth ulceration	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Nausea	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	17	17.9	11.5	26.8
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Odynophagia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oesophageal irritation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oesophagitis	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oral disorder	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oral dysaesthesia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oral mucosal erythema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oral pain	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pancreatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pancreatitis acute	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Paraesthesia oral	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Proctitis ulcerative	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rectal prolapse	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Regurgitation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sensitivity of teeth	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Stomatitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Swollen tongue	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tongue coated	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tongue discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tongue ulceration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tooth discolouration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Toothache	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Vomiting	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	13	13.7	8.2	22.0
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
General disorders and administration site conditions	-Total	USA	64	22.8	49	76.6	64.9	85.3
		Europe (EU)	95	33.8	69	72.6	62.9	80.6
		Asia (AS)	122	43.4	84	68.9	60.2	76.4
	Asthenia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	26	27.4	19.4	37.1
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Axillary pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Catheter site pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Chest discomfort	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Chest pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Chills	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Condition aggravated	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Death	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Disease progression	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Face oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	17	13.9	8.9	21.2
	Facial pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fatigue	USA	64	22.8	27	42.2	30.9	54.4
		Europe (EU)	95	33.8	23	24.2	16.7	33.7
		Asia (AS)	122	43.4	17	13.9	8.9	21.2
	Feeling abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Feeling cold	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Feeling hot	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gait disturbance	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	General physical health deterioration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Generalised oedema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Impaired healing	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Influenza like illness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Injection site bruising	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Localised oedema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Malaise	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	18	14.8	9.5	22.1
	Mucosal dryness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Mucosal inflammation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	18	18.9	12.3	28.0
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Multiple organ dysfunction syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Non-cardiac chest pain	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Oedema	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oedema peripheral	USA	64	22.8	19	29.7	19.9	41.8
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Pain	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Peripheral swelling	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Pyrexia	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	27	28.4	20.3	38.2
		Asia (AS)	122	43.4	34	27.9	20.7	36.4
	Swelling	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Temperature intolerance	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Xerosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Hepatobiliary disorders	-Total	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Cholecystitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Cholelithiasis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gallbladder polyp	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hepatic function abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Hepatic steatosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hepatocellular injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperbilirubinaemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Liver disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Liver injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumobilia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Portal vein thrombosis	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Immune system disorders	-Total	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Contrast media allergy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Drug hypersensitivity	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Food allergy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypersensitivity	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Seasonal allergy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Infections and infestations	-Total	USA	64	22.8	41	64.1	51.8	74.7
		Europe (EU)	95	33.8	61	64.2	54.2	73.1
		Asia (AS)	122	43.4	55	45.1	36.5	53.9
	Abdominal abscess	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Acute sinusitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Appendicitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Arthritis infective	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Atypical pneumonia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacteraemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacterial disease carrier	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacterial infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacterial vaginosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bronchitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Candida infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cellulitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Chronic sinusitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Clostridium difficile colitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Conjunctivitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Corona virus infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cystitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cystitis escherichia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Device related infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Diverticulitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ear infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Empyema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Enterococcal bacteraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epididymitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epstein-Barr virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Escherichia bacteraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Escherichia infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Escherichia urinary tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eye infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Febrile infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Folliculitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fungal infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Gastroenteritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Genital candidiasis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Genital herpes	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gingivitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Herpes simplex	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Herpes virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Herpes zoster	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Infectious colitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Influenza	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lower respiratory tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lung infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Lyme disease	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymph node tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Meningitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasal herpes	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasopharyngitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Oral candidiasis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oral fungal infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oropharyngeal candidiasis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Otitis externa	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Otitis media	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Paronychia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Peritonitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pharyngitis	USA	64	22.8	2	3.1	0.9	10.7

		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pleural infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumocystis jirovecii pneumonia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonia	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	15	15.8	9.8	24.4
		Asia (AS)	122	43.4	22	18.0	12.2	25.8
	Pneumonia bacterial	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonia cytomegaloviral	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonia haemophilus	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonia influenzal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonia pseudomonal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonia streptococcal	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pyelonephritis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pyelonephritis acute	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pyuria	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rectal abscess	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory tract infection bacterial	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhinitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Sepsis	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Septic shock	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinusitis	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Sinusitis bacterial	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Staphylococcal infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Systemic infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tinea cruris	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tinea infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tinea pedis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tonsillitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tooth infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tracheitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Upper respiratory tract infection	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Urethritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary tract infection	USA	64	22.8	14	21.9	13.5	33.4
		Europe (EU)	95	33.8	14	14.7	9.0	23.2
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Urosepsis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Varicella	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Varicella zoster virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Viral hepatitis carrier	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Viral infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vulvovaginal candidiasis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Injury, poisoning and procedural complications	-Total	USA	64	22.8	13	20.3	12.3	31.7
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Contusion	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epicondylitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fall	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Fracture	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Heart injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Incision site pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Joint dislocation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Laceration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ligament sprain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Limb injury	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle rupture	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle strain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Procedural pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Procedural pneumothorax	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rib fracture	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Scar	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin abrasion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Subdural haematoma	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tendon rupture	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thermal burn	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Wound	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Wound complication	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Wrist fracture	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Investigations	-Total	USA	64	22.8	51	79.7	68.3	87.7
		Europe (EU)	95	33.8	68	71.6	61.8	79.7
		Asia (AS)	122	43.4	104	85.2	77.9	90.5
	Alanine aminotransferase	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Alanine aminotransferase increased	USA	64	22.8	20	31.3	21.2	43.4
		Europe (EU)	95	33.8	20	21.1	14.1	30.3
		Asia (AS)	122	43.4	52	42.6	34.2	51.5
	Albumin urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Alpha hydroxybutyrate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Amylase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Aspartate aminotransferase increased	USA	64	22.8	28	43.8	32.3	55.9
		Europe (EU)	95	33.8	29	30.5	22.2	40.4
		Asia (AS)	122	43.4	69	56.6	47.7	65.0
	Bacterial test	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bilirubin conjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	20	16.4	10.9	24.0
	Blood albumin decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood alkaline phosphatase	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood alkaline phosphatase decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood alkaline phosphatase increased	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	25	20.5	14.3	28.5
	Blood bilirubin increased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	19	15.6	10.2	23.0
	Blood bilirubin unconjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Blood calcium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood calcium increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood chloride increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood cholesterol increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Blood creatine increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood creatine phosphokinase MB increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Blood creatine phosphokinase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	16	16.8	10.6	25.6
		Asia (AS)	122	43.4	37	30.3	22.9	39.0
	Blood creatinine	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood creatinine increased	USA	64	22.8	17	26.6	17.3	38.5
		Europe (EU)	95	33.8	21	22.1	14.9	31.4
		Asia (AS)	122	43.4	24	19.7	13.6	27.6
	Blood fibrinogen increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Blood glucose increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Blood iron decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood ketone body increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood lactate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Blood magnesium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood phosphorus increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Blood potassium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood potassium increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood pressure increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Blood sodium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood thyroid stimulating hormone increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood triglycerides increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Blood urea increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Blood uric acid decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood uric acid increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3

	Blood urine	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Blood urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	C-reactive protein increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Carbon dioxide decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Complement factor C1 decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Computerised tomogram thorax abnormal	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Crystal urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cystatin C increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Electrocardiogram QT prolonged	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Electrocardiogram ST-T change	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Fibrin D dimer increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Fibrin degradation products increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Free fatty acids increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gamma-glutamyltransferase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	19	15.6	10.2	23.0
	Glomerular filtration rate decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Glutamate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Granulocyte count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haematocrit decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haemoglobin decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Heart rate increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Hepatic enzyme increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	International normalised ratio increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Intraocular pressure increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Laboratory test abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lipase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Liver function test increased	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymphocyte count decreased	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	12	9.8	5.7	16.4
	Lymphocyte count increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Mean cell volume increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Myoglobin blood increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Neutrophil count decreased	USA	64	22.8	10	15.6	8.7	26.4
		Europe (EU)	95	33.8	7	7.4	3.6	14.4

		Asia (AS)	122	43.4	64	52.5	43.7	61.1
	Neutrophil count increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Neutrophil percentage increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Occult blood positive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Oxygen saturation decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	PO2 decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Platelet count decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	26	21.3	15.0	29.4
	Platelet count increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Procalcitonin increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Protein total decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Protein total increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Protein urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Prothrombin time prolonged	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Red blood cell count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Serum amyloid A protein increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Thrombin time prolonged	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Total bile acids increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Transaminases increased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Transferrin increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Troponin T increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Troponin increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary sediment present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urine ketone body present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Urine leukocyte esterase positive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urobilinogen urine increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Weight decreased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
	Weight increased	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	19	15.6	10.2	23.0
	White blood cell count decreased	USA	64	22.8	18	28.1	18.6	40.1
		Europe (EU)	95	33.8	12	12.6	7.4	20.8
		Asia (AS)	122	43.4	42	34.4	26.6	43.2
	White blood cells urine positive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
Metabolism and nutrition disorders	-Total	USA	64	22.8	30	46.9	35.2	58.9
		Europe (EU)	95	33.8	44	46.3	36.6	56.3
		Asia (AS)	122	43.4	73	59.8	51.0	68.1
	Abnormal loss of weight	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Acidosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Alkalosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cell death	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Decreased appetite	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	24	19.7	13.6	27.6
	Dehydration	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Electrolyte imbalance	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Failure to thrive	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fluid retention	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypercalcaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Hypercholesterolaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hyperglycaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
	Hyperkalaemia	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Hyperlipidaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Hypermagnesaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hypernatraemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hyperphosphataemia	USA	64	22.8	6	9.4	4.4	19.0

		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Hypertriglyceridaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Hyperuricaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Hypoalbuminaemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	32	26.2	19.2	34.7
	Hypocalcaemia	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	19	15.6	10.2	23.0
	Hypochloraemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Hypoglycaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypokalaemia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	14	14.7	9.0	23.2
		Asia (AS)	122	43.4	21	17.2	11.5	24.9
	Hypomagnesaemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Hyponatraemia	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	19	15.6	10.2	23.0
	Hypophosphataemia	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	10	10.5	5.8	18.3
		Asia (AS)	122	43.4	20	16.4	10.9	24.0
	Hypoproteinaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Increased appetite	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vitamin D deficiency	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Musculoskeletal and connective tissue disorders	-Total	USA	64	22.8	41	64.1	51.8	74.7
		Europe (EU)	95	33.8	40	42.1	32.7	52.2
		Asia (AS)	122	43.4	43	35.2	27.3	44.1
	Arthralgia	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	6	6.3	2.9	13.1

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Arthropathy	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Back pain	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	12	9.8	5.7	16.4
	Bone pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Bursitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Coccydynia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Costochondritis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Flank pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Groin pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypercreatinaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Intervertebral disc protrusion	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Joint range of motion decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Joint stiffness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Joint swelling	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle fatigue	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Muscle haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Muscle spasms	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Muscular weakness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Musculoskeletal chest pain	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Musculoskeletal pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	12	12.6	7.4	20.8
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Musculoskeletal stiffness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Myalgia	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Myopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neck pain	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Osteopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pain in extremity	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Pain in jaw	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhabdomyolysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rotator cuff syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Spinal column stenosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Spinal osteoarthritis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Tendon disorder	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tendon pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Anogenital warts	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Basal cell carcinoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bowen's disease	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cancer pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gallbladder cancer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Metastases to central nervous system	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal cell carcinoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Squamous cell carcinoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Squamous cell carcinoma of skin	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tumour pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Nervous system disorders	-Total	USA	64	22.8	43	67.2	55.0	77.4
		Europe (EU)	95	33.8	47	49.5	39.6	59.4
		Asia (AS)	122	43.4	55	45.1	36.5	53.9
	Ageusia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aphasia	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ataxia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Balance disorder	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Brain oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebellar haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebral haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebral microhaemorrhage	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebrovascular accident	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Disturbance in attention	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dizziness	USA	64	22.8	14	21.9	13.5	33.4
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Dizziness postural	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dysarthria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dysgeusia	USA	64	22.8	14	21.9	13.5	33.4
		Europe (EU)	95	33.8	20	21.1	14.1	30.3
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Dyskinesia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Epilepsy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Facial paralysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haemorrhage intracranial	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Headache	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	13	13.7	8.2	22.0
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Hemiplegia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyperaesthesia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypersomnia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypoaesthesia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	16	13.1	8.2	20.2
	Hypotonia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lethargy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lumbar radiculopathy	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lumbosacral radiculopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Memory impairment	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Migraine	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Migraine with aura	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neuralgia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neuropathy peripheral	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

	Paraesthesia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Paralysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Parosmia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Peripheral sensory neuropathy	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Polyneuropathy chronic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Post herpetic neuralgia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Presyncope	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Psychomotor skills impaired	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Restless legs syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sciatica	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Seizure	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Sensory disturbance	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Slow speech	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Somnolence	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Spinal cord haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Syncope	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tension headache	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tremor	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Visual field defect	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Product issues	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Device dislocation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Psychiatric disorders	-Total	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	17	17.9	11.5	26.8
		Asia (AS)	122	43.4	24	19.7	13.6	27.6
	Abnormal behaviour	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Abnormal dreams	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Adjustment disorder with mixed anxiety and depressed mood	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Anxiety	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Bradyphrenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Confusional state	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Delirium	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Depressed mood	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Depression	USA	64	22.8	2	3.1	0.9	10.7

		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fear of falling	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Insomnia	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Irritability	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Libido decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Mental status changes	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Mood altered	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Psychomotor retardation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Restlessness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Sleep disorder	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Renal and urinary disorders	-Total	USA	64	22.8	19	29.7	19.9	41.8
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Acute kidney injury	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Azotaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Cystitis haemorrhagic	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dysuria	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Haematuria	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Haemorrhage urinary tract	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hydronephrosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Micturition urgency	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nephritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nephrolithiasis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nocturia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Obstructive nephropathy	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pollakiuria	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Proteinuria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Renal colic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal failure	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal impairment	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Strangury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urethral stenosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Urinary incontinence	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary retention	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urinary tract pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urine flow decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Reproductive system and breast disorders	-Total	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Benign prostatic hyperplasia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Breast discharge	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Erectile dysfunction	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Galactorrhoea	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Genital ulceration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Metrorrhagia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ovarian cyst	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pelvic discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pelvic fluid collection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Perineal pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Postmenopausal haemorrhage	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Prostatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Uterine polyp	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vaginal haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vulvovaginal dryness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vulvovaginal erythema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Respiratory, thoracic and mediastinal disorders	-Total	USA	64	22.8	39	60.9	48.7	71.9
		Europe (EU)	95	33.8	59	62.1	52.1	71.2
		Asia (AS)	122	43.4	69	56.6	47.7	65.0
	Acute respiratory failure	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aspiration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bronchospasm	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Choking	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cough	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	23	24.2	16.7	33.7
		Asia (AS)	122	43.4	27	22.1	15.7	30.3
	Dry throat	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dysphonia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Dyspnoea	USA	64	22.8	10	15.6	8.7	26.4
		Europe (EU)	95	33.8	18	18.9	12.3	28.0
		Asia (AS)	122	43.4	19	15.6	10.2	23.0
	Dyspnoea exertional	USA	64	22.8	3	4.7	1.6	12.9

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Epistaxis	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Haemoptysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Hiccups	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypoxia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Interstitial lung disease	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Laryngeal haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lung consolidation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasal congestion	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasal dryness	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasal polyps	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oropharyngeal discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oropharyngeal pain	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Paranasal sinus discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pharyngeal disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pleural effusion	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7

		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Pleural thickening	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pleuritic pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonitis	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	10	10.5	5.8	18.3
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Pneumothorax	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Productive cough	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Pulmonary embolism	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pulmonary hypertension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pulmonary mass	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pulmonary pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiration abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Respiratory distress	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory failure	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhinalgia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhinitis allergic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rhinorrhoea	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Sinus congestion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sleep apnoea syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Sputum discoloured	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Throat irritation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Upper-airway cough syndrome	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vocal cord leukoplakia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Wheezing	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Skin and subcutaneous tissue disorders	-Total	USA	64	22.8	32	50.0	38.1	61.9
		Europe (EU)	95	33.8	29	30.5	22.2	40.4
		Asia (AS)	122	43.4	39	32.0	24.4	40.7
	Acne	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Alopecia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Chloasma	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Decubitus ulcer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dermal cyst	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dermatitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dermatitis acneiform	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1

	Dermatitis allergic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dermatitis bullous	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dry skin	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Ecchymosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Eczema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Erythema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hair growth abnormal	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hair texture abnormal	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hirsutism	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperhidrosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperkeratosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypertrichosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Madarosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nail discolouration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nail disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Night sweats	USA	64	22.8	2	3.1	0.9	10.7

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Onychalgia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Onycholysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Onychomadesis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Pain of skin	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Palmar-plantar erythrodysaesthesia syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Photosensitivity reaction	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pruritus	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Pruritus generalised	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Purpura	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rash	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Rash erythematous	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rash macular	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rash maculo-papular	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rash papular	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Scab	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Scar pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Skin discolouration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin hyperpigmentation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin lesion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Swelling face	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Urticaria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Surgical and medical procedures	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Astringent therapy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eye excision	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hip arthroplasty	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Therapy cessation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Vascular disorders	-Total	USA	64	22.8	32	50.0	38.1	61.9
		Europe (EU)	95	33.8	32	33.7	25.0	43.7
		Asia (AS)	122	43.4	51	41.8	33.4	50.7
	Aortic dissection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Circulatory collapse	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Deep vein thrombosis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Embolism	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Embolism venous	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Flushing	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hot flush	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypertension	USA	64	22.8	24	37.5	26.7	49.7
		Europe (EU)	95	33.8	24	25.3	17.6	34.8
		Asia (AS)	122	43.4	48	39.3	31.1	48.2
	Hypotension	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Lymphoedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Orthostatic hypotension	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pallor	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Phlebitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Raynaud's phenomenon	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Shock haemorrhagic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Superior vena cava syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Thrombophlebitis superficial	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Thrombosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEANY_SG.xls
26MAR2021 13:27

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	116	41.3	61	52.6	43.6	61.4
		1	77	27.4	46	59.7	48.6	70.0
		>= 2	88	31.3	62	70.5	60.2	79.0
	Anaemia	0	116	41.3	43	37.1	28.8	46.1
		1	77	27.4	39	50.6	39.7	61.5
		>= 2	88	31.3	47	53.4	43.1	63.5
	Anaemia macrocytic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Aplastic anaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bone marrow oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cytopenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Disseminated intravascular coagulation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Febrile neutropenia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Haemorrhagic anaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperfibrinogenaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Leukocytosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Leukopenia	0	116	41.3	15	12.9	8.0	20.2
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	8	9.1	4.7	16.9
	Lymph node pain	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymphadenopathy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymphopenia	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	6	6.8	3.2	14.1
	Neutropenia	0	116	41.3	19	16.4	10.7	24.2
		1	77	27.4	19	24.7	16.4	35.4
		>= 2	88	31.3	23	26.1	18.1	36.2
	Neutrophilia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pancytopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Thrombocytopenia	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	9	10.2	5.5	18.3
	Thrombocytosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
Cardiac disorders	-Total	0	116	41.3	15	12.9	8.0	20.2
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	17	19.3	12.4	28.8
	Acute coronary syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Acute myocardial infarction	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Angina pectoris	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Aortic valve calcification	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Atrial fibrillation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Atrial flutter	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bradycardia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	0	0.0		0.0	4.2
	Bundle branch block right	0	116	41.3	0	0.0		0.0	3.2
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	1	1.1		0.2	6.2
	Cardiac failure	0	116	41.3	1	0.9		0.2	4.7
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	1	1.1		0.2	6.2
	Cardio-respiratory arrest	0	116	41.3	0	0.0		0.0	3.2
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	1	1.1		0.2	6.2
	Extrasystoles	0	116	41.3	1	0.9		0.2	4.7
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	0	0.0		0.0	4.2
	Myocardial ischaemia	0	116	41.3	0	0.0		0.0	3.2
		1	77	27.4	1	1.3		0.2	7.0
		>= 2	88	31.3	0	0.0		0.0	4.2
	Nodal arrhythmia	0	116	41.3	0	0.0		0.0	3.2
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	3	3.4		1.2	9.5
	Palpitations	0	116	41.3	3	2.6		0.9	7.3
		1	77	27.4	1	1.3		0.2	7.0
		>= 2	88	31.3	0	0.0		0.0	4.2
	Pericardial effusion	0	116	41.3	0	0.0		0.0	3.2
		1	77	27.4	2	2.6		0.7	9.0
		>= 2	88	31.3	3	3.4		1.2	9.5
	Sinus bradycardia	0	116	41.3	1	0.9		0.2	4.7
		1	77	27.4	1	1.3		0.2	7.0
		>= 2	88	31.3	2	2.3		0.6	7.9
	Sinus tachycardia	0	116	41.3	0	0.0		0.0	3.2
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	2	2.3		0.6	7.9
	Stress cardiomyopathy	0	116	41.3	1	0.9		0.2	4.7
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	0	0.0		0.0	4.2
	Supraventricular tachycardia	0	116	41.3	1	0.9		0.2	4.7
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	0	0.0		0.0	4.2
	Tachycardia	0	116	41.3	3	2.6		0.9	7.3
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	4	4.5		1.8	11.1
	Ventricular extrasystoles	0	116	41.3	1	0.9		0.2	4.7
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	0	0.0		0.0	4.2
	Ventricular pre-excitation	0	116	41.3	0	0.0		0.0	3.2
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	1	1.1		0.2	6.2

Congenital, familial and genetic disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gilbert's syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hydrocele	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Ear and labyrinth disorders	-Total	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	9	10.2	5.5	18.3
	Ear congestion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ear discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ear pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Tinnitus	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vertigo	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	6	6.8	3.2	14.1
Endocrine disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Adrenal insufficiency	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperthyroidism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypothyroidism	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
Eye disorders	-Total	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	17	22.1	14.3	32.5
		>= 2	88	31.3	14	15.9	9.7	25.0
	Abnormal sensation in eye	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Blepharitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cataract	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Chalazion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Conjunctival cyst	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Conjunctival haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Diplopia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dry eye	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Eye swelling	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eyelid oedema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Eyelid ptosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Keratitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ocular discomfort	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Periorbital oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	1	1.1	0.2	6.2
	Photophobia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Photopsia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ulcerative keratitis	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vision blurred	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	5	5.7	2.5	12.6
	Visual acuity reduced	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Gastrointestinal disorders	-Total	0	116	41.3	81	69.8	60.9	77.4
		1	77	27.4	56	72.7	61.9	81.4
		>= 2	88	31.3	67	76.1	66.3	83.8
	Abdominal discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Abdominal distension	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Abdominal pain	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Abdominal pain lower	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Abdominal pain upper	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Abdominal symptom	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Anal incontinence	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Aphthous ulcer	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ascites	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Colitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Constipation	0	116	41.3	51	44.0	35.3	53.0
		1	77	27.4	33	42.9	32.4	54.0
		>= 2	88	31.3	34	38.6	29.1	49.1
	Dental caries	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Dental dysaesthesia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Diarrhoea	0	116	41.3	25	21.6	15.0	29.9
		1	77	27.4	22	28.6	19.7	39.5
		>= 2	88	31.3	23	26.1	18.1	36.2
	Diverticular perforation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dry mouth	0	116	41.3	14	12.1	7.3	19.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	20	22.7	15.2	32.5
	Dyspepsia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Dysphagia	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	9	10.2	5.5	18.3
	Enteritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Epigastric discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Eructation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Faeces soft	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Flatulence	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Frequent bowel movements	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastric ulcer	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastritis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Gastritis erosive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Gastrointestinal haemorrhage	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastrointestinal inflammation	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrointestinal oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastrointestinal wall thickening	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrooesophageal reflux disease	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Gingival bleeding	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Gingival swelling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Glossitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Glossodynia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haematochezia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemorrhoids	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypoaesthesia oral	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Impaired gastric emptying	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intestinal obstruction	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Irritable bowel syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Large intestine perforation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Melaena	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Mouth ulceration	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Nausea	0	116	41.3	18	15.5	10.0	23.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	11	12.5	7.1	21.0
	Odynophagia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oesophageal irritation	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oesophagitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oral disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Oral dysaesthesia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oral mucosal erythema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Oral pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Pancreatitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pancreatitis acute	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Paraesthesia oral	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Proctitis ulcerative	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rectal prolapse	0	116	41.3	1	0.9	0.2	4.7

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Regurgitation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sensitivity of teeth	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Stomatitis	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	6	6.8	3.2	14.1
	Swollen tongue	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tongue coated	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tongue discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tongue ulceration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tooth discolouration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Toothache	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Vomiting	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	12	15.6	9.1	25.3
		>= 2	88	31.3	10	11.4	6.3	19.7
General disorders and administration site conditions	-Total	0	116	41.3	75	64.7	55.6	72.8
		1	77	27.4	57	74.0	63.3	82.5
		>= 2	88	31.3	70	79.5	70.0	86.7
	Asthenia	0	116	41.3	19	16.4	10.7	24.2
		1	77	27.4	11	14.3	8.2	23.8
		>= 2	88	31.3	9	10.2	5.5	18.3
	Axillary pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Catheter site pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Chest discomfort	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	5	5.7	2.5	12.6
	Chest pain	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Chills	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Condition aggravated	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Death	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Disease progression	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	11	14.3	8.2	23.8
		>= 2	88	31.3	9	10.2	5.5	18.3
	Face oedema	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	8	9.1	4.7	16.9
	Facial pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fatigue	0	116	41.3	25	21.6	15.0	29.9
		1	77	27.4	16	20.8	13.2	31.1
		>= 2	88	31.3	26	29.5	21.0	39.8
	Feeling abnormal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Feeling cold	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Feeling hot	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gait disturbance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	General physical health deterioration	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Generalised oedema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Impaired healing	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2

	Influenza like illness	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Injection site bruising	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Localised oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Malaise	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	6	6.8	3.2	14.1
	Mucosal dryness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Mucosal inflammation	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Multiple organ dysfunction syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Non-cardiac chest pain	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oedema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oedema peripheral	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	19	21.6	14.3	31.3
	Pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Peripheral swelling	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pyrexia	0	116	41.3	23	19.8	13.6	28.0
		1	77	27.4	23	29.9	20.8	40.8
		>= 2	88	31.3	26	29.5	21.0	39.8
	Swelling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Temperature intolerance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9

	Xerosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Hepatobiliary disorders	-Total	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	7	8.0	3.9	15.5
	Cholecystitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cholelithiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gallbladder polyp	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hepatic function abnormal	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hepatic steatosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hepatocellular injury	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hyperbilirubinaemia	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Liver disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Liver injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumobilia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Portal vein thrombosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Immune system disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Contrast media allergy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Drug hypersensitivity	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Food allergy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypersensitivity	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Seasonal allergy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
Infections and infestations	-Total	0	116	41.3	52	44.8	36.1	53.9
		1	77	27.4	46	59.7	48.6	70.0
		>= 2	88	31.3	59	67.0	56.7	76.0
	Abdominal abscess	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Acute sinusitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Appendicitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Arthritis infective	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Atypical pneumonia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bacteraemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Bacterial disease carrier	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bacterial infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bacterial vaginosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bronchitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	2	2.3	0.6	7.9
	Candida infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Cellulitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Chronic sinusitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Clostridium difficile colitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Conjunctivitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Corona virus infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cystitis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cystitis escherichia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Device related infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Diverticulitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ear infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Empyema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Enterococcal bacteraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Epididymitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Epstein-Barr virus infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Escherichia bacteraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

Escherichia infection	0	116	41.3	0	0.0	0.0	3.2	
	1	77	27.4	0	0.0	0.0	4.8	
	>= 2	88	31.3	1	1.1	0.2	6.2	
Escherichia urinary tract infection	0	116	41.3	0	0.0	0.0	3.2	
	1	77	27.4	0	0.0	0.0	4.8	
	>= 2	88	31.3	1	1.1	0.2	6.2	
Eye infection	0	116	41.3	0	0.0	0.0	3.2	
	1	77	27.4	0	0.0	0.0	4.8	
	>= 2	88	31.3	1	1.1	0.2	6.2	
Febrile infection	0	116	41.3	0	0.0	0.0	3.2	
	1	77	27.4	0	0.0	0.0	4.8	
	>= 2	88	31.3	1	1.1	0.2	6.2	
Folliculitis	0	116	41.3	2	1.7	0.5	6.1	
	1	77	27.4	1	1.3	0.2	7.0	
	>= 2	88	31.3	0	0.0	0.0	4.2	
Fungal infection	0	116	41.3	0	0.0	0.0	3.2	
	1	77	27.4	2	2.6	0.7	9.0	
	>= 2	88	31.3	1	1.1	0.2	6.2	
Gastroenteritis	0	116	41.3	2	1.7	0.5	6.1	
	1	77	27.4	0	0.0	0.0	4.8	
	>= 2	88	31.3	0	0.0	0.0	4.2	
Genital candidiasis	0	116	41.3	0	0.0	0.0	3.2	
	1	77	27.4	0	0.0	0.0	4.8	
	>= 2	88	31.3	1	1.1	0.2	6.2	
Genital herpes	0	116	41.3	1	0.9	0.2	4.7	
	1	77	27.4	1	1.3	0.2	7.0	
	>= 2	88	31.3	0	0.0	0.0	4.2	
Gingivitis	0	116	41.3	0	0.0	0.0	3.2	
	1	77	27.4	0	0.0	0.0	4.8	
	>= 2	88	31.3	1	1.1	0.2	6.2	
Herpes simplex	0	116	41.3	0	0.0	0.0	3.2	
	1	77	27.4	1	1.3	0.2	7.0	
	>= 2	88	31.3	0	0.0	0.0	4.2	
Herpes virus infection	0	116	41.3	2	1.7	0.5	6.1	
	1	77	27.4	0	0.0	0.0	4.8	
	>= 2	88	31.3	1	1.1	0.2	6.2	
Herpes zoster	0	116	41.3	4	3.4	1.3	8.5	
	1	77	27.4	2	2.6	0.7	9.0	
	>= 2	88	31.3	5	5.7	2.5	12.6	
Infection	0	116	41.3	0	0.0	0.0	3.2	
	1	77	27.4	0	0.0	0.0	4.8	
	>= 2	88	31.3	1	1.1	0.2	6.2	
Infectious colitis	0	116	41.3	0	0.0	0.0	3.2	
	1	77	27.4	1	1.3	0.2	7.0	
	>= 2	88	31.3	0	0.0	0.0	4.2	

	Influenza	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lower respiratory tract infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lung infection	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Lyme disease	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lymph node tuberculosis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Meningitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasal herpes	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasopharyngitis	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Oral candidiasis	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Oral fungal infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oropharyngeal candidiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Otitis externa	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Otitis media	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Paronychia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Peritonitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pharyngitis	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pleural infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumocystis jirovecii pneumonia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	18	20.5	13.3	30.0
	Pneumonia bacterial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia cytomegaloviral	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia haemophilus	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonia influenzal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonia pseudomonal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia streptococcal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pyelonephritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pyelonephritis acute	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pyuria	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rectal abscess	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Renal tuberculosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiratory tract infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiratory tract infection bacterial	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Sepsis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	5	5.7	2.5	12.6
	Septic shock	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sinusitis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Sinusitis bacterial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Skin infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Staphylococcal infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Systemic infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tinea cruris	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tinea infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tinea pedis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Tonsillitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tooth infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tracheitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Tuberculosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Upper respiratory tract infection	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	7	8.0	3.9	15.5
	Urethritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urinary tract infection	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	16	18.2	11.5	27.5
	Urosepsis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Varicella	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Varicella zoster virus infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Viral hepatitis carrier	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Viral infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vulvovaginal candidiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Injury, poisoning and procedural complications	-Total	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	15	17.0	10.6	26.2
	Contusion	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Epicondylitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Fall	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Fracture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Heart injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Incision site pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Joint dislocation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Laceration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ligament sprain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Limb injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Muscle rupture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Muscle strain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Procedural pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Procedural pneumothorax	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rib fracture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Scar	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Skin abrasion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Skin injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Subdural haematoma	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tendon rupture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Thermal burn	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Wound	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Wound complication	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Wrist fracture	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Investigations	-Total	0	116	41.3	90	77.6	69.2	84.2
		1	77	27.4	62	80.5	70.3	87.8
		>= 2	88	31.3	71	80.7	71.2	87.6
	Alanine aminotransferase	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Alanine aminotransferase increased	0	116	41.3	41	35.3	27.2	44.4
		1	77	27.4	20	26.0	17.5	36.7
		>= 2	88	31.3	31	35.2	26.1	45.6
	Albumin urine present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Alpha hydroxybutyrate dehydrogenase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Amylase increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Aspartate aminotransferase increased	0	116	41.3	49	42.2	33.6	51.3
		1	77	27.4	33	42.9	32.4	54.0
		>= 2	88	31.3	44	50.0	39.8	60.2
	Bacterial test	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bilirubin conjugated increased	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	6	6.8	3.2	14.1
	Blood albumin decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood alkaline phosphatase	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood alkaline phosphatase decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood alkaline phosphatase increased	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	12	15.6	9.1	25.3
		>= 2	88	31.3	14	15.9	9.7	25.0
	Blood bilirubin increased	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	8	9.1	4.7	16.9
	Blood bilirubin unconjugated increased	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood calcium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood calcium increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood chloride increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood cholesterol increased	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Blood creatine increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood creatine phosphokinase MB increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood creatine phosphokinase increased	0	116	41.3	27	23.3	16.5	31.7
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	18	20.5	13.3	30.0
	Blood creatinine	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood creatinine increased	0	116	41.3	18	15.5	10.0	23.2
		1	77	27.4	19	24.7	16.4	35.4
		>= 2	88	31.3	25	28.4	20.0	38.6
	Blood fibrinogen increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Blood glucose increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood iron decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood ketone body increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood lactate dehydrogenase increased	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood magnesium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood phosphorus increased	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood potassium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood potassium increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood pressure increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood sodium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood thyroid stimulating hormone increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood triglycerides increased	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood urea increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood uric acid decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood uric acid increased	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9

	Blood urine	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood urine present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	C-reactive protein increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Carbon dioxide decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Complement factor C1 decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Computerised tomogram thorax abnormal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Crystal urine present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cystatin C increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Electrocardiogram QT prolonged	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	7	8.0	3.9	15.5
	Electrocardiogram ST-T change	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Fibrin D dimer increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Fibrin degradation products increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Free fatty acids increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gamma-glutamyltransferase increased	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	9	10.2	5.5	18.3
	Glomerular filtration rate decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Glutamate dehydrogenase increased	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Granulocyte count decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haematocrit decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemoglobin decreased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Heart rate increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hepatic enzyme increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	International normalised ratio increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intraocular pressure increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Laboratory test abnormal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lipase increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Liver function test increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lymphocyte count decreased	0	116	41.3	12	10.3	6.0	17.2
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	8	9.1	4.7	16.9
	Lymphocyte count increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Mean cell volume increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Myoglobin blood increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neutrophil count decreased	0	116	41.3	36	31.0	23.3	39.9
		1	77	27.4	18	23.4	15.3	34.0

		>= 2	88	31.3	27	30.7	22.0	41.0
	Neutrophil count increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Neutrophil percentage increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Occult blood positive	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oxygen saturation decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	PO2 decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Platelet count decreased	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	11	14.3	8.2	23.8
		>= 2	88	31.3	11	12.5	7.1	21.0
	Platelet count increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Procalcitonin increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Protein total decreased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Protein total increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Protein urine present	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Prothrombin time prolonged	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Red blood cell count decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Serum amyloid A protein increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Thrombin time prolonged	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Total bile acids increased	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Transaminases increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	1	1.1	0.2	6.2
	Transferrin increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Troponin T increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Troponin increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Urinary sediment present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urine ketone body present	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Urine leukocyte esterase positive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urobilinogen urine increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Weight decreased	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	7	8.0	3.9	15.5
	Weight increased	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	10	11.4	6.3	19.7
	White blood cell count decreased	0	116	41.3	31	26.7	19.5	35.4
		1	77	27.4	17	22.1	14.3	32.5
		>= 2	88	31.3	24	27.3	19.1	37.4
	White blood cells urine positive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
Metabolism and nutrition disorders	-Total	0	116	41.3	59	50.9	41.9	59.8
		1	77	27.4	36	46.8	36.0	57.8
		>= 2	88	31.3	52	59.1	48.6	68.8
	Abnormal loss of weight	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Acidosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Alkalosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cell death	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Decreased appetite	0	116	41.3	12	10.3	6.0	17.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	13	14.8	8.8	23.7
	Dehydration	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Electrolyte imbalance	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Failure to thrive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fluid retention	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypercalcaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Hypercholesterolaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperglycaemia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	7	8.0	3.9	15.5
	Hyperkalaemia	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Hyperlipidaemia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypermagnesaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypernatraemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperphosphataemia	0	116	41.3	15	12.9	8.0	20.2

		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	11	12.5	7.1	21.0
	Hypertriglyceridaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Hyperuricaemia	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hypoalbuminaemia	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	17	19.3	12.4	28.8
	Hypocalcaemia	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	13	14.8	8.8	23.7
	Hypochloraemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hypoglycaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypokalaemia	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	14	15.9	9.7	25.0
	Hypomagnesaemia	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	10	11.4	6.3	19.7
	Hyponatraemia	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	8	9.1	4.7	16.9
	Hypophosphataemia	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	14	18.2	11.2	28.2
		>= 2	88	31.3	15	17.0	10.6	26.2
	Hypoproteinaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Increased appetite	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vitamin D deficiency	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Musculoskeletal and connective tissue disorders	-Total	0	116	41.3	46	39.7	31.2	48.8
		1	77	27.4	37	48.1	37.3	59.0
		>= 2	88	31.3	41	46.6	36.5	56.9
	Arthralgia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	5	6.5	2.8	14.3

		>= 2	88	31.3	3	3.4	1.2	9.5
	Arthropathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Back pain	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	15	17.0	10.6	26.2
	Bone pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bursitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Coccydynia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Costochondritis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Flank pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Groin pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypercreatinaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intervertebral disc protrusion	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Joint range of motion decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Joint stiffness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Joint swelling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Muscle fatigue	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Muscle haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Muscle spasms	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	10	11.4	6.3	19.7
	Muscular weakness	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Musculoskeletal chest pain	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Musculoskeletal pain	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	8	9.1	4.7	16.9
	Musculoskeletal stiffness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Myalgia	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	3	3.4	1.2	9.5
	Myopathy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neck pain	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	6	6.8	3.2	14.1
	Osteopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pain in extremity	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	11	12.5	7.1	21.0
	Pain in jaw	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rhabdomyolysis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rotator cuff syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Spinal column stenosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Spinal osteoarthritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Tendon disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tendon pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Anogenital warts	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Basal cell carcinoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bowen's disease	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cancer pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gallbladder cancer	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Metastases to central nervous system	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal cell carcinoma	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Squamous cell carcinoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Squamous cell carcinoma of skin	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tumour pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
Nervous system disorders	-Total	0	116	41.3	54	46.6	37.7	55.6
		1	77	27.4	45	58.4	47.3	68.8
		>= 2	88	31.3	46	52.3	42.0	62.4
	Ageusia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Aphasia	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ataxia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Balance disorder	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Brain oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Cerebellar haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cerebral haematoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cerebral microhaemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cerebrovascular accident	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Disturbance in attention	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dizziness	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	12	13.6	8.0	22.3
	Dizziness postural	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dysarthria	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dysgeusia	0	116	41.3	20	17.2	11.4	25.1
		1	77	27.4	14	18.2	11.2	28.2
		>= 2	88	31.3	8	9.1	4.7	16.9
	Dyskinesia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Epilepsy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Facial paralysis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Haemorrhage intracranial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Headache	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	14	18.2	11.2	28.2
		>= 2	88	31.3	9	10.2	5.5	18.3
	Hemiplegia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperaesthesia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypersomnia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypoaesthesia	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	7	8.0	3.9	15.5
	Hypotonia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lethargy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lumbar radiculopathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lumbosacral radiculopathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Memory impairment	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Migraine	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Migraine with aura	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Neuralgia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neuropathy peripheral	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	3	3.4	1.2	9.5

	Paraesthesia	0	116	41.3	4	3.4	1.3	8.5	
		1	77	27.4	4	5.2	2.0	12.6	
		>= 2	88	31.3	4	4.5	1.8	11.1	
	Paralysis	0	116	41.3	1	0.9	0.2	4.7	
		1	77	27.4	0	0.0	0.0	4.8	
		>= 2	88	31.3	0	0.0	0.0	4.2	
	Parosmia	0	116	41.3	1	0.9	0.2	4.7	
		1	77	27.4	0	0.0	0.0	4.8	
		>= 2	88	31.3	0	0.0	0.0	4.2	
	Peripheral sensory neuropathy	0	116	41.3	3	2.6	0.9	7.3	
		1	77	27.4	2	2.6	0.7	9.0	
		>= 2	88	31.3	4	4.5	1.8	11.1	
	Polyneuropathy chronic	0	116	41.3	1	0.9	0.2	4.7	
		1	77	27.4	0	0.0	0.0	4.8	
		>= 2	88	31.3	0	0.0	0.0	4.2	
	Post herpetic neuralgia	0	116	41.3	0	0.0	0.0	3.2	
		1	77	27.4	1	1.3	0.2	7.0	
		>= 2	88	31.3	0	0.0	0.0	4.2	
	Presyncope	0	116	41.3	1	0.9	0.2	4.7	
		1	77	27.4	1	1.3	0.2	7.0	
		>= 2	88	31.3	1	1.1	0.2	6.2	
	Psychomotor skills impaired	0	116	41.3	0	0.0	0.0	3.2	
		1	77	27.4	0	0.0	0.0	4.8	
		>= 2	88	31.3	1	1.1	0.2	6.2	
	Restless legs syndrome	0	116	41.3	1	0.9	0.2	4.7	
		1	77	27.4	1	1.3	0.2	7.0	
		>= 2	88	31.3	0	0.0	0.0	4.2	
	Sciatica	0	116	41.3	1	0.9	0.2	4.7	
		1	77	27.4	1	1.3	0.2	7.0	
		>= 2	88	31.3	4	4.5	1.8	11.1	
	Seizure	0	116	41.3	2	1.7	0.5	6.1	
		1	77	27.4	2	2.6	0.7	9.0	
		>= 2	88	31.3	2	2.3	0.6	7.9	
	Sensory disturbance	0	116	41.3	0	0.0	0.0	3.2	
		1	77	27.4	1	1.3	0.2	7.0	
		>= 2	88	31.3	0	0.0	0.0	4.2	
	Slow speech	0	116	41.3	0	0.0	0.0	3.2	
		1	77	27.4	0	0.0	0.0	4.8	
		>= 2	88	31.3	1	1.1	0.2	6.2	
	Somnolence	0	116	41.3	1	0.9	0.2	4.7	
		1	77	27.4	1	1.3	0.2	7.0	
		>= 2	88	31.3	0	0.0	0.0	4.2	
	Spinal cord haematoma	0	116	41.3	0	0.0	0.0	3.2	
		1	77	27.4	0	0.0	0.0	4.8	
		>= 2	88	31.3	1	1.1	0.2	6.2	

	Syncope	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Tension headache	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tremor	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Visual field defect	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Product issues	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Device dislocation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Psychiatric disorders	-Total	0	116	41.3	20	17.2	11.4	25.1
		1	77	27.4	15	19.5	12.2	29.7
		>= 2	88	31.3	21	23.9	16.2	33.7
	Abnormal behaviour	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Abnormal dreams	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Adjustment disorder with mixed anxiety and depressed mood	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Anxiety	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Bradyphrenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Confusional state	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Delirium	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Depressed mood	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Depression	0	116	41.3	5	4.3	1.9	9.7

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fear of falling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Insomnia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	9	10.2	5.5	18.3
	Irritability	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Libido decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Mental status changes	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Mood altered	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Psychomotor retardation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Restlessness	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sleep disorder	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Renal and urinary disorders	-Total	0	116	41.3	15	12.9	8.0	20.2
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	18	20.5	13.3	30.0
	Acute kidney injury	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Azotaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Cystitis haemorrhagic	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dysuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	8	9.1	4.7	16.9
	Haematuria	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemorrhage urinary tract	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hydronephrosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Micturition urgency	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Nephritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nephrolithiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Nocturia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Obstructive nephropathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pollakiuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Proteinuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Renal colic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal failure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal impairment	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Strangury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Urethral stenosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Urinary incontinence	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urinary retention	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Urinary tract pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urine flow decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Reproductive system and breast disorders	-Total	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	8	9.1	4.7	16.9
	Benign prostatic hyperplasia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Breast discharge	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Erectile dysfunction	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Galactorrhoea	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Genital ulceration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Metrorrhagia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ovarian cyst	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pelvic discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pelvic fluid collection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Perineal pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Postmenopausal haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Prostatitis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Uterine polyp	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vaginal haemorrhage	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vulvovaginal dryness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vulvovaginal erythema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Respiratory, thoracic and mediastinal disorders	-Total	0	116	41.3	63	54.3	45.3	63.1
		1	77	27.4	50	64.9	53.8	74.7
		>= 2	88	31.3	54	61.4	50.9	70.9
	Acute respiratory failure	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Aspiration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bronchospasm	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Choking	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cough	0	116	41.3	19	16.4	10.7	24.2
		1	77	27.4	26	33.8	24.2	44.9
		>= 2	88	31.3	20	22.7	15.2	32.5
	Dry throat	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dysphonia	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Dyspnoea	0	116	41.3	15	12.9	8.0	20.2
		1	77	27.4	14	18.2	11.2	28.2
		>= 2	88	31.3	18	20.5	13.3	30.0
	Dyspnoea exertional	0	116	41.3	2	1.7	0.5	6.1

		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Epistaxis	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	3	3.4	1.2	9.5
	Haemoptysis	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Hiccups	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypoxia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Interstitial lung disease	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Laryngeal haemorrhage	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lung consolidation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasal congestion	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Nasal dryness	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasal polyps	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oropharyngeal discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oropharyngeal pain	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	5	5.7	2.5	12.6
	Paranasal sinus discomfort	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pharyngeal disorder	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pleural effusion	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	3	3.9	1.3	10.8

		>= 2	88	31.3	5	5.7	2.5	12.6
	Pleural thickening	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pleuritic pain	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonitis	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	11	14.3	8.2	23.8
		>= 2	88	31.3	12	13.6	8.0	22.3
	Pneumothorax	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Productive cough	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	6	6.8	3.2	14.1
	Pulmonary embolism	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Pulmonary hypertension	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pulmonary mass	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pulmonary pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiration abnormal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiratory distress	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Respiratory failure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinalgia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinitis allergic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinorrhoea	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Sinus congestion	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sleep apnoea syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sputum discoloured	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Throat irritation	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Upper-airway cough syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Vocal cord leukoplakia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Wheezing	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Skin and subcutaneous tissue disorders	-Total	0	116	41.3	32	27.6	20.3	36.3
		1	77	27.4	35	45.5	34.8	56.5
		>= 2	88	31.3	33	37.5	28.1	47.9
	Acne	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Alopecia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	4	4.5	1.8	11.1
	Chloasma	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Decubitus ulcer	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dermal cyst	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dermatitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dermatitis acneiform	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9

	Dermatitis allergic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dermatitis bullous	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dry skin	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Ecchymosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eczema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Erythema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hair growth abnormal	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Hair texture abnormal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hirsutism	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hyperhidrosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperkeratosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypertrichosis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	0	0.0	0.0	4.2
	Madarosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Nail discolouration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nail disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Night sweats	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Onychalgia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Onycholysis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Onychomadesis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pain of skin	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Palmar-plantar erythrodysaesthesia syndrome	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Photosensitivity reaction	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pruritus	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Pruritus generalised	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Purpura	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rash	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	10	11.4	6.3	19.7
	Rash erythematous	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Rash macular	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Rash maculo-papular	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rash papular	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Scab	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	1	1.1	0.2	6.2
	Scar pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Skin discolouration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Skin hyperpigmentation	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Skin lesion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Swelling face	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urticaria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Surgical and medical procedures	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	2	2.3	0.6	7.9
	Astringent therapy	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eye excision	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hip arthroplasty	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Therapy cessation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Vascular disorders	-Total	0	116	41.3	37	31.9	24.1	40.8
		1	77	27.4	31	40.3	30.0	51.4
		>= 2	88	31.3	47	53.4	43.1	63.5
	Aortic dissection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Circulatory collapse	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Deep vein thrombosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9

	Embolism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Embolism venous	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Flushing	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haematoma	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hot flush	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypertension	0	116	41.3	33	28.4	21.0	37.2
		1	77	27.4	27	35.1	25.3	46.2
		>= 2	88	31.3	36	40.9	31.2	51.4
	Hypotension	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Lymphoedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Orthostatic hypotension	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pallor	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Phlebitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Raynaud's phenomenon	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Shock haemorrhagic	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Superior vena cava syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Thrombophlebitis superficial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Thrombosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEANY_SG.xls
26MAR2021 13:27

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Asian	128	45.6	85	66.4	57.9	74.0
		Non-Asian	135	48.0	75	55.6	47.1	63.7
		Unknown	18	6.4	9	50.0	29.0	71.0
	Anaemia	Asian	128	45.6	61	47.7	39.2	56.3
		Non-Asian	135	48.0	61	45.2	37.0	53.6
		Unknown	18	6.4	7	38.9	20.3	61.4
	Anaemia macrocytic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aplastic anaemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bone marrow oedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cytopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Disseminated intravascular coagulation	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Febrile neutropenia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhagic anaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperfibrinogenaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Leukocytosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Leukopenia	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	18	13.3	8.6	20.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymph node pain	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphadenopathy	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	23	17.0	11.6	24.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutropenia	Asian	128	45.6	24	18.8	12.9	26.4
		Non-Asian	135	48.0	34	25.2	18.6	33.1
		Unknown	18	6.4	3	16.7	5.8	39.2
	Neutrophilia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancytopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytopenia	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	13	9.6	5.7	15.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
Cardiac disorders	-Total	Asian	128	45.6	20	15.6	10.3	22.9
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	Acute coronary syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Acute myocardial infarction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Angina pectoris	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aortic valve calcification	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Atrial fibrillation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Atrial flutter	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bradycardia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0		0.0	17.6
	Bundle branch block right	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6
	Cardiac failure	Asian	128	45.6	2	1.6		0.4	5.5
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6
	Cardio-respiratory arrest	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6
	Extrasystoles	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Myocardial ischaemia	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6
	Nodal arrhythmia	Asian	128	45.6	3	2.3		0.8	6.7
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6
	Palpitations	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	2	1.5		0.4	5.2
		Unknown	18	6.4	1	5.6		1.0	25.8
	Pericardial effusion	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	4	3.0		1.2	7.4
		Unknown	18	6.4	0	0.0		0.0	17.6
	Sinus bradycardia	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	2	1.5		0.4	5.2
		Unknown	18	6.4	1	5.6		1.0	25.8
	Sinus tachycardia	Asian	128	45.6	2	1.6		0.4	5.5
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6
	Stress cardiomyopathy	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Supraventricular tachycardia	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6
	Tachycardia	Asian	128	45.6	4	3.1		1.2	7.8
		Non-Asian	135	48.0	3	2.2		0.8	6.3
		Unknown	18	6.4	0	0.0		0.0	17.6
	Ventricular extrasystoles	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6
	Ventricular pre-excitation	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6

Congenital, familial and genetic disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gilbert's syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hydrocele	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Ear and labyrinth disorders	-Total	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	2	11.1	3.1	32.8
	Ear congestion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ear discomfort	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ear pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinnitus	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vertigo	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	2	11.1	3.1	32.8
Endocrine disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Adrenal insufficiency	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperthyroidism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypothyroidism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Eye disorders	-Total	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	26	19.3	13.5	26.7
		Unknown	18	6.4	3	16.7	5.8	39.2
	Abnormal sensation in eye	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Blepharitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cataract	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chalazion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Conjunctival cyst	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Conjunctival haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diplopia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dry eye	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Eye swelling	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eyelid oedema	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eyelid ptosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Keratitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ocular discomfort	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Periorbital oedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Photophobia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Photopsia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ulcerative keratitis	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vision blurred	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Visual acuity reduced	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Gastrointestinal disorders	-Total	Asian	128	45.6	84	65.6	57.0	73.3
		Non-Asian	135	48.0	106	78.5	70.9	84.6
		Unknown	18	6.4	14	77.8	54.8	91.0
	Abdominal discomfort	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal distension	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal pain	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	1	5.6	1.0	25.8
	Abdominal pain lower	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal pain upper	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Abdominal symptom	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anal incontinence	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aphthous ulcer	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ascites	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Constipation	Asian	128	45.6	55	43.0	34.7	51.6
		Non-Asian	135	48.0	55	40.7	32.8	49.2
		Unknown	18	6.4	8	44.4	24.6	66.3
	Dental caries	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Dental dysaesthesia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diarrhoea	Asian	128	45.6	25	19.5	13.6	27.2
		Non-Asian	135	48.0	41	30.4	23.2	38.6
		Unknown	18	6.4	4	22.2	9.0	45.2
	Diverticular perforation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dry mouth	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	32	23.7	17.3	31.5
		Unknown	18	6.4	4	22.2	9.0	45.2
	Dyspepsia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	3	16.7	5.8	39.2
	Dysphagia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	15	11.1	6.9	17.5
		Unknown	18	6.4	1	5.6	1.0	25.8
	Enteritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epigastric discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eructation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Faeces soft	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Flatulence	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Frequent bowel movements	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastric ulcer	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastritis erosive	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Gastrointestinal haemorrhage	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal inflammation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal oedema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal wall thickening	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrooesophageal reflux disease	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Gingival bleeding	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gingival swelling	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Glossitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Glossodynia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematochezia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhoids	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoaesthesia oral	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Impaired gastric emptying	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intestinal obstruction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Irritable bowel syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Large intestine perforation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Melaena	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mouth ulceration	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nausea	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	23	17.0	11.6	24.3
		Unknown	18	6.4	3	16.7	5.8	39.2
	Odynophagia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oesophageal irritation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oesophagitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral dysaesthesia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral mucosal erythema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancreatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancreatitis acute	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Paraesthesia oral	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Proctitis ulcerative	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rectal prolapse	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Regurgitation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sensitivity of teeth	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Stomatitis	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Swollen tongue	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tongue coated	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tongue discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tongue ulceration	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tooth discolouration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Toothache	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vomiting	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	2	11.1	3.1	32.8
General disorders and administration site conditions	-Total	Asian	128	45.6	89	69.5	61.1	76.8
		Non-Asian	135	48.0	101	74.8	66.9	81.4
		Unknown	18	6.4	12	66.7	43.7	83.7
	Asthenia	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	23	17.0	11.6	24.3
		Unknown	18	6.4	5	27.8	12.5	50.9
	Axillary pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Catheter site pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chest discomfort	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3

		Unknown	18	6.4	0	0.0	0.0	17.6
	Chest pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chills	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Condition aggravated	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Death	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Disease progression	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Face oedema	Asian	128	45.6	17	13.3	8.5	20.2
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Facial pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fatigue	Asian	128	45.6	19	14.8	9.7	22.0
		Non-Asian	135	48.0	44	32.6	25.3	40.9
		Unknown	18	6.4	4	22.2	9.0	45.2
	Feeling abnormal	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Feeling cold	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Feeling hot	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gait disturbance	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	General physical health deterioration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Generalised oedema	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Impaired healing	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6

	Influenza like illness	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Injection site bruising	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Localised oedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Malaise	Asian	128	45.6	19	14.8	9.7	22.0
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Mucosal dryness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mucosal inflammation	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Multiple organ dysfunction syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Non-cardiac chest pain	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Oedema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oedema peripheral	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	25	18.5	12.9	25.9
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pain	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Peripheral swelling	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pyrexia	Asian	128	45.6	36	28.1	21.1	36.5
		Non-Asian	135	48.0	32	23.7	17.3	31.5
		Unknown	18	6.4	4	22.2	9.0	45.2
	Swelling	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Temperature intolerance	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8

	Xerosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Hepatobiliary disorders	-Total	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	13	9.6	5.7	15.8
		Unknown	18	6.4	3	16.7	5.8	39.2
	Cholecystitis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cholelithiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gallbladder polyp	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatic function abnormal	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatic steatosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatocellular injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	3	16.7	5.8	39.2
	Hyperbilirubinaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Liver disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Liver injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumobilia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Portal vein thrombosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
Immune system disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Contrast media allergy	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Drug hypersensitivity	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Food allergy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypersensitivity	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Seasonal allergy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Infections and infestations	-Total	Asian	128	45.6	59	46.1	37.7	54.7
		Non-Asian	135	48.0	90	66.7	58.4	74.1
		Unknown	18	6.4	8	44.4	24.6	66.3
	Abdominal abscess	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Acute sinusitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Appendicitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Arthritis infective	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Atypical pneumonia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Bacterial disease carrier	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bacterial infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Bacterial vaginosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bronchitis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Candida infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Cellulitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chronic sinusitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Clostridium difficile colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Conjunctivitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Corona virus infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis escherichia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Device related infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diverticulitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ear infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Empyema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Enterococcal bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epididymitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epstein-Barr virus infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Escherichia bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Escherichia infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Escherichia urinary tract infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eye infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Febrile infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Folliculitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fungal infection	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastroenteritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Genital candidiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Genital herpes	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gingivitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Herpes simplex	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Herpes virus infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Herpes zoster	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Infectious colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Influenza	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lower respiratory tract infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lung infection	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Lyme disease	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymph node tuberculosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Meningitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal herpes	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasopharyngitis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral candidiasis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral fungal infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oropharyngeal candidiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Otitis externa	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Otitis media	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Paronychia	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Peritonitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pharyngitis	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleural infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumocystis jirovecii pneumonia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia	Asian	128	45.6	23	18.0	12.3	25.5
		Non-Asian	135	48.0	20	14.8	9.8	21.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumonia bacterial	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia cytomegaloviral	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia haemophilus	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia influenzal	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia pseudomonal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumonia streptococcal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyelonephritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyelonephritis acute	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyuria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rectal abscess	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal tuberculosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory tract infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2

		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory tract infection bacterial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sepsis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Septic shock	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinusitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Sinusitis bacterial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Staphylococcal infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Systemic infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinea cruris	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinea infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinea pedis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tonsillitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tooth infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tracheitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Tuberculosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Upper respiratory tract infection	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urethritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary tract infection	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	27	20.0	14.1	27.5
		Unknown	18	6.4	1	5.6	1.0	25.8
	Urosepsis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Varicella	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Varicella zoster virus infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Viral hepatitis carrier	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Viral infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vulvovaginal candidiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Injury, poisoning and procedural complications	-Total	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	18	13.3	8.6	20.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Contusion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epicondylitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fall	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fracture	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Heart injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Incision site pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint dislocation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Laceration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ligament sprain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Limb injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle rupture	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle strain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Procedural pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Procedural pneumothorax	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rib fracture	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Scar	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin abrasion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Subdural haematoma	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tendon rupture	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thermal burn	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wound	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wound complication	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wrist fracture	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Investigations	-Total	Asian	128	45.6	109	85.2	78.0	90.3
		Non-Asian	135	48.0	101	74.8	66.9	81.4
		Unknown	18	6.4	13	72.2	49.1	87.5
	Alanine aminotransferase	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alanine aminotransferase increased	Asian	128	45.6	52	40.6	32.5	49.3
		Non-Asian	135	48.0	37	27.4	20.6	35.5
		Unknown	18	6.4	3	16.7	5.8	39.2
	Albumin urine present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alpha hydroxybutyrate dehydrogenase increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Amylase increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aspartate aminotransferase increased	Asian	128	45.6	71	55.5	46.8	63.8
		Non-Asian	135	48.0	51	37.8	30.0	46.2
		Unknown	18	6.4	4	22.2	9.0	45.2
	Bacterial test	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bilirubin conjugated increased	Asian	128	45.6	20	15.6	10.3	22.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood albumin decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood alkaline phosphatase	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood alkaline phosphatase decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood alkaline phosphatase increased	Asian	128	45.6	25	19.5	13.6	27.2
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood bilirubin increased	Asian	128	45.6	19	14.8	9.7	22.0
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Blood bilirubin unconjugated increased	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood calcium decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood calcium increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood chloride increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood cholesterol increased	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine phosphokinase MB increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine phosphokinase increased	Asian	128	45.6	37	28.9	21.8	37.3
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	5	27.8	12.5	50.9
	Blood creatinine	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatinine increased	Asian	128	45.6	24	18.8	12.9	26.4
		Non-Asian	135	48.0	34	25.2	18.6	33.1
		Unknown	18	6.4	4	22.2	9.0	45.2
	Blood fibrinogen increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Blood glucose increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood iron decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood ketone body increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood lactate dehydrogenase increased	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood magnesium decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood phosphorus increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood potassium decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood potassium increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood pressure increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood sodium decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood thyroid stimulating hormone increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood triglycerides increased	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood urea increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood uric acid decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood uric acid increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Blood urine	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood urine present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	C-reactive protein increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Carbon dioxide decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Complement factor C1 decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Computerised tomogram thorax abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Crystal urine present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystatin C increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrocardiogram QT prolonged	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrocardiogram ST-T change	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fibrin D dimer increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fibrin degradation products increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Free fatty acids increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gamma-glutamyltransferase increased	Asian	128	45.6	19	14.8	9.7	22.0
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Glomerular filtration rate decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Glutamate dehydrogenase increased	Asian	128	45.6	2	1.6	0.4	5.5

		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Granulocyte count decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematocrit decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemoglobin decreased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Heart rate increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatic enzyme increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	International normalised ratio increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intraocular pressure increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Laboratory test abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Lipase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Liver function test increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphocyte count decreased	Asian	128	45.6	14	10.9	6.6	17.5
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	2	11.1	3.1	32.8
	Lymphocyte count increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mean cell volume increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Myoglobin blood increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutrophil count decreased	Asian	128	45.6	66	51.6	43.0	60.0
		Non-Asian	135	48.0	14	10.4	6.3	16.7

		Unknown	18	6.4	1	5.6	1.0	25.8
	Neutrophil count increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutrophil percentage increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Occult blood positive	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oxygen saturation decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	PO2 decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Platelet count decreased	Asian	128	45.6	26	20.3	14.3	28.1
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Platelet count increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Procalcitonin increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Protein total decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Protein total increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Protein urine present	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Prothrombin time prolonged	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Red blood cell count decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Serum amyloid A protein increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombin time prolonged	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Total bile acids increased	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Transaminases increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Transferrin increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Troponin T increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Troponin increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary sediment present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urine ketone body present	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urine leukocyte esterase positive	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urobilinogen urine increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Weight decreased	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Weight increased	Asian	128	45.6	19	14.8	9.7	22.0
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	White blood cell count decreased	Asian	128	45.6	45	35.2	27.4	43.8
		Non-Asian	135	48.0	23	17.0	11.6	24.3
		Unknown	18	6.4	4	22.2	9.0	45.2
	White blood cells urine positive	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Metabolism and nutrition disorders	-Total	Asian	128	45.6	77	60.2	51.5	68.2
		Non-Asian	135	48.0	63	46.7	38.5	55.1
		Unknown	18	6.4	7	38.9	20.3	61.4
	Abnormal loss of weight	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Acidosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alkalosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cell death	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Decreased appetite	Asian	128	45.6	25	19.5	13.6	27.2
		Non-Asian	135	48.0	12	8.9	5.2	14.9
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dehydration	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Electrolyte imbalance	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Failure to thrive	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fluid retention	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercalcaemia	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercholesterolaemia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperglycaemia	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperkalaemia	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyperlipidaemia	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypermagnesaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypernatraemia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperphosphataemia	Asian	128	45.6	15	11.7	7.2	18.4

		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypertriglyceridaemia	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperuricaemia	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoalbuminaemia	Asian	128	45.6	32	25.0	18.3	33.2
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypocalcaemia	Asian	128	45.6	20	15.6	10.3	22.9
		Non-Asian	135	48.0	13	9.6	5.7	15.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypochloraemia	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoglycaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypokalaemia	Asian	128	45.6	21	16.4	11.0	23.8
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypomagnesaemia	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyponatraemia	Asian	128	45.6	19	14.8	9.7	22.0
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypophosphataemia	Asian	128	45.6	21	16.4	11.0	23.8
		Non-Asian	135	48.0	12	8.9	5.2	14.9
		Unknown	18	6.4	2	11.1	3.1	32.8
	Hypoproteinaemia	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Increased appetite	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vitamin D deficiency	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Musculoskeletal and connective tissue disorders	-Total	Asian	128	45.6	47	36.7	28.9	45.3
		Non-Asian	135	48.0	67	49.6	41.3	58.0
		Unknown	18	6.4	10	55.6	33.7	75.4
	Arthralgia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	11	8.1	4.6	14.0

		Unknown	18	6.4	1	5.6	1.0	25.8
	Arthropathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Back pain	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	24	17.8	12.2	25.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Bone pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bursitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Coccydynia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Costochondritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Flank pain	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Groin pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercreatinaemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intervertebral disc protrusion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint range of motion decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint stiffness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint swelling	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Muscle fatigue	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Muscle spasms	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	3	16.7	5.8	39.2
	Muscular weakness	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Musculoskeletal chest pain	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Musculoskeletal pain	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	2	11.1	3.1	32.8
	Musculoskeletal stiffness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Myalgia	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	2	11.1	3.1	32.8
	Myopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neck pain	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Osteopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain in extremity	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	18	13.3	8.6	20.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain in jaw	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Rhabdomyolysis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rotator cuff syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Spinal column stenosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Spinal osteoarthritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Tendon disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tendon pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Anogenital warts	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Basal cell carcinoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bowen's disease	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cancer pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gallbladder cancer	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Metastases to central nervous system	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal cell carcinoma	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Squamous cell carcinoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Squamous cell carcinoma of skin	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tumour pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
Nervous system disorders	-Total	Asian	128	45.6	59	46.1	37.7	54.7
		Non-Asian	135	48.0	78	57.8	49.3	65.8
		Unknown	18	6.4	8	44.4	24.6	66.3
	Ageusia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aphasia	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ataxia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Balance disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Brain oedema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebellar haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebral haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebral microhaemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebrovascular accident	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Disturbance in attention	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dizziness	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	20	14.8	9.8	21.8
		Unknown	18	6.4	2	11.1	3.1	32.8
	Dizziness postural	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysarthria	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysgeusia	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	29	21.5	15.4	29.1
		Unknown	18	6.4	3	16.7	5.8	39.2
	Dyskinesia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epilepsy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Facial paralysis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	1	5.6	1.0	25.8
	Haemorrhage intracranial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Headache	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	21	15.6	10.4	22.6
		Unknown	18	6.4	4	22.2	9.0	45.2
	Hemiplegia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperaesthesia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Hypersomnia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoaesthesia	Asian	128	45.6	17	13.3	8.5	20.2
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypotonia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lethargy	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lumbar radiculopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lumbosacral radiculopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Memory impairment	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Migraine	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Migraine with aura	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Neuralgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Neuropathy peripheral	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	1	5.6	1.0	25.8

	Paraesthesia	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	Paralysis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Parosmia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Peripheral sensory neuropathy	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Polyneuropathy chronic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Post herpetic neuralgia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Presyncope	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Psychomotor skills impaired	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Restless legs syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sciatica	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Seizure	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sensory disturbance	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Slow speech	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Somnolence	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Spinal cord haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Syncope	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tension headache	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tremor	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Visual field defect	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Product issues	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Device dislocation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Psychiatric disorders	-Total	Asian	128	45.6	27	21.1	14.9	29.0
		Non-Asian	135	48.0	25	18.5	12.9	25.9
		Unknown	18	6.4	4	22.2	9.0	45.2
	Abnormal behaviour	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abnormal dreams	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Adjustment disorder with mixed anxiety and depressed mood	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anxiety	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bradyphrenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Confusional state	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Delirium	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Depressed mood	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Depression	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Fear of falling	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Insomnia	Asian	128	45.6	17	13.3	8.5	20.2
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Irritability	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Libido decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mental status changes	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mood altered	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Psychomotor retardation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Restlessness	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sleep disorder	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Renal and urinary disorders	-Total	Asian	128	45.6	17	13.3	8.5	20.2
		Non-Asian	135	48.0	25	18.5	12.9	25.9
		Unknown	18	6.4	1	5.6	1.0	25.8
	Acute kidney injury	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Azotaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis haemorrhagic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysuria	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematuria	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2

		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhage urinary tract	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hydronephrosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Micturition urgency	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nephritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nephrolithiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nocturia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Obstructive nephropathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pollakiuria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Proteinuria	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal colic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal impairment	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Strangury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urethral stenosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Urinary incontinence	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary retention	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Urinary tract pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urine flow decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Reproductive system and breast disorders	-Total	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	3	16.7	5.8	39.2
	Benign prostatic hyperplasia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Breast discharge	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Erectile dysfunction	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Galactorrhoea	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Genital ulceration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Metrorrhagia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Ovarian cyst	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pelvic discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pelvic fluid collection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Perineal pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Postmenopausal haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Prostatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Uterine polyp	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vaginal haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vulvovaginal dryness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vulvovaginal erythema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Respiratory, thoracic and mediastinal disorders	-Total	Asian	128	45.6	73	57.0	48.4	65.3
		Non-Asian	135	48.0	85	63.0	54.6	70.6
		Unknown	18	6.4	9	50.0	29.0	71.0
	Acute respiratory failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aspiration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bronchospasm	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Choking	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cough	Asian	128	45.6	30	23.4	16.9	31.5
		Non-Asian	135	48.0	31	23.0	16.7	30.7
		Unknown	18	6.4	4	22.2	9.0	45.2
	Dry throat	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysphonia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dyspnoea	Asian	128	45.6	19	14.8	9.7	22.0
		Non-Asian	135	48.0	25	18.5	12.9	25.9
		Unknown	18	6.4	3	16.7	5.8	39.2
	Dyspnoea exertional	Asian	128	45.6	9	7.0	3.7	12.8

		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epistaxis	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Haemoptysis	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hiccups	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoxia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Interstitial lung disease	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Laryngeal haemorrhage	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lung consolidation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal congestion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal dryness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal polyps	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oropharyngeal discomfort	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oropharyngeal pain	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	0	0.0	0.0	17.6
	Paranasal sinus discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pharyngeal disorder	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleural effusion	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	7	5.2	2.5	10.3

		Unknown	18	6.4	1	5.6	1.0	25.8
	Pleural thickening	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleuritic pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonitis	Asian	128	45.6	14	10.9	6.6	17.5
		Non-Asian	135	48.0	16	11.9	7.4	18.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Pneumothorax	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Productive cough	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary embolism	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	Pulmonary hypertension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary mass	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiration abnormal	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory distress	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Respiratory failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinalgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinitis allergic	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinorrhoea	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

	Sinus congestion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sleep apnoea syndrome	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sputum discoloured	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Throat irritation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Upper-airway cough syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Vocal cord leukoplakia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wheezing	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Skin and subcutaneous tissue disorders	-Total	Asian	128	45.6	42	32.8	25.3	41.3
		Non-Asian	135	48.0	50	37.0	29.4	45.4
		Unknown	18	6.4	8	44.4	24.6	66.3
	Acne	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alopecia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chloasma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Decubitus ulcer	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermal cyst	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermatitis acneiform	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8

	Dermatitis allergic	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermatitis bullous	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dry skin	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Ecchymosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eczema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Erythema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hair growth abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hair texture abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hirsutism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyperhidrosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyperkeratosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypertrichosis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Madarosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nail discolouration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nail disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Night sweats	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Onychalgia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Onycholysis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Onychomadesis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain of skin	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Palmar-plantar erythrodysaesthesia syndrome	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Photosensitivity reaction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pruritus	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pruritus generalised	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Purpura	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rash	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Rash erythematous	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rash macular	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Rash maculo-papular	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rash papular	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Scab	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2

		Unknown	18	6.4	0	0.0	0.0	17.6
	Scar pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin discolouration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin hyperpigmentation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin lesion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Swelling face	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Urticaria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Surgical and medical procedures	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Astringent therapy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eye excision	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hip arthroplasty	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Therapy cessation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Vascular disorders	-Total	Asian	128	45.6	54	42.2	34.0	50.8
		Non-Asian	135	48.0	54	40.0	32.1	48.4
		Unknown	18	6.4	7	38.9	20.3	61.4
	Aortic dissection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Circulatory collapse	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Deep vein thrombosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8

	Embolism	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Embolism venous	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Flushing	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematoma	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hot flush	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypertension	Asian	128	45.6	51	39.8	31.8	48.5
		Non-Asian	135	48.0	42	31.1	23.9	39.4
		Unknown	18	6.4	3	16.7	5.8	39.2
	Hypotension	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphoedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Orthostatic hypotension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Pallor	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Phlebitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Raynaud's phenomenon	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Shock haemorrhagic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Superior vena cava syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombophlebitis superficial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Thrombosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEANY_SG.xls
26MAR2021 13:27

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Female	152	54.1	101	66.4	58.6	73.5
		Male	129	45.9	68	52.7	44.1	61.1
	Anaemia	Female	152	54.1	81	53.3	45.4	61.0
		Male	129	45.9	48	37.2	29.4	45.8
	Anaemia macrocytic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Aplastic anaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bone marrow oedema	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cytopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Disseminated intravascular coagulation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Febrile neutropenia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Haemorrhagic anaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperfibrinogenaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Leukocytosis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Leukopenia	Female	152	54.1	19	12.5	8.2	18.7
		Male	129	45.9	11	8.5	4.8	14.6
	Lymph node pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lymphadenopathy	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Lymphopenia	Female	152	54.1	15	9.9	6.1	15.6
		Male	129	45.9	8	6.2	3.2	11.8
	Neutropenia	Female	152	54.1	40	26.3	20.0	33.8
		Male	129	45.9	21	16.3	10.9	23.6
	Neutrophilia	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Pancytopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Thrombocytopenia	Female	152	54.1	17	11.2	7.1	17.2
		Male	129	45.9	7	5.4	2.7	10.8
	Thrombocytosis	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	0	0.0	0.0	2.9
Cardiac disorders	-Total	Female	152	54.1	18	11.8	7.6	17.9
		Male	129	45.9	21	16.3	10.9	23.6
	Acute coronary syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Acute myocardial infarction	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Angina pectoris	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Aortic valve calcification	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Atrial fibrillation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Atrial flutter	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Bradycardia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Bundle branch block right	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cardiac failure	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cardio-respiratory arrest	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Extrasystoles	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Myocardial ischaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Nodal arrhythmia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Palpitations	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Pericardial effusion	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Sinus bradycardia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5

	Sinus tachycardia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Stress cardiomyopathy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Supraventricular tachycardia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tachycardia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Ventricular extrasystoles	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Ventricular pre-excitation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Congenital, familial and genetic disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Gilbert's syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hydrocele	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Ear and labyrinth disorders	-Total	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	10	7.8	4.3	13.7
	Ear congestion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Ear discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Ear pain	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Tinnitus	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Vertigo	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	4	3.1	1.2	7.7
Endocrine disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Adrenal insufficiency	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hyperthyroidism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypothyroidism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Eye disorders	-Total	Female	152	54.1	30	19.7	14.2	26.8
		Male	129	45.9	10	7.8	4.3	13.7

	Abnormal sensation in eye	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blepharitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cataract	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Chalazion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Conjunctival cyst	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Conjunctival haemorrhage	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Diplopia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dry eye	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Eye swelling	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Eyelid oedema	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	0	0.0	0.0	2.9
	Eyelid ptosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Keratitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Ocular discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Periorbital oedema	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Photophobia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Photopsia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Ulcerative keratitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vision blurred	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	1	0.8	0.1	4.3
	Visual acuity reduced	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Gastrointestinal disorders	-Total	Female	152	54.1	119	78.3	71.1	84.1
		Male	129	45.9	85	65.9	57.4	73.5
	Abdominal discomfort	Female	152	54.1	2	1.3	0.4	4.7

		Male	129	45.9	3	2.3	0.8	6.6
	Abdominal distension	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	2	1.6	0.4	5.5
	Abdominal pain	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	5	3.9	1.7	8.8
	Abdominal pain lower	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Abdominal pain upper	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	8	6.2	3.2	11.8
	Abdominal symptom	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Anal incontinence	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Aphthous ulcer	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Ascites	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Constipation	Female	152	54.1	71	46.7	39.0	54.6
		Male	129	45.9	47	36.4	28.6	45.0
	Dental caries	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dental dysaesthesia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Diarrhoea	Female	152	54.1	42	27.6	21.1	35.2
		Male	129	45.9	28	21.7	15.5	29.6
	Diverticular perforation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dry mouth	Female	152	54.1	28	18.4	13.1	25.3
		Male	129	45.9	19	14.7	9.6	21.9
	Dyspepsia	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	3	2.3	0.8	6.6
	Dysphagia	Female	152	54.1	15	9.9	6.1	15.6
		Male	129	45.9	5	3.9	1.7	8.8
	Enteritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Epigastric discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Eructation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Faeces soft	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Flatulence	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Frequent bowel movements	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastric ulcer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastritis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastritis erosive	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrointestinal haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Gastrointestinal inflammation	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrointestinal oedema	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gastrointestinal wall thickening	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrooesophageal reflux disease	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	4	3.1	1.2	7.7
	Gingival bleeding	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Gingival swelling	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Glossitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Glossodynia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haematochezia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Haemorrhoids	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hypoaesthesia oral	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Impaired gastric emptying	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Intestinal obstruction	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Irritable bowel syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Large intestine perforation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Melaena	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Mouth ulceration	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	3	2.3	0.8	6.6
	Nausea	Female	152	54.1	31	20.4	14.8	27.5
		Male	129	45.9	11	8.5	4.8	14.6
	Odynophagia	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	0	0.0	0.0	2.9
	Oesophageal irritation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oesophagitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Oral disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Oral dysaesthesia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oral mucosal erythema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Oral pain	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	1	0.8	0.1	4.3
	Pancreatitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pancreatitis acute	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Paraesthesia oral	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Proctitis ulcerative	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rectal prolapse	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Regurgitation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Sensitivity of teeth	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Stomatitis	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	4	3.1	1.2	7.7
	Swollen tongue	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Tongue coated	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tongue discomfort	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tongue ulceration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tooth discolouration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Toothache	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	5	3.9	1.7	8.8
	Vomiting	Female	152	54.1	22	14.5	9.8	20.9
		Male	129	45.9	10	7.8	4.3	13.7
General disorders and administration site conditions	-Total	Female	152	54.1	114	75.0	67.6	81.2
		Male	129	45.9	88	68.2	59.8	75.6
	Asthenia	Female	152	54.1	25	16.4	11.4	23.2
		Male	129	45.9	14	10.9	6.6	17.4
	Axillary pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Catheter site pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Chest discomfort	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	3	2.3	0.8	6.6
	Chest pain	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	6	4.7	2.1	9.8
	Chills	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Condition aggravated	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Death	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Disease progression	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	12	9.3	5.4	15.6
	Face oedema	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	5	3.9	1.7	8.8
	Facial pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Fatigue	Female	152	54.1	34	22.4	16.5	29.6
		Male	129	45.9	33	25.6	18.8	33.7
	Feeling abnormal	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Feeling cold	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Feeling hot	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gait disturbance	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	General physical health deterioration	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Generalised oedema	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Impaired healing	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Influenza like illness	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Injection site bruising	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Localised oedema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Malaise	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	9	7.0	3.7	12.7
	Mucosal dryness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Mucosal inflammation	Female	152	54.1	18	11.8	7.6	17.9
		Male	129	45.9	3	2.3	0.8	6.6
	Multiple organ dysfunction syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Non-cardiac chest pain	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	4	3.1	1.2	7.7
	Oedema	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Oedema peripheral	Female	152	54.1	26	17.1	11.9	23.9
		Male	129	45.9	16	12.4	7.8	19.2
	Pain	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Peripheral swelling	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Pyrexia	Female	152	54.1	42	27.6	21.1	35.2
		Male	129	45.9	30	23.3	16.8	31.3
	Swelling	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Temperature intolerance	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Xerosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Hepatobiliary disorders	-Total	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	16	12.4	7.8	19.2
	Cholecystitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cholelithiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gallbladder polyp	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hepatic function abnormal	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hepatic steatosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hepatocellular injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Hyperbilirubinaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	6	4.7	2.1	9.8
	Liver disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Liver injury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pneumobilia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Portal vein thrombosis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
Immune system disorders	-Total	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Contrast media allergy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Drug hypersensitivity	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Food allergy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypersensitivity	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Seasonal allergy	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
Infections and infestations	-Total	Female	152	54.1	87	57.2	49.3	64.8

		Male	129	45.9	70	54.3	45.7	62.6
	Abdominal abscess	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Acute sinusitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Appendicitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Arthritis infective	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Atypical pneumonia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bacteraemia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Bacterial disease carrier	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Bacterial infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bacterial vaginosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bronchitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	Candida infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cellulitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Chronic sinusitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Clostridium difficile colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Conjunctivitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Corona virus infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Cystitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Cystitis escherichia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Device related infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Diverticulitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9

	Ear infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Empyema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Enterococcal bacteraemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Epididymitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Epstein-Barr virus infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Escherichia bacteraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Escherichia infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Escherichia urinary tract infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Eye infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Febrile infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Folliculitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Fungal infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Gastroenteritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Genital candidiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Genital herpes	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Gingivitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Herpes simplex	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Herpes virus infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Herpes zoster	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	4	3.1	1.2	7.7
	Infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Infectious colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Influenza	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lower respiratory tract infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Lung infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Lyme disease	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lymph node tuberculosis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Meningitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nasal herpes	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nasopharyngitis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	5	3.9	1.7	8.8
	Oral candidiasis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	5	3.9	1.7	8.8
	Oral fungal infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Oropharyngeal candidiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Otitis externa	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Otitis media	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Paronychia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Peritonitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pharyngitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Pleural infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumocystis jirovecii pneumonia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Pneumonia	Female	152	54.1	22	14.5	9.8	20.9
		Male	129	45.9	22	17.1	11.5	24.5
	Pneumonia bacterial	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonia cytomegaloviral	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pneumonia haemophilus	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonia influenzal	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonia pseudomonal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pneumonia streptococcal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pyelonephritis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Pyelonephritis acute	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pyuria	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rectal abscess	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Renal tuberculosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Respiratory tract infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Respiratory tract infection bacterial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rhinitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Sepsis	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	4	3.1	1.2	7.7
	Septic shock	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sinusitis	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	1	0.8	0.1	4.3
	Sinusitis bacterial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Skin infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Staphylococcal infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Systemic infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Tinea cruris	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tinea infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tinea pedis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Tonsillitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tooth infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tracheitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tuberculosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Upper respiratory tract infection	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	4	3.1	1.2	7.7
	Urethritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urinary tract infection	Female	152	54.1	26	17.1	11.9	23.9
		Male	129	45.9	12	9.3	5.4	15.6
	Urosepsis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Varicella	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Varicella zoster virus infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Viral hepatitis carrier	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Viral infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Vulvovaginal candidiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Injury, poisoning and procedural complications	-Total	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	15	11.6	7.2	18.3
	Contusion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	4	3.1	1.2	7.7
	Epicondylitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Fall	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	6	4.7	2.1	9.8

	Fracture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Heart injury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Incision site pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Joint dislocation	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Laceration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ligament sprain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Limb injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Muscle rupture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Muscle strain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Procedural pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Procedural pneumothorax	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rib fracture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Scar	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin abrasion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Subdural haematoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tendon rupture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Thermal burn	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Wound	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Wound complication	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
	Wrist fracture	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Investigations	-Total	Female	152	54.1	127	83.6	76.8	88.6
		Male	129	45.9	96	74.4	66.3	81.2
	Alanine aminotransferase	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Alanine aminotransferase increased	Female	152	54.1	57	37.5	30.2	45.4
		Male	129	45.9	35	27.1	20.2	35.4
	Albumin urine present	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Alpha hydroxybutyrate dehydrogenase increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Amylase increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Aspartate aminotransferase increased	Female	152	54.1	73	48.0	40.2	55.9
		Male	129	45.9	53	41.1	33.0	49.7
	Bacterial test	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bilirubin conjugated increased	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	7	5.4	2.7	10.8
	Blood albumin decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood alkaline phosphatase	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood alkaline phosphatase decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood alkaline phosphatase increased	Female	152	54.1	22	14.5	9.8	20.9
		Male	129	45.9	13	10.1	6.0	16.5
	Blood bilirubin increased	Female	152	54.1	18	11.8	7.6	17.9
		Male	129	45.9	9	7.0	3.7	12.7
	Blood bilirubin unconjugated increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	5	3.9	1.7	8.8
	Blood calcium decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Blood calcium increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood chloride increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood cholesterol increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	4	3.1	1.2	7.7

	Blood creatine increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Blood creatine phosphokinase MB increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Blood creatine phosphokinase increased	Female	152	54.1	33	21.7	15.9	28.9
		Male	129	45.9	20	15.5	10.3	22.7
	Blood creatinine	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood creatinine increased	Female	152	54.1	27	17.8	12.5	24.6
		Male	129	45.9	35	27.1	20.2	35.4
	Blood fibrinogen increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood glucose increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Blood iron decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood ketone body increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood lactate dehydrogenase increased	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	3	2.3	0.8	6.6
	Blood magnesium decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood phosphorus increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Blood potassium decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood potassium increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood pressure increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Blood sodium decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Blood thyroid stimulating hormone increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood triglycerides increased	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Blood urea increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Blood uric acid decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Blood uric acid increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Blood urine	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Blood urine present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	C-reactive protein increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Carbon dioxide decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Complement factor C1 decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Computerised tomogram thorax abnormal	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Crystal urine present	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cystatin C increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Electrocardiogram QT prolonged	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	2	1.6	0.4	5.5
	Electrocardiogram ST-T change	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Fibrin D dimer increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Fibrin degradation products increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Free fatty acids increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gamma-glutamyltransferase increased	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	7	5.4	2.7	10.8
	Glomerular filtration rate decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Glutamate dehydrogenase increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Granulocyte count decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haematocrit decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haemoglobin decreased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Heart rate increased	Female	152	54.1	3	2.0	0.7	5.6

		Male	129	45.9	3	2.3	0.8	6.6
	Hepatic enzyme increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	International normalised ratio increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Intraocular pressure increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Laboratory test abnormal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lipase increased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Liver function test increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Lymphocyte count decreased	Female	152	54.1	15	9.9	6.1	15.6
		Male	129	45.9	12	9.3	5.4	15.6
	Lymphocyte count increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Mean cell volume increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Myoglobin blood increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Neutrophil count decreased	Female	152	54.1	54	35.5	28.4	43.4
		Male	129	45.9	27	20.9	14.8	28.7
	Neutrophil count increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Neutrophil percentage increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Occult blood positive	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Oxygen saturation decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	PO2 decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Platelet count decreased	Female	152	54.1	25	16.4	11.4	23.2
		Male	129	45.9	8	6.2	3.2	11.8
	Platelet count increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Procalcitonin increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Protein total decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3

	Protein total increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Protein urine present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Prothrombin time prolonged	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Red blood cell count decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Serum amyloid A protein increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombin time prolonged	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Total bile acids increased	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	4	3.1	1.2	7.7
	Transaminases increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	4	3.1	1.2	7.7
	Transferrin increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Troponin T increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Troponin increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Urinary sediment present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urine ketone body present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Urine leukocyte esterase positive	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urobilinogen urine increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Weight decreased	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	4	3.1	1.2	7.7
	Weight increased	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	10	7.8	4.3	13.7
	White blood cell count decreased	Female	152	54.1	46	30.3	23.5	38.0
		Male	129	45.9	26	20.2	14.1	27.9
	White blood cells urine positive	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
Metabolism and nutrition disorders	-Total	Female	152	54.1	88	57.9	49.9	65.5
		Male	129	45.9	59	45.7	37.4	54.3

	Abnormal loss of weight	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Acidosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Alkalosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cell death	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Decreased appetite	Female	152	54.1	20	13.2	8.7	19.5
		Male	129	45.9	18	14.0	9.0	21.0
	Dehydration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	5	3.9	1.7	8.8
	Electrolyte imbalance	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Failure to thrive	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Fluid retention	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypercalcaemia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hypercholesterolaemia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Hyperglycaemia	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	7	5.4	2.7	10.8
	Hyperkalaemia	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	8	6.2	3.2	11.8
	Hyperlipidaemia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hypermagnesaemia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hypernatraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hyperphosphataemia	Female	152	54.1	23	15.1	10.3	21.7
		Male	129	45.9	9	7.0	3.7	12.7
	Hypertriglyceridaemia	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Hyperuricaemia	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	5	3.9	1.7	8.8
	Hypoalbuminaemia	Female	152	54.1	25	16.4	11.4	23.2
		Male	129	45.9	12	9.3	5.4	15.6
	Hypocalcaemia	Female	152	54.1	23	15.1	10.3	21.7

		Male	129	45.9	11	8.5	4.8	14.6
	Hypochloraemia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Hypoglycaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypokalaemia	Female	152	54.1	25	16.4	11.4	23.2
		Male	129	45.9	13	10.1	6.0	16.5
	Hypomagnesaemia	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	8	6.2	3.2	11.8
	Hyponatraemia	Female	152	54.1	15	9.9	6.1	15.6
		Male	129	45.9	15	11.6	7.2	18.3
	Hypophosphataemia	Female	152	54.1	21	13.8	9.2	20.2
		Male	129	45.9	14	10.9	6.6	17.4
	Hypoproteinaemia	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	1	0.8	0.1	4.3
	Increased appetite	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Vitamin D deficiency	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Musculoskeletal and connective tissue disorders	-Total	Female	152	54.1	70	46.1	38.3	54.0
		Male	129	45.9	54	41.9	33.7	50.5
	Arthralgia	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	6	4.7	2.1	9.8
	Arthropathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Back pain	Female	152	54.1	19	12.5	8.2	18.7
		Male	129	45.9	19	14.7	9.6	21.9
	Bone pain	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Bursitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Coccydynia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Costochondritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Flank pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Groin pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypercreatinaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Intervertebral disc protrusion	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	4	3.1	1.2	7.7
	Joint range of motion decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Joint stiffness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Joint swelling	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Muscle fatigue	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Muscle haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Muscle spasms	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	8	6.2	3.2	11.8
	Muscular weakness	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	4	3.1	1.2	7.7
	Musculoskeletal chest pain	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	5	3.9	1.7	8.8
	Musculoskeletal pain	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	11	8.5	4.8	14.6
	Musculoskeletal stiffness	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Myalgia	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	7	5.4	2.7	10.8
	Myopathy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Neck pain	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	5	3.9	1.7	8.8
	Osteopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pain in extremity	Female	152	54.1	18	11.8	7.6	17.9
		Male	129	45.9	8	6.2	3.2	11.8
	Pain in jaw	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Rhabdomyolysis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rotator cuff syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Spinal column stenosis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9

	Spinal osteoarthritis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tendon disorder	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tendon pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	5	3.9	1.7	8.8
	Anogenital warts	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Basal cell carcinoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Bowen's disease	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cancer pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gallbladder cancer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Metastases to central nervous system	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Renal cell carcinoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Squamous cell carcinoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Squamous cell carcinoma of skin	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tumour pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Nervous system disorders	-Total	Female	152	54.1	80	52.6	44.7	60.4
		Male	129	45.9	65	50.4	41.9	58.9
	Ageusia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Aphasia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Ataxia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Balance disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Brain oedema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cerebellar haemorrhage	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
	Cerebral haematoma	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cerebral microhaemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cerebrovascular accident	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Disturbance in attention	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Dizziness	Female	152	54.1	20	13.2	8.7	19.5
		Male	129	45.9	18	14.0	9.0	21.0
	Dizziness postural	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dysarthria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dysgeusia	Female	152	54.1	24	15.8	10.8	22.4
		Male	129	45.9	18	14.0	9.0	21.0
	Dyskinesia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Epilepsy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Facial paralysis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Haemorrhage intracranial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Headache	Female	152	54.1	17	11.2	7.1	17.2
		Male	129	45.9	17	13.2	8.4	20.1
	Hemiplegia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperaesthesia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypersomnia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypoaesthesia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	6	4.7	2.1	9.8
	Hypotonia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lethargy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lumbar radiculopathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Lumbosacral radiculopathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Memory impairment	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Migraine	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Migraine with aura	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neuralgia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Neuropathy peripheral	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	5	3.9	1.7	8.8
	Paraesthesia	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	6	4.7	2.1	9.8
	Paralysis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Parosmia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Peripheral sensory neuropathy	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	3	2.3	0.8	6.6
	Polyneuropathy chronic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Post herpetic neuralgia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Presyncope	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Psychomotor skills impaired	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Restless legs syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Sciatica	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Seizure	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Sensory disturbance	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Slow speech	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Somnolence	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9

	Spinal cord haematoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Syncope	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	Tension headache	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tremor	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Visual field defect	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
Product issues	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Device dislocation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Psychiatric disorders	-Total	Female	152	54.1	30	19.7	14.2	26.8
		Male	129	45.9	26	20.2	14.1	27.9
	Abnormal behaviour	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Abnormal dreams	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Adjustment disorder with mixed anxiety and depressed mood	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Anxiety	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	4	3.1	1.2	7.7
	Bradyphrenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Confusional state	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	4	3.1	1.2	7.7
	Delirium	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Depressed mood	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Depression	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Fear of falling	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Insomnia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	8	6.2	3.2	11.8
	Irritability	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Libido decreased	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	2	1.6	0.4	5.5
	Mental status changes	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Mood altered	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Psychomotor retardation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Restlessness	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Sleep disorder	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Renal and urinary disorders	-Total	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	27	20.9	14.8	28.7
	Acute kidney injury	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	5	3.9	1.7	8.8
	Azotaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cystitis haemorrhagic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dysuria	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	6	4.7	2.1	9.8
	Haematuria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	4	3.1	1.2	7.7
	Haemorrhage urinary tract	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hydronephrosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Micturition urgency	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Nephritis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Nephrolithiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nocturia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Obstructive nephropathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pollakiuria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Proteinuria	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9

	Renal colic	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Renal disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Renal failure	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Renal impairment	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Strangury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urethral stenosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urinary incontinence	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Urinary retention	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	5	3.9	1.7	8.8
	Urinary tract pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urine flow decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Reproductive system and breast disorders	-Total	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	14	10.9	6.6	17.4
	Benign prostatic hyperplasia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Breast discharge	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Erectile dysfunction	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	9	7.0	3.7	12.7
	Galactorrhoea	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Genital ulceration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Metrorrhagia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Ovarian cyst	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pelvic discomfort	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pelvic fluid collection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Perineal pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Postmenopausal haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Prostatitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Uterine polyp	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vaginal haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vulvovaginal dryness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vulvovaginal erythema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Respiratory, thoracic and mediastinal disorders	-Total	Female	152	54.1	91	59.9	51.9	67.3
		Male	129	45.9	76	58.9	50.3	67.0
	Acute respiratory failure	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Aspiration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Bronchospasm	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Choking	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cough	Female	152	54.1	35	23.0	17.0	30.3
		Male	129	45.9	30	23.3	16.8	31.3
	Dry throat	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Dysphonia	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	5	3.9	1.7	8.8
	Dyspnoea	Female	152	54.1	26	17.1	11.9	23.9
		Male	129	45.9	21	16.3	10.9	23.6
	Dyspnoea exertional	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	8	6.2	3.2	11.8
	Epistaxis	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	6	4.7	2.1	9.8
	Haemoptysis	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	5	3.9	1.7	8.8
	Hiccups	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hypoxia	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	4	3.1	1.2	7.7
	Interstitial lung disease	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Laryngeal haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lung consolidation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nasal congestion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Nasal dryness	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Nasal polyps	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oropharyngeal discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oropharyngeal pain	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	5	3.9	1.7	8.8
	Paranasal sinus discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pharyngeal disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pleural effusion	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	4	3.1	1.2	7.7
	Pleural thickening	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pleuritic pain	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonitis	Female	152	54.1	20	13.2	8.7	19.5
		Male	129	45.9	12	9.3	5.4	15.6
	Pneumothorax	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Productive cough	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	7	5.4	2.7	10.8
	Pulmonary embolism	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	7	5.4	2.7	10.8
	Pulmonary hypertension	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pulmonary mass	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pulmonary pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Respiration abnormal	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Respiratory distress	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Respiratory failure	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rhinalgia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rhinitis allergic	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Rhinorrhoea	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Sinus congestion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sleep apnoea syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Sputum discoloured	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Throat irritation	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Upper-airway cough syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Vocal cord leukoplakia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Wheezing	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
Skin and subcutaneous tissue disorders	-Total	Female	152	54.1	63	41.4	33.9	49.4
		Male	129	45.9	37	28.7	21.6	37.0
	Acne	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Alopecia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	2	1.6	0.4	5.5
	Chloasma	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Decubitus ulcer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dermal cyst	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dermatitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Dermatitis acneiform	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Dermatitis allergic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dermatitis bullous	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Dry skin	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	6	4.7	2.1	9.8
	Ecchymosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Eczema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Erythema	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Hair growth abnormal	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hair texture abnormal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hirsutism	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Hyperhidrosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Hyperkeratosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypertrichosis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Madarosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nail discolouration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nail disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Night sweats	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Onychalgia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Onycholysis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Onychomadesis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Pain of skin	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Palmar-plantar erythrodysaesthesia syndrome	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	0	0.0	0.0	2.9
	Photosensitivity reaction	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pruritus	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	Pruritus generalised	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Purpura	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rash	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	7	5.4	2.7	10.8
	Rash erythematous	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Rash macular	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Rash maculo-papular	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Rash papular	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Scab	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Scar pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin discolouration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin hyperpigmentation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Skin lesion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Swelling face	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urticaria	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Surgical and medical procedures	-Total	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Astringent therapy	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Eye excision	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Hip arthroplasty	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Therapy cessation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Vascular disorders	-Total	Female	152	54.1	63	41.4	33.9	49.4
		Male	129	45.9	52	40.3	32.2	48.9
	Aortic dissection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Circulatory collapse	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Deep vein thrombosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Embolism	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Embolism venous	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Flushing	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Haematoma	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Hot flush	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hypertension	Female	152	54.1	51	33.6	26.5	41.4
		Male	129	45.9	45	34.9	27.2	43.4
	Hypotension	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Lymphoedema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Orthostatic hypotension	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Pallor	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Phlebitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Raynaud's phenomenon	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Shock haemorrhagic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Superior vena cava syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Thrombophlebitis superficial	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEANY_SG.xls
26MAR2021 13:27

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1-2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	69	24.6	19.9	29.9
Sex	Female	152	54.1	36	23.7	17.6	31.0
	Male	129	45.9	33	25.6	18.8	33.7
Age	< 65	176	62.6	55	31.3	24.9	38.4
	>= 65	105	37.4	14	13.3	8.1	21.1
ECOG performance status	0	84	29.9	26	31.0	22.1	41.5
	1	190	67.6	42	22.1	16.8	28.5
	2	6	2.1	0	0.0	0.0	39.0
	Missing	1	0.4	1	100.0	20.7	100.0
Geographic region	USA	64	22.8	9	14.1	7.6	24.6
	Europe (EU)	95	33.8	33	34.7	25.9	44.7
	Asia (AS)	122	43.4	27	22.1	15.7	30.3
Race/ethnicity	Asian	128	45.6	27	21.1	14.9	29.0
	Non-Asian	135	48.0	36	26.7	19.9	34.7
	Unknown	18	6.4	6	33.3	16.3	56.3
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	34	29.3	21.8	38.2
	1	77	27.4	17	22.1	14.3	32.5
	>= 2	88	31.3	18	20.5	13.3	30.0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AEGR12_SG.xls
26MAR2021 10:18

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1-2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	67	23.8	19.2	29.2
Sex	Female	152	54.1	35	23.0	17.0	30.3
	Male	129	45.9	32	24.8	18.2	32.9
Age	< 65	176	62.6	53	30.1	23.8	37.3
	>= 65	105	37.4	14	13.3	8.1	21.1
ECOG performance status	0	84	29.9	26	31.0	22.1	41.5
	1	190	67.6	40	21.1	15.9	27.4
	2	6	2.1	0	0.0	0.0	39.0
	Missing	1	0.4	1	100.0	20.7	100.0
Geographic region	USA	64	22.8	9	14.1	7.6	24.6
	Europe (EU)	95	33.8	33	34.7	25.9	44.7
	Asia (AS)	122	43.4	25	20.5	14.3	28.5
Race/ethnicity	Asian	128	45.6	25	19.5	13.6	27.2
	Non-Asian	135	48.0	36	26.7	19.9	34.7
	Unknown	18	6.4	6	33.3	16.3	56.3
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	33	28.4	21.0	37.2
	1	77	27.4	17	22.1	14.3	32.5
	>= 2	88	31.3	17	19.3	12.4	28.8

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw_B63_06NOV2020_SE_TO_AEGR12_SG.xls
26MAR2021 9:56

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1-2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	n/a	281	100.0	125	44.5	38.8	50.3
	Anaemia	n/a	281	100.0	83	29.5	24.5	35.1
	Aplastic anaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Bone marrow oedema	n/a	281	100.0	1	0.4	0.1	2.0
	Cytopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Febrile neutropenia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperfibrinogenaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Leukocytosis	n/a	281	100.0	3	1.1	0.4	3.1
	Leukopenia	n/a	281	100.0	22	7.8	5.2	11.6
	Lymph node pain	n/a	281	100.0	1	0.4	0.1	2.0
	Lymphadenopathy	n/a	281	100.0	2	0.7	0.2	2.6
	Lymphopenia	n/a	281	100.0	6	2.1	1.0	4.6
	Neutropenia	n/a	281	100.0	31	11.0	7.9	15.2
	Neutrophilia	n/a	281	100.0	1	0.4	0.1	2.0
	Pancytopenia	n/a	281	100.0	2	0.7	0.2	2.6
	Thrombocytopenia	n/a	281	100.0	16	5.7	3.5	9.0
	Thrombocytosis	n/a	281	100.0	5	1.8	0.8	4.1
Cardiac disorders	-Total	n/a	281	100.0	34	12.1	8.8	16.4
	Acute coronary syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Angina pectoris	n/a	281	100.0	1	0.4	0.1	2.0
	Aortic valve calcification	n/a	281	100.0	1	0.4	0.1	2.0
	Atrial fibrillation	n/a	281	100.0	1	0.4	0.1	2.0
	Atrial flutter	n/a	281	100.0	2	0.7	0.2	2.6
	Bradycardia	n/a	281	100.0	1	0.4	0.1	2.0
	Bundle branch block right	n/a	281	100.0	1	0.4	0.1	2.0

	Cardiac failure	n/a	281	100.0	2	0.7	0.2	2.6
	Extrasystoles	n/a	281	100.0	1	0.4	0.1	2.0
	Myocardial ischaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Nodal arrhythmia	n/a	281	100.0	3	1.1	0.4	3.1
	Palpitations	n/a	281	100.0	4	1.4	0.6	3.6
	Pericardial effusion	n/a	281	100.0	3	1.1	0.4	3.1
	Sinus bradycardia	n/a	281	100.0	4	1.4	0.6	3.6
	Sinus tachycardia	n/a	281	100.0	2	0.7	0.2	2.6
	Tachycardia	n/a	281	100.0	7	2.5	1.2	5.1
	Ventricular extrasystoles	n/a	281	100.0	1	0.4	0.1	2.0
	Ventricular pre-excitation	n/a	281	100.0	1	0.4	0.1	2.0
Congenital, familial and genetic disorders	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Gilbert's syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Hydrocele	n/a	281	100.0	1	0.4	0.1	2.0
Ear and labyrinth disorders	-Total	n/a	281	100.0	20	7.1	4.7	10.7
	Ear congestion	n/a	281	100.0	2	0.7	0.2	2.6
	Ear discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Ear pain	n/a	281	100.0	4	1.4	0.6	3.6
	Tinnitus	n/a	281	100.0	4	1.4	0.6	3.6
	Vertigo	n/a	281	100.0	10	3.6	1.9	6.4
Endocrine disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Hyperthyroidism	n/a	281	100.0	1	0.4	0.1	2.0
	Hypothyroidism	n/a	281	100.0	2	0.7	0.2	2.6
Eye disorders	-Total	n/a	281	100.0	38	13.5	10.0	18.0
	Abnormal sensation in eye	n/a	281	100.0	1	0.4	0.1	2.0
	Blepharitis	n/a	281	100.0	1	0.4	0.1	2.0
	Chalazion	n/a	281	100.0	1	0.4	0.1	2.0
	Conjunctival cyst	n/a	281	100.0	1	0.4	0.1	2.0
	Conjunctival haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Diplopia	n/a	281	100.0	1	0.4	0.1	2.0

	Dry eye	n/a	281	100.0	7	2.5	1.2	5.1
	Eye swelling	n/a	281	100.0	2	0.7	0.2	2.6
	Eyelid oedema	n/a	281	100.0	5	1.8	0.8	4.1
	Eyelid ptosis	n/a	281	100.0	1	0.4	0.1	2.0
	Keratitis	n/a	281	100.0	1	0.4	0.1	2.0
	Ocular discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Periorbital oedema	n/a	281	100.0	6	2.1	1.0	4.6
	Photophobia	n/a	281	100.0	1	0.4	0.1	2.0
	Photopsia	n/a	281	100.0	2	0.7	0.2	2.6
	Ulcerative keratitis	n/a	281	100.0	1	0.4	0.1	2.0
	Vision blurred	n/a	281	100.0	14	5.0	3.0	8.2
	Visual acuity reduced	n/a	281	100.0	1	0.4	0.1	2.0
Gastrointestinal disorders	-Total	n/a	281	100.0	199	70.8	65.3	75.8
	Abdominal discomfort	n/a	281	100.0	5	1.8	0.8	4.1
	Abdominal distension	n/a	281	100.0	8	2.8	1.4	5.5
	Abdominal pain	n/a	281	100.0	18	6.4	4.1	9.9
	Abdominal pain lower	n/a	281	100.0	2	0.7	0.2	2.6
	Abdominal pain upper	n/a	281	100.0	14	5.0	3.0	8.2
	Abdominal symptom	n/a	281	100.0	1	0.4	0.1	2.0
	Anal incontinence	n/a	281	100.0	2	0.7	0.2	2.6
	Aphthous ulcer	n/a	281	100.0	1	0.4	0.1	2.0
	Ascites	n/a	281	100.0	3	1.1	0.4	3.1
	Constipation	n/a	281	100.0	116	41.3	35.7	47.1
	Dental dysaesthesia	n/a	281	100.0	1	0.4	0.1	2.0
	Diarrhoea	n/a	281	100.0	65	23.1	18.6	28.4
	Dry mouth	n/a	281	100.0	47	16.7	12.8	21.5
	Dyspepsia	n/a	281	100.0	9	3.2	1.7	6.0
	Dysphagia	n/a	281	100.0	20	7.1	4.7	10.7
	Enteritis	n/a	281	100.0	1	0.4	0.1	2.0
	Epigastric discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Eructation	n/a	281	100.0	1	0.4	0.1	2.0

	Faeces soft	n/a	281	100.0	1	0.4	0.1	2.0
	Flatulence	n/a	281	100.0	2	0.7	0.2	2.6
	Frequent bowel movements	n/a	281	100.0	1	0.4	0.1	2.0
	Gastric ulcer	n/a	281	100.0	1	0.4	0.1	2.0
	Gastritis	n/a	281	100.0	3	1.1	0.4	3.1
	Gastritis erosive	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal inflammation	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal oedema	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal wall thickening	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrooesophageal reflux disease	n/a	281	100.0	9	3.2	1.7	6.0
	Gingival bleeding	n/a	281	100.0	3	1.1	0.4	3.1
	Gingival swelling	n/a	281	100.0	1	0.4	0.1	2.0
	Glossitis	n/a	281	100.0	1	0.4	0.1	2.0
	Glossodynia	n/a	281	100.0	1	0.4	0.1	2.0
	Haematochezia	n/a	281	100.0	2	0.7	0.2	2.6
	Haemorrhoids	n/a	281	100.0	7	2.5	1.2	5.1
	Hypoaesthesia oral	n/a	281	100.0	5	1.8	0.8	4.1
	Impaired gastric emptying	n/a	281	100.0	1	0.4	0.1	2.0
	Irritable bowel syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Melaena	n/a	281	100.0	1	0.4	0.1	2.0
	Mouth ulceration	n/a	281	100.0	9	3.2	1.7	6.0
	Nausea	n/a	281	100.0	42	14.9	11.3	19.6
	Odynophagia	n/a	281	100.0	5	1.8	0.8	4.1
	Oesophageal irritation	n/a	281	100.0	1	0.4	0.1	2.0
	Oesophagitis	n/a	281	100.0	3	1.1	0.4	3.1
	Oral disorder	n/a	281	100.0	2	0.7	0.2	2.6
	Oral dysaesthesia	n/a	281	100.0	1	0.4	0.1	2.0
	Oral mucosal erythema	n/a	281	100.0	1	0.4	0.1	2.0
	Oral pain	n/a	281	100.0	7	2.5	1.2	5.1

	Pancreatitis	n/a	281	100.0	1	0.4	0.1	2.0
	Paraesthesia oral	n/a	281	100.0	1	0.4	0.1	2.0
	Rectal prolapse	n/a	281	100.0	1	0.4	0.1	2.0
	Regurgitation	n/a	281	100.0	1	0.4	0.1	2.0
	Sensitivity of teeth	n/a	281	100.0	1	0.4	0.1	2.0
	Stomatitis	n/a	281	100.0	8	2.8	1.4	5.5
	Swollen tongue	n/a	281	100.0	1	0.4	0.1	2.0
	Tongue coated	n/a	281	100.0	1	0.4	0.1	2.0
	Tongue discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Tongue ulceration	n/a	281	100.0	1	0.4	0.1	2.0
	Tooth discolouration	n/a	281	100.0	1	0.4	0.1	2.0
	Toothache	n/a	281	100.0	8	2.8	1.4	5.5
	Vomiting	n/a	281	100.0	29	10.3	7.3	14.4
General disorders and administration site conditions	-Total	n/a	281	100.0	192	68.3	62.7	73.5
	Asthenia	n/a	281	100.0	37	13.2	9.7	17.6
	Axillary pain	n/a	281	100.0	1	0.4	0.1	2.0
	Catheter site pain	n/a	281	100.0	1	0.4	0.1	2.0
	Chest discomfort	n/a	281	100.0	9	3.2	1.7	6.0
	Chest pain	n/a	281	100.0	8	2.8	1.4	5.5
	Chills	n/a	281	100.0	4	1.4	0.6	3.6
	Face oedema	n/a	281	100.0	18	6.4	4.1	9.9
	Facial pain	n/a	281	100.0	1	0.4	0.1	2.0
	Fatigue	n/a	281	100.0	61	21.7	17.3	26.9
	Feeling abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Feeling cold	n/a	281	100.0	1	0.4	0.1	2.0
	Feeling hot	n/a	281	100.0	1	0.4	0.1	2.0
	Gait disturbance	n/a	281	100.0	7	2.5	1.2	5.1
	General physical health deterioration	n/a	281	100.0	2	0.7	0.2	2.6
	Generalised oedema	n/a	281	100.0	3	1.1	0.4	3.1
	Impaired healing	n/a	281	100.0	4	1.4	0.6	3.6
	Influenza like illness	n/a	281	100.0	3	1.1	0.4	3.1

	Injection site bruising	n/a	281	100.0	1	0.4	0.1	2.0
	Localised oedema	n/a	281	100.0	2	0.7	0.2	2.6
	Malaise	n/a	281	100.0	20	7.1	4.7	10.7
	Mucosal dryness	n/a	281	100.0	1	0.4	0.1	2.0
	Mucosal inflammation	n/a	281	100.0	21	7.5	4.9	11.2
	Non-cardiac chest pain	n/a	281	100.0	11	3.9	2.2	6.9
	Oedema	n/a	281	100.0	4	1.4	0.6	3.6
	Oedema peripheral	n/a	281	100.0	42	14.9	11.3	19.6
	Pain	n/a	281	100.0	6	2.1	1.0	4.6
	Peripheral swelling	n/a	281	100.0	8	2.8	1.4	5.5
	Pyrexia	n/a	281	100.0	71	25.3	20.5	30.7
	Swelling	n/a	281	100.0	1	0.4	0.1	2.0
	Temperature intolerance	n/a	281	100.0	3	1.1	0.4	3.1
	Xerosis	n/a	281	100.0	1	0.4	0.1	2.0
Hepatobiliary disorders	-Total	n/a	281	100.0	19	6.8	4.4	10.3
	Cholecystitis	n/a	281	100.0	2	0.7	0.2	2.6
	Hepatic function abnormal	n/a	281	100.0	3	1.1	0.4	3.1
	Hepatic steatosis	n/a	281	100.0	1	0.4	0.1	2.0
	Hepatocellular injury	n/a	281	100.0	3	1.1	0.4	3.1
	Hyperbilirubinaemia	n/a	281	100.0	6	2.1	1.0	4.6
	Liver disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumobilia	n/a	281	100.0	1	0.4	0.1	2.0
	Portal vein thrombosis	n/a	281	100.0	2	0.7	0.2	2.6
Immune system disorders	-Total	n/a	281	100.0	6	2.1	1.0	4.6
	Contrast media allergy	n/a	281	100.0	1	0.4	0.1	2.0
	Drug hypersensitivity	n/a	281	100.0	1	0.4	0.1	2.0
	Food allergy	n/a	281	100.0	1	0.4	0.1	2.0
	Hypersensitivity	n/a	281	100.0	1	0.4	0.1	2.0
	Seasonal allergy	n/a	281	100.0	2	0.7	0.2	2.6
Infections and infestations	-Total	n/a	281	100.0	122	43.4	37.7	49.3

	Abdominal abscess	n/a	281	100.0	1	0.4	0.1	2.0
	Acute sinusitis	n/a	281	100.0	1	0.4	0.1	2.0
	Arthritis infective	n/a	281	100.0	1	0.4	0.1	2.0
	Atypical pneumonia	n/a	281	100.0	1	0.4	0.1	2.0
	Bacteraemia	n/a	281	100.0	2	0.7	0.2	2.6
	Bacterial disease carrier	n/a	281	100.0	1	0.4	0.1	2.0
	Bacterial vaginosis	n/a	281	100.0	1	0.4	0.1	2.0
	Bronchitis	n/a	281	100.0	7	2.5	1.2	5.1
	Candida infection	n/a	281	100.0	1	0.4	0.1	2.0
	Cellulitis	n/a	281	100.0	1	0.4	0.1	2.0
	Chronic sinusitis	n/a	281	100.0	3	1.1	0.4	3.1
	Conjunctivitis	n/a	281	100.0	1	0.4	0.1	2.0
	Corona virus infection	n/a	281	100.0	1	0.4	0.1	2.0
	Cystitis	n/a	281	100.0	2	0.7	0.2	2.6
	Cystitis escherichia	n/a	281	100.0	1	0.4	0.1	2.0
	Ear infection	n/a	281	100.0	1	0.4	0.1	2.0
	Epididymitis	n/a	281	100.0	1	0.4	0.1	2.0
	Epstein-Barr virus infection	n/a	281	100.0	1	0.4	0.1	2.0
	Escherichia bacteraemia	n/a	281	100.0	1	0.4	0.1	2.0
	Escherichia infection	n/a	281	100.0	1	0.4	0.1	2.0
	Escherichia urinary tract infection	n/a	281	100.0	1	0.4	0.1	2.0
	Eye infection	n/a	281	100.0	1	0.4	0.1	2.0
	Febrile infection	n/a	281	100.0	1	0.4	0.1	2.0
	Folliculitis	n/a	281	100.0	3	1.1	0.4	3.1
	Fungal infection	n/a	281	100.0	3	1.1	0.4	3.1
	Gastroenteritis	n/a	281	100.0	2	0.7	0.2	2.6
	Genital candidiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Genital herpes	n/a	281	100.0	2	0.7	0.2	2.6
	Gingivitis	n/a	281	100.0	1	0.4	0.1	2.0
	Herpes simplex	n/a	281	100.0	1	0.4	0.1	2.0
	Herpes virus infection	n/a	281	100.0	3	1.1	0.4	3.1

	Herpes zoster	n/a	281	100.0	11	3.9	2.2	6.9
	Infection	n/a	281	100.0	1	0.4	0.1	2.0
	Influenza	n/a	281	100.0	3	1.1	0.4	3.1
	Lower respiratory tract infection	n/a	281	100.0	1	0.4	0.1	2.0
	Lung infection	n/a	281	100.0	1	0.4	0.1	2.0
	Lyme disease	n/a	281	100.0	1	0.4	0.1	2.0
	Lymph node tuberculosis	n/a	281	100.0	2	0.7	0.2	2.6
	Nasal herpes	n/a	281	100.0	1	0.4	0.1	2.0
	Nasopharyngitis	n/a	281	100.0	9	3.2	1.7	6.0
	Oral candidiasis	n/a	281	100.0	9	3.2	1.7	6.0
	Oral fungal infection	n/a	281	100.0	2	0.7	0.2	2.6
	Oropharyngeal candidiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Otitis externa	n/a	281	100.0	2	0.7	0.2	2.6
	Otitis media	n/a	281	100.0	1	0.4	0.1	2.0
	Paronychia	n/a	281	100.0	7	2.5	1.2	5.1
	Pharyngitis	n/a	281	100.0	4	1.4	0.6	3.6
	Pneumonia	n/a	281	100.0	17	6.0	3.8	9.5
	Pneumonia influenzal	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia pseudomonal	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia streptococcal	n/a	281	100.0	1	0.4	0.1	2.0
	Pyelonephritis	n/a	281	100.0	1	0.4	0.1	2.0
	Pyuria	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory tract infection	n/a	281	100.0	2	0.7	0.2	2.6
	Respiratory tract infection bacterial	n/a	281	100.0	1	0.4	0.1	2.0
	Rhinitis	n/a	281	100.0	5	1.8	0.8	4.1
	Sepsis	n/a	281	100.0	1	0.4	0.1	2.0
	Sinusitis	n/a	281	100.0	7	2.5	1.2	5.1
	Skin infection	n/a	281	100.0	2	0.7	0.2	2.6
	Staphylococcal infection	n/a	281	100.0	1	0.4	0.1	2.0
	Systemic infection	n/a	281	100.0	1	0.4	0.1	2.0

	Tinea cruris	n/a	281	100.0	1	0.4	0.1	2.0
	Tinea infection	n/a	281	100.0	1	0.4	0.1	2.0
	Tinea pedis	n/a	281	100.0	2	0.7	0.2	2.6
	Tonsillitis	n/a	281	100.0	1	0.4	0.1	2.0
	Tooth infection	n/a	281	100.0	1	0.4	0.1	2.0
	Tracheitis	n/a	281	100.0	1	0.4	0.1	2.0
	Tuberculosis	n/a	281	100.0	1	0.4	0.1	2.0
	Upper respiratory tract infection	n/a	281	100.0	13	4.6	2.7	7.8
	Urethritis	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary tract infection	n/a	281	100.0	29	10.3	7.3	14.4
	Varicella	n/a	281	100.0	1	0.4	0.1	2.0
	Varicella zoster virus infection	n/a	281	100.0	1	0.4	0.1	2.0
	Viral hepatitis carrier	n/a	281	100.0	1	0.4	0.1	2.0
	Viral infection	n/a	281	100.0	2	0.7	0.2	2.6
	Vulvovaginal candidiasis	n/a	281	100.0	1	0.4	0.1	2.0
Injury, poisoning and procedural complications	-Total	n/a	281	100.0	25	8.9	6.1	12.8
	Contusion	n/a	281	100.0	5	1.8	0.8	4.1
	Epicondylitis	n/a	281	100.0	1	0.4	0.1	2.0
	Fall	n/a	281	100.0	8	2.8	1.4	5.5
	Incision site pain	n/a	281	100.0	1	0.4	0.1	2.0
	Injury	n/a	281	100.0	1	0.4	0.1	2.0
	Joint dislocation	n/a	281	100.0	2	0.7	0.2	2.6
	Laceration	n/a	281	100.0	1	0.4	0.1	2.0
	Ligament sprain	n/a	281	100.0	2	0.7	0.2	2.6
	Limb injury	n/a	281	100.0	2	0.7	0.2	2.6
	Muscle rupture	n/a	281	100.0	1	0.4	0.1	2.0
	Muscle strain	n/a	281	100.0	2	0.7	0.2	2.6
	Procedural pain	n/a	281	100.0	2	0.7	0.2	2.6
	Procedural pneumothorax	n/a	281	100.0	1	0.4	0.1	2.0
	Rib fracture	n/a	281	100.0	1	0.4	0.1	2.0
	Scar	n/a	281	100.0	1	0.4	0.1	2.0

	Skin abrasion	n/a	281	100.0	1	0.4	0.1	2.0
	Skin injury	n/a	281	100.0	1	0.4	0.1	2.0
	Tendon rupture	n/a	281	100.0	1	0.4	0.1	2.0
	Thermal burn	n/a	281	100.0	1	0.4	0.1	2.0
	Wound	n/a	281	100.0	2	0.7	0.2	2.6
	Wound complication	n/a	281	100.0	1	0.4	0.1	2.0
	Wrist fracture	n/a	281	100.0	1	0.4	0.1	2.0
Investigations	-Total	n/a	281	100.0	209	74.4	69.0	79.1
	Alanine aminotransferase increased	n/a	281	100.0	83	29.5	24.5	35.1
	Albumin urine present	n/a	281	100.0	1	0.4	0.1	2.0
	Alpha hydroxybutyrate dehydrogenase increased	n/a	281	100.0	2	0.7	0.2	2.6
	Amylase increased	n/a	281	100.0	2	0.7	0.2	2.6
	Aspartate aminotransferase increased	n/a	281	100.0	111	39.5	34.0	45.3
	Bacterial test	n/a	281	100.0	1	0.4	0.1	2.0
	Bilirubin conjugated increased	n/a	281	100.0	19	6.8	4.4	10.3
	Blood albumin decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood alkaline phosphatase	n/a	281	100.0	1	0.4	0.1	2.0
	Blood alkaline phosphatase decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood alkaline phosphatase increased	n/a	281	100.0	31	11.0	7.9	15.2
	Blood bilirubin increased	n/a	281	100.0	25	8.9	6.1	12.8
	Blood bilirubin unconjugated increased	n/a	281	100.0	8	2.8	1.4	5.5
	Blood calcium decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood calcium increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood chloride increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood cholesterol increased	n/a	281	100.0	8	2.8	1.4	5.5
	Blood creatine increased	n/a	281	100.0	3	1.1	0.4	3.1
	Blood creatine phosphokinase MB increased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood creatine phosphokinase increased	n/a	281	100.0	34	12.1	8.8	16.4
	Blood creatinine	n/a	281	100.0	1	0.4	0.1	2.0
	Blood creatinine increased	n/a	281	100.0	60	21.4	17.0	26.5

	Blood fibrinogen increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood glucose increased	n/a	281	100.0	3	1.1	0.4	3.1
	Blood iron decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood ketone body increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood lactate dehydrogenase increased	n/a	281	100.0	10	3.6	1.9	6.4
	Blood magnesium decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood phosphorus increased	n/a	281	100.0	7	2.5	1.2	5.1
	Blood potassium decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood potassium increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood pressure increased	n/a	281	100.0	3	1.1	0.4	3.1
	Blood sodium decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood thyroid stimulating hormone increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood triglycerides increased	n/a	281	100.0	8	2.8	1.4	5.5
	Blood urea increased	n/a	281	100.0	6	2.1	1.0	4.6
	Blood uric acid decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood uric acid increased	n/a	281	100.0	7	2.5	1.2	5.1
	Blood urine	n/a	281	100.0	3	1.1	0.4	3.1
	Blood urine present	n/a	281	100.0	1	0.4	0.1	2.0
	C-reactive protein increased	n/a	281	100.0	3	1.1	0.4	3.1
	Carbon dioxide decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Complement factor C1 decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Computerised tomogram thorax abnormal	n/a	281	100.0	2	0.7	0.2	2.6
	Crystal urine present	n/a	281	100.0	1	0.4	0.1	2.0
	Cystatin C increased	n/a	281	100.0	1	0.4	0.1	2.0
	Electrocardiogram QT prolonged	n/a	281	100.0	14	5.0	3.0	8.2
	Electrocardiogram ST-T change	n/a	281	100.0	2	0.7	0.2	2.6
	Fibrin D dimer increased	n/a	281	100.0	2	0.7	0.2	2.6
	Fibrin degradation products increased	n/a	281	100.0	1	0.4	0.1	2.0
	Free fatty acids increased	n/a	281	100.0	1	0.4	0.1	2.0
	Gamma-glutamyltransferase increased	n/a	281	100.0	17	6.0	3.8	9.5
	Glomerular filtration rate decreased	n/a	281	100.0	2	0.7	0.2	2.6

	Glutamate dehydrogenase increased	n/a	281	100.0	2	0.7	0.2	2.6
	Granulocyte count decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Haematocrit decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Haemoglobin decreased	n/a	281	100.0	5	1.8	0.8	4.1
	Heart rate increased	n/a	281	100.0	6	2.1	1.0	4.6
	Hepatic enzyme increased	n/a	281	100.0	2	0.7	0.2	2.6
	International normalised ratio increased	n/a	281	100.0	2	0.7	0.2	2.6
	Intraocular pressure increased	n/a	281	100.0	1	0.4	0.1	2.0
	Laboratory test abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Lipase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Liver function test increased	n/a	281	100.0	2	0.7	0.2	2.6
	Lymphocyte count decreased	n/a	281	100.0	13	4.6	2.7	7.8
	Lymphocyte count increased	n/a	281	100.0	1	0.4	0.1	2.0
	Mean cell volume increased	n/a	281	100.0	1	0.4	0.1	2.0
	Myoglobin blood increased	n/a	281	100.0	1	0.4	0.1	2.0
	Neutrophil count decreased	n/a	281	100.0	45	16.0	12.2	20.8
	Neutrophil count increased	n/a	281	100.0	2	0.7	0.2	2.6
	Neutrophil percentage increased	n/a	281	100.0	1	0.4	0.1	2.0
	Occult blood positive	n/a	281	100.0	3	1.1	0.4	3.1
	Platelet count decreased	n/a	281	100.0	25	8.9	6.1	12.8
	Platelet count increased	n/a	281	100.0	5	1.8	0.8	4.1
	Procalcitonin increased	n/a	281	100.0	1	0.4	0.1	2.0
	Protein total decreased	n/a	281	100.0	3	1.1	0.4	3.1
	Protein total increased	n/a	281	100.0	1	0.4	0.1	2.0
	Protein urine present	n/a	281	100.0	2	0.7	0.2	2.6
	Prothrombin time prolonged	n/a	281	100.0	1	0.4	0.1	2.0
	Red blood cell count decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Serum amyloid A protein increased	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombin time prolonged	n/a	281	100.0	1	0.4	0.1	2.0
	Total bile acids increased	n/a	281	100.0	9	3.2	1.7	6.0

	Transaminases increased	n/a	281	100.0	7	2.5	1.2	5.1
	Transferrin increased	n/a	281	100.0	1	0.4	0.1	2.0
	Troponin T increased	n/a	281	100.0	1	0.4	0.1	2.0
	Troponin increased	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary sediment present	n/a	281	100.0	1	0.4	0.1	2.0
	Urine ketone body present	n/a	281	100.0	3	1.1	0.4	3.1
	Urine leukocyte esterase positive	n/a	281	100.0	1	0.4	0.1	2.0
	Urobilinogen urine increased	n/a	281	100.0	2	0.7	0.2	2.6
	Weight decreased	n/a	281	100.0	18	6.4	4.1	9.9
	Weight increased	n/a	281	100.0	24	8.5	5.8	12.4
	White blood cell count decreased	n/a	281	100.0	57	20.3	16.0	25.4
	White blood cells urine positive	n/a	281	100.0	3	1.1	0.4	3.1
Metabolism and nutrition disorders	-Total	n/a	281	100.0	138	49.1	43.3	54.9
	Abnormal loss of weight	n/a	281	100.0	1	0.4	0.1	2.0
	Alkalosis	n/a	281	100.0	1	0.4	0.1	2.0
	Cell death	n/a	281	100.0	1	0.4	0.1	2.0
	Decreased appetite	n/a	281	100.0	36	12.8	9.4	17.2
	Dehydration	n/a	281	100.0	4	1.4	0.6	3.6
	Electrolyte imbalance	n/a	281	100.0	1	0.4	0.1	2.0
	Fluid retention	n/a	281	100.0	1	0.4	0.1	2.0
	Hypercalcaemia	n/a	281	100.0	6	2.1	1.0	4.6
	Hypercholesterolaemia	n/a	281	100.0	5	1.8	0.8	4.1
	Hyperglycaemia	n/a	281	100.0	18	6.4	4.1	9.9
	Hyperkalaemia	n/a	281	100.0	12	4.3	2.5	7.3
	Hyperlipidaemia	n/a	281	100.0	7	2.5	1.2	5.1
	Hypermagnesaemia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypernatraemia	n/a	281	100.0	2	0.7	0.2	2.6
	Hyperphosphataemia	n/a	281	100.0	31	11.0	7.9	15.2
	Hypertriglyceridaemia	n/a	281	100.0	7	2.5	1.2	5.1
	Hyperuricaemia	n/a	281	100.0	10	3.6	1.9	6.4
	Hypoalbuminaemia	n/a	281	100.0	37	13.2	9.7	17.6

	Hypocalcaemia	n/a	281	100.0	31	11.0	7.9	15.2
	Hypochloraemia	n/a	281	100.0	5	1.8	0.8	4.1
	Hypoglycaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypokalaemia	n/a	281	100.0	29	10.3	7.3	14.4
	Hypomagnesaemia	n/a	281	100.0	21	7.5	4.9	11.2
	Hyponatraemia	n/a	281	100.0	18	6.4	4.1	9.9
	Hypophosphataemia	n/a	281	100.0	15	5.3	3.3	8.6
	Hypoproteinaemia	n/a	281	100.0	6	2.1	1.0	4.6
	Increased appetite	n/a	281	100.0	1	0.4	0.1	2.0
	Vitamin D deficiency	n/a	281	100.0	1	0.4	0.1	2.0
Musculoskeletal and connective tissue disorders	-Total	n/a	281	100.0	119	42.3	36.7	48.2
	Arthralgia	n/a	281	100.0	12	4.3	2.5	7.3
	Arthropathy	n/a	281	100.0	1	0.4	0.1	2.0
	Back pain	n/a	281	100.0	35	12.5	9.1	16.8
	Bone pain	n/a	281	100.0	4	1.4	0.6	3.6
	Bursitis	n/a	281	100.0	1	0.4	0.1	2.0
	Coccydynia	n/a	281	100.0	1	0.4	0.1	2.0
	Costochondritis	n/a	281	100.0	2	0.7	0.2	2.6
	Flank pain	n/a	281	100.0	3	1.1	0.4	3.1
	Groin pain	n/a	281	100.0	1	0.4	0.1	2.0
	Hypercreatinaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Intervertebral disc protrusion	n/a	281	100.0	2	0.7	0.2	2.6
	Joint range of motion decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Joint stiffness	n/a	281	100.0	1	0.4	0.1	2.0
	Joint swelling	n/a	281	100.0	2	0.7	0.2	2.6
	Muscle fatigue	n/a	281	100.0	1	0.4	0.1	2.0
	Muscle spasms	n/a	281	100.0	22	7.8	5.2	11.6
	Muscular weakness	n/a	281	100.0	8	2.8	1.4	5.5
	Musculoskeletal chest pain	n/a	281	100.0	6	2.1	1.0	4.6
	Musculoskeletal pain	n/a	281	100.0	24	8.5	5.8	12.4

	Musculoskeletal stiffness	n/a	281	100.0	1	0.4	0.1	2.0
	Myalgia	n/a	281	100.0	23	8.2	5.5	12.0
	Myopathy	n/a	281	100.0	2	0.7	0.2	2.6
	Neck pain	n/a	281	100.0	14	5.0	3.0	8.2
	Osteopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Pain in extremity	n/a	281	100.0	25	8.9	6.1	12.8
	Pain in jaw	n/a	281	100.0	2	0.7	0.2	2.6
	Rotator cuff syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Spinal column stenosis	n/a	281	100.0	2	0.7	0.2	2.6
	Spinal osteoarthritis	n/a	281	100.0	1	0.4	0.1	2.0
	Tendon disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Tendon pain	n/a	281	100.0	1	0.4	0.1	2.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	281	100.0	8	2.8	1.4	5.5
	Anogenital warts	n/a	281	100.0	1	0.4	0.1	2.0
	Basal cell carcinoma	n/a	281	100.0	1	0.4	0.1	2.0
	Bowen's disease	n/a	281	100.0	1	0.4	0.1	2.0
	Metastases to central nervous system	n/a	281	100.0	1	0.4	0.1	2.0
	Renal cell carcinoma	n/a	281	100.0	1	0.4	0.1	2.0
	Squamous cell carcinoma	n/a	281	100.0	1	0.4	0.1	2.0
	Squamous cell carcinoma of skin	n/a	281	100.0	1	0.4	0.1	2.0
	Tumour pain	n/a	281	100.0	1	0.4	0.1	2.0
Nervous system disorders	-Total	n/a	281	100.0	141	50.2	44.4	56.0
	Ageusia	n/a	281	100.0	2	0.7	0.2	2.6
	Aphasia	n/a	281	100.0	1	0.4	0.1	2.0
	Ataxia	n/a	281	100.0	1	0.4	0.1	2.0
	Balance disorder	n/a	281	100.0	2	0.7	0.2	2.6
	Brain oedema	n/a	281	100.0	2	0.7	0.2	2.6
	Cerebellar haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Disturbance in attention	n/a	281	100.0	2	0.7	0.2	2.6
	Dizziness	n/a	281	100.0	37	13.2	9.7	17.6
	Dizziness postural	n/a	281	100.0	1	0.4	0.1	2.0

	Dysarthria	n/a	281	100.0	1	0.4	0.1	2.0
	Dysgeusia	n/a	281	100.0	42	14.9	11.3	19.6
	Dyskinesia	n/a	281	100.0	1	0.4	0.1	2.0
	Headache	n/a	281	100.0	32	11.4	8.2	15.6
	Hemiplegia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperaesthesia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypersomnia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypoaesthesia	n/a	281	100.0	18	6.4	4.1	9.9
	Hypotonia	n/a	281	100.0	1	0.4	0.1	2.0
	Lethargy	n/a	281	100.0	1	0.4	0.1	2.0
	Lumbar radiculopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Memory impairment	n/a	281	100.0	2	0.7	0.2	2.6
	Migraine with aura	n/a	281	100.0	1	0.4	0.1	2.0
	Neuralgia	n/a	281	100.0	1	0.4	0.1	2.0
	Neuropathy peripheral	n/a	281	100.0	12	4.3	2.5	7.3
	Paraesthesia	n/a	281	100.0	12	4.3	2.5	7.3
	Paralysis	n/a	281	100.0	1	0.4	0.1	2.0
	Parosmia	n/a	281	100.0	1	0.4	0.1	2.0
	Peripheral sensory neuropathy	n/a	281	100.0	9	3.2	1.7	6.0
	Polyneuropathy chronic	n/a	281	100.0	1	0.4	0.1	2.0
	Post herpetic neuralgia	n/a	281	100.0	1	0.4	0.1	2.0
	Presyncope	n/a	281	100.0	3	1.1	0.4	3.1
	Psychomotor skills impaired	n/a	281	100.0	1	0.4	0.1	2.0
	Restless legs syndrome	n/a	281	100.0	2	0.7	0.2	2.6
	Sciatica	n/a	281	100.0	4	1.4	0.6	3.6
	Seizure	n/a	281	100.0	5	1.8	0.8	4.1
	Sensory disturbance	n/a	281	100.0	1	0.4	0.1	2.0
	Slow speech	n/a	281	100.0	1	0.4	0.1	2.0
	Somnolence	n/a	281	100.0	2	0.7	0.2	2.6
	Syncope	n/a	281	100.0	4	1.4	0.6	3.6

	Tension headache	n/a	281	100.0	1	0.4	0.1	2.0
	Tremor	n/a	281	100.0	1	0.4	0.1	2.0
	Visual field defect	n/a	281	100.0	2	0.7	0.2	2.6
Product issues	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Device dislocation	n/a	281	100.0	1	0.4	0.1	2.0
Psychiatric disorders	-Total	n/a	281	100.0	54	19.2	15.0	24.2
	Abnormal behaviour	n/a	281	100.0	1	0.4	0.1	2.0
	Abnormal dreams	n/a	281	100.0	1	0.4	0.1	2.0
	Adjustment disorder with mixed anxiety and depressed mood	n/a	281	100.0	1	0.4	0.1	2.0
	Anxiety	n/a	281	100.0	12	4.3	2.5	7.3
	Bradyphrenia	n/a	281	100.0	1	0.4	0.1	2.0
	Confusional state	n/a	281	100.0	5	1.8	0.8	4.1
	Delirium	n/a	281	100.0	3	1.1	0.4	3.1
	Depressed mood	n/a	281	100.0	1	0.4	0.1	2.0
	Depression	n/a	281	100.0	5	1.8	0.8	4.1
	Fear of falling	n/a	281	100.0	1	0.4	0.1	2.0
	Insomnia	n/a	281	100.0	20	7.1	4.7	10.7
	Irritability	n/a	281	100.0	1	0.4	0.1	2.0
	Libido decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Mental status changes	n/a	281	100.0	1	0.4	0.1	2.0
	Mood altered	n/a	281	100.0	1	0.4	0.1	2.0
	Psychomotor retardation	n/a	281	100.0	2	0.7	0.2	2.6
	Restlessness	n/a	281	100.0	5	1.8	0.8	4.1
	Sleep disorder	n/a	281	100.0	2	0.7	0.2	2.6
Renal and urinary disorders	-Total	n/a	281	100.0	41	14.6	10.9	19.2
	Acute kidney injury	n/a	281	100.0	6	2.1	1.0	4.6
	Azotaemia	n/a	281	100.0	2	0.7	0.2	2.6
	Cystitis haemorrhagic	n/a	281	100.0	1	0.4	0.1	2.0
	Dysuria	n/a	281	100.0	11	3.9	2.2	6.9
	Haematuria	n/a	281	100.0	3	1.1	0.4	3.1
	Haemorrhage urinary tract	n/a	281	100.0	1	0.4	0.1	2.0

	Micturition urgency	n/a	281	100.0	1	0.4	0.1	2.0
	Nephritis	n/a	281	100.0	1	0.4	0.1	2.0
	Nocturia	n/a	281	100.0	3	1.1	0.4	3.1
	Pollakiuria	n/a	281	100.0	2	0.7	0.2	2.6
	Proteinuria	n/a	281	100.0	2	0.7	0.2	2.6
	Renal colic	n/a	281	100.0	1	0.4	0.1	2.0
	Renal disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Renal failure	n/a	281	100.0	2	0.7	0.2	2.6
	Renal impairment	n/a	281	100.0	1	0.4	0.1	2.0
	Strangury	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary incontinence	n/a	281	100.0	2	0.7	0.2	2.6
	Urinary retention	n/a	281	100.0	6	2.1	1.0	4.6
	Urinary tract pain	n/a	281	100.0	1	0.4	0.1	2.0
	Urine flow decreased	n/a	281	100.0	1	0.4	0.1	2.0
Reproductive system and breast disorders	-Total	n/a	281	100.0	22	7.8	5.2	11.6
	Benign prostatic hyperplasia	n/a	281	100.0	3	1.1	0.4	3.1
	Breast discharge	n/a	281	100.0	1	0.4	0.1	2.0
	Erectile dysfunction	n/a	281	100.0	9	3.2	1.7	6.0
	Galactorrhoea	n/a	281	100.0	1	0.4	0.1	2.0
	Genital ulceration	n/a	281	100.0	1	0.4	0.1	2.0
	Metrorrhagia	n/a	281	100.0	1	0.4	0.1	2.0
	Pelvic discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Pelvic fluid collection	n/a	281	100.0	1	0.4	0.1	2.0
	Perineal pain	n/a	281	100.0	1	0.4	0.1	2.0
	Postmenopausal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Prostatitis	n/a	281	100.0	1	0.4	0.1	2.0
	Uterine polyp	n/a	281	100.0	1	0.4	0.1	2.0
	Vaginal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Vulvovaginal dryness	n/a	281	100.0	1	0.4	0.1	2.0
	Vulvovaginal erythema	n/a	281	100.0	1	0.4	0.1	2.0

Respiratory, thoracic and mediastinal disorders	-Total	n/a	281	100.0	153	54.4	48.6	60.2
	Aspiration	n/a	281	100.0	1	0.4	0.1	2.0
	Bronchospasm	n/a	281	100.0	1	0.4	0.1	2.0
	Choking	n/a	281	100.0	1	0.4	0.1	2.0
	Cough	n/a	281	100.0	64	22.8	18.3	28.0
	Dry throat	n/a	281	100.0	2	0.7	0.2	2.6
	Dysphonia	n/a	281	100.0	12	4.3	2.5	7.3
	Dyspnoea	n/a	281	100.0	39	13.9	10.3	18.4
	Dyspnoea exertional	n/a	281	100.0	12	4.3	2.5	7.3
	Epistaxis	n/a	281	100.0	14	5.0	3.0	8.2
	Haemoptysis	n/a	281	100.0	11	3.9	2.2	6.9
	Hiccups	n/a	281	100.0	2	0.7	0.2	2.6
	Hypoxia	n/a	281	100.0	1	0.4	0.1	2.0
	Interstitial lung disease	n/a	281	100.0	4	1.4	0.6	3.6
	Laryngeal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Nasal congestion	n/a	281	100.0	4	1.4	0.6	3.6
	Nasal dryness	n/a	281	100.0	4	1.4	0.6	3.6
	Nasal polyps	n/a	281	100.0	1	0.4	0.1	2.0
	Oropharyngeal discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Oropharyngeal pain	n/a	281	100.0	21	7.5	4.9	11.2
	Paranasal sinus discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Pharyngeal disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Pleural effusion	n/a	281	100.0	7	2.5	1.2	5.1
	Pleural thickening	n/a	281	100.0	2	0.7	0.2	2.6
	Pleuritic pain	n/a	281	100.0	2	0.7	0.2	2.6
	Pneumonitis	n/a	281	100.0	26	9.3	6.4	13.2
	Pneumothorax	n/a	281	100.0	2	0.7	0.2	2.6
	Productive cough	n/a	281	100.0	14	5.0	3.0	8.2
	Pulmonary embolism	n/a	281	100.0	4	1.4	0.6	3.6
	Pulmonary mass	n/a	281	100.0	1	0.4	0.1	2.0
	Pulmonary pain	n/a	281	100.0	1	0.4	0.1	2.0

	Respiration abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Rhinalgia	n/a	281	100.0	1	0.4	0.1	2.0
	Rhinitis allergic	n/a	281	100.0	2	0.7	0.2	2.6
	Rhinorrhoea	n/a	281	100.0	3	1.1	0.4	3.1
	Sinus congestion	n/a	281	100.0	1	0.4	0.1	2.0
	Sleep apnoea syndrome	n/a	281	100.0	3	1.1	0.4	3.1
	Sputum discoloured	n/a	281	100.0	1	0.4	0.1	2.0
	Throat irritation	n/a	281	100.0	2	0.7	0.2	2.6
	Upper-airway cough syndrome	n/a	281	100.0	2	0.7	0.2	2.6
	Vocal cord leukoplakia	n/a	281	100.0	1	0.4	0.1	2.0
	Wheezing	n/a	281	100.0	2	0.7	0.2	2.6
Skin and subcutaneous tissue disorders	-Total	n/a	281	100.0	100	35.6	30.2	41.3
	Acne	n/a	281	100.0	1	0.4	0.1	2.0
	Alopecia	n/a	281	100.0	14	5.0	3.0	8.2
	Chloasma	n/a	281	100.0	1	0.4	0.1	2.0
	Decubitus ulcer	n/a	281	100.0	1	0.4	0.1	2.0
	Dermal cyst	n/a	281	100.0	1	0.4	0.1	2.0
	Dermatitis	n/a	281	100.0	1	0.4	0.1	2.0
	Dermatitis acneiform	n/a	281	100.0	7	2.5	1.2	5.1
	Dermatitis allergic	n/a	281	100.0	1	0.4	0.1	2.0
	Dermatitis bullous	n/a	281	100.0	2	0.7	0.2	2.6
	Dry skin	n/a	281	100.0	12	4.3	2.5	7.3
	Ecchymosis	n/a	281	100.0	1	0.4	0.1	2.0
	Eczema	n/a	281	100.0	2	0.7	0.2	2.6
	Erythema	n/a	281	100.0	4	1.4	0.6	3.6
	Hair growth abnormal	n/a	281	100.0	6	2.1	1.0	4.6
	Hair texture abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Hirsutism	n/a	281	100.0	7	2.5	1.2	5.1
	Hyperhidrosis	n/a	281	100.0	2	0.7	0.2	2.6
	Hyperkeratosis	n/a	281	100.0	1	0.4	0.1	2.0

	Hypertrichosis	n/a	281	100.0	6	2.1	1.0	4.6
	Madarosis	n/a	281	100.0	1	0.4	0.1	2.0
	Nail discolouration	n/a	281	100.0	1	0.4	0.1	2.0
	Nail disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Night sweats	n/a	281	100.0	2	0.7	0.2	2.6
	Onychalgia	n/a	281	100.0	1	0.4	0.1	2.0
	Onycholysis	n/a	281	100.0	1	0.4	0.1	2.0
	Onychomadesis	n/a	281	100.0	3	1.1	0.4	3.1
	Pain of skin	n/a	281	100.0	1	0.4	0.1	2.0
	Palmar-plantar erythrodysaesthesia syndrome	n/a	281	100.0	5	1.8	0.8	4.1
	Photosensitivity reaction	n/a	281	100.0	1	0.4	0.1	2.0
	Pruritus	n/a	281	100.0	7	2.5	1.2	5.1
	Pruritus generalised	n/a	281	100.0	1	0.4	0.1	2.0
	Purpura	n/a	281	100.0	1	0.4	0.1	2.0
	Rash	n/a	281	100.0	23	8.2	5.5	12.0
	Rash erythematous	n/a	281	100.0	2	0.7	0.2	2.6
	Rash macular	n/a	281	100.0	4	1.4	0.6	3.6
	Rash maculo-papular	n/a	281	100.0	2	0.7	0.2	2.6
	Rash papular	n/a	281	100.0	1	0.4	0.1	2.0
	Scab	n/a	281	100.0	2	0.7	0.2	2.6
	Scar pain	n/a	281	100.0	1	0.4	0.1	2.0
	Skin discolouration	n/a	281	100.0	1	0.4	0.1	2.0
	Skin hyperpigmentation	n/a	281	100.0	1	0.4	0.1	2.0
	Skin lesion	n/a	281	100.0	1	0.4	0.1	2.0
	Swelling face	n/a	281	100.0	6	2.1	1.0	4.6
	Urticaria	n/a	281	100.0	2	0.7	0.2	2.6
Surgical and medical procedures	-Total	n/a	281	100.0	6	2.1	1.0	4.6
	Astringent therapy	n/a	281	100.0	5	1.8	0.8	4.1
	Therapy cessation	n/a	281	100.0	1	0.4	0.1	2.0
Vascular disorders	-Total	n/a	281	100.0	72	25.6	20.9	31.0
	Aortic dissection	n/a	281	100.0	1	0.4	0.1	2.0

	Circulatory collapse	n/a	281	100.0	1	0.4	0.1	2.0
	Deep vein thrombosis	n/a	281	100.0	2	0.7	0.2	2.6
	Embolism	n/a	281	100.0	3	1.1	0.4	3.1
	Flushing	n/a	281	100.0	1	0.4	0.1	2.0
	Haematoma	n/a	281	100.0	3	1.1	0.4	3.1
	Hot flush	n/a	281	100.0	3	1.1	0.4	3.1
	Hypertension	n/a	281	100.0	51	18.1	14.1	23.1
	Hypotension	n/a	281	100.0	4	1.4	0.6	3.6
	Lymphoedema	n/a	281	100.0	2	0.7	0.2	2.6
	Orthostatic hypotension	n/a	281	100.0	2	0.7	0.2	2.6
	Pallor	n/a	281	100.0	1	0.4	0.1	2.0
	Phlebitis	n/a	281	100.0	1	0.4	0.1	2.0
	Raynaud's phenomenon	n/a	281	100.0	1	0.4	0.1	2.0
	Superior vena cava syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombophlebitis superficial	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombosis	n/a	281	100.0	2	0.7	0.2	2.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR12_SG.xls
26MAR2021 14:20

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1-2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	< 65	176	62.6	73	41.5	34.5	48.9
		>= 65	105	37.4	52	49.5	40.1	58.9
	Anaemia	< 65	176	62.6	50	28.4	22.3	35.5
		>= 65	105	37.4	33	31.4	23.3	40.8
	Aplastic anaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bone marrow oedema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cytopenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Febrile neutropenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperfibrinogenaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Leukocytosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Leukopenia	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	5	4.8	2.1	10.7
	Lymph node pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lymphadenopathy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymphopenia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	4	3.8	1.5	9.4
	Neutropenia	< 65	176	62.6	20	11.4	7.5	16.9
		>= 65	105	37.4	11	10.5	6.0	17.8
	Neutrophilia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pancytopenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Thrombocytopenia	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	7	6.7	3.3	13.1
	Thrombocytosis	< 65	176	62.6	2	1.1	0.3	4.0

		>= 65	105	37.4	3	2.9	1.0	8.1
Cardiac disorders	-Total	< 65	176	62.6	20	11.4	7.5	16.9
		>= 65	105	37.4	14	13.3	8.1	21.1
	Acute coronary syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Angina pectoris	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Aortic valve calcification	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Atrial fibrillation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Atrial flutter	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bradycardia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bundle branch block right	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cardiac failure	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Extrasystoles	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Myocardial ischaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nodal arrhythmia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Palpitations	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pericardial effusion	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sinus bradycardia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sinus tachycardia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tachycardia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Ventricular extrasystoles	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ventricular pre-excitation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Congenital, familial and genetic disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Gilbert's syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hydrocele	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Ear and labyrinth disorders	-Total	< 65	176	62.6	14	8.0	4.8	12.9
		>= 65	105	37.4	6	5.7	2.6	11.9
	Ear congestion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ear discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ear pain	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tinnitus	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Vertigo	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	3	2.9	1.0	8.1
Endocrine disorders	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperthyroidism	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypothyroidism	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
Eye disorders	-Total	< 65	176	62.6	29	16.5	11.7	22.7
		>= 65	105	37.4	9	8.6	4.6	15.5
	Abnormal sensation in eye	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blepharitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Chalazion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Conjunctival cyst	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Conjunctival haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diplopia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dry eye	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eye swelling	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

	Eyelid oedema	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Eyelid ptosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Keratitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ocular discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Periorbital oedema	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Photophobia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Photopsia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ulcerative keratitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vision blurred	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Visual acuity reduced	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Gastrointestinal disorders	-Total	< 65	176	62.6	121	68.8	61.6	75.1
		>= 65	105	37.4	78	74.3	65.2	81.7
	Abdominal discomfort	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Abdominal distension	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
	Abdominal pain	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	5	4.8	2.1	10.7
	Abdominal pain lower	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Abdominal pain upper	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	5	4.8	2.1	10.7
	Abdominal symptom	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Anal incontinence	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Aphthous ulcer	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ascites	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Constipation	< 65	176	62.6	71	40.3	33.4	47.7

		>= 65	105	37.4	45	42.9	33.8	52.4
	Dental dysaesthesia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diarrhoea	< 65	176	62.6	38	21.6	16.2	28.2
		>= 65	105	37.4	27	25.7	18.3	34.8
	Dry mouth	< 65	176	62.6	23	13.1	8.9	18.8
		>= 65	105	37.4	24	22.9	15.9	31.8
	Dyspepsia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	3	2.9	1.0	8.1
	Dysphagia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	14	13.3	8.1	21.1
	Enteritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Epigastric discomfort	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eructation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Faeces soft	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Flatulence	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Frequent bowel movements	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastric ulcer	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastritis	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastritis erosive	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastrointestinal haemorrhage	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastrointestinal inflammation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrointestinal oedema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrointestinal wall thickening	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrooesophageal reflux disease	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	5	4.8	2.1	10.7
	Gingival bleeding	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2

	Gingival swelling	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Glossitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Glossodynia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haematochezia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Haemorrhoids	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	4	3.8	1.5	9.4
	Hypoaesthesia oral	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	0	0.0	0.0	3.5
	Impaired gastric emptying	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Irritable bowel syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Melaena	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mouth ulceration	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	6	5.7	2.6	11.9
	Nausea	< 65	176	62.6	24	13.6	9.3	19.5
		>= 65	105	37.4	18	17.1	11.1	25.5
	Odynophagia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oesophageal irritation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oesophagitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oral disorder	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oral dysaesthesia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oral mucosal erythema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oral pain	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	3	2.9	1.0	8.1
	Pancreatitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Paraesthesia oral	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Rectal prolapse	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Regurgitation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sensitivity of teeth	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Stomatitis	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Swollen tongue	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tongue coated	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tongue discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tongue ulceration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tooth discolouration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Toothache	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Vomiting	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	13	12.4	7.4	20.0
General disorders and administration site conditions	-Total	< 65	176	62.6	118	67.0	59.8	73.6
		>= 65	105	37.4	74	70.5	61.2	78.4
	Asthenia	< 65	176	62.6	24	13.6	9.3	19.5
		>= 65	105	37.4	13	12.4	7.4	20.0
	Axillary pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Catheter site pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Chest discomfort	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	4	3.8	1.5	9.4
	Chest pain	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
	Chills	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Face oedema	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	5	4.8	2.1	10.7
	Facial pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fatigue	< 65	176	62.6	30	17.0	12.2	23.3

		>= 65	105	37.4	31	29.5	21.6	38.8
	Feeling abnormal	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Feeling cold	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Feeling hot	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gait disturbance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	6	5.7	2.6	11.9
	General physical health deterioration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Generalised oedema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Impaired healing	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Influenza like illness	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Injection site bruising	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Localised oedema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Malaise	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Mucosal dryness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mucosal inflammation	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	9	8.6	4.6	15.5
	Non-cardiac chest pain	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	3	2.9	1.0	8.1
	Oedema	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oedema peripheral	< 65	176	62.6	19	10.8	7.0	16.2
		>= 65	105	37.4	23	21.9	15.1	30.7
	Pain	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Peripheral swelling	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
	Pyrexia	< 65	176	62.6	43	24.4	18.7	31.3
		>= 65	105	37.4	28	26.7	19.1	35.8
	Swelling	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Temperature intolerance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Xerosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Hepatobiliary disorders	-Total	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	11	10.5	6.0	17.8
	Cholecystitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hepatic function abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hepatic steatosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hepatocellular injury	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperbilirubinaemia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Liver disorder	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pneumobilia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Portal vein thrombosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Immune system disorders	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Contrast media allergy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Drug hypersensitivity	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Food allergy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypersensitivity	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Seasonal allergy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Infections and infestations	-Total	< 65	176	62.6	81	46.0	38.8	53.4
		>= 65	105	37.4	41	39.0	30.3	48.6
	Abdominal abscess	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Acute sinusitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Arthritis infective	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Atypical pneumonia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bacteraemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bacterial disease carrier	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bacterial vaginosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bronchitis	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Candida infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cellulitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Chronic sinusitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Conjunctivitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Corona virus infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cystitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cystitis escherichia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ear infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Epididymitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Epstein-Barr virus infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Escherichia bacteraemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Escherichia infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Escherichia urinary tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Eye infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Febrile infection	< 65	176	62.6	0	0.0	0.0	2.1

		>= 65	105	37.4	1	1.0	0.2	5.2
	Folliculitis	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fungal infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastroenteritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Genital candidiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Genital herpes	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gingivitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Herpes simplex	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Herpes virus infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Herpes zoster	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	2	1.9	0.5	6.7
	Infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Influenza	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lower respiratory tract infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lung infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lyme disease	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymph node tuberculosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Nasal herpes	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nasopharyngitis	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oral candidiasis	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	6	5.7	2.6	11.9
	Oral fungal infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oropharyngeal candidiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Otitis externa	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Otitis media	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Paronychia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pharyngitis	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	7	6.7	3.3	13.1
	Pneumonia influenzal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia pseudomonal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia streptococcal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyelonephritis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pyuria	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory tract infection bacterial	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rhinitis	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sepsis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sinusitis	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	1	1.0	0.2	5.2
	Skin infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Staphylococcal infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Systemic infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tinea cruris	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tinea infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Tinea pedis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tonsillitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tooth infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tracheitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tuberculosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Upper respiratory tract infection	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Urethritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary tract infection	< 65	176	62.6	18	10.2	6.6	15.6
		>= 65	105	37.4	11	10.5	6.0	17.8
	Varicella	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Varicella zoster virus infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Viral hepatitis carrier	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Viral infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vulvovaginal candidiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Injury, poisoning and procedural complications	-Total	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	13	12.4	7.4	20.0
	Contusion	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Epicondylitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fall	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	6	5.7	2.6	11.9
	Incision site pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Joint dislocation	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Laceration	< 65	176	62.6	0	0.0	0.0	2.1

		>= 65	105	37.4	1	1.0	0.2	5.2
	Ligament sprain	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Limb injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Muscle rupture	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscle strain	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Procedural pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Procedural pneumothorax	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rib fracture	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Scar	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Skin abrasion	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Skin injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tendon rupture	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Thermal burn	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Wound	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Wound complication	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Wrist fracture	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Investigations	-Total	< 65	176	62.6	133	75.6	68.7	81.3
		>= 65	105	37.4	76	72.4	63.2	80.0
	Alanine aminotransferase increased	< 65	176	62.6	57	32.4	25.9	39.6
		>= 65	105	37.4	26	24.8	17.5	33.8
	Albumin urine present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Alpha hydroxybutyrate dehydrogenase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Amylase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Aspartate aminotransferase increased	< 65	176	62.6	72	40.9	33.9	48.3
		>= 65	105	37.4	39	37.1	28.5	46.7
	Bacterial test	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bilirubin conjugated increased	< 65	176	62.6	14	8.0	4.8	12.9
		>= 65	105	37.4	5	4.8	2.1	10.7
	Blood albumin decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood alkaline phosphatase	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood alkaline phosphatase decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood alkaline phosphatase increased	< 65	176	62.6	21	11.9	7.9	17.6
		>= 65	105	37.4	10	9.5	5.3	16.6
	Blood bilirubin increased	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	12	11.4	6.7	18.9
	Blood bilirubin unconjugated increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood calcium decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood calcium increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood chloride increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood cholesterol increased	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood creatine increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood creatine phosphokinase MB increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood creatine phosphokinase increased	< 65	176	62.6	27	15.3	10.8	21.4
		>= 65	105	37.4	7	6.7	3.3	13.1
	Blood creatinine	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood creatinine increased	< 65	176	62.6	38	21.6	16.2	28.2
		>= 65	105	37.4	22	21.0	14.3	29.7
	Blood fibrinogen increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood glucose increased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5

	Blood iron decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood ketone body increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood lactate dehydrogenase increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	4	3.8	1.5	9.4
	Blood magnesium decreased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood phosphorus increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood potassium decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood potassium increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood pressure increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood sodium decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood thyroid stimulating hormone increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood triglycerides increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood urea increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood uric acid decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood uric acid increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood urine	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood urine present	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	C-reactive protein increased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Carbon dioxide decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Complement factor C1 decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Computerised tomogram thorax abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Crystal urine present	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Cystatin C increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Electrocardiogram QT prolonged	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	5	4.8	2.1	10.7
	Electrocardiogram ST-T change	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Fibrin D dimer increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Fibrin degradation products increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Free fatty acids increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gamma-glutamyltransferase increased	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	2	1.9	0.5	6.7
	Glomerular filtration rate decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Glutamate dehydrogenase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Granulocyte count decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haematocrit decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haemoglobin decreased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	0	0.0	0.0	3.5
	Heart rate increased	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hepatic enzyme increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	International normalised ratio increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Intraocular pressure increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Laboratory test abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lipase increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Liver function test increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymphocyte count decreased	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	3	2.9	1.0	8.1

	Lymphocyte count increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mean cell volume increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Myoglobin blood increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neutrophil count decreased	< 65	176	62.6	35	19.9	14.7	26.4
		>= 65	105	37.4	10	9.5	5.3	16.6
	Neutrophil count increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neutrophil percentage increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Occult blood positive	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Platelet count decreased	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	8	7.6	3.9	14.3
	Platelet count increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Procalcitonin increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Protein total decreased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Protein total increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Protein urine present	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Prothrombin time prolonged	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Red blood cell count decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Serum amyloid A protein increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Thrombin time prolonged	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Total bile acids increased	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Transaminases increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Transferrin increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Troponin T increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Troponin increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary sediment present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urine ketone body present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Urine leukocyte esterase positive	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urobilinogen urine increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Weight decreased	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	10	9.5	5.3	16.6
	Weight increased	< 65	176	62.6	18	10.2	6.6	15.6
		>= 65	105	37.4	6	5.7	2.6	11.9
	White blood cell count decreased	< 65	176	62.6	43	24.4	18.7	31.3
		>= 65	105	37.4	14	13.3	8.1	21.1
	White blood cells urine positive	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
Metabolism and nutrition disorders	-Total	< 65	176	62.6	81	46.0	38.8	53.4
		>= 65	105	37.4	57	54.3	44.8	63.5
	Abnormal loss of weight	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Alkalosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cell death	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Decreased appetite	< 65	176	62.6	18	10.2	6.6	15.6
		>= 65	105	37.4	18	17.1	11.1	25.5
	Dehydration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Electrolyte imbalance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fluid retention	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypercalcaemia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypercholesterolaemia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperglycaemia	< 65	176	62.6	10	5.7	3.1	10.1

		>= 65	105	37.4	8	7.6	3.9	14.3
	Hyperkalaemia	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Hyperlipidaemia	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypermagnesaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hypernatraemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperphosphataemia	< 65	176	62.6	23	13.1	8.9	18.8
		>= 65	105	37.4	8	7.6	3.9	14.3
	Hypertriglyceridaemia	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hyperuricaemia	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypoalbuminaemia	< 65	176	62.6	29	16.5	11.7	22.7
		>= 65	105	37.4	8	7.6	3.9	14.3
	Hypocalcaemia	< 65	176	62.6	20	11.4	7.5	16.9
		>= 65	105	37.4	11	10.5	6.0	17.8
	Hypochloraemia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hypoglycaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypokalaemia	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	16	15.2	9.6	23.3
	Hypomagnesaemia	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	5	4.8	2.1	10.7
	Hyponatraemia	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	5	4.8	2.1	10.7
	Hypophosphataemia	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	5	4.8	2.1	10.7
	Hypoproteinaemia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Increased appetite	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vitamin D deficiency	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Musculoskeletal and connective tissue disorders	-Total	< 65	176	62.6	77	43.8	36.6	51.1
		>= 65	105	37.4	42	40.0	31.1	49.6
	Arthralgia	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	4	3.8	1.5	9.4

	Arthropathy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Back pain	< 65	176	62.6	22	12.5	8.4	18.2
		>= 65	105	37.4	13	12.4	7.4	20.0
	Bone pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Bursitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Coccydynia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Costochondritis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Flank pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Groin pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypercreatinaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Intervertebral disc protrusion	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Joint range of motion decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Joint stiffness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Joint swelling	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Muscle fatigue	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscle spasms	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	9	8.6	4.6	15.5
	Muscular weakness	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	5	4.8	2.1	10.7
	Musculoskeletal chest pain	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Musculoskeletal pain	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	7	6.7	3.3	13.1
	Musculoskeletal stiffness	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Myalgia	< 65	176	62.6	18	10.2	6.6	15.6
		>= 65	105	37.4	5	4.8	2.1	10.7

	Myopathy	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neck pain	< 65	176	62.6	11	6.3	3.5	10.8
		>= 65	105	37.4	3	2.9	1.0	8.1
	Osteopenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pain in extremity	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	10	9.5	5.3	16.6
	Pain in jaw	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rotator cuff syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Spinal column stenosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Spinal osteoarthritis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tendon disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tendon pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	5	4.8	2.1	10.7
	Anogenital warts	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Basal cell carcinoma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bowen's disease	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Metastases to central nervous system	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Renal cell carcinoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Squamous cell carcinoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Squamous cell carcinoma of skin	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tumour pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Nervous system disorders	-Total	< 65	176	62.6	80	45.5	38.3	52.8
		>= 65	105	37.4	61	58.1	48.5	67.1
	Ageusia	< 65	176	62.6	0	0.0	0.0	2.1

		>= 65	105	37.4	2	1.9	0.5	6.7
	Aphasia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ataxia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Balance disorder	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Brain oedema	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cerebellar haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Disturbance in attention	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dizziness	< 65	176	62.6	20	11.4	7.5	16.9
		>= 65	105	37.4	17	16.2	10.4	24.4
	Dizziness postural	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dysarthria	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dysgeusia	< 65	176	62.6	18	10.2	6.6	15.6
		>= 65	105	37.4	24	22.9	15.9	31.8
	Dyskinesia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Headache	< 65	176	62.6	25	14.2	9.8	20.1
		>= 65	105	37.4	7	6.7	3.3	13.1
	Hemiplegia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperaesthesia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypersomnia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypoaesthesia	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	9	8.6	4.6	15.5
	Hypotonia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lethargy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lumbar radiculopathy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Memory impairment	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

	Migraine with aura	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neuralgia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neuropathy peripheral	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Paraesthesia	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Paralysis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Parosmia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Peripheral sensory neuropathy	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Polyneuropathy chronic	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Post herpetic neuralgia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Presyncope	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Psychomotor skills impaired	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Restless legs syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sciatica	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Seizure	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Sensory disturbance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Slow speech	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Somnolence	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Syncope	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Tension headache	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tremor	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Visual field defect	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
Product issues	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Device dislocation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Psychiatric disorders	-Total	< 65	176	62.6	36	20.5	15.2	27.0
		>= 65	105	37.4	18	17.1	11.1	25.5
	Abnormal behaviour	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Abnormal dreams	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Adjustment disorder with mixed anxiety and depressed mood	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Anxiety	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	3	2.9	1.0	8.1
	Bradyphrenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Confusional state	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Delirium	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Depressed mood	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Depression	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Fear of falling	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Insomnia	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	4	3.8	1.5	9.4
	Irritability	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Libido decreased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mental status changes	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Mood altered	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Psychomotor retardation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Restlessness	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	4	3.8	1.5	9.4
	Sleep disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Renal and urinary disorders	-Total	< 65	176	62.6	22	12.5	8.4	18.2
		>= 65	105	37.4	19	18.1	11.9	26.5
	Acute kidney injury	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Azotaemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cystitis haemorrhagic	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dysuria	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	4	3.8	1.5	9.4
	Haematuria	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haemorrhage urinary tract	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Micturition urgency	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nephritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nocturia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pollakiuria	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Proteinuria	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Renal colic	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Renal disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Renal failure	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Renal impairment	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Strangury	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary incontinence	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Urinary retention	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1

	Urinary tract pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urine flow decreased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Reproductive system and breast disorders	-Total	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	6	5.7	2.6	11.9
	Benign prostatic hyperplasia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Breast discharge	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Erectile dysfunction	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Galactorrhoea	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Genital ulceration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Metrorrhagia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pelvic discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pelvic fluid collection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Perineal pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Postmenopausal haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Prostatitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Uterine polyp	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vaginal haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vulvovaginal dryness	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Vulvovaginal erythema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Respiratory, thoracic and mediastinal disorders	-Total	< 65	176	62.6	98	55.7	48.3	62.8
		>= 65	105	37.4	55	52.4	42.9	61.7
	Aspiration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Bronchospasm	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Choking	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cough	< 65	176	62.6	41	23.3	17.7	30.1
		>= 65	105	37.4	23	21.9	15.1	30.7
	Dry throat	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dysphonia	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Dyspnoea	< 65	176	62.6	24	13.6	9.3	19.5
		>= 65	105	37.4	15	14.3	8.9	22.2
	Dyspnoea exertional	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	6	5.7	2.6	11.9
	Epistaxis	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	6	5.7	2.6	11.9
	Haemoptysis	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hiccups	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hypoxia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Interstitial lung disease	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Laryngeal haemorrhage	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nasal congestion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Nasal dryness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Nasal polyps	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oropharyngeal discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oropharyngeal pain	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	6	5.7	2.6	11.9
	Paranasal sinus discomfort	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pharyngeal disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pleural effusion	< 65	176	62.6	5	2.8	1.2	6.5

		>= 65	105	37.4	2	1.9	0.5	6.7
	Pleural thickening	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pleuritic pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pneumonitis	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	9	8.6	4.6	15.5
	Pneumothorax	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Productive cough	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	6	5.7	2.6	11.9
	Pulmonary embolism	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pulmonary mass	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pulmonary pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiration abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rhinalgia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rhinitis allergic	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rhinorrhoea	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sinus congestion	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sleep apnoea syndrome	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sputum discoloured	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Throat irritation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Upper-airway cough syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Vocal cord leukoplakia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Wheezing	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
Skin and subcutaneous tissue disorders	-Total	< 65	176	62.6	63	35.8	29.1	43.1
		>= 65	105	37.4	37	35.2	26.8	44.7

	Acne	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Alopecia	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Chloasma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Decubitus ulcer	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermal cyst	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermatitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermatitis acneiform	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermatitis allergic	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dermatitis bullous	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Dry skin	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Ecchymosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eczema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Erythema	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hair growth abnormal	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hair texture abnormal	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hirsutism	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperhidrosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hyperkeratosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypertrichosis	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	0	0.0	0.0	3.5
	Madarosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Nail discolouration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nail disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Night sweats	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Onychalgia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Onycholysis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Onychomadesis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pain of skin	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Palmar-plantar erythrodysaesthesia syndrome	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Photosensitivity reaction	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pruritus	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	4	3.8	1.5	9.4
	Pruritus generalised	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Purpura	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rash	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	7	6.7	3.3	13.1
	Rash erythematous	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rash macular	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Rash maculo-papular	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rash papular	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Scab	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Scar pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Skin discolouration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Skin hyperpigmentation	< 65	176	62.6	0	0.0	0.0	2.1

		>= 65	105	37.4	1	1.0	0.2	5.2
	Skin lesion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Swelling face	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Urticaria	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Surgical and medical procedures	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Astringent therapy	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Therapy cessation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Vascular disorders	-Total	< 65	176	62.6	43	24.4	18.7	31.3
		>= 65	105	37.4	29	27.6	20.0	36.8
	Aortic dissection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Circulatory collapse	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Deep vein thrombosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Embolism	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Flushing	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haematoma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hot flush	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hypertension	< 65	176	62.6	31	17.6	12.7	23.9
		>= 65	105	37.4	20	19.0	12.7	27.6
	Hypotension	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Lymphoedema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Orthostatic hypotension	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pallor	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Phlebitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Raynaud's phenomenon	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Superior vena cava syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Thrombophlebitis superficial	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Thrombosis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR12_SG.xls
26MAR2021 14:20

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1-2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	84	29.9	36	42.9	32.8	53.5
		1	190	67.6	87	45.8	38.9	52.9
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia	0	84	29.9	23	27.4	19.0	37.7
		1	190	67.6	59	31.1	24.9	38.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Aplastic anaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bone marrow oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Febrile neutropenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperfibrinogenaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Leukocytosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Leukopenia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymph node pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Lymphadenopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphopenia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutropenia	0	84	29.9	14	16.7	10.2	26.1
		1	190	67.6	17	8.9	5.7	13.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophilia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytopenia	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytosis	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Cardiac disorders	-Total	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	28	14.7	10.4	20.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute coronary syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Angina pectoris	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aortic valve calcification	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Atrial fibrillation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Atrial flutter	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bradycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bundle branch block right	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cardiac failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Extrasystoles	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myocardial ischaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nodal arrhythmia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Palpitations	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pericardial effusion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinus bradycardia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinus tachycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tachycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Ventricular extrasystoles	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ventricular pre-excitation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Congenital, familial and genetic disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gilbert's syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hydrocele	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Ear and labyrinth disorders	-Total	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear congestion	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear pain	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tinnitus	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Vertigo	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Endocrine disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperthyroidism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypothyroidism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Eye disorders	-Total	0	84	29.9	15	17.9	11.1	27.4
		1	190	67.6	22	11.6	7.8	16.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal sensation in eye	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blepharitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chalazion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Conjunctival cyst	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Conjunctival haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diplopia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry eye	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eye swelling	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eyelid oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eyelid ptosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Keratitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ocular discomfort	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Periorbital oedema	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Photophobia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Photopsia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ulcerative keratitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vision blurred	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Visual acuity reduced	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Gastrointestinal disorders	-Total	0	84	29.9	65	77.4	67.4	85.0
		1	190	67.6	128	67.4	60.4	73.6
		2	6	2.1	5	83.3	43.6	97.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Abdominal discomfort	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal distension	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Abdominal pain lower	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain upper	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal symptom	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anal incontinence	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aphthous ulcer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ascites	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Constipation	0	84	29.9	42	50.0	39.5	60.5
		1	190	67.6	71	37.4	30.8	44.4
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Dental dysaesthesia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diarrhoea	0	84	29.9	21	25.0	17.0	35.2
		1	190	67.6	41	21.6	16.3	28.0
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry mouth	0	84	29.9	20	23.8	16.0	33.9
		1	190	67.6	26	13.7	9.5	19.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspepsia	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysphagia	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Enteritis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epigastric discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eructation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Faeces soft	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Flatulence	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Frequent bowel movements	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastric ulcer	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastritis erosive	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal inflammation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal wall thickening	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrooesophageal reflux disease	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gingival bleeding	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gingival swelling	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glossitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glossodynia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematochezia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhoids	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoaesthesia oral	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Impaired gastric emptying	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Irritable bowel syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Melaena	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Mouth ulceration	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	7	3.7	1.8	7.4

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nausea	0	84	29.9	13	15.5	9.3	24.7
		1	190	67.6	27	14.2	10.0	19.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	1	100.0	20.7	100.0
	Odynophagia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oesophageal irritation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oesophagitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral dysaesthesia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral mucosal erythema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancreatitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paraesthesia oral	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rectal prolapse	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Regurgitation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Sensitivity of teeth	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Stomatitis	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Swollen tongue	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tongue coated	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tongue discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tongue ulceration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tooth discolouration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Toothache	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vomiting	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	17	8.9	5.7	13.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
General disorders and administration site conditions	-Total	0	84	29.9	56	66.7	56.1	75.8
		1	190	67.6	129	67.9	61.0	74.1
		2	6	2.1	6	100.0	61.0	100.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Asthenia	0	84	29.9	14	16.7	10.2	26.1
		1	190	67.6	22	11.6	7.8	16.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Axillary pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Catheter site pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chills	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Face oedema	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Facial pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fatigue	0	84	29.9	17	20.2	13.0	30.0
		1	190	67.6	41	21.6	16.3	28.0
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Feeling abnormal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Feeling cold	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Feeling hot	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gait disturbance	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	General physical health deterioration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Generalised oedema	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Impaired healing	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Influenza like illness	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Injection site bruising	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Localised oedema	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Malaise	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mucosal dryness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mucosal inflammation	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Non-cardiac chest pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oedema peripheral	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	30	15.8	11.3	21.6
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Peripheral swelling	0	84	29.9	3	3.6	1.2	10.0

		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyrexia	0	84	29.9	25	29.8	21.0	40.2
		1	190	67.6	42	22.1	16.8	28.5
		2	6	2.1	4	66.7	30.0	90.3
		Missing	1	0.4	0	0.0	0.0	79.3
	Swelling	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Temperature intolerance	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Xerosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Hepatobiliary disorders	-Total	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Cholecystitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic function abnormal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic steatosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatocellular injury	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperbilirubinaemia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Liver disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumobilia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Portal vein thrombosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
Immune system disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Contrast media allergy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Drug hypersensitivity	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Food allergy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypersensitivity	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Seasonal allergy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Infections and infestations	-Total	0	84	29.9	44	52.4	41.8	62.7
		1	190	67.6	77	40.5	33.8	47.6
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal abscess	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute sinusitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Arthritis infective	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Atypical pneumonia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacterial disease carrier	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacterial vaginosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bronchitis	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Candida infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cellulitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chronic sinusitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Conjunctivitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Corona virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis escherichia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Epididymitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epstein-Barr virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Escherichia bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Escherichia infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Escherichia urinary tract infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eye infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Febrile infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Folliculitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fungal infection	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastroenteritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Genital candidiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Genital herpes	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Gingivitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Herpes simplex	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Herpes virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Herpes zoster	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Influenza	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lower respiratory tract infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lung infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lyme disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymph node tuberculosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasal herpes	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasopharyngitis	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral candidiasis	0	84	29.9	2	2.4	0.7	8.3

		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral fungal infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oropharyngeal candidiasis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Otitis externa	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Otitis media	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paronychia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pharyngitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia influenzal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia pseudomonal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia streptococcal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyelonephritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory tract infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory tract infection bacterial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinitis	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sepsis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinusitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Staphylococcal infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Systemic infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tinea cruris	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tinea infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tinea pedis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tonsillitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Tooth infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tracheitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tuberculosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Upper respiratory tract infection	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urethritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary tract infection	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	17	8.9	5.7	13.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Varicella	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Varicella zoster virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Viral hepatitis carrier	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Viral infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vulvovaginal candidiasis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Injury, poisoning and procedural complications	-Total	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	18	9.5	6.1	14.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Contusion	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epicondylitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fall	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Incision site pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint dislocation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Laceration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ligament sprain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Limb injury	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle rupture	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle strain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Procedural pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Procedural pneumothorax	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rib fracture	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Scar	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin abrasion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tendon rupture	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thermal burn	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wound	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wound complication	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wrist fracture	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Investigations	-Total	0	84	29.9	59	70.2	59.8	79.0
		1	190	67.6	147	77.4	70.9	82.7
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Alanine aminotransferase increased	0	84	29.9	20	23.8	16.0	33.9
		1	190	67.6	61	32.1	25.9	39.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	1	100.0	20.7	100.0
	Albumin urine present	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alpha hydroxybutyrate dehydrogenase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Amylase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aspartate aminotransferase increased	0	84	29.9	27	32.1	23.1	42.7
		1	190	67.6	82	43.2	36.3	50.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	1	100.0	20.7	100.0
	Bacterial test	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bilirubin conjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood albumin decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase increased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	28	14.7	10.4	20.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin increased	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin unconjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood calcium decreased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood calcium increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood chloride increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood cholesterol increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine increased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase MB increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase increased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	30	15.8	11.3	21.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatinine	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatinine increased	0	84	29.9	17	20.2	13.0	30.0
		1	190	67.6	42	22.1	16.8	28.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood fibrinogen increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood glucose increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood iron decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood ketone body increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Blood lactate dehydrogenase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood magnesium decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood phosphorus increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood potassium decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood potassium increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood pressure increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood sodium decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood thyroid stimulating hormone increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood triglycerides increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood urea increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood uric acid decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood uric acid increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Blood urine	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	C-reactive protein increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Carbon dioxide decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Complement factor C1 decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Computerised tomogram thorax abnormal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Crystal urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystatin C increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrocardiogram QT prolonged	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrocardiogram ST-T change	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fibrin D dimer increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fibrin degradation products increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Free fatty acids increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gamma-glutamyltransferase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	17	8.9	5.7	13.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glomerular filtration rate decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glutamate dehydrogenase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Granulocyte count decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematocrit decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemoglobin decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Heart rate increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic enzyme increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	International normalised ratio increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intraocular pressure increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Laboratory test abnormal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lipase increased	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Liver function test increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphocyte count decreased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphocyte count increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mean cell volume increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myoglobin blood increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil count decreased	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	33	17.4	12.6	23.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil count increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil percentage increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Occult blood positive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count decreased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	22	11.6	7.8	16.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Procalcitonin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Protein total decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Protein total increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Protein urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Prothrombin time prolonged	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Red blood cell count decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Serum amyloid A protein increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombin time prolonged	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Total bile acids increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Transaminases increased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Transferrin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Troponin T increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Troponin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary sediment present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urine ketone body present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urine leukocyte esterase positive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urobilinogen urine increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Weight decreased	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Weight increased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	White blood cell count decreased	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	47	24.7	19.1	31.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	White blood cells urine positive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Metabolism and nutrition disorders	-Total	0	84	29.9	40	47.6	37.3	58.2
		1	190	67.6	98	51.6	44.5	58.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal loss of weight	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alkalosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cell death	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Decreased appetite	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	28	14.7	10.4	20.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dehydration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrolyte imbalance	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fluid retention	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercalcaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercholesterolaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperglycaemia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperkalaemia	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperlipidaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypermagnesaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypernatraemia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperphosphataemia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	24	12.6	8.6	18.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Hypertriglyceridaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperuricaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoalbuminaemia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	29	15.3	10.8	21.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypocalcaemia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	27	14.2	10.0	19.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypochloraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoglycaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypokalaemia	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypomagnesaemia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyponatraemia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypophosphataemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoproteinaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Increased appetite	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vitamin D deficiency	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Musculoskeletal and connective tissue disorders	-Total	0	84	29.9	41	48.8	38.4	59.3
		1	190	67.6	75	39.5	32.8	46.6
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Arthralgia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Arthropathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Back pain	0	84	29.9	14	16.7	10.2	26.1
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bone pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bursitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Coccydynia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Costochondritis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Flank pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Groin pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercreatinaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intervertebral disc protrusion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint range of motion decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint stiffness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint swelling	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle fatigue	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle spasms	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	16	8.4	5.2	13.2
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscular weakness	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal chest pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal pain	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	16	8.4	5.2	13.2
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal stiffness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myalgia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neck pain	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	1	16.7	3.0	56.4

		Missing	1	0.4	0	0.0	0.0	79.3
	Osteopenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain in extremity	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	18	9.5	6.1	14.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain in jaw	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rotator cuff syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Spinal column stenosis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Spinal osteoarthritis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tendon disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tendon pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anogenital warts	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Basal cell carcinoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bowen's disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Metastases to central nervous system	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal cell carcinoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Squamous cell carcinoma	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Squamous cell carcinoma of skin	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tumour pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Nervous system disorders	-Total	0	84	29.9	37	44.0	33.9	54.7
		1	190	67.6	100	52.6	45.6	59.6
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	1	100.0	20.7	100.0
	Ageusia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aphasia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ataxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Balance disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Brain oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebellar haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Disturbance in attention	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dizziness	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	28	14.7	10.4	20.5
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dizziness postural	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysarthria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysgeusia	0	84	29.9	13	15.5	9.3	24.7
		1	190	67.6	28	14.7	10.4	20.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyskinesia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Headache	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	22	11.6	7.8	16.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	1	100.0	20.7	100.0
	Hemiplegia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperaesthesia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypersomnia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoaesthesia	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypotonia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lethargy	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lumbar radiculopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Memory impairment	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Migraine with aura	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neuralgia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neuropathy peripheral	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paraesthesia	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paralysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Parosmia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Peripheral sensory neuropathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Polyneuropathy chronic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Post herpetic neuralgia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Presyncope	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Psychomotor skills impaired	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Restless legs syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sciatica	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Seizure	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Sensory disturbance	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Slow speech	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Somnolence	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Syncope	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tension headache	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tremor	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Visual field defect	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Product issues	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Device dislocation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Psychiatric disorders	-Total	0	84	29.9	16	19.0	12.1	28.7
		1	190	67.6	36	18.9	14.0	25.1
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal behaviour	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal dreams	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Adjustment disorder with mixed anxiety and depressed mood	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anxiety	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Bradyphrenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Confusional state	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Delirium	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Depressed mood	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Depression	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fear of falling	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Insomnia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	18	9.5	6.1	14.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Irritability	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Libido decreased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mental status changes	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mood altered	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Psychomotor retardation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Restlessness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sleep disorder	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Renal and urinary disorders	-Total	0	84	29.9	14	16.7	10.2	26.1
		1	190	67.6	24	12.6	8.6	18.1
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute kidney injury	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Azotaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis haemorrhagic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Dysuria	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhage urinary tract	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Micturition urgency	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Nephritis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nocturia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pollakiuria	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Proteinuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal colic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal disorder	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal failure	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal impairment	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Strangury	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary incontinence	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary retention	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary tract pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urine flow decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Reproductive system and breast disorders	-Total	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Benign prostatic hyperplasia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Breast discharge	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Erectile dysfunction	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Galactorrhoea	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Genital ulceration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Metrorrhagia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pelvic discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pelvic fluid collection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Perineal pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Postmenopausal haemorrhage	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Prostatitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Uterine polyp	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vaginal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vulvovaginal dryness	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vulvovaginal erythema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Respiratory, thoracic and mediastinal disorders	-Total	0	84	29.9	51	60.7	50.0	70.5
		1	190	67.6	99	52.1	45.0	59.1
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Aspiration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bronchospasm	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Choking	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Cough	0	84	29.9	23	27.4	19.0	37.7
		1	190	67.6	39	20.5	15.4	26.8
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry throat	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysphonia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	29	15.3	10.8	21.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea exertional	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epistaxis	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemoptysis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hiccups	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Interstitial lung disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Laryngeal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasal congestion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Nasal dryness	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasal polyps	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oropharyngeal discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oropharyngeal pain	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paranasal sinus discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pharyngeal disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural effusion	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural thickening	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleuritic pain	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonitis	0	84	29.9	14	16.7	10.2	26.1
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumothorax	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Productive cough	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Pulmonary embolism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary mass	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiration abnormal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinalgia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinitis allergic	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinorrhoea	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinus congestion	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sleep apnoea syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sputum discoloured	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Throat irritation	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Upper-airway cough syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vocal cord leukoplakia	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wheezing	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Skin and subcutaneous tissue disorders	-Total	0	84	29.9	37	44.0	33.9	54.7
		1	190	67.6	59	31.1	24.9	38.0
		2	6	2.1	4	66.7	30.0	90.3
		Missing	1	0.4	0	0.0	0.0	79.3
	Acne	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alopecia	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chloasma	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Decubitus ulcer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermal cyst	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis acneiform	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis allergic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis bullous	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry skin	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	6	3.2	1.5	6.7

		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Ecchymosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eczema	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Erythema	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hair growth abnormal	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hair texture abnormal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hirsutism	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperhidrosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperkeratosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertrichosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Madarosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nail discolouration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nail disorder	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Night sweats	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Onychalgia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Onycholysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Onychomadesis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain of skin	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Palmar-plantar erythrodysaesthesia syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Photosensitivity reaction	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pruritus	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pruritus generalised	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Purpura	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash erythematous	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Rash macular	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash maculo-papular	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash papular	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Scab	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Scar pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin discolouration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin hyperpigmentation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin lesion	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Swelling face	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urticaria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Surgical and medical procedures	-Total	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Astringent therapy	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Therapy cessation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Vascular disorders	-Total	0	84	29.9	17	20.2	13.0	30.0
		1	190	67.6	54	28.4	22.5	35.2
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Aortic dissection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Circulatory collapse	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Deep vein thrombosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Flushing	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hot flush	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertension	0	84	29.9	12	14.3	8.4	23.3
		1	190	67.6	38	20.0	14.9	26.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypotension	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphoedema	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Orthostatic hypotension	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pallor	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Phlebitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Raynaud's phenomenon	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Superior vena cava syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombophlebitis superficial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR12_SG.xls
26MAR2021 14:20

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1-2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	USA	64	22.8	30	46.9	35.2	58.9
		Europe (EU)	95	33.8	39	41.1	31.7	51.1
		Asia (AS)	122	43.4	56	45.9	37.3	54.7
	Anaemia	USA	64	22.8	18	28.1	18.6	40.1
		Europe (EU)	95	33.8	27	28.4	20.3	38.2
		Asia (AS)	122	43.4	38	31.1	23.6	39.8
	Aplastic anaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bone marrow oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cytopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Febrile neutropenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyperfibrinogenaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Leukocytosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Leukopenia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	10	10.5	5.8	18.3
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Lymph node pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lymphadenopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lymphopenia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neutropenia	USA	64	22.8	13	20.3	12.3	31.7

		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Neutrophilia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pancytopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thrombocytopenia	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Thrombocytosis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Cardiac disorders	-Total	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	18	14.8	9.5	22.1
	Acute coronary syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Angina pectoris	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aortic valve calcification	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Atrial fibrillation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Atrial flutter	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Bradycardia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bundle branch block right	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cardiac failure	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Extrasystoles	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Myocardial ischaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nodal arrhythmia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Palpitations	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pericardial effusion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinus bradycardia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinus tachycardia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Tachycardia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Ventricular extrasystoles	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Ventricular pre-excitation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Congenital, familial and genetic disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gilbert's syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hydrocele	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Ear and labyrinth disorders	-Total	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Ear congestion	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ear discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ear pain	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Tinnitus	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Vertigo	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
Endocrine disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperthyroidism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypothyroidism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Eye disorders	-Total	USA	64	22.8	16	25.0	16.0	36.8
		Europe (EU)	95	33.8	13	13.7	8.2	22.0
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Abnormal sensation in eye	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blepharitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Chalazion	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Conjunctival cyst	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Conjunctival haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Diplopia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dry eye	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eye swelling	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eyelid oedema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1

	Eyelid ptosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Keratitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ocular discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Periorbital oedema	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Photophobia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Photopsia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ulcerative keratitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vision blurred	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Visual acuity reduced	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Gastrointestinal disorders	-Total	USA	64	22.8	51	79.7	68.3	87.7
		Europe (EU)	95	33.8	71	74.7	65.2	82.4
		Asia (AS)	122	43.4	77	63.1	54.3	71.2
	Abdominal discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Abdominal distension	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Abdominal pain	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Abdominal pain lower	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Abdominal pain upper	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Abdominal symptom	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Anal incontinence	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Aphthous ulcer	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ascites	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Constipation	USA	64	22.8	25	39.1	28.1	51.3
		Europe (EU)	95	33.8	39	41.1	31.7	51.1
		Asia (AS)	122	43.4	52	42.6	34.2	51.5
	Dental dysaesthesia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Diarrhoea	USA	64	22.8	18	28.1	18.6	40.1
		Europe (EU)	95	33.8	25	26.3	18.5	36.0
		Asia (AS)	122	43.4	22	18.0	12.2	25.8
	Dry mouth	USA	64	22.8	19	29.7	19.9	41.8
		Europe (EU)	95	33.8	18	18.9	12.3	28.0
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Dyspepsia	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Dysphagia	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Enteritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epigastric discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eructation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Faeces soft	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Flatulence	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Frequent bowel movements	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastric ulcer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastritis erosive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastrointestinal inflammation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal wall thickening	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrooesophageal reflux disease	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gingival bleeding	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Gingival swelling	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Glossitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Glossodynia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haematochezia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haemorrhoids	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hypoaesthesia oral	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0

	Impaired gastric emptying	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Irritable bowel syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Melaena	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Mouth ulceration	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Nausea	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	17	17.9	11.5	26.8
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Odynophagia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oesophageal irritation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oesophagitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oral disorder	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oral dysaesthesia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oral mucosal erythema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oral pain	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pancreatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Paraesthesia oral	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rectal prolapse	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Regurgitation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sensitivity of teeth	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Stomatitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Swollen tongue	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tongue coated	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tongue discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tongue ulceration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tooth discolouration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Toothache	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Vomiting	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	13	13.7	8.2	22.0
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
General disorders and administration site conditions	-Total	USA	64	22.8	48	75.0	63.2	84.0
		Europe (EU)	95	33.8	66	69.5	59.6	77.8
		Asia (AS)	122	43.4	78	63.9	55.1	71.9
	Asthenia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	25	26.3	18.5	36.0
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Axillary pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Catheter site pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Chest discomfort	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Chest pain	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Chills	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Face oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	17	13.9	8.9	21.2
	Facial pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fatigue	USA	64	22.8	26	40.6	29.5	52.9
		Europe (EU)	95	33.8	19	20.0	13.2	29.1
		Asia (AS)	122	43.4	16	13.1	8.2	20.2
	Feeling abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Feeling cold	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Feeling hot	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gait disturbance	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	General physical health deterioration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Generalised oedema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Impaired healing	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Influenza like illness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Injection site bruising	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Localised oedema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Malaise	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4

		Asia (AS)	122	43.4	17	13.9	8.9	21.2
	Mucosal dryness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Mucosal inflammation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	18	18.9	12.3	28.0
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Non-cardiac chest pain	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Oedema	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oedema peripheral	USA	64	22.8	19	29.7	19.9	41.8
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Pain	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Peripheral swelling	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Pyrexia	USA	64	22.8	10	15.6	8.7	26.4
		Europe (EU)	95	33.8	27	28.4	20.3	38.2
		Asia (AS)	122	43.4	34	27.9	20.7	36.4
	Swelling	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Temperature intolerance	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Xerosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Hepatobiliary disorders	-Total	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Cholecystitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hepatic function abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Hepatic steatosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Hepatocellular injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperbilirubinaemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Liver disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumobilia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Portal vein thrombosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Immune system disorders	-Total	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Contrast media allergy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Drug hypersensitivity	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Food allergy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypersensitivity	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Seasonal allergy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Infections and infestations	-Total	USA	64	22.8	30	46.9	35.2	58.9
		Europe (EU)	95	33.8	51	53.7	43.7	63.4
		Asia (AS)	122	43.4	41	33.6	25.8	42.4
	Abdominal abscess	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Acute sinusitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Arthritis infective	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Atypical pneumonia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacteraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacterial disease carrier	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacterial vaginosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bronchitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Candida infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cellulitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Chronic sinusitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Conjunctivitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Corona virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cystitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cystitis escherichia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ear infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epididymitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epstein-Barr virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Escherichia bacteraemia	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Escherichia infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Escherichia urinary tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eye infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Febrile infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Folliculitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fungal infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Gastroenteritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Genital candidiasis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Genital herpes	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gingivitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Herpes simplex	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Herpes virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Herpes zoster	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Influenza	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lower respiratory tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lung infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lyme disease	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymph node tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nasal herpes	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasopharyngitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Oral candidiasis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oral fungal infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oropharyngeal candidiasis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Otitis externa	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Otitis media	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Paronychia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Pharyngitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Pneumonia influenzal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Pneumonia pseudomonal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonia streptococcal	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pyelonephritis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pyuria	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory tract infection bacterial	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhinitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Sepsis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinusitis	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Skin infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Staphylococcal infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Systemic infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tinea cruris	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tinea infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tinea pedis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Tonsillitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tooth infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tracheitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Upper respiratory tract infection	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Urethritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary tract infection	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Varicella	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Varicella zoster virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Viral hepatitis carrier	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Viral infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vulvovaginal candidiasis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Injury, poisoning and procedural complications	-Total	USA	64	22.8	13	20.3	12.3	31.7
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Contusion	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epicondylitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fall	USA	64	22.8	5	7.8	3.4	17.0

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Incision site pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Joint dislocation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Laceration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ligament sprain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Limb injury	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle rupture	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle strain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Procedural pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Procedural pneumothorax	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rib fracture	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Scar	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin abrasion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tendon rupture	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thermal burn	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Wound	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Wound complication	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Wrist fracture	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Investigations	-Total	USA	64	22.8	49	76.6	64.9	85.3
		Europe (EU)	95	33.8	60	63.2	53.1	72.2
		Asia (AS)	122	43.4	100	82.0	74.2	87.8
	Alanine aminotransferase increased	USA	64	22.8	18	28.1	18.6	40.1
		Europe (EU)	95	33.8	16	16.8	10.6	25.6
		Asia (AS)	122	43.4	49	40.2	31.9	49.0
	Albumin urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Alpha hydroxybutyrate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Amylase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Aspartate aminotransferase increased	USA	64	22.8	25	39.1	28.1	51.3
		Europe (EU)	95	33.8	25	26.3	18.5	36.0
		Asia (AS)	122	43.4	61	50.0	41.3	58.7
	Bacterial test	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bilirubin conjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	19	15.6	10.2	23.0
	Blood albumin decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood alkaline phosphatase	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood alkaline phosphatase decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Blood alkaline phosphatase increased	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	21	17.2	11.5	24.9
	Blood bilirubin increased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	17	13.9	8.9	21.2
	Blood bilirubin unconjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Blood calcium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood calcium increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood chloride increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood cholesterol increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Blood creatine increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood creatine phosphokinase MB increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Blood creatine phosphokinase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	25	20.5	14.3	28.5
	Blood creatinine	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood creatinine increased	USA	64	22.8	17	26.6	17.3	38.5
		Europe (EU)	95	33.8	20	21.1	14.1	30.3
		Asia (AS)	122	43.4	23	18.9	12.9	26.7
	Blood fibrinogen increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood glucose increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Blood iron decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Blood ketone body increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood lactate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Blood magnesium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood phosphorus increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Blood potassium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood potassium increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood pressure increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Blood sodium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood thyroid stimulating hormone increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood triglycerides increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Blood urea increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Blood uric acid decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood uric acid increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Blood urine	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Blood urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	C-reactive protein increased	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Carbon dioxide decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Complement factor C1 decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Computerised tomogram thorax abnormal	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Crystal urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cystatin C increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Electrocardiogram QT prolonged	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Electrocardiogram ST-T change	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Fibrin D dimer increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Fibrin degradation products increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Free fatty acids increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gamma-glutamyltransferase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	16	13.1	8.2	20.2
	Glomerular filtration rate decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Glutamate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Granulocyte count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haematocrit decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haemoglobin decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Heart rate increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Hepatic enzyme increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	International normalised ratio increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Intraocular pressure increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Laboratory test abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lipase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Liver function test increased	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymphocyte count decreased	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Lymphocyte count increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Mean cell volume increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Myoglobin blood increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Neutrophil count decreased	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	36	29.5	22.1	38.1
	Neutrophil count increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Neutrophil percentage increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Occult blood positive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Platelet count decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	18	14.8	9.5	22.1
	Platelet count increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Procalcitonin increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Protein total decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Protein total increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Protein urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Prothrombin time prolonged	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Red blood cell count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Serum amyloid A protein increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Thrombin time prolonged	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Total bile acids increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Transaminases increased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Transferrin increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Troponin T increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Troponin increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary sediment present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urine ketone body present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Urine leukocyte esterase positive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urobilinogen urine increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Weight decreased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
	Weight increased	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	17	13.9	8.9	21.2
	White blood cell count decreased	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	10	10.5	5.8	18.3
		Asia (AS)	122	43.4	32	26.2	19.2	34.7
	White blood cells urine positive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
Metabolism and nutrition disorders	-Total	USA	64	22.8	27	42.2	30.9	54.4
		Europe (EU)	95	33.8	42	44.2	34.6	54.2
		Asia (AS)	122	43.4	69	56.6	47.7	65.0
	Abnormal loss of weight	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Alkalosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cell death	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Decreased appetite	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	23	18.9	12.9	26.7
	Dehydration	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Electrolyte imbalance	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Fluid retention	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypercalcaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hypercholesterolaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hyperglycaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
	Hyperkalaemia	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hyperlipidaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Hypermagnesaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hypernatraemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hyperphosphataemia	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Hypertriglyceridaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Hyperuricaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Hypoalbuminaemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	32	26.2	19.2	34.7
	Hypocalcaemia	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	17	13.9	8.9	21.2
	Hypochloraemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Hypoglycaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypokalaemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	13	13.7	8.2	22.0
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Hypomagnesaemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Hyponatraemia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	12	9.8	5.7	16.4
	Hypophosphataemia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Hypoproteinaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Increased appetite	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vitamin D deficiency	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Musculoskeletal and connective tissue disorders	-Total	USA	64	22.8	38	59.4	47.1	70.5
		Europe (EU)	95	33.8	38	40.0	30.7	50.1
		Asia (AS)	122	43.4	43	35.2	27.3	44.1
	Arthralgia	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Arthropathy	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Back pain	USA	64	22.8	13	20.3	12.3	31.7
		Europe (EU)	95	33.8	10	10.5	5.8	18.3
		Asia (AS)	122	43.4	12	9.8	5.7	16.4
	Bone pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Bursitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Coccydynia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Costochondritis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Flank pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Groin pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypercreatinaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Intervertebral disc protrusion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Joint range of motion decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Joint stiffness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Joint swelling	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle fatigue	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Muscle spasms	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Muscular weakness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Musculoskeletal chest pain	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Musculoskeletal pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	12	12.6	7.4	20.8
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Musculoskeletal stiffness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Myalgia	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Myopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Neck pain	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Osteopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pain in extremity	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Pain in jaw	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rotator cuff syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Spinal column stenosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Spinal osteoarthritis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tendon disorder	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tendon pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Anogenital warts	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Basal cell carcinoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bowen's disease	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Metastases to central nervous system	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal cell carcinoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Squamous cell carcinoma	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Squamous cell carcinoma of skin	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tumour pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Nervous system disorders	-Total	USA	64	22.8	41	64.1	51.8	74.7
		Europe (EU)	95	33.8	46	48.4	38.6	58.3
		Asia (AS)	122	43.4	54	44.3	35.8	53.1
	Ageusia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aphasia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ataxia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Balance disorder	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Brain oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebellar haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Disturbance in attention	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dizziness	USA	64	22.8	13	20.3	12.3	31.7
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Dizziness postural	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dysarthria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dysgeusia	USA	64	22.8	14	21.9	13.5	33.4
		Europe (EU)	95	33.8	20	21.1	14.1	30.3
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Dyskinesia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Headache	USA	64	22.8	14	21.9	13.5	33.4
		Europe (EU)	95	33.8	12	12.6	7.4	20.8
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Hemiplegia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyperaesthesia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypersomnia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypoaesthesia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	16	13.1	8.2	20.2
	Hypotonia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lethargy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lumbar radiculopathy	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Memory impairment	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Migraine with aura	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neuralgia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neuropathy peripheral	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Paraesthesia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Paralysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Parosmia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Peripheral sensory neuropathy	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Polyneuropathy chronic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Post herpetic neuralgia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Presyncope	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Psychomotor skills impaired	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Restless legs syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sciatica	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Seizure	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Sensory disturbance	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Slow speech	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Somnolence	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Syncope	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tension headache	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tremor	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Visual field defect	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

Product issues	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Device dislocation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Psychiatric disorders	-Total	USA	64	22.8	14	21.9	13.5	33.4
		Europe (EU)	95	33.8	17	17.9	11.5	26.8
		Asia (AS)	122	43.4	23	18.9	12.9	26.7
	Abnormal behaviour	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Abnormal dreams	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Adjustment disorder with mixed anxiety and depressed mood	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Anxiety	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Bradyphrenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Confusional state	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Delirium	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Depressed mood	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Depression	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fear of falling	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Insomnia	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Irritability	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Libido decreased	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Mental status changes	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Mood altered	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Psychomotor retardation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Restlessness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Sleep disorder	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Renal and urinary disorders	-Total	USA	64	22.8	18	28.1	18.6	40.1
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Acute kidney injury	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Azotaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Cystitis haemorrhagic	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dysuria	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Haematuria	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Haemorrhage urinary tract	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Micturition urgency	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nephritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nocturia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pollakiuria	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Proteinuria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Renal colic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal failure	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal impairment	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Strangury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urinary incontinence	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary retention	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urinary tract pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urine flow decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Reproductive system and breast disorders	-Total	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	10	10.5	5.8	18.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Benign prostatic hyperplasia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Breast discharge	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Erectile dysfunction	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Galactorrhoea	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Genital ulceration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Metrorrhagia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pelvic discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pelvic fluid collection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Perineal pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Postmenopausal haemorrhage	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Prostatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Uterine polyp	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vaginal haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vulvovaginal dryness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vulvovaginal erythema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Respiratory, thoracic and mediastinal disorders	-Total	USA	64	22.8	38	59.4	47.1	70.5
		Europe (EU)	95	33.8	51	53.7	43.7	63.4
		Asia (AS)	122	43.4	64	52.5	43.7	61.1
	Aspiration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bronchospasm	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Choking	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cough	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	23	24.2	16.7	33.7
		Asia (AS)	122	43.4	26	21.3	15.0	29.4
	Dry throat	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dysphonia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Dyspnoea	USA	64	22.8	10	15.6	8.7	26.4
		Europe (EU)	95	33.8	13	13.7	8.2	22.0
		Asia (AS)	122	43.4	16	13.1	8.2	20.2
	Dyspnoea exertional	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Epistaxis	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Haemoptysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Hiccups	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypoxia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Interstitial lung disease	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Laryngeal haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nasal congestion	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasal dryness	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasal polyps	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oropharyngeal discomfort	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oropharyngeal pain	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Paranasal sinus discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pharyngeal disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pleural effusion	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pleural thickening	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pleuritic pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonitis	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Pneumothorax	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Productive cough	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Pulmonary embolism	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pulmonary mass	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pulmonary pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiration abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rhinalgia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhinitis allergic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rhinorrhoea	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinus congestion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sleep apnoea syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Sputum discoloured	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Throat irritation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Upper-airway cough syndrome	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vocal cord leukoplakia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Wheezing	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Skin and subcutaneous tissue disorders	-Total	USA	64	22.8	32	50.0	38.1	61.9
		Europe (EU)	95	33.8	29	30.5	22.2	40.4
		Asia (AS)	122	43.4	39	32.0	24.4	40.7
	Acne	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Alopecia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Chloasma	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Decubitus ulcer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dermal cyst	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dermatitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Dermatitis acneiform	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Dermatitis allergic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dermatitis bullous	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dry skin	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Ecchymosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Eczema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Erythema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hair growth abnormal	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hair texture abnormal	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hirsutism	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperhidrosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperkeratosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypertrichosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Madarosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nail discolouration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Nail disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Night sweats	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Onychalgia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Onycholysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Onychomadesis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Pain of skin	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Palmar-plantar erythrodysaesthesia syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Photosensitivity reaction	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pruritus	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Pruritus generalised	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Purpura	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rash	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Rash erythematous	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rash macular	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rash maculo-papular	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rash papular	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Scab	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Scar pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Skin discolouration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin hyperpigmentation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin lesion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Swelling face	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Urticaria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Surgical and medical procedures	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Astringent therapy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Therapy cessation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Vascular disorders	-Total	USA	64	22.8	17	26.6	17.3	38.5
		Europe (EU)	95	33.8	23	24.2	16.7	33.7
		Asia (AS)	122	43.4	32	26.2	19.2	34.7
	Aortic dissection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Circulatory collapse	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Deep vein thrombosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Embolism	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Flushing	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haematoma	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hot flush	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypertension	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	14	14.7	9.0	23.2
		Asia (AS)	122	43.4	28	23.0	16.4	31.2
	Hypotension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lymphoedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Orthostatic hypotension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pallor	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Phlebitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Raynaud's phenomenon	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Superior vena cava syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Thrombophlebitis superficial	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thrombosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR12_SG.xls
26MAR2021 14:20

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1-2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	116	41.3	48	41.4	32.8	50.5
		1	77	27.4	34	44.2	33.6	55.3
		>= 2	88	31.3	43	48.9	38.7	59.1
	Anaemia	0	116	41.3	32	27.6	20.3	36.3
		1	77	27.4	23	29.9	20.8	40.8
		>= 2	88	31.3	28	31.8	23.0	42.1
	Aplastic anaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bone marrow oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cytopenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Febrile neutropenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperfibrinogenaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Leukocytosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Leukopenia	0	116	41.3	14	12.1	7.3	19.2
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	3	3.4	1.2	9.5
	Lymph node pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymphadenopathy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymphopenia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Neutropenia	0	116	41.3	11	9.5	5.4	16.2

		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	7	8.0	3.9	15.5
	Neutrophilia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pancytopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Thrombocytopenia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Thrombocytosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
Cardiac disorders	-Total	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	15	17.0	10.6	26.2
	Acute coronary syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Angina pectoris	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Aortic valve calcification	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Atrial fibrillation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Atrial flutter	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bradycardia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bundle branch block right	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cardiac failure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Extrasystoles	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Myocardial ischaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Nodal arrhythmia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Palpitations	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pericardial effusion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Sinus bradycardia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Sinus tachycardia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Tachycardia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Ventricular extrasystoles	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ventricular pre-excitation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Congenital, familial and genetic disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gilbert's syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hydrocele	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Ear and labyrinth disorders	-Total	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	8	9.1	4.7	16.9
	Ear congestion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ear discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ear pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9

	Tinnitus	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vertigo	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	5	5.7	2.5	12.6
Endocrine disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hyperthyroidism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypothyroidism	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
Eye disorders	-Total	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	17	22.1	14.3	32.5
		>= 2	88	31.3	13	14.8	8.8	23.7
	Abnormal sensation in eye	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blepharitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Chalazion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Conjunctival cyst	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Conjunctival haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Diplopia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dry eye	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Eye swelling	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eyelid oedema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9

	Eyelid ptosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Keratitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ocular discomfort	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Periorbital oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	1	1.1	0.2	6.2
	Photophobia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Photopsia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ulcerative keratitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vision blurred	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	5	5.7	2.5	12.6
	Visual acuity reduced	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Gastrointestinal disorders	-Total	0	116	41.3	79	68.1	59.2	75.9
		1	77	27.4	55	71.4	60.5	80.3
		>= 2	88	31.3	65	73.9	63.8	81.9
	Abdominal discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Abdominal distension	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Abdominal pain	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Abdominal pain lower	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Abdominal pain upper	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Abdominal symptom	0	116	41.3	1	0.9	0.2	4.7

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Anal incontinence	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Aphthous ulcer	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ascites	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Constipation	0	116	41.3	51	44.0	35.3	53.0
		1	77	27.4	32	41.6	31.2	52.7
		>= 2	88	31.3	33	37.5	28.1	47.9
	Dental dysaesthesia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Diarrhoea	0	116	41.3	24	20.7	14.3	28.9
		1	77	27.4	21	27.3	18.6	38.1
		>= 2	88	31.3	20	22.7	15.2	32.5
	Dry mouth	0	116	41.3	14	12.1	7.3	19.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	20	22.7	15.2	32.5
	Dyspepsia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Dysphagia	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	9	10.2	5.5	18.3
	Enteritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Epigastric discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Eructation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Faeces soft	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Flatulence	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Frequent bowel movements	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastric ulcer	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastritis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Gastritis erosive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrointestinal haemorrhage	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrointestinal inflammation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrointestinal oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastrointestinal wall thickening	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrooesophageal reflux disease	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Gingival bleeding	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Gingival swelling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Glossitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Glossodynia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haematochezia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemorrhoids	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypoaesthesia oral	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2

	Impaired gastric emptying	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Irritable bowel syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Melaena	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Mouth ulceration	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Nausea	0	116	41.3	18	15.5	10.0	23.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	11	12.5	7.1	21.0
	Odynophagia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oesophageal irritation	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oesophagitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oral disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Oral dysaesthesia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oral mucosal erythema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Oral pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Pancreatitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Paraesthesia oral	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rectal prolapse	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Regurgitation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sensitivity of teeth	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Stomatitis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Swollen tongue	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tongue coated	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tongue discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tongue ulceration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tooth discolouration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Toothache	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Vomiting	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	9	10.2	5.5	18.3
General disorders and administration site conditions	-Total	0	116	41.3	71	61.2	52.1	69.6
		1	77	27.4	52	67.5	56.5	76.9
		>= 2	88	31.3	69	78.4	68.7	85.7
	Asthenia	0	116	41.3	18	15.5	10.0	23.2
		1	77	27.4	11	14.3	8.2	23.8
		>= 2	88	31.3	8	9.1	4.7	16.9
	Axillary pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Catheter site pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Chest discomfort	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Chest pain	0	116	41.3	6	5.2	2.4	10.8

		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Chills	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Face oedema	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	8	9.1	4.7	16.9
	Facial pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fatigue	0	116	41.3	24	20.7	14.3	28.9
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	24	27.3	19.1	37.4
	Feeling abnormal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Feeling cold	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Feeling hot	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gait disturbance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	General physical health deterioration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Generalised oedema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Impaired healing	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Influenza like illness	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Injection site bruising	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Localised oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Malaise	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	4	5.2	2.0	12.6

		>= 2	88	31.3	6	6.8	3.2	14.1
	Mucosal dryness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Mucosal inflammation	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Non-cardiac chest pain	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oedema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oedema peripheral	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	19	21.6	14.3	31.3
	Pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Peripheral swelling	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pyrexia	0	116	41.3	23	19.8	13.6	28.0
		1	77	27.4	22	28.6	19.7	39.5
		>= 2	88	31.3	26	29.5	21.0	39.8
	Swelling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Temperature intolerance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Xerosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Hepatobiliary disorders	-Total	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	5	5.7	2.5	12.6
	Cholecystitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hepatic function abnormal	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hepatic steatosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Hepatocellular injury	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hyperbilirubinaemia	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Liver disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumobilia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Portal vein thrombosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
Immune system disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Contrast media allergy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Drug hypersensitivity	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Food allergy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypersensitivity	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Seasonal allergy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
Infections and infestations	-Total	0	116	41.3	39	33.6	25.7	42.6
		1	77	27.4	37	48.1	37.3	59.0
		>= 2	88	31.3	46	52.3	42.0	62.4
	Abdominal abscess	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Acute sinusitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Arthritis infective	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Atypical pneumonia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bacteraemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bacterial disease carrier	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bacterial vaginosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bronchitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	2	2.3	0.6	7.9
	Candida infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cellulitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Chronic sinusitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Conjunctivitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Corona virus infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cystitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cystitis escherichia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ear infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Epididymitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Epstein-Barr virus infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Escherichia bacteraemia	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Escherichia infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Escherichia urinary tract infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eye infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Febrile infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Folliculitis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fungal infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastroenteritis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Genital candidiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Genital herpes	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gingivitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Herpes simplex	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Herpes virus infection	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Herpes zoster	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Influenza	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Lower respiratory tract infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lung infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lyme disease	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lymph node tuberculosis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasal herpes	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasopharyngitis	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Oral candidiasis	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Oral fungal infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oropharyngeal candidiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Otitis externa	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Otitis media	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Paronychia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pharyngitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	8	9.1	4.7	16.9
	Pneumonia influenzal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Pneumonia pseudomonal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia streptococcal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pyelonephritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pyuria	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Respiratory tract infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiratory tract infection bacterial	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Sepsis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sinusitis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Skin infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Staphylococcal infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Systemic infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tinea cruris	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tinea infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tinea pedis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9

	Tonsillitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tooth infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tracheitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tuberculosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Upper respiratory tract infection	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	7	8.0	3.9	15.5
	Urethritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urinary tract infection	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	13	14.8	8.8	23.7
	Varicella	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Varicella zoster virus infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Viral hepatitis carrier	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Viral infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vulvovaginal candidiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Injury, poisoning and procedural complications	-Total	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	14	15.9	9.7	25.0
	Contusion	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Epicondylitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Fall	0	116	41.3	3	2.6	0.9	7.3

		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Incision site pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Joint dislocation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Laceration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ligament sprain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Limb injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Muscle rupture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Muscle strain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Procedural pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Procedural pneumothorax	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rib fracture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Scar	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Skin abrasion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Skin injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tendon rupture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Thermal burn	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Wound	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Wound complication	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Wrist fracture	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Investigations	-Total	0	116	41.3	85	73.3	64.6	80.5
		1	77	27.4	58	75.3	64.6	83.6
		>= 2	88	31.3	66	75.0	65.0	82.9
	Alanine aminotransferase increased	0	116	41.3	39	33.6	25.7	42.6
		1	77	27.4	16	20.8	13.2	31.1
		>= 2	88	31.3	28	31.8	23.0	42.1
	Albumin urine present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Alpha hydroxybutyrate dehydrogenase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Amylase increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Aspartate aminotransferase increased	0	116	41.3	46	39.7	31.2	48.8
		1	77	27.4	29	37.7	27.7	48.8
		>= 2	88	31.3	36	40.9	31.2	51.4
	Bacterial test	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bilirubin conjugated increased	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Blood albumin decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood alkaline phosphatase	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood alkaline phosphatase decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Blood alkaline phosphatase increased	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	13	14.8	8.8	23.7
	Blood bilirubin increased	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	7	8.0	3.9	15.5
	Blood bilirubin unconjugated increased	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood calcium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood calcium increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood chloride increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood cholesterol increased	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Blood creatine increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood creatine phosphokinase MB increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood creatine phosphokinase increased	0	116	41.3	17	14.7	9.4	22.2
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	11	12.5	7.1	21.0
	Blood creatinine	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood creatinine increased	0	116	41.3	17	14.7	9.4	22.2
		1	77	27.4	19	24.7	16.4	35.4
		>= 2	88	31.3	24	27.3	19.1	37.4
	Blood fibrinogen increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood glucose increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood iron decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Blood ketone body increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood lactate dehydrogenase increased	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood magnesium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood phosphorus increased	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood potassium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood potassium increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood pressure increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood sodium decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood thyroid stimulating hormone increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood triglycerides increased	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood urea increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood uric acid decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood uric acid increased	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Blood urine	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood urine present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	C-reactive protein increased	0	116	41.3	1	0.9	0.2	4.7

		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Carbon dioxide decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Complement factor C1 decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Computerised tomogram thorax abnormal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Crystal urine present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cystatin C increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Electrocardiogram QT prolonged	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	7	8.0	3.9	15.5
	Electrocardiogram ST-T change	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Fibrin D dimer increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Fibrin degradation products increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Free fatty acids increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gamma-glutamyltransferase increased	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	7	8.0	3.9	15.5
	Glomerular filtration rate decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Glutamate dehydrogenase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Granulocyte count decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haematocrit decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemoglobin decreased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Heart rate increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hepatic enzyme increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	International normalised ratio increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intraocular pressure increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Laboratory test abnormal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lipase increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Liver function test increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lymphocyte count decreased	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	4	4.5	1.8	11.1
	Lymphocyte count increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Mean cell volume increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Myoglobin blood increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neutrophil count decreased	0	116	41.3	19	16.4	10.7	24.2
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	17	19.3	12.4	28.8
	Neutrophil count increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Neutrophil percentage increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Occult blood positive	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Platelet count decreased	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	9	10.2	5.5	18.3
	Platelet count increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Procalcitonin increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Protein total decreased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Protein total increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Protein urine present	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Prothrombin time prolonged	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Red blood cell count decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Serum amyloid A protein increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Thrombin time prolonged	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Total bile acids increased	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Transaminases increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Transferrin increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Troponin T increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Troponin increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Urinary sediment present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urine ketone body present	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Urine leukocyte esterase positive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urobilinogen urine increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Weight decreased	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	7	8.0	3.9	15.5
	Weight increased	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	9	10.2	5.5	18.3
	White blood cell count decreased	0	116	41.3	23	19.8	13.6	28.0
		1	77	27.4	15	19.5	12.2	29.7
		>= 2	88	31.3	19	21.6	14.3	31.3
	White blood cells urine positive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
Metabolism and nutrition disorders	-Total	0	116	41.3	57	49.1	40.2	58.1
		1	77	27.4	34	44.2	33.6	55.3
		>= 2	88	31.3	47	53.4	43.1	63.5
	Abnormal loss of weight	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Alkalosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cell death	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Decreased appetite	0	116	41.3	12	10.3	6.0	17.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	11	12.5	7.1	21.0
	Dehydration	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Electrolyte imbalance	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Fluid retention	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypercalcaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hypercholesterolaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperglycaemia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	7	8.0	3.9	15.5
	Hyperkalaemia	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hyperlipidaemia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypermagnesaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypernatraemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperphosphataemia	0	116	41.3	15	12.9	8.0	20.2
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	10	11.4	6.3	19.7
	Hypertriglyceridaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Hyperuricaemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hypoalbuminaemia	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	17	19.3	12.4	28.8
	Hypocalcaemia	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	12	13.6	8.0	22.3
	Hypochloraemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hypoglycaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1		0.2	6.2
	Hypokalaemia	0	116	41.3	9	7.8		4.1	14.1
		1	77	27.4	9	11.7		6.3	20.7
		>= 2	88	31.3	11	12.5		7.1	21.0
	Hypomagnesaemia	0	116	41.3	6	5.2		2.4	10.8
		1	77	27.4	5	6.5		2.8	14.3
		>= 2	88	31.3	10	11.4		6.3	19.7
	Hyponatraemia	0	116	41.3	8	6.9		3.5	13.0
		1	77	27.4	5	6.5		2.8	14.3
		>= 2	88	31.3	5	5.7		2.5	12.6
	Hypophosphataemia	0	116	41.3	3	2.6		0.9	7.3
		1	77	27.4	6	7.8		3.6	16.0
		>= 2	88	31.3	6	6.8		3.2	14.1
	Hypoproteinaemia	0	116	41.3	2	1.7		0.5	6.1
		1	77	27.4	2	2.6		0.7	9.0
		>= 2	88	31.3	2	2.3		0.6	7.9
	Increased appetite	0	116	41.3	0	0.0		0.0	3.2
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	1	1.1		0.2	6.2
	Vitamin D deficiency	0	116	41.3	1	0.9		0.2	4.7
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	0	0.0		0.0	4.2
Musculoskeletal and connective tissue disorders	-Total	0	116	41.3	45	38.8		30.4	47.9
		1	77	27.4	35	45.5		34.8	56.5
		>= 2	88	31.3	39	44.3		34.4	54.7
	Arthralgia	0	116	41.3	5	4.3		1.9	9.7
		1	77	27.4	4	5.2		2.0	12.6
		>= 2	88	31.3	3	3.4		1.2	9.5
	Arthropathy	0	116	41.3	0	0.0		0.0	3.2
		1	77	27.4	1	1.3		0.2	7.0
		>= 2	88	31.3	0	0.0		0.0	4.2
	Back pain	0	116	41.3	10	8.6		4.7	15.1
		1	77	27.4	10	13.0		7.2	22.3
		>= 2	88	31.3	15	17.0		10.6	26.2
	Bone pain	0	116	41.3	1	0.9		0.2	4.7
		1	77	27.4	2	2.6		0.7	9.0
		>= 2	88	31.3	1	1.1		0.2	6.2
	Bursitis	0	116	41.3	0	0.0		0.0	3.2
		1	77	27.4	1	1.3		0.2	7.0
		>= 2	88	31.3	0	0.0		0.0	4.2
	Coccydynia	0	116	41.3	0	0.0		0.0	3.2
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	1	1.1		0.2	6.2
	Costochondritis	0	116	41.3	1	0.9		0.2	4.7
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	1	1.1		0.2	6.2

	Flank pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Groin pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypercreatinaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intervertebral disc protrusion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Joint range of motion decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Joint stiffness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Joint swelling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Muscle fatigue	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Muscle spasms	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	10	11.4	6.3	19.7
	Muscular weakness	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Musculoskeletal chest pain	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Musculoskeletal pain	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	8	9.1	4.7	16.9
	Musculoskeletal stiffness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Myalgia	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	3	3.4	1.2	9.5
	Myopathy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Neck pain	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	6	6.8	3.2	14.1
	Osteopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pain in extremity	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	10	11.4	6.3	19.7
	Pain in jaw	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rotator cuff syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Spinal column stenosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Spinal osteoarthritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tendon disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tendon pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Anogenital warts	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Basal cell carcinoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bowen's disease	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Metastases to central nervous system	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal cell carcinoma	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Squamous cell carcinoma	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Squamous cell carcinoma of skin	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tumour pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Nervous system disorders	-Total	0	116	41.3	52	44.8	36.1	53.9
		1	77	27.4	44	57.1	46.0	67.6
		>= 2	88	31.3	45	51.1	40.9	61.3
	Ageusia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Aphasia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ataxia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Balance disorder	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Brain oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Cerebellar haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Disturbance in attention	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dizziness	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	12	15.6	9.1	25.3
		>= 2	88	31.3	12	13.6	8.0	22.3
	Dizziness postural	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dysarthria	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dysgeusia	0	116	41.3	20	17.2	11.4	25.1
		1	77	27.4	14	18.2	11.2	28.2
		>= 2	88	31.3	8	9.1	4.7	16.9
	Dyskinesia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Headache	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	9	10.2	5.5	18.3
	Hemiplegia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperaesthesia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypersomnia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypoaesthesia	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	7	8.0	3.9	15.5
	Hypotonia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lethargy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lumbar radiculopathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Memory impairment	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Migraine with aura	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Neuralgia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neuropathy peripheral	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	3	3.4	1.2	9.5
	Paraesthesia	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	4	4.5	1.8	11.1
	Paralysis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Parosmia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Peripheral sensory neuropathy	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Polyneuropathy chronic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Post herpetic neuralgia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Presyncope	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Psychomotor skills impaired	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Restless legs syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sciatica	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Seizure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Sensory disturbance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Slow speech	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Somnolence	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Syncope	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Tension headache	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tremor	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Visual field defect	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

Product issues	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Device dislocation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Psychiatric disorders	-Total	0	116	41.3	19	16.4	10.7	24.2
		1	77	27.4	15	19.5	12.2	29.7
		>= 2	88	31.3	20	22.7	15.2	32.5
	Abnormal behaviour	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Abnormal dreams	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Adjustment disorder with mixed anxiety and depressed mood	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Anxiety	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Bradyphrenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Confusional state	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Delirium	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Depressed mood	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Depression	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fear of falling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Insomnia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	9	10.2	5.5	18.3
	Irritability	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Libido decreased	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Mental status changes	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Mood altered	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Psychomotor retardation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Restlessness	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sleep disorder	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Renal and urinary disorders	-Total	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	18	20.5	13.3	30.0
	Acute kidney injury	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Azotaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Cystitis haemorrhagic	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dysuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	8	9.1	4.7	16.9
	Haematuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemorrhage urinary tract	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Micturition urgency	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Nephritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nocturia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	1	1.1	0.2	6.2
	Pollakiuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Proteinuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Renal colic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal failure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal impairment	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Strangury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Urinary incontinence	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urinary retention	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Urinary tract pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urine flow decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Reproductive system and breast disorders	-Total	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	7	8.0	3.9	15.5
	Benign prostatic hyperplasia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Breast discharge	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Erectile dysfunction	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9

	Galactorrhoea	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Genital ulceration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Metrorrhagia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pelvic discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pelvic fluid collection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Perineal pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Postmenopausal haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Prostatitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Uterine polyp	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vaginal haemorrhage	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vulvovaginal dryness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vulvovaginal erythema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Respiratory, thoracic and mediastinal disorders	-Total	0	116	41.3	56	48.3	39.4	57.3
		1	77	27.4	46	59.7	48.6	70.0
		>= 2	88	31.3	51	58.0	47.5	67.7
	Aspiration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bronchospasm	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Choking	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cough	0	116	41.3	18	15.5	10.0	23.2
		1	77	27.4	26	33.8	24.2	44.9
		>= 2	88	31.3	20	22.7	15.2	32.5
	Dry throat	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dysphonia	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Dyspnoea	0	116	41.3	12	10.3	6.0	17.2
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	17	19.3	12.4	28.8
	Dyspnoea exertional	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Epistaxis	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	3	3.4	1.2	9.5
	Haemoptysis	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Hiccups	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypoxia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Interstitial lung disease	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Laryngeal haemorrhage	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasal congestion	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Nasal dryness	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasal polyps	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oropharyngeal discomfort	0	116	41.3	1	0.9	0.2	4.7

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oropharyngeal pain	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	5	5.7	2.5	12.6
	Paranasal sinus discomfort	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pharyngeal disorder	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pleural effusion	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pleural thickening	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pleuritic pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonitis	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	11	12.5	7.1	21.0
	Pneumothorax	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Productive cough	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	6	6.8	3.2	14.1
	Pulmonary embolism	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pulmonary mass	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pulmonary pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiration abnormal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinalgia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinitis allergic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinorrhoea	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sinus congestion	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sleep apnoea syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sputum discoloured	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Throat irritation	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Upper-airway cough syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Vocal cord leukoplakia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Wheezing	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Skin and subcutaneous tissue disorders	-Total	0	116	41.3	32	27.6	20.3	36.3
		1	77	27.4	35	45.5	34.8	56.5
		>= 2	88	31.3	33	37.5	28.1	47.9
	Acne	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Alopecia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	4	4.5	1.8	11.1
	Chloasma	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Decubitus ulcer	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dermal cyst	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dermatitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Dermatitis acneiform	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Dermatitis allergic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dermatitis bullous	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dry skin	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Ecchymosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eczema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Erythema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hair growth abnormal	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Hair texture abnormal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hirsutism	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hyperhidrosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperkeratosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypertrichosis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	0	0.0	0.0	4.2
	Madarosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Nail discolouration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Nail disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Night sweats	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Onychalgia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Onycholysis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Onychomadesis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pain of skin	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Palmar-plantar erythrodysaesthesia syndrome	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Photosensitivity reaction	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pruritus	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Pruritus generalised	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Purpura	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rash	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	10	11.4	6.3	19.7
	Rash erythematous	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Rash macular	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Rash maculo-papular	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rash papular	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Scab	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Scar pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Skin discolouration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Skin hyperpigmentation	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Skin lesion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Swelling face	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urticaria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Surgical and medical procedures	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Astringent therapy	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Therapy cessation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Vascular disorders	-Total	0	116	41.3	20	17.2	11.4	25.1
		1	77	27.4	19	24.7	16.4	35.4
		>= 2	88	31.3	33	37.5	28.1	47.9
	Aortic dissection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Circulatory collapse	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Deep vein thrombosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Embolism	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	2	2.3	0.6	7.9
	Flushing	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haematoma	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hot flush	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypertension	0	116	41.3	16	13.8	8.7	21.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	22	25.0	17.1	35.0
	Hypotension	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Lymphoedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Orthostatic hypotension	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pallor	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Phlebitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Raynaud's phenomenon	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Superior vena cava syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Thrombophlebitis superficial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Thrombosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR12_SG.xls
26MAR2021 14:20

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1-2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Asian	128	45.6	59	46.1	37.7	54.7
		Non-Asian	135	48.0	59	43.7	35.6	52.1
		Unknown	18	6.4	7	38.9	20.3	61.4
	Anaemia	Asian	128	45.6	40	31.3	23.9	39.7
		Non-Asian	135	48.0	38	28.1	21.2	36.3
		Unknown	18	6.4	5	27.8	12.5	50.9
	Aplastic anaemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bone marrow oedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cytopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Febrile neutropenia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperfibrinogenaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Leukocytosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Leukopenia	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	13	9.6	5.7	15.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymph node pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphadenopathy	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutropenia	Asian	128	45.6	8	6.3	3.2	11.8

		Non-Asian	135	48.0	20	14.8	9.8	21.8
		Unknown	18	6.4	3	16.7	5.8	39.2
	Neutrophilia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancytopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytopenia	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
Cardiac disorders	-Total	Asian	128	45.6	19	14.8	9.7	22.0
		Non-Asian	135	48.0	13	9.6	5.7	15.8
		Unknown	18	6.4	2	11.1	3.1	32.8
	Acute coronary syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Angina pectoris	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aortic valve calcification	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Atrial fibrillation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Atrial flutter	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bradycardia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bundle branch block right	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cardiac failure	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Extrasystoles	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Myocardial ischaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Nodal arrhythmia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Palpitations	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pericardial effusion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinus bradycardia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Sinus tachycardia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tachycardia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ventricular extrasystoles	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ventricular pre-excitation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Congenital, familial and genetic disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gilbert's syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hydrocele	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Ear and labyrinth disorders	-Total	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Ear congestion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ear discomfort	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ear pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6

	Tinnitus	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vertigo	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	2	11.1	3.1	32.8
Endocrine disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyperthyroidism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypothyroidism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Eye disorders	-Total	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	25	18.5	12.9	25.9
		Unknown	18	6.4	3	16.7	5.8	39.2
	Abnormal sensation in eye	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blepharitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chalazion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Conjunctival cyst	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Conjunctival haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diplopia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dry eye	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Eye swelling	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eyelid oedema	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Eyelid ptosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Keratitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ocular discomfort	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Periorbital oedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Photophobia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Photopsia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ulcerative keratitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vision blurred	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Visual acuity reduced	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Gastrointestinal disorders	-Total	Asian	128	45.6	82	64.1	55.5	71.9
		Non-Asian	135	48.0	103	76.3	68.5	82.7
		Unknown	18	6.4	14	77.8	54.8	91.0
	Abdominal discomfort	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal distension	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal pain	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	1	5.6	1.0	25.8
	Abdominal pain lower	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal pain upper	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Abdominal symptom	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anal incontinence	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aphthous ulcer	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ascites	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Constipation	Asian	128	45.6	54	42.2	34.0	50.8
		Non-Asian	135	48.0	54	40.0	32.1	48.4
		Unknown	18	6.4	8	44.4	24.6	66.3
	Dental dysaesthesia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diarrhoea	Asian	128	45.6	23	18.0	12.3	25.5
		Non-Asian	135	48.0	38	28.1	21.2	36.3
		Unknown	18	6.4	4	22.2	9.0	45.2
	Dry mouth	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	32	23.7	17.3	31.5
		Unknown	18	6.4	4	22.2	9.0	45.2
	Dyspepsia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	3	16.7	5.8	39.2
	Dysphagia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	15	11.1	6.9	17.5
		Unknown	18	6.4	1	5.6	1.0	25.8
	Enteritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epigastric discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eructation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Faeces soft	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Flatulence	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Frequent bowel movements	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastric ulcer	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastritis erosive	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal haemorrhage	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal inflammation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal oedema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal wall thickening	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrooesophageal reflux disease	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Gingival bleeding	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gingival swelling	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Glossitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Glossodynia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematochezia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhoids	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoaesthesia oral	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

	Impaired gastric emptying	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Irritable bowel syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Melaena	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mouth ulceration	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nausea	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	23	17.0	11.6	24.3
		Unknown	18	6.4	3	16.7	5.8	39.2
	Odynophagia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oesophageal irritation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oesophagitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral dysaesthesia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral mucosal erythema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancreatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Paraesthesia oral	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rectal prolapse	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Regurgitation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sensitivity of teeth	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Stomatitis	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Swollen tongue	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tongue coated	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tongue discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tongue ulceration	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tooth discolouration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Toothache	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vomiting	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	2	11.1	3.1	32.8
General disorders and administration site conditions	-Total	Asian	128	45.6	82	64.1	55.5	71.9
		Non-Asian	135	48.0	99	73.3	65.3	80.1
		Unknown	18	6.4	11	61.1	38.6	79.7
	Asthenia	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	22	16.3	11.0	23.4
		Unknown	18	6.4	5	27.8	12.5	50.9
	Axillary pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Catheter site pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chest discomfort	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chest pain	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chills	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Face oedema	Asian	128	45.6	17	13.3	8.5	20.2
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Facial pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fatigue	Asian	128	45.6	18	14.1	9.1	21.1
		Non-Asian	135	48.0	40	29.6	22.6	37.8
		Unknown	18	6.4	3	16.7	5.8	39.2
	Feeling abnormal	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Feeling cold	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Feeling hot	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gait disturbance	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	General physical health deterioration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Generalised oedema	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Impaired healing	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Influenza like illness	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Injection site bruising	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Localised oedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Malaise	Asian	128	45.6	18	14.1	9.1	21.1
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	1	5.6	1.0	25.8
	Mucosal dryness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mucosal inflammation	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Non-cardiac chest pain	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Oedema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oedema peripheral	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	25	18.5	12.9	25.9
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pain	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Peripheral swelling	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pyrexia	Asian	128	45.6	36	28.1	21.1	36.5
		Non-Asian	135	48.0	31	23.0	16.7	30.7
		Unknown	18	6.4	4	22.2	9.0	45.2
	Swelling	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Temperature intolerance	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Xerosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Hepatobiliary disorders	-Total	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	3	16.7	5.8	39.2
	Cholecystitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatic function abnormal	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatic steatosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Hepatocellular injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	3	16.7	5.8	39.2
	Hyperbilirubinaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Liver disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumobilia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Portal vein thrombosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Immune system disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Contrast media allergy	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Drug hypersensitivity	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Food allergy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypersensitivity	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Seasonal allergy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Infections and infestations	-Total	Asian	128	45.6	44	34.4	26.7	43.0
		Non-Asian	135	48.0	71	52.6	44.2	60.8
		Unknown	18	6.4	7	38.9	20.3	61.4
	Abdominal abscess	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Acute sinusitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Arthritis infective	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Atypical pneumonia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Bacterial disease carrier	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bacterial vaginosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bronchitis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Candida infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cellulitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chronic sinusitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Conjunctivitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Corona virus infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis escherichia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ear infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Epididymitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epstein-Barr virus infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Escherichia bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Escherichia infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Escherichia urinary tract infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eye infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Febrile infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Folliculitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fungal infection	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastroenteritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Genital candidiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Genital herpes	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gingivitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Herpes simplex	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Herpes virus infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Herpes zoster	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Influenza	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2

		Unknown	18	6.4	0	0.0	0.0	17.6
	Lower respiratory tract infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lung infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Lyme disease	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymph node tuberculosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal herpes	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasopharyngitis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral candidiasis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral fungal infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oropharyngeal candidiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Otitis externa	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Otitis media	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Paronychia	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pharyngitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia influenzal	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Pneumonia pseudomonal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumonia streptococcal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyelonephritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyuria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory tract infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory tract infection bacterial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sepsis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinusitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Skin infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Staphylococcal infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Systemic infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinea cruris	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinea infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinea pedis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Tonsillitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tooth infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tracheitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tuberculosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Upper respiratory tract infection	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urethritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary tract infection	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	21	15.6	10.4	22.6
		Unknown	18	6.4	1	5.6	1.0	25.8
	Varicella	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Varicella zoster virus infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Viral hepatitis carrier	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Viral infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vulvovaginal candidiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Injury, poisoning and procedural complications	-Total	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	18	13.3	8.6	20.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Contusion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epicondylitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fall	Asian	128	45.6	4	3.1	1.2	7.8

		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Incision site pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint dislocation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Laceration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ligament sprain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Limb injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle rupture	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle strain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Procedural pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Procedural pneumothorax	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rib fracture	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Scar	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin abrasion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tendon rupture	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Thermal burn	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wound	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wound complication	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wrist fracture	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Investigations	-Total	Asian	128	45.6	103	80.5	72.8	86.4
		Non-Asian	135	48.0	93	68.9	60.6	76.1
		Unknown	18	6.4	13	72.2	49.1	87.5
	Alanine aminotransferase increased	Asian	128	45.6	49	38.3	30.3	46.9
		Non-Asian	135	48.0	32	23.7	17.3	31.5
		Unknown	18	6.4	2	11.1	3.1	32.8
	Albumin urine present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alpha hydroxybutyrate dehydrogenase increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Amylase increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aspartate aminotransferase increased	Asian	128	45.6	63	49.2	40.7	57.8
		Non-Asian	135	48.0	44	32.6	25.3	40.9
		Unknown	18	6.4	4	22.2	9.0	45.2
	Bacterial test	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bilirubin conjugated increased	Asian	128	45.6	19	14.8	9.7	22.0
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood albumin decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood alkaline phosphatase	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood alkaline phosphatase decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Blood alkaline phosphatase increased	Asian	128	45.6	21	16.4	11.0	23.8
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood bilirubin increased	Asian	128	45.6	17	13.3	8.5	20.2
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Blood bilirubin unconjugated increased	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood calcium decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood calcium increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood chloride increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood cholesterol increased	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine phosphokinase MB increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine phosphokinase increased	Asian	128	45.6	25	19.5	13.6	27.2
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	3	16.7	5.8	39.2
	Blood creatinine	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatinine increased	Asian	128	45.6	23	18.0	12.3	25.5
		Non-Asian	135	48.0	33	24.4	18.0	32.3
		Unknown	18	6.4	4	22.2	9.0	45.2
	Blood fibrinogen increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood glucose increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood iron decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Blood ketone body increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood lactate dehydrogenase increased	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood magnesium decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood phosphorus increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood potassium decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood potassium increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood pressure increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood sodium decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood thyroid stimulating hormone increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood triglycerides increased	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood urea increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood uric acid decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood uric acid increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood urine	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood urine present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	C-reactive protein increased	Asian	128	45.6	3	2.3	0.8	6.7

		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Carbon dioxide decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Complement factor C1 decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Computerised tomogram thorax abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Crystal urine present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystatin C increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrocardiogram QT prolonged	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrocardiogram ST-T change	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fibrin D dimer increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fibrin degradation products increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Free fatty acids increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gamma-glutamyltransferase increased	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Glomerular filtration rate decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Glutamate dehydrogenase increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Granulocyte count decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematocrit decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemoglobin decreased	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Heart rate increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatic enzyme increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	International normalised ratio increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intraocular pressure increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Laboratory test abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Lipase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Liver function test increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphocyte count decreased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphocyte count increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mean cell volume increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Myoglobin blood increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutrophil count decreased	Asian	128	45.6	36	28.1	21.1	36.5
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Neutrophil count increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutrophil percentage increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Occult blood positive	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Platelet count decreased	Asian	128	45.6	18	14.1	9.1	21.1
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Platelet count increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Procalcitonin increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Protein total decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Protein total increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Protein urine present	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Prothrombin time prolonged	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Red blood cell count decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Serum amyloid A protein increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombin time prolonged	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Total bile acids increased	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Transaminases increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Transferrin increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Troponin T increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Troponin increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary sediment present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urine ketone body present	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urine leukocyte esterase positive	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urobilinogen urine increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Weight decreased	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Weight increased	Asian	128	45.6	17	13.3	8.5	20.2
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	White blood cell count decreased	Asian	128	45.6	34	26.6	19.7	34.8
		Non-Asian	135	48.0	20	14.8	9.8	21.8
		Unknown	18	6.4	3	16.7	5.8	39.2
	White blood cells urine positive	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Metabolism and nutrition disorders	-Total	Asian	128	45.6	73	57.0	48.4	65.3
		Non-Asian	135	48.0	58	43.0	34.9	51.4
		Unknown	18	6.4	7	38.9	20.3	61.4
	Abnormal loss of weight	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alkalosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cell death	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Decreased appetite	Asian	128	45.6	24	18.8	12.9	26.4
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dehydration	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Electrolyte imbalance	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fluid retention	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercalcaemia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercholesterolaemia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperglycaemia	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperkalaemia	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyperlipidaemia	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypermagnesaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypernatraemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperphosphataemia	Asian	128	45.6	15	11.7	7.2	18.4
		Non-Asian	135	48.0	16	11.9	7.4	18.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypertriglyceridaemia	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperuricaemia	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoalbuminaemia	Asian	128	45.6	32	25.0	18.3	33.2
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypocalcaemia	Asian	128	45.6	18	14.1	9.1	21.1
		Non-Asian	135	48.0	12	8.9	5.2	14.9
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypochloraemia	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoglycaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypokalaemia	Asian	128	45.6	14	10.9	6.6	17.5
		Non-Asian	135	48.0	15	11.1	6.9	17.5
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypomagnesaemia	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyponatraemia	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypophosphataemia	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypoproteinaemia	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Increased appetite	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vitamin D deficiency	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Musculoskeletal and connective tissue disorders	-Total	Asian	128	45.6	47	36.7	28.9	45.3
		Non-Asian	135	48.0	63	46.7	38.5	55.1
		Unknown	18	6.4	9	50.0	29.0	71.0
	Arthralgia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Arthropathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Back pain	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	21	15.6	10.4	22.6
		Unknown	18	6.4	2	11.1	3.1	32.8
	Bone pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bursitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Coccydynia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Costochondritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Flank pain	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Groin pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercreatinaemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intervertebral disc protrusion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint range of motion decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint stiffness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint swelling	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Muscle fatigue	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle spasms	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	3	16.7	5.8	39.2
	Muscular weakness	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Musculoskeletal chest pain	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Musculoskeletal pain	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	2	11.1	3.1	32.8
	Musculoskeletal stiffness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Myalgia	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	2	11.1	3.1	32.8
	Myopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

	Neck pain	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Osteopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain in extremity	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain in jaw	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Rotator cuff syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Spinal column stenosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Spinal osteoarthritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tendon disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tendon pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anogenital warts	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Basal cell carcinoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bowen's disease	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Metastases to central nervous system	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal cell carcinoma	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Squamous cell carcinoma	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Squamous cell carcinoma of skin	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tumour pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Nervous system disorders	-Total	Asian	128	45.6	58	45.3	37.0	53.9
		Non-Asian	135	48.0	75	55.6	47.1	63.7
		Unknown	18	6.4	8	44.4	24.6	66.3
	Ageusia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aphasia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ataxia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Balance disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Brain oedema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebellar haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Disturbance in attention	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dizziness	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	19	14.1	9.2	20.9
		Unknown	18	6.4	2	11.1	3.1	32.8
	Dizziness postural	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysarthria	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysgeusia	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	29	21.5	15.4	29.1
		Unknown	18	6.4	3	16.7	5.8	39.2
	Dyskinesia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Headache	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	20	14.8	9.8	21.8
		Unknown	18	6.4	4	22.2	9.0	45.2
	Hemiplegia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperaesthesia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Hypersomnia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoaesthesia	Asian	128	45.6	17	13.3	8.5	20.2
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypotonia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lethargy	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lumbar radiculopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Memory impairment	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Migraine with aura	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Neuralgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neuropathy peripheral	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Paraesthesia	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	Paralysis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Parosmia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Peripheral sensory neuropathy	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Polyneuropathy chronic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Post herpetic neuralgia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Presyncope	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Psychomotor skills impaired	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Restless legs syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sciatica	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Seizure	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sensory disturbance	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Slow speech	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Somnolence	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Syncope	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tension headache	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tremor	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Visual field defect	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

Product issues	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Device dislocation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Psychiatric disorders	-Total	Asian	128	45.6	26	20.3	14.3	28.1
		Non-Asian	135	48.0	24	17.8	12.2	25.1
		Unknown	18	6.4	4	22.2	9.0	45.2
	Abnormal behaviour	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abnormal dreams	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Adjustment disorder with mixed anxiety and depressed mood	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anxiety	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bradyphrenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Confusional state	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Delirium	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Depressed mood	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Depression	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Fear of falling	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Insomnia	Asian	128	45.6	17	13.3	8.5	20.2
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Irritability	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Libido decreased	Asian	128	45.6	2	1.6	0.4	5.5

		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mental status changes	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mood altered	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Psychomotor retardation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Restlessness	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sleep disorder	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Renal and urinary disorders	-Total	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	24	17.8	12.2	25.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Acute kidney injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Azotaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis haemorrhagic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysuria	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematuria	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhage urinary tract	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Micturition urgency	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nephritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nocturia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2

		Unknown	18	6.4	0	0.0	0.0	17.6
	Pollakiuria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Proteinuria	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal colic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal impairment	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Strangury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary incontinence	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary retention	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Urinary tract pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urine flow decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Reproductive system and breast disorders	-Total	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	Benign prostatic hyperplasia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Breast discharge	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Erectile dysfunction	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	1	5.6	1.0	25.8

	Galactorrhoea	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Genital ulceration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Metrorrhagia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pelvic discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pelvic fluid collection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Perineal pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Postmenopausal haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Prostatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Uterine polyp	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vaginal haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vulvovaginal dryness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vulvovaginal erythema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Respiratory, thoracic and mediastinal disorders	-Total	Asian	128	45.6	67	52.3	43.7	60.8
		Non-Asian	135	48.0	78	57.8	49.3	65.8
		Unknown	18	6.4	8	44.4	24.6	66.3
	Aspiration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bronchospasm	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Choking	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cough	Asian	128	45.6	29	22.7	16.3	30.6
		Non-Asian	135	48.0	31	23.0	16.7	30.7
		Unknown	18	6.4	4	22.2	9.0	45.2
	Dry throat	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysphonia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dyspnoea	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	21	15.6	10.4	22.6
		Unknown	18	6.4	2	11.1	3.1	32.8
	Dyspnoea exertional	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epistaxis	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Haemoptysis	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hiccups	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoxia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Interstitial lung disease	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Laryngeal haemorrhage	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal congestion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal dryness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal polyps	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oropharyngeal discomfort	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oropharyngeal pain	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	0	0.0	0.0	17.6
	Paranasal sinus discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pharyngeal disorder	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleural effusion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pleural thickening	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleuritic pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonitis	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumothorax	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Productive cough	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary embolism	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary mass	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiration abnormal	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinalgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinitis allergic	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinorrhoea	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinus congestion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sleep apnoea syndrome	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sputum discoloured	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Throat irritation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Upper-airway cough syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Vocal cord leukoplakia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wheezing	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Skin and subcutaneous tissue disorders	-Total	Asian	128	45.6	42	32.8	25.3	41.3
		Non-Asian	135	48.0	50	37.0	29.4	45.4
		Unknown	18	6.4	8	44.4	24.6	66.3
	Acne	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alopecia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chloasma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Decubitus ulcer	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermal cyst	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Dermatitis acneiform	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dermatitis allergic	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermatitis bullous	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dry skin	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Ecchymosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eczema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Erythema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hair growth abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hair texture abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hirsutism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyperhidrosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyperkeratosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypertrichosis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Madarosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nail discolouration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Nail disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Night sweats	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Onychalgia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Onycholysis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Onychomadesis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain of skin	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Palmar-plantar erythrodysaesthesia syndrome	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Photosensitivity reaction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pruritus	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pruritus generalised	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Purpura	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rash	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Rash erythematous	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rash macular	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Rash maculo-papular	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rash papular	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Scab	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Scar pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin discolouration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin hyperpigmentation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin lesion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Swelling face	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Urticaria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Surgical and medical procedures	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Astringent therapy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Therapy cessation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Vascular disorders	-Total	Asian	128	45.6	34	26.6	19.7	34.8
		Non-Asian	135	48.0	33	24.4	18.0	32.3
		Unknown	18	6.4	5	27.8	12.5	50.9
	Aortic dissection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Circulatory collapse	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Deep vein thrombosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Embolism	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2

		Unknown	18	6.4	0	0.0	0.0	17.6
	Flushing	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hot flush	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypertension	Asian	128	45.6	30	23.4	16.9	31.5
		Non-Asian	135	48.0	18	13.3	8.6	20.1
		Unknown	18	6.4	3	16.7	5.8	39.2
	Hypotension	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphoedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Orthostatic hypotension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pallor	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Phlebitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Raynaud's phenomenon	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Superior vena cava syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombophlebitis superficial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR12_SG.xls
26MAR2021 14:20

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1-2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Female	152	54.1	77	50.7	42.8	58.5
		Male	129	45.9	48	37.2	29.4	45.8
	Anaemia	Female	152	54.1	51	33.6	26.5	41.4
		Male	129	45.9	32	24.8	18.2	32.9
	Aplastic anaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bone marrow oedema	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cytopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Febrile neutropenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hyperfibrinogenaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Leukocytosis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Leukopenia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	10	7.8	4.3	13.7
	Lymph node pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lymphadenopathy	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Lymphopenia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Neutropenia	Female	152	54.1	21	13.8	9.2	20.2
		Male	129	45.9	10	7.8	4.3	13.7
	Neutrophilia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pancytopenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Thrombocytopenia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	4	3.1	1.2	7.7
	Thrombocytosis	Female	152	54.1	5	3.3	1.4	7.5

		Male	129	45.9	0	0.0	0.0	2.9
Cardiac disorders	-Total	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	18	14.0	9.0	21.0
	Acute coronary syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Angina pectoris	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Aortic valve calcification	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Atrial fibrillation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Atrial flutter	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Bradycardia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Bundle branch block right	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cardiac failure	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Extrasystoles	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Myocardial ischaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Nodal arrhythmia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Palpitations	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Pericardial effusion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Sinus bradycardia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Sinus tachycardia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Tachycardia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Ventricular extrasystoles	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Ventricular pre-excitation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Congenital, familial and genetic disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5

	Gilbert's syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hydrocele	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Ear and labyrinth disorders	-Total	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	9	7.0	3.7	12.7
	Ear congestion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Ear discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Ear pain	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Tinnitus	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Vertigo	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	3	2.3	0.8	6.6
Endocrine disorders	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperthyroidism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypothyroidism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Eye disorders	-Total	Female	152	54.1	29	19.1	13.6	26.1
		Male	129	45.9	9	7.0	3.7	12.7
	Abnormal sensation in eye	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blepharitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Chalazion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Conjunctival cyst	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Conjunctival haemorrhage	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Diplopia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dry eye	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Eye swelling	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9

	Eyelid oedema	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	0	0.0	0.0	2.9
	Eyelid ptosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Keratitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ocular discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Periorbital oedema	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Photophobia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Photopsia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Ulcerative keratitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vision blurred	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	1	0.8	0.1	4.3
	Visual acuity reduced	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Gastrointestinal disorders	-Total	Female	152	54.1	116	76.3	69.0	82.4
		Male	129	45.9	83	64.3	55.8	72.1
	Abdominal discomfort	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Abdominal distension	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	2	1.6	0.4	5.5
	Abdominal pain	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	5	3.9	1.7	8.8
	Abdominal pain lower	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Abdominal pain upper	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	8	6.2	3.2	11.8
	Abdominal symptom	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Anal incontinence	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Aphthous ulcer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ascites	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Constipation	Female	152	54.1	70	46.1	38.3	54.0

		Male	129	45.9	46	35.7	27.9	44.2
	Dental dysaesthesia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Diarrhoea	Female	152	54.1	38	25.0	18.8	32.4
		Male	129	45.9	27	20.9	14.8	28.7
	Dry mouth	Female	152	54.1	28	18.4	13.1	25.3
		Male	129	45.9	19	14.7	9.6	21.9
	Dyspepsia	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	3	2.3	0.8	6.6
	Dysphagia	Female	152	54.1	15	9.9	6.1	15.6
		Male	129	45.9	5	3.9	1.7	8.8
	Enteritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Epigastric discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Eructation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Faeces soft	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Flatulence	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Frequent bowel movements	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastric ulcer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastritis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastritis erosive	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrointestinal haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrointestinal inflammation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrointestinal oedema	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gastrointestinal wall thickening	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrooesophageal reflux disease	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	4	3.1	1.2	7.7
	Gingival bleeding	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3

	Gingival swelling	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Glossitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Glossodynia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haematochezia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Haemorrhoids	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hypoaesthesia oral	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Impaired gastric emptying	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Irritable bowel syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Melaena	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Mouth ulceration	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	3	2.3	0.8	6.6
	Nausea	Female	152	54.1	31	20.4	14.8	27.5
		Male	129	45.9	11	8.5	4.8	14.6
	Odynophagia	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	0	0.0	0.0	2.9
	Oesophageal irritation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oesophagitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Oral disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Oral dysaesthesia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oral mucosal erythema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Oral pain	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	1	0.8	0.1	4.3
	Pancreatitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Paraesthesia oral	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Rectal prolapse	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Regurgitation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Sensitivity of teeth	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Stomatitis	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	2	1.6	0.4	5.5
	Swollen tongue	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tongue coated	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tongue discomfort	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tongue ulceration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tooth discolouration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Toothache	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	5	3.9	1.7	8.8
	Vomiting	Female	152	54.1	19	12.5	8.2	18.7
		Male	129	45.9	10	7.8	4.3	13.7
General disorders and administration site conditions	-Total	Female	152	54.1	111	73.0	65.5	79.4
		Male	129	45.9	81	62.8	54.2	70.6
	Asthenia	Female	152	54.1	25	16.4	11.4	23.2
		Male	129	45.9	12	9.3	5.4	15.6
	Axillary pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Catheter site pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Chest discomfort	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	2	1.6	0.4	5.5
	Chest pain	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	5	3.9	1.7	8.8
	Chills	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Face oedema	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	5	3.9	1.7	8.8
	Facial pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Fatigue	Female	152	54.1	29	19.1	13.6	26.1

		Male	129	45.9	32	24.8	18.2	32.9
	Feeling abnormal	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Feeling cold	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Feeling hot	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gait disturbance	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	General physical health deterioration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Generalised oedema	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Impaired healing	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Influenza like illness	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Injection site bruising	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Localised oedema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Malaise	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	9	7.0	3.7	12.7
	Mucosal dryness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Mucosal inflammation	Female	152	54.1	18	11.8	7.6	17.9
		Male	129	45.9	3	2.3	0.8	6.6
	Non-cardiac chest pain	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	4	3.1	1.2	7.7
	Oedema	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Oedema peripheral	Female	152	54.1	26	17.1	11.9	23.9
		Male	129	45.9	16	12.4	7.8	19.2
	Pain	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Peripheral swelling	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Pyrexia	Female	152	54.1	41	27.0	20.6	34.5
		Male	129	45.9	30	23.3	16.8	31.3
	Swelling	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Temperature intolerance	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Xerosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Hepatobiliary disorders	-Total	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	13	10.1	6.0	16.5
	Cholecystitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Hepatic function abnormal	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hepatic steatosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hepatocellular injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Hyperbilirubinaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	5	3.9	1.7	8.8
	Liver disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumobilia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Portal vein thrombosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Immune system disorders	-Total	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Contrast media allergy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Drug hypersensitivity	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Food allergy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypersensitivity	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Seasonal allergy	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
Infections and infestations	-Total	Female	152	54.1	73	48.0	40.2	55.9
		Male	129	45.9	49	38.0	30.1	46.6
	Abdominal abscess	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Acute sinusitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Arthritis infective	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Atypical pneumonia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bacteraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Bacterial disease carrier	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Bacterial vaginosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bronchitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	Candida infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cellulitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Chronic sinusitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Conjunctivitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Corona virus infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cystitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Cystitis escherichia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ear infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Epididymitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Epstein-Barr virus infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Escherichia bacteraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Escherichia infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Escherichia urinary tract infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Eye infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Febrile infection	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Folliculitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Fungal infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Gastroenteritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Genital candidiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Genital herpes	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Gingivitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Herpes simplex	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Herpes virus infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Herpes zoster	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	4	3.1	1.2	7.7
	Infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Influenza	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lower respiratory tract infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lung infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lyme disease	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lymph node tuberculosis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Nasal herpes	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nasopharyngitis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	5	3.9	1.7	8.8
	Oral candidiasis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	5	3.9	1.7	8.8
	Oral fungal infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Oropharyngeal candidiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Otitis externa	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Otitis media	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Paronychia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Pharyngitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Pneumonia	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	9	7.0	3.7	12.7
	Pneumonia influenzal	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonia pseudomonal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pneumonia streptococcal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pyelonephritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pyuria	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Respiratory tract infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Respiratory tract infection bacterial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rhinitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Sepsis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sinusitis	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	1	0.8	0.1	4.3
	Skin infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Staphylococcal infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Systemic infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tinea cruris	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tinea infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Tinea pedis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Tonsillitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tooth infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tracheitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tuberculosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Upper respiratory tract infection	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	4	3.1	1.2	7.7
	Urethritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urinary tract infection	Female	152	54.1	23	15.1	10.3	21.7
		Male	129	45.9	6	4.7	2.1	9.8
	Varicella	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Varicella zoster virus infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Viral hepatitis carrier	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Viral infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Vulvovaginal candidiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Injury, poisoning and procedural complications	-Total	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	14	10.9	6.6	17.4
	Contusion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	4	3.1	1.2	7.7
	Epicondylitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Fall	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	6	4.7	2.1	9.8
	Incision site pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Joint dislocation	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Laceration	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Ligament sprain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Limb injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Muscle rupture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Muscle strain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Procedural pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Procedural pneumothorax	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rib fracture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Scar	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin abrasion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tendon rupture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Thermal burn	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Wound	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Wound complication	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Wrist fracture	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Investigations	-Total	Female	152	54.1	118	77.6	70.4	83.5
		Male	129	45.9	91	70.5	62.2	77.7
	Alanine aminotransferase increased	Female	152	54.1	50	32.9	25.9	40.7
		Male	129	45.9	33	25.6	18.8	33.7
	Albumin urine present	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Alpha hydroxybutyrate dehydrogenase increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Amylase increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3

	Aspartate aminotransferase increased	Female	152	54.1	65	42.8	35.2	50.7
		Male	129	45.9	46	35.7	27.9	44.2
	Bacterial test	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bilirubin conjugated increased	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	6	4.7	2.1	9.8
	Blood albumin decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood alkaline phosphatase	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood alkaline phosphatase decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood alkaline phosphatase increased	Female	152	54.1	21	13.8	9.2	20.2
		Male	129	45.9	10	7.8	4.3	13.7
	Blood bilirubin increased	Female	152	54.1	18	11.8	7.6	17.9
		Male	129	45.9	7	5.4	2.7	10.8
	Blood bilirubin unconjugated increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	4	3.1	1.2	7.7
	Blood calcium decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Blood calcium increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood chloride increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood cholesterol increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	4	3.1	1.2	7.7
	Blood creatine increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Blood creatine phosphokinase MB increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Blood creatine phosphokinase increased	Female	152	54.1	26	17.1	11.9	23.9
		Male	129	45.9	8	6.2	3.2	11.8
	Blood creatinine	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood creatinine increased	Female	152	54.1	26	17.1	11.9	23.9
		Male	129	45.9	34	26.4	19.5	34.6
	Blood fibrinogen increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood glucose increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3

	Blood iron decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood ketone body increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood lactate dehydrogenase increased	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	2	1.6	0.4	5.5
	Blood magnesium decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood phosphorus increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Blood potassium decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood potassium increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood pressure increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Blood sodium decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood thyroid stimulating hormone increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood triglycerides increased	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Blood urea increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Blood uric acid decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood uric acid increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Blood urine	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Blood urine present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	C-reactive protein increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Carbon dioxide decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Complement factor C1 decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Computerised tomogram thorax abnormal	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Crystal urine present	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
	Cystatin C increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Electrocardiogram QT prolonged	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	2	1.6	0.4	5.5
	Electrocardiogram ST-T change	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Fibrin D dimer increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Fibrin degradation products increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Free fatty acids increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gamma-glutamyltransferase increased	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	4	3.1	1.2	7.7
	Glomerular filtration rate decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Glutamate dehydrogenase increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Granulocyte count decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haematocrit decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haemoglobin decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Heart rate increased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hepatic enzyme increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	International normalised ratio increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Intraocular pressure increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Laboratory test abnormal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lipase increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Liver function test increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Lymphocyte count decreased	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	4	3.1	1.2	7.7

	Lymphocyte count increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Mean cell volume increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Myoglobin blood increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Neutrophil count decreased	Female	152	54.1	27	17.8	12.5	24.6
		Male	129	45.9	18	14.0	9.0	21.0
	Neutrophil count increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Neutrophil percentage increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Occult blood positive	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Platelet count decreased	Female	152	54.1	19	12.5	8.2	18.7
		Male	129	45.9	6	4.7	2.1	9.8
	Platelet count increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Procalcitonin increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Protein total decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Protein total increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Protein urine present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Prothrombin time prolonged	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Red blood cell count decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Serum amyloid A protein increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombin time prolonged	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Total bile acids increased	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	4	3.1	1.2	7.7
	Transaminases increased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	Transferrin increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Troponin T increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Troponin increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urinary sediment present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urine ketone body present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Urine leukocyte esterase positive	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urobilinogen urine increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Weight decreased	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	4	3.1	1.2	7.7
	Weight increased	Female	152	54.1	15	9.9	6.1	15.6
		Male	129	45.9	9	7.0	3.7	12.7
	White blood cell count decreased	Female	152	54.1	34	22.4	16.5	29.6
		Male	129	45.9	23	17.8	12.2	25.3
	White blood cells urine positive	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
Metabolism and nutrition disorders	-Total	Female	152	54.1	83	54.6	46.7	62.3
		Male	129	45.9	55	42.6	34.4	51.3
	Abnormal loss of weight	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Alkalosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cell death	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Decreased appetite	Female	152	54.1	20	13.2	8.7	19.5
		Male	129	45.9	16	12.4	7.8	19.2
	Dehydration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	4	3.1	1.2	7.7
	Electrolyte imbalance	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Fluid retention	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypercalcaemia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Hypercholesterolaemia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Hyperglycaemia	Female	152	54.1	11	7.2	4.1	12.5

		Male	129	45.9	7	5.4	2.7	10.8
	Hyperkalaemia	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	7	5.4	2.7	10.8
	Hyperlipidaemia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hypermagnesaemia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hypernatraemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Hyperphosphataemia	Female	152	54.1	23	15.1	10.3	21.7
		Male	129	45.9	8	6.2	3.2	11.8
	Hypertriglyceridaemia	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Hyperuricaemia	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	4	3.1	1.2	7.7
	Hypoalbuminaemia	Female	152	54.1	25	16.4	11.4	23.2
		Male	129	45.9	12	9.3	5.4	15.6
	Hypocalcaemia	Female	152	54.1	21	13.8	9.2	20.2
		Male	129	45.9	10	7.8	4.3	13.7
	Hypochloraemia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Hypoglycaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypokalaemia	Female	152	54.1	18	11.8	7.6	17.9
		Male	129	45.9	11	8.5	4.8	14.6
	Hypomagnesaemia	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	8	6.2	3.2	11.8
	Hyponatraemia	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	7	5.4	2.7	10.8
	Hypophosphataemia	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	7	5.4	2.7	10.8
	Hypoproteinaemia	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	1	0.8	0.1	4.3
	Increased appetite	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Vitamin D deficiency	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Musculoskeletal and connective tissue disorders	-Total	Female	152	54.1	69	45.4	37.7	53.3
		Male	129	45.9	50	38.8	30.8	47.4
	Arthralgia	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	5	3.9	1.7	8.8

	Arthropathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Back pain	Female	152	54.1	19	12.5	8.2	18.7
		Male	129	45.9	16	12.4	7.8	19.2
	Bone pain	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Bursitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Coccydynia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Costochondritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Flank pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Groin pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypercreatinaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Intervertebral disc protrusion	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Joint range of motion decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Joint stiffness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Joint swelling	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Muscle fatigue	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Muscle spasms	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	8	6.2	3.2	11.8
	Muscular weakness	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	2	1.6	0.4	5.5
	Musculoskeletal chest pain	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	4	3.1	1.2	7.7
	Musculoskeletal pain	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	11	8.5	4.8	14.6
	Musculoskeletal stiffness	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Myalgia	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	7	5.4	2.7	10.8

	Myopathy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Neck pain	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	5	3.9	1.7	8.8
	Osteopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pain in extremity	Female	152	54.1	17	11.2	7.1	17.2
		Male	129	45.9	8	6.2	3.2	11.8
	Pain in jaw	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Rotator cuff syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Spinal column stenosis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Spinal osteoarthritis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tendon disorder	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tendon pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	4	3.1	1.2	7.7
	Anogenital warts	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Basal cell carcinoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Bowen's disease	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Metastases to central nervous system	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Renal cell carcinoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Squamous cell carcinoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Squamous cell carcinoma of skin	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tumour pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Nervous system disorders	-Total	Female	152	54.1	79	52.0	44.1	59.8
		Male	129	45.9	62	48.1	39.6	56.6
	Ageusia	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	1	0.8	0.1	4.3
	Aphasia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Ataxia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Balance disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Brain oedema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cerebellar haemorrhage	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Disturbance in attention	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Dizziness	Female	152	54.1	20	13.2	8.7	19.5
		Male	129	45.9	17	13.2	8.4	20.1
	Dizziness postural	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dysarthria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dysgeusia	Female	152	54.1	24	15.8	10.8	22.4
		Male	129	45.9	18	14.0	9.0	21.0
	Dyskinesia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Headache	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	16	12.4	7.8	19.2
	Hemiplegia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperaesthesia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypersomnia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypoaesthesia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	6	4.7	2.1	9.8
	Hypotonia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lethargy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lumbar radiculopathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Memory impairment	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5

	Migraine with aura	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neuralgia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neuropathy peripheral	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	5	3.9	1.7	8.8
	Paraesthesia	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	6	4.7	2.1	9.8
	Paralysis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Parosmia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Peripheral sensory neuropathy	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	3	2.3	0.8	6.6
	Polyneuropathy chronic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Post herpetic neuralgia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Presyncope	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Psychomotor skills impaired	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Restless legs syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Sciatica	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Seizure	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Sensory disturbance	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Slow speech	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Somnolence	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Syncope	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Tension headache	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tremor	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Visual field defect	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
Product issues	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Device dislocation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Psychiatric disorders	-Total	Female	152	54.1	29	19.1	13.6	26.1
		Male	129	45.9	25	19.4	13.5	27.0
	Abnormal behaviour	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Abnormal dreams	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Adjustment disorder with mixed anxiety and depressed mood	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Anxiety	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	4	3.1	1.2	7.7
	Bradyphrenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Confusional state	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	4	3.1	1.2	7.7
	Delirium	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Depressed mood	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Depression	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Fear of falling	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Insomnia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	8	6.2	3.2	11.8
	Irritability	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Libido decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Mental status changes	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Mood altered	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Psychomotor retardation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Restlessness	Female	152	54.1	4	2.6	1.0	6.6

		Male	129	45.9	1	0.8	0.1	4.3
	Sleep disorder	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Renal and urinary disorders	-Total	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	25	19.4	13.5	27.0
	Acute kidney injury	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Azotaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cystitis haemorrhagic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dysuria	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	6	4.7	2.1	9.8
	Haematuria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Haemorrhage urinary tract	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Micturition urgency	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Nephritis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Nocturia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Pollakiuria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Proteinuria	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Renal colic	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Renal disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Renal failure	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Renal impairment	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Strangury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urinary incontinence	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Urinary retention	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	4	3.1	1.2	7.7

	Urinary tract pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urine flow decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Reproductive system and breast disorders	-Total	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	14	10.9	6.6	17.4
	Benign prostatic hyperplasia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Breast discharge	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Erectile dysfunction	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	9	7.0	3.7	12.7
	Galactorrhoea	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Genital ulceration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Metrorrhagia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pelvic discomfort	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pelvic fluid collection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Perineal pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Postmenopausal haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Prostatitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Uterine polyp	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vaginal haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vulvovaginal dryness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vulvovaginal erythema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Respiratory, thoracic and mediastinal disorders	-Total	Female	152	54.1	86	56.6	48.6	64.2
		Male	129	45.9	67	51.9	43.4	60.4
	Aspiration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Bronchospasm	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Choking	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cough	Female	152	54.1	34	22.4	16.5	29.6
		Male	129	45.9	30	23.3	16.8	31.3
	Dry throat	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Dysphonia	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	5	3.9	1.7	8.8
	Dyspnoea	Female	152	54.1	21	13.8	9.2	20.2
		Male	129	45.9	18	14.0	9.0	21.0
	Dyspnoea exertional	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	8	6.2	3.2	11.8
	Epistaxis	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	6	4.7	2.1	9.8
	Haemoptysis	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	5	3.9	1.7	8.8
	Hiccups	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hypoxia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Interstitial lung disease	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Laryngeal haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nasal congestion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Nasal dryness	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Nasal polyps	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oropharyngeal discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oropharyngeal pain	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	5	3.9	1.7	8.8
	Paranasal sinus discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pharyngeal disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pleural effusion	Female	152	54.1	5	3.3	1.4	7.5

		Male	129	45.9	2	1.6	0.4	5.5
	Pleural thickening	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pleuritic pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonitis	Female	152	54.1	18	11.8	7.6	17.9
		Male	129	45.9	8	6.2	3.2	11.8
	Pneumothorax	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Productive cough	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	7	5.4	2.7	10.8
	Pulmonary embolism	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pulmonary mass	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pulmonary pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Respiration abnormal	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rhinalgia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rhinitis allergic	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Rhinorrhoea	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Sinus congestion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sleep apnoea syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Sputum discoloured	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Throat irritation	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Upper-airway cough syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Vocal cord leukoplakia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Wheezing	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
Skin and subcutaneous tissue disorders	-Total	Female	152	54.1	63	41.4	33.9	49.4
		Male	129	45.9	37	28.7	21.6	37.0

	Acne	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Alopecia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	2	1.6	0.4	5.5
	Chloasma	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Decubitus ulcer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dermal cyst	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dermatitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dermatitis acneiform	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Dermatitis allergic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dermatitis bullous	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Dry skin	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	6	4.7	2.1	9.8
	Ecchymosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Eczema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Erythema	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Hair growth abnormal	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hair texture abnormal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hirsutism	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Hyperhidrosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Hyperkeratosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypertrichosis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Madarosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Nail discolouration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nail disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Night sweats	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Onychalgia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Onycholysis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Onychomadesis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Pain of skin	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Palmar-plantar erythrodysaesthesia syndrome	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	0	0.0	0.0	2.9
	Photosensitivity reaction	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pruritus	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	Pruritus generalised	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Purpura	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rash	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	7	5.4	2.7	10.8
	Rash erythematous	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Rash macular	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Rash maculo-papular	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Rash papular	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Scab	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Scar pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin discolouration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin hyperpigmentation	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
	Skin lesion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Swelling face	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urticaria	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Surgical and medical procedures	-Total	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Astringent therapy	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Therapy cessation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Vascular disorders	-Total	Female	152	54.1	39	25.7	19.4	33.1
		Male	129	45.9	33	25.6	18.8	33.7
	Aortic dissection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Circulatory collapse	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Deep vein thrombosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Embolism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Flushing	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Haematoma	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hot flush	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hypertension	Female	152	54.1	24	15.8	10.8	22.4
		Male	129	45.9	27	20.9	14.8	28.7
	Hypotension	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lymphoedema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Orthostatic hypotension	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pallor	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Phlebitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Raynaud's phenomenon	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Superior vena cava syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombophlebitis superficial	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR12_SG.xls
26MAR2021 14:20

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1-2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	n/a	281	100.0	125	44.5	38.8	50.3
	Anaemia	n/a	281	100.0	83	29.5	24.5	35.1
	Aplastic anaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Bone marrow oedema	n/a	281	100.0	1	0.4	0.1	2.0
	Cytopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Febrile neutropenia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperfibrinogenaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Leukocytosis	n/a	281	100.0	3	1.1	0.4	3.1
	Leukopenia	n/a	281	100.0	22	7.8	5.2	11.6
	Lymph node pain	n/a	281	100.0	1	0.4	0.1	2.0
	Lymphadenopathy	n/a	281	100.0	2	0.7	0.2	2.6
	Lymphopenia	n/a	281	100.0	6	2.1	1.0	4.6
	Neutropenia	n/a	281	100.0	31	11.0	7.9	15.2
	Neutrophilia	n/a	281	100.0	1	0.4	0.1	2.0
	Pancytopenia	n/a	281	100.0	2	0.7	0.2	2.6
	Thrombocytopenia	n/a	281	100.0	16	5.7	3.5	9.0
	Thrombocytosis	n/a	281	100.0	5	1.8	0.8	4.1
Cardiac disorders	-Total	n/a	281	100.0	34	12.1	8.8	16.4
	Acute coronary syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Angina pectoris	n/a	281	100.0	1	0.4	0.1	2.0
	Aortic valve calcification	n/a	281	100.0	1	0.4	0.1	2.0
	Atrial fibrillation	n/a	281	100.0	1	0.4	0.1	2.0
	Atrial flutter	n/a	281	100.0	2	0.7	0.2	2.6
	Bradycardia	n/a	281	100.0	1	0.4	0.1	2.0
	Bundle branch block right	n/a	281	100.0	1	0.4	0.1	2.0

	Cardiac failure	n/a	281	100.0	2	0.7	0.2	2.6
	Extrasystoles	n/a	281	100.0	1	0.4	0.1	2.0
	Myocardial ischaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Nodal arrhythmia	n/a	281	100.0	3	1.1	0.4	3.1
	Palpitations	n/a	281	100.0	4	1.4	0.6	3.6
	Pericardial effusion	n/a	281	100.0	3	1.1	0.4	3.1
	Sinus bradycardia	n/a	281	100.0	4	1.4	0.6	3.6
	Sinus tachycardia	n/a	281	100.0	2	0.7	0.2	2.6
	Tachycardia	n/a	281	100.0	7	2.5	1.2	5.1
	Ventricular extrasystoles	n/a	281	100.0	1	0.4	0.1	2.0
	Ventricular pre-excitation	n/a	281	100.0	1	0.4	0.1	2.0
Congenital, familial and genetic disorders	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Gilbert's syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Hydrocele	n/a	281	100.0	1	0.4	0.1	2.0
Ear and labyrinth disorders	-Total	n/a	281	100.0	20	7.1	4.7	10.7
	Ear congestion	n/a	281	100.0	2	0.7	0.2	2.6
	Ear discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Ear pain	n/a	281	100.0	4	1.4	0.6	3.6
	Tinnitus	n/a	281	100.0	4	1.4	0.6	3.6
	Vertigo	n/a	281	100.0	10	3.6	1.9	6.4
Endocrine disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Hyperthyroidism	n/a	281	100.0	1	0.4	0.1	2.0
	Hypothyroidism	n/a	281	100.0	2	0.7	0.2	2.6
Eye disorders	-Total	n/a	281	100.0	38	13.5	10.0	18.0
	Abnormal sensation in eye	n/a	281	100.0	1	0.4	0.1	2.0
	Blepharitis	n/a	281	100.0	1	0.4	0.1	2.0
	Chalazion	n/a	281	100.0	1	0.4	0.1	2.0
	Conjunctival cyst	n/a	281	100.0	1	0.4	0.1	2.0
	Conjunctival haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Diplopia	n/a	281	100.0	1	0.4	0.1	2.0

	Dry eye	n/a	281	100.0	7	2.5	1.2	5.1
	Eye swelling	n/a	281	100.0	2	0.7	0.2	2.6
	Eyelid oedema	n/a	281	100.0	5	1.8	0.8	4.1
	Eyelid ptosis	n/a	281	100.0	1	0.4	0.1	2.0
	Keratitis	n/a	281	100.0	1	0.4	0.1	2.0
	Ocular discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Periorbital oedema	n/a	281	100.0	6	2.1	1.0	4.6
	Photophobia	n/a	281	100.0	1	0.4	0.1	2.0
	Photopsia	n/a	281	100.0	2	0.7	0.2	2.6
	Ulcerative keratitis	n/a	281	100.0	1	0.4	0.1	2.0
	Vision blurred	n/a	281	100.0	14	5.0	3.0	8.2
	Visual acuity reduced	n/a	281	100.0	1	0.4	0.1	2.0
Gastrointestinal disorders	-Total	n/a	281	100.0	199	70.8	65.3	75.8
	Abdominal discomfort	n/a	281	100.0	5	1.8	0.8	4.1
	Abdominal distension	n/a	281	100.0	8	2.8	1.4	5.5
	Abdominal pain	n/a	281	100.0	18	6.4	4.1	9.9
	Abdominal pain lower	n/a	281	100.0	2	0.7	0.2	2.6
	Abdominal pain upper	n/a	281	100.0	14	5.0	3.0	8.2
	Abdominal symptom	n/a	281	100.0	1	0.4	0.1	2.0
	Anal incontinence	n/a	281	100.0	2	0.7	0.2	2.6
	Aphthous ulcer	n/a	281	100.0	1	0.4	0.1	2.0
	Ascites	n/a	281	100.0	3	1.1	0.4	3.1
	Constipation	n/a	281	100.0	116	41.3	35.7	47.1
	Dental dysaesthesia	n/a	281	100.0	1	0.4	0.1	2.0
	Diarrhoea	n/a	281	100.0	65	23.1	18.6	28.4
	Dry mouth	n/a	281	100.0	47	16.7	12.8	21.5
	Dyspepsia	n/a	281	100.0	9	3.2	1.7	6.0
	Dysphagia	n/a	281	100.0	20	7.1	4.7	10.7
	Enteritis	n/a	281	100.0	1	0.4	0.1	2.0
	Epigastric discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Eructation	n/a	281	100.0	1	0.4	0.1	2.0

	Faeces soft	n/a	281	100.0	1	0.4	0.1	2.0
	Flatulence	n/a	281	100.0	2	0.7	0.2	2.6
	Frequent bowel movements	n/a	281	100.0	1	0.4	0.1	2.0
	Gastric ulcer	n/a	281	100.0	1	0.4	0.1	2.0
	Gastritis	n/a	281	100.0	3	1.1	0.4	3.1
	Gastritis erosive	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal inflammation	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal oedema	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal wall thickening	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrooesophageal reflux disease	n/a	281	100.0	9	3.2	1.7	6.0
	Gingival bleeding	n/a	281	100.0	3	1.1	0.4	3.1
	Gingival swelling	n/a	281	100.0	1	0.4	0.1	2.0
	Glossitis	n/a	281	100.0	1	0.4	0.1	2.0
	Glossodynia	n/a	281	100.0	1	0.4	0.1	2.0
	Haematochezia	n/a	281	100.0	2	0.7	0.2	2.6
	Haemorrhoids	n/a	281	100.0	7	2.5	1.2	5.1
	Hypoaesthesia oral	n/a	281	100.0	5	1.8	0.8	4.1
	Impaired gastric emptying	n/a	281	100.0	1	0.4	0.1	2.0
	Irritable bowel syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Melaena	n/a	281	100.0	1	0.4	0.1	2.0
	Mouth ulceration	n/a	281	100.0	9	3.2	1.7	6.0
	Nausea	n/a	281	100.0	42	14.9	11.3	19.6
	Odynophagia	n/a	281	100.0	5	1.8	0.8	4.1
	Oesophageal irritation	n/a	281	100.0	1	0.4	0.1	2.0
	Oesophagitis	n/a	281	100.0	3	1.1	0.4	3.1
	Oral disorder	n/a	281	100.0	2	0.7	0.2	2.6
	Oral dysaesthesia	n/a	281	100.0	1	0.4	0.1	2.0
	Oral mucosal erythema	n/a	281	100.0	1	0.4	0.1	2.0
	Oral pain	n/a	281	100.0	7	2.5	1.2	5.1

	Pancreatitis	n/a	281	100.0	1	0.4	0.1	2.0
	Paraesthesia oral	n/a	281	100.0	1	0.4	0.1	2.0
	Rectal prolapse	n/a	281	100.0	1	0.4	0.1	2.0
	Regurgitation	n/a	281	100.0	1	0.4	0.1	2.0
	Sensitivity of teeth	n/a	281	100.0	1	0.4	0.1	2.0
	Stomatitis	n/a	281	100.0	8	2.8	1.4	5.5
	Swollen tongue	n/a	281	100.0	1	0.4	0.1	2.0
	Tongue coated	n/a	281	100.0	1	0.4	0.1	2.0
	Tongue discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Tongue ulceration	n/a	281	100.0	1	0.4	0.1	2.0
	Tooth discolouration	n/a	281	100.0	1	0.4	0.1	2.0
	Toothache	n/a	281	100.0	8	2.8	1.4	5.5
	Vomiting	n/a	281	100.0	29	10.3	7.3	14.4
General disorders and administration site conditions	-Total	n/a	281	100.0	193	68.7	63.0	73.8
	Asthenia	n/a	281	100.0	37	13.2	9.7	17.6
	Axillary pain	n/a	281	100.0	1	0.4	0.1	2.0
	Catheter site pain	n/a	281	100.0	1	0.4	0.1	2.0
	Chest discomfort	n/a	281	100.0	9	3.2	1.7	6.0
	Chest pain	n/a	281	100.0	8	2.8	1.4	5.5
	Chills	n/a	281	100.0	4	1.4	0.6	3.6
	Disease progression	n/a	281	100.0	2	0.7	0.2	2.6
	Face oedema	n/a	281	100.0	18	6.4	4.1	9.9
	Facial pain	n/a	281	100.0	1	0.4	0.1	2.0
	Fatigue	n/a	281	100.0	61	21.7	17.3	26.9
	Feeling abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Feeling cold	n/a	281	100.0	1	0.4	0.1	2.0
	Feeling hot	n/a	281	100.0	1	0.4	0.1	2.0
	Gait disturbance	n/a	281	100.0	7	2.5	1.2	5.1
	General physical health deterioration	n/a	281	100.0	2	0.7	0.2	2.6
	Generalised oedema	n/a	281	100.0	3	1.1	0.4	3.1
	Impaired healing	n/a	281	100.0	4	1.4	0.6	3.6

	Influenza like illness	n/a	281	100.0	3	1.1	0.4	3.1
	Injection site bruising	n/a	281	100.0	1	0.4	0.1	2.0
	Localised oedema	n/a	281	100.0	2	0.7	0.2	2.6
	Malaise	n/a	281	100.0	20	7.1	4.7	10.7
	Mucosal dryness	n/a	281	100.0	1	0.4	0.1	2.0
	Mucosal inflammation	n/a	281	100.0	21	7.5	4.9	11.2
	Non-cardiac chest pain	n/a	281	100.0	11	3.9	2.2	6.9
	Oedema	n/a	281	100.0	4	1.4	0.6	3.6
	Oedema peripheral	n/a	281	100.0	42	14.9	11.3	19.6
	Pain	n/a	281	100.0	6	2.1	1.0	4.6
	Peripheral swelling	n/a	281	100.0	8	2.8	1.4	5.5
	Pyrexia	n/a	281	100.0	71	25.3	20.5	30.7
	Swelling	n/a	281	100.0	1	0.4	0.1	2.0
	Temperature intolerance	n/a	281	100.0	3	1.1	0.4	3.1
	Xerosis	n/a	281	100.0	1	0.4	0.1	2.0
Hepatobiliary disorders	-Total	n/a	281	100.0	19	6.8	4.4	10.3
	Cholecystitis	n/a	281	100.0	2	0.7	0.2	2.6
	Hepatic function abnormal	n/a	281	100.0	3	1.1	0.4	3.1
	Hepatic steatosis	n/a	281	100.0	1	0.4	0.1	2.0
	Hepatocellular injury	n/a	281	100.0	3	1.1	0.4	3.1
	Hyperbilirubinaemia	n/a	281	100.0	6	2.1	1.0	4.6
	Liver disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumobilia	n/a	281	100.0	1	0.4	0.1	2.0
	Portal vein thrombosis	n/a	281	100.0	2	0.7	0.2	2.6
Immune system disorders	-Total	n/a	281	100.0	6	2.1	1.0	4.6
	Contrast media allergy	n/a	281	100.0	1	0.4	0.1	2.0
	Drug hypersensitivity	n/a	281	100.0	1	0.4	0.1	2.0
	Food allergy	n/a	281	100.0	1	0.4	0.1	2.0
	Hypersensitivity	n/a	281	100.0	1	0.4	0.1	2.0
	Seasonal allergy	n/a	281	100.0	2	0.7	0.2	2.6

Infections and infestations	-Total	n/a	281	100.0	122	43.4	37.7	49.3
	Abdominal abscess	n/a	281	100.0	1	0.4	0.1	2.0
	Acute sinusitis	n/a	281	100.0	1	0.4	0.1	2.0
	Arthritis infective	n/a	281	100.0	1	0.4	0.1	2.0
	Atypical pneumonia	n/a	281	100.0	1	0.4	0.1	2.0
	Bacteraemia	n/a	281	100.0	2	0.7	0.2	2.6
	Bacterial disease carrier	n/a	281	100.0	1	0.4	0.1	2.0
	Bacterial vaginosis	n/a	281	100.0	1	0.4	0.1	2.0
	Bronchitis	n/a	281	100.0	7	2.5	1.2	5.1
	Candida infection	n/a	281	100.0	1	0.4	0.1	2.0
	Cellulitis	n/a	281	100.0	1	0.4	0.1	2.0
	Chronic sinusitis	n/a	281	100.0	3	1.1	0.4	3.1
	Conjunctivitis	n/a	281	100.0	1	0.4	0.1	2.0
	Corona virus infection	n/a	281	100.0	1	0.4	0.1	2.0
	Cystitis	n/a	281	100.0	2	0.7	0.2	2.6
	Cystitis escherichia	n/a	281	100.0	1	0.4	0.1	2.0
	Ear infection	n/a	281	100.0	1	0.4	0.1	2.0
	Epididymitis	n/a	281	100.0	1	0.4	0.1	2.0
	Epstein-Barr virus infection	n/a	281	100.0	1	0.4	0.1	2.0
	Escherichia bacteraemia	n/a	281	100.0	1	0.4	0.1	2.0
	Escherichia infection	n/a	281	100.0	1	0.4	0.1	2.0
	Escherichia urinary tract infection	n/a	281	100.0	1	0.4	0.1	2.0
	Eye infection	n/a	281	100.0	1	0.4	0.1	2.0
	Febrile infection	n/a	281	100.0	1	0.4	0.1	2.0
	Folliculitis	n/a	281	100.0	3	1.1	0.4	3.1
	Fungal infection	n/a	281	100.0	3	1.1	0.4	3.1
	Gastroenteritis	n/a	281	100.0	2	0.7	0.2	2.6
	Genital candidiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Genital herpes	n/a	281	100.0	2	0.7	0.2	2.6
	Gingivitis	n/a	281	100.0	1	0.4	0.1	2.0
	Herpes simplex	n/a	281	100.0	1	0.4	0.1	2.0

	Herpes virus infection	n/a	281	100.0	3	1.1	0.4	3.1
	Herpes zoster	n/a	281	100.0	11	3.9	2.2	6.9
	Infection	n/a	281	100.0	1	0.4	0.1	2.0
	Influenza	n/a	281	100.0	3	1.1	0.4	3.1
	Lower respiratory tract infection	n/a	281	100.0	1	0.4	0.1	2.0
	Lung infection	n/a	281	100.0	1	0.4	0.1	2.0
	Lyme disease	n/a	281	100.0	1	0.4	0.1	2.0
	Lymph node tuberculosis	n/a	281	100.0	2	0.7	0.2	2.6
	Nasal herpes	n/a	281	100.0	1	0.4	0.1	2.0
	Nasopharyngitis	n/a	281	100.0	9	3.2	1.7	6.0
	Oral candidiasis	n/a	281	100.0	9	3.2	1.7	6.0
	Oral fungal infection	n/a	281	100.0	2	0.7	0.2	2.6
	Oropharyngeal candidiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Otitis externa	n/a	281	100.0	2	0.7	0.2	2.6
	Otitis media	n/a	281	100.0	1	0.4	0.1	2.0
	Paronychia	n/a	281	100.0	7	2.5	1.2	5.1
	Pharyngitis	n/a	281	100.0	4	1.4	0.6	3.6
	Pneumonia	n/a	281	100.0	17	6.0	3.8	9.5
	Pneumonia influenzal	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia pseudomonal	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia streptococcal	n/a	281	100.0	1	0.4	0.1	2.0
	Pyelonephritis	n/a	281	100.0	1	0.4	0.1	2.0
	Pyuria	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory tract infection	n/a	281	100.0	2	0.7	0.2	2.6
	Respiratory tract infection bacterial	n/a	281	100.0	1	0.4	0.1	2.0
	Rhinitis	n/a	281	100.0	5	1.8	0.8	4.1
	Sepsis	n/a	281	100.0	1	0.4	0.1	2.0
	Sinusitis	n/a	281	100.0	7	2.5	1.2	5.1
	Skin infection	n/a	281	100.0	2	0.7	0.2	2.6
	Staphylococcal infection	n/a	281	100.0	1	0.4	0.1	2.0

	Systemic infection	n/a	281	100.0	1	0.4	0.1	2.0
	Tinea cruris	n/a	281	100.0	1	0.4	0.1	2.0
	Tinea infection	n/a	281	100.0	1	0.4	0.1	2.0
	Tinea pedis	n/a	281	100.0	2	0.7	0.2	2.6
	Tonsillitis	n/a	281	100.0	1	0.4	0.1	2.0
	Tooth infection	n/a	281	100.0	1	0.4	0.1	2.0
	Tracheitis	n/a	281	100.0	1	0.4	0.1	2.0
	Tuberculosis	n/a	281	100.0	1	0.4	0.1	2.0
	Upper respiratory tract infection	n/a	281	100.0	13	4.6	2.7	7.8
	Urethritis	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary tract infection	n/a	281	100.0	29	10.3	7.3	14.4
	Varicella	n/a	281	100.0	1	0.4	0.1	2.0
	Varicella zoster virus infection	n/a	281	100.0	1	0.4	0.1	2.0
	Viral hepatitis carrier	n/a	281	100.0	1	0.4	0.1	2.0
	Viral infection	n/a	281	100.0	2	0.7	0.2	2.6
	Vulvovaginal candidiasis	n/a	281	100.0	1	0.4	0.1	2.0
Injury, poisoning and procedural complications	-Total	n/a	281	100.0	25	8.9	6.1	12.8
	Contusion	n/a	281	100.0	5	1.8	0.8	4.1
	Epicondylitis	n/a	281	100.0	1	0.4	0.1	2.0
	Fall	n/a	281	100.0	8	2.8	1.4	5.5
	Incision site pain	n/a	281	100.0	1	0.4	0.1	2.0
	Injury	n/a	281	100.0	1	0.4	0.1	2.0
	Joint dislocation	n/a	281	100.0	2	0.7	0.2	2.6
	Laceration	n/a	281	100.0	1	0.4	0.1	2.0
	Ligament sprain	n/a	281	100.0	2	0.7	0.2	2.6
	Limb injury	n/a	281	100.0	2	0.7	0.2	2.6
	Muscle rupture	n/a	281	100.0	1	0.4	0.1	2.0
	Muscle strain	n/a	281	100.0	2	0.7	0.2	2.6
	Procedural pain	n/a	281	100.0	2	0.7	0.2	2.6
	Procedural pneumothorax	n/a	281	100.0	1	0.4	0.1	2.0
	Rib fracture	n/a	281	100.0	1	0.4	0.1	2.0

	Scar	n/a	281	100.0	1	0.4	0.1	2.0
	Skin abrasion	n/a	281	100.0	1	0.4	0.1	2.0
	Skin injury	n/a	281	100.0	1	0.4	0.1	2.0
	Tendon rupture	n/a	281	100.0	1	0.4	0.1	2.0
	Thermal burn	n/a	281	100.0	1	0.4	0.1	2.0
	Wound	n/a	281	100.0	2	0.7	0.2	2.6
	Wound complication	n/a	281	100.0	1	0.4	0.1	2.0
	Wrist fracture	n/a	281	100.0	1	0.4	0.1	2.0
Investigations	-Total	n/a	281	100.0	209	74.4	69.0	79.1
	Alanine aminotransferase increased	n/a	281	100.0	83	29.5	24.5	35.1
	Albumin urine present	n/a	281	100.0	1	0.4	0.1	2.0
	Alpha hydroxybutyrate dehydrogenase increased	n/a	281	100.0	2	0.7	0.2	2.6
	Amylase increased	n/a	281	100.0	2	0.7	0.2	2.6
	Aspartate aminotransferase increased	n/a	281	100.0	111	39.5	34.0	45.3
	Bacterial test	n/a	281	100.0	1	0.4	0.1	2.0
	Bilirubin conjugated increased	n/a	281	100.0	19	6.8	4.4	10.3
	Blood albumin decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood alkaline phosphatase	n/a	281	100.0	1	0.4	0.1	2.0
	Blood alkaline phosphatase decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood alkaline phosphatase increased	n/a	281	100.0	31	11.0	7.9	15.2
	Blood bilirubin increased	n/a	281	100.0	25	8.9	6.1	12.8
	Blood bilirubin unconjugated increased	n/a	281	100.0	8	2.8	1.4	5.5
	Blood calcium decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood calcium increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood chloride increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood cholesterol increased	n/a	281	100.0	8	2.8	1.4	5.5
	Blood creatine increased	n/a	281	100.0	3	1.1	0.4	3.1
	Blood creatine phosphokinase MB increased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood creatine phosphokinase increased	n/a	281	100.0	34	12.1	8.8	16.4
	Blood creatinine	n/a	281	100.0	1	0.4	0.1	2.0

	Blood creatinine increased	n/a	281	100.0	60	21.4	17.0	26.5
	Blood fibrinogen increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood glucose increased	n/a	281	100.0	3	1.1	0.4	3.1
	Blood iron decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood ketone body increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood lactate dehydrogenase increased	n/a	281	100.0	10	3.6	1.9	6.4
	Blood magnesium decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood phosphorus increased	n/a	281	100.0	7	2.5	1.2	5.1
	Blood potassium decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood potassium increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood pressure increased	n/a	281	100.0	3	1.1	0.4	3.1
	Blood sodium decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood thyroid stimulating hormone increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood triglycerides increased	n/a	281	100.0	8	2.8	1.4	5.5
	Blood urea increased	n/a	281	100.0	6	2.1	1.0	4.6
	Blood uric acid decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood uric acid increased	n/a	281	100.0	7	2.5	1.2	5.1
	Blood urine	n/a	281	100.0	3	1.1	0.4	3.1
	Blood urine present	n/a	281	100.0	1	0.4	0.1	2.0
	C-reactive protein increased	n/a	281	100.0	3	1.1	0.4	3.1
	Carbon dioxide decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Complement factor C1 decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Computerised tomogram thorax abnormal	n/a	281	100.0	2	0.7	0.2	2.6
	Crystal urine present	n/a	281	100.0	1	0.4	0.1	2.0
	Cystatin C increased	n/a	281	100.0	1	0.4	0.1	2.0
	Electrocardiogram QT prolonged	n/a	281	100.0	14	5.0	3.0	8.2
	Electrocardiogram ST-T change	n/a	281	100.0	2	0.7	0.2	2.6
	Fibrin D dimer increased	n/a	281	100.0	2	0.7	0.2	2.6
	Fibrin degradation products increased	n/a	281	100.0	1	0.4	0.1	2.0
	Free fatty acids increased	n/a	281	100.0	1	0.4	0.1	2.0
	Gamma-glutamyltransferase increased	n/a	281	100.0	17	6.0	3.8	9.5

	Glomerular filtration rate decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Glutamate dehydrogenase increased	n/a	281	100.0	2	0.7	0.2	2.6
	Granulocyte count decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Haematocrit decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Haemoglobin decreased	n/a	281	100.0	5	1.8	0.8	4.1
	Heart rate increased	n/a	281	100.0	6	2.1	1.0	4.6
	Hepatic enzyme increased	n/a	281	100.0	2	0.7	0.2	2.6
	International normalised ratio increased	n/a	281	100.0	2	0.7	0.2	2.6
	Intraocular pressure increased	n/a	281	100.0	1	0.4	0.1	2.0
	Laboratory test abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Lipase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Liver function test increased	n/a	281	100.0	2	0.7	0.2	2.6
	Lymphocyte count decreased	n/a	281	100.0	13	4.6	2.7	7.8
	Lymphocyte count increased	n/a	281	100.0	1	0.4	0.1	2.0
	Mean cell volume increased	n/a	281	100.0	1	0.4	0.1	2.0
	Myoglobin blood increased	n/a	281	100.0	1	0.4	0.1	2.0
	Neutrophil count decreased	n/a	281	100.0	45	16.0	12.2	20.8
	Neutrophil count increased	n/a	281	100.0	2	0.7	0.2	2.6
	Neutrophil percentage increased	n/a	281	100.0	1	0.4	0.1	2.0
	Occult blood positive	n/a	281	100.0	3	1.1	0.4	3.1
	Platelet count decreased	n/a	281	100.0	25	8.9	6.1	12.8
	Platelet count increased	n/a	281	100.0	5	1.8	0.8	4.1
	Procalcitonin increased	n/a	281	100.0	1	0.4	0.1	2.0
	Protein total decreased	n/a	281	100.0	3	1.1	0.4	3.1
	Protein total increased	n/a	281	100.0	1	0.4	0.1	2.0
	Protein urine present	n/a	281	100.0	2	0.7	0.2	2.6
	Prothrombin time prolonged	n/a	281	100.0	1	0.4	0.1	2.0
	Red blood cell count decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Serum amyloid A protein increased	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombin time prolonged	n/a	281	100.0	1	0.4	0.1	2.0

	Total bile acids increased	n/a	281	100.0	9	3.2	1.7	6.0
	Transaminases increased	n/a	281	100.0	7	2.5	1.2	5.1
	Transferrin increased	n/a	281	100.0	1	0.4	0.1	2.0
	Troponin T increased	n/a	281	100.0	1	0.4	0.1	2.0
	Troponin increased	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary sediment present	n/a	281	100.0	1	0.4	0.1	2.0
	Urine ketone body present	n/a	281	100.0	3	1.1	0.4	3.1
	Urine leukocyte esterase positive	n/a	281	100.0	1	0.4	0.1	2.0
	Urobilinogen urine increased	n/a	281	100.0	2	0.7	0.2	2.6
	Weight decreased	n/a	281	100.0	18	6.4	4.1	9.9
	Weight increased	n/a	281	100.0	24	8.5	5.8	12.4
	White blood cell count decreased	n/a	281	100.0	57	20.3	16.0	25.4
	White blood cells urine positive	n/a	281	100.0	3	1.1	0.4	3.1
Metabolism and nutrition disorders	-Total	n/a	281	100.0	138	49.1	43.3	54.9
	Abnormal loss of weight	n/a	281	100.0	1	0.4	0.1	2.0
	Alkalosis	n/a	281	100.0	1	0.4	0.1	2.0
	Cell death	n/a	281	100.0	1	0.4	0.1	2.0
	Decreased appetite	n/a	281	100.0	36	12.8	9.4	17.2
	Dehydration	n/a	281	100.0	4	1.4	0.6	3.6
	Electrolyte imbalance	n/a	281	100.0	1	0.4	0.1	2.0
	Fluid retention	n/a	281	100.0	1	0.4	0.1	2.0
	Hypercalcaemia	n/a	281	100.0	6	2.1	1.0	4.6
	Hypercholesterolaemia	n/a	281	100.0	5	1.8	0.8	4.1
	Hyperglycaemia	n/a	281	100.0	18	6.4	4.1	9.9
	Hyperkalaemia	n/a	281	100.0	12	4.3	2.5	7.3
	Hyperlipidaemia	n/a	281	100.0	7	2.5	1.2	5.1
	Hypermagnesaemia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypernatraemia	n/a	281	100.0	2	0.7	0.2	2.6
	Hyperphosphataemia	n/a	281	100.0	31	11.0	7.9	15.2
	Hypertriglyceridaemia	n/a	281	100.0	7	2.5	1.2	5.1
	Hyperuricaemia	n/a	281	100.0	10	3.6	1.9	6.4

	Hypoalbuminaemia	n/a	281	100.0	37	13.2	9.7	17.6
	Hypocalcaemia	n/a	281	100.0	31	11.0	7.9	15.2
	Hypochloraemia	n/a	281	100.0	5	1.8	0.8	4.1
	Hypoglycaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypokalaemia	n/a	281	100.0	29	10.3	7.3	14.4
	Hypomagnesaemia	n/a	281	100.0	21	7.5	4.9	11.2
	Hyponatraemia	n/a	281	100.0	18	6.4	4.1	9.9
	Hypophosphataemia	n/a	281	100.0	15	5.3	3.3	8.6
	Hypoproteinaemia	n/a	281	100.0	6	2.1	1.0	4.6
	Increased appetite	n/a	281	100.0	1	0.4	0.1	2.0
	Vitamin D deficiency	n/a	281	100.0	1	0.4	0.1	2.0
Musculoskeletal and connective tissue disorders	-Total	n/a	281	100.0	119	42.3	36.7	48.2
	Arthralgia	n/a	281	100.0	12	4.3	2.5	7.3
	Arthropathy	n/a	281	100.0	1	0.4	0.1	2.0
	Back pain	n/a	281	100.0	35	12.5	9.1	16.8
	Bone pain	n/a	281	100.0	4	1.4	0.6	3.6
	Bursitis	n/a	281	100.0	1	0.4	0.1	2.0
	Coccydynia	n/a	281	100.0	1	0.4	0.1	2.0
	Costochondritis	n/a	281	100.0	2	0.7	0.2	2.6
	Flank pain	n/a	281	100.0	3	1.1	0.4	3.1
	Groin pain	n/a	281	100.0	1	0.4	0.1	2.0
	Hypercreatinaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Intervertebral disc protrusion	n/a	281	100.0	2	0.7	0.2	2.6
	Joint range of motion decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Joint stiffness	n/a	281	100.0	1	0.4	0.1	2.0
	Joint swelling	n/a	281	100.0	2	0.7	0.2	2.6
	Muscle fatigue	n/a	281	100.0	1	0.4	0.1	2.0
	Muscle spasms	n/a	281	100.0	22	7.8	5.2	11.6
	Muscular weakness	n/a	281	100.0	8	2.8	1.4	5.5
	Musculoskeletal chest pain	n/a	281	100.0	6	2.1	1.0	4.6

	Musculoskeletal pain	n/a	281	100.0	24	8.5	5.8	12.4
	Musculoskeletal stiffness	n/a	281	100.0	1	0.4	0.1	2.0
	Myalgia	n/a	281	100.0	23	8.2	5.5	12.0
	Myopathy	n/a	281	100.0	2	0.7	0.2	2.6
	Neck pain	n/a	281	100.0	14	5.0	3.0	8.2
	Osteopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Pain in extremity	n/a	281	100.0	25	8.9	6.1	12.8
	Pain in jaw	n/a	281	100.0	2	0.7	0.2	2.6
	Rotator cuff syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Spinal column stenosis	n/a	281	100.0	2	0.7	0.2	2.6
	Spinal osteoarthritis	n/a	281	100.0	1	0.4	0.1	2.0
	Tendon disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Tendon pain	n/a	281	100.0	1	0.4	0.1	2.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	281	100.0	8	2.8	1.4	5.5
	Anogenital warts	n/a	281	100.0	1	0.4	0.1	2.0
	Basal cell carcinoma	n/a	281	100.0	1	0.4	0.1	2.0
	Bowen's disease	n/a	281	100.0	1	0.4	0.1	2.0
	Metastases to central nervous system	n/a	281	100.0	1	0.4	0.1	2.0
	Renal cell carcinoma	n/a	281	100.0	1	0.4	0.1	2.0
	Squamous cell carcinoma	n/a	281	100.0	1	0.4	0.1	2.0
	Squamous cell carcinoma of skin	n/a	281	100.0	1	0.4	0.1	2.0
	Tumour pain	n/a	281	100.0	1	0.4	0.1	2.0
Nervous system disorders	-Total	n/a	281	100.0	141	50.2	44.4	56.0
	Ageusia	n/a	281	100.0	2	0.7	0.2	2.6
	Aphasia	n/a	281	100.0	1	0.4	0.1	2.0
	Ataxia	n/a	281	100.0	1	0.4	0.1	2.0
	Balance disorder	n/a	281	100.0	2	0.7	0.2	2.6
	Brain oedema	n/a	281	100.0	2	0.7	0.2	2.6
	Cerebellar haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Disturbance in attention	n/a	281	100.0	2	0.7	0.2	2.6
	Dizziness	n/a	281	100.0	37	13.2	9.7	17.6

	Dizziness postural	n/a	281	100.0	1	0.4	0.1	2.0
	Dysarthria	n/a	281	100.0	1	0.4	0.1	2.0
	Dysgeusia	n/a	281	100.0	42	14.9	11.3	19.6
	Dyskinesia	n/a	281	100.0	1	0.4	0.1	2.0
	Headache	n/a	281	100.0	32	11.4	8.2	15.6
	Hemiplegia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperaesthesia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypersomnia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypoaesthesia	n/a	281	100.0	18	6.4	4.1	9.9
	Hypotonia	n/a	281	100.0	1	0.4	0.1	2.0
	Lethargy	n/a	281	100.0	1	0.4	0.1	2.0
	Lumbar radiculopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Memory impairment	n/a	281	100.0	2	0.7	0.2	2.6
	Migraine with aura	n/a	281	100.0	1	0.4	0.1	2.0
	Neuralgia	n/a	281	100.0	1	0.4	0.1	2.0
	Neuropathy peripheral	n/a	281	100.0	12	4.3	2.5	7.3
	Paraesthesia	n/a	281	100.0	12	4.3	2.5	7.3
	Paralysis	n/a	281	100.0	1	0.4	0.1	2.0
	Parosmia	n/a	281	100.0	1	0.4	0.1	2.0
	Peripheral sensory neuropathy	n/a	281	100.0	9	3.2	1.7	6.0
	Polyneuropathy chronic	n/a	281	100.0	1	0.4	0.1	2.0
	Post herpetic neuralgia	n/a	281	100.0	1	0.4	0.1	2.0
	Presyncope	n/a	281	100.0	3	1.1	0.4	3.1
	Psychomotor skills impaired	n/a	281	100.0	1	0.4	0.1	2.0
	Restless legs syndrome	n/a	281	100.0	2	0.7	0.2	2.6
	Sciatica	n/a	281	100.0	4	1.4	0.6	3.6
	Seizure	n/a	281	100.0	5	1.8	0.8	4.1
	Sensory disturbance	n/a	281	100.0	1	0.4	0.1	2.0
	Slow speech	n/a	281	100.0	1	0.4	0.1	2.0
	Somnolence	n/a	281	100.0	2	0.7	0.2	2.6

	Syncope	n/a	281	100.0	4	1.4	0.6	3.6
	Tension headache	n/a	281	100.0	1	0.4	0.1	2.0
	Tremor	n/a	281	100.0	1	0.4	0.1	2.0
	Visual field defect	n/a	281	100.0	2	0.7	0.2	2.6
Product issues	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Device dislocation	n/a	281	100.0	1	0.4	0.1	2.0
Psychiatric disorders	-Total	n/a	281	100.0	54	19.2	15.0	24.2
	Abnormal behaviour	n/a	281	100.0	1	0.4	0.1	2.0
	Abnormal dreams	n/a	281	100.0	1	0.4	0.1	2.0
	Adjustment disorder with mixed anxiety and depressed mood	n/a	281	100.0	1	0.4	0.1	2.0
	Anxiety	n/a	281	100.0	12	4.3	2.5	7.3
	Bradyphrenia	n/a	281	100.0	1	0.4	0.1	2.0
	Confusional state	n/a	281	100.0	5	1.8	0.8	4.1
	Delirium	n/a	281	100.0	3	1.1	0.4	3.1
	Depressed mood	n/a	281	100.0	1	0.4	0.1	2.0
	Depression	n/a	281	100.0	5	1.8	0.8	4.1
	Fear of falling	n/a	281	100.0	1	0.4	0.1	2.0
	Insomnia	n/a	281	100.0	20	7.1	4.7	10.7
	Irritability	n/a	281	100.0	1	0.4	0.1	2.0
	Libido decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Mental status changes	n/a	281	100.0	1	0.4	0.1	2.0
	Mood altered	n/a	281	100.0	1	0.4	0.1	2.0
	Psychomotor retardation	n/a	281	100.0	2	0.7	0.2	2.6
	Restlessness	n/a	281	100.0	5	1.8	0.8	4.1
	Sleep disorder	n/a	281	100.0	2	0.7	0.2	2.6
Renal and urinary disorders	-Total	n/a	281	100.0	41	14.6	10.9	19.2
	Acute kidney injury	n/a	281	100.0	6	2.1	1.0	4.6
	Azotaemia	n/a	281	100.0	2	0.7	0.2	2.6
	Cystitis haemorrhagic	n/a	281	100.0	1	0.4	0.1	2.0
	Dysuria	n/a	281	100.0	11	3.9	2.2	6.9
	Haematuria	n/a	281	100.0	3	1.1	0.4	3.1

	Haemorrhage urinary tract	n/a	281	100.0	1	0.4	0.1	2.0
	Micturition urgency	n/a	281	100.0	1	0.4	0.1	2.0
	Nephritis	n/a	281	100.0	1	0.4	0.1	2.0
	Nocturia	n/a	281	100.0	3	1.1	0.4	3.1
	Pollakiuria	n/a	281	100.0	2	0.7	0.2	2.6
	Proteinuria	n/a	281	100.0	2	0.7	0.2	2.6
	Renal colic	n/a	281	100.0	1	0.4	0.1	2.0
	Renal disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Renal failure	n/a	281	100.0	2	0.7	0.2	2.6
	Renal impairment	n/a	281	100.0	1	0.4	0.1	2.0
	Strangury	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary incontinence	n/a	281	100.0	2	0.7	0.2	2.6
	Urinary retention	n/a	281	100.0	6	2.1	1.0	4.6
	Urinary tract pain	n/a	281	100.0	1	0.4	0.1	2.0
	Urine flow decreased	n/a	281	100.0	1	0.4	0.1	2.0
Reproductive system and breast disorders	-Total	n/a	281	100.0	22	7.8	5.2	11.6
	Benign prostatic hyperplasia	n/a	281	100.0	3	1.1	0.4	3.1
	Breast discharge	n/a	281	100.0	1	0.4	0.1	2.0
	Erectile dysfunction	n/a	281	100.0	9	3.2	1.7	6.0
	Galactorrhoea	n/a	281	100.0	1	0.4	0.1	2.0
	Genital ulceration	n/a	281	100.0	1	0.4	0.1	2.0
	Metrorrhagia	n/a	281	100.0	1	0.4	0.1	2.0
	Pelvic discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Pelvic fluid collection	n/a	281	100.0	1	0.4	0.1	2.0
	Perineal pain	n/a	281	100.0	1	0.4	0.1	2.0
	Postmenopausal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Prostatitis	n/a	281	100.0	1	0.4	0.1	2.0
	Uterine polyp	n/a	281	100.0	1	0.4	0.1	2.0
	Vaginal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Vulvovaginal dryness	n/a	281	100.0	1	0.4	0.1	2.0

	Vulvovaginal erythema	n/a	281	100.0	1	0.4	0.1	2.0
Respiratory, thoracic and mediastinal disorders	-Total	n/a	281	100.0	153	54.4	48.6	60.2
	Aspiration	n/a	281	100.0	1	0.4	0.1	2.0
	Bronchospasm	n/a	281	100.0	1	0.4	0.1	2.0
	Choking	n/a	281	100.0	1	0.4	0.1	2.0
	Cough	n/a	281	100.0	64	22.8	18.3	28.0
	Dry throat	n/a	281	100.0	2	0.7	0.2	2.6
	Dysphonia	n/a	281	100.0	12	4.3	2.5	7.3
	Dyspnoea	n/a	281	100.0	39	13.9	10.3	18.4
	Dyspnoea exertional	n/a	281	100.0	12	4.3	2.5	7.3
	Epistaxis	n/a	281	100.0	14	5.0	3.0	8.2
	Haemoptysis	n/a	281	100.0	11	3.9	2.2	6.9
	Hiccups	n/a	281	100.0	2	0.7	0.2	2.6
	Hypoxia	n/a	281	100.0	1	0.4	0.1	2.0
	Interstitial lung disease	n/a	281	100.0	4	1.4	0.6	3.6
	Laryngeal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Nasal congestion	n/a	281	100.0	4	1.4	0.6	3.6
	Nasal dryness	n/a	281	100.0	4	1.4	0.6	3.6
	Nasal polyps	n/a	281	100.0	1	0.4	0.1	2.0
	Oropharyngeal discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Oropharyngeal pain	n/a	281	100.0	21	7.5	4.9	11.2
	Paranasal sinus discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Pharyngeal disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Pleural effusion	n/a	281	100.0	7	2.5	1.2	5.1
	Pleural thickening	n/a	281	100.0	2	0.7	0.2	2.6
	Pleuritic pain	n/a	281	100.0	2	0.7	0.2	2.6
	Pneumonitis	n/a	281	100.0	26	9.3	6.4	13.2
	Pneumothorax	n/a	281	100.0	2	0.7	0.2	2.6
	Productive cough	n/a	281	100.0	14	5.0	3.0	8.2
	Pulmonary embolism	n/a	281	100.0	4	1.4	0.6	3.6
	Pulmonary mass	n/a	281	100.0	1	0.4	0.1	2.0

	Pulmonary pain	n/a	281	100.0	1	0.4	0.1	2.0
	Respiration abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Rhinalgia	n/a	281	100.0	1	0.4	0.1	2.0
	Rhinitis allergic	n/a	281	100.0	2	0.7	0.2	2.6
	Rhinorrhoea	n/a	281	100.0	3	1.1	0.4	3.1
	Sinus congestion	n/a	281	100.0	1	0.4	0.1	2.0
	Sleep apnoea syndrome	n/a	281	100.0	3	1.1	0.4	3.1
	Sputum discoloured	n/a	281	100.0	1	0.4	0.1	2.0
	Throat irritation	n/a	281	100.0	2	0.7	0.2	2.6
	Upper-airway cough syndrome	n/a	281	100.0	2	0.7	0.2	2.6
	Vocal cord leukoplakia	n/a	281	100.0	1	0.4	0.1	2.0
	Wheezing	n/a	281	100.0	2	0.7	0.2	2.6
Skin and subcutaneous tissue disorders	-Total	n/a	281	100.0	100	35.6	30.2	41.3
	Acne	n/a	281	100.0	1	0.4	0.1	2.0
	Alopecia	n/a	281	100.0	14	5.0	3.0	8.2
	Chloasma	n/a	281	100.0	1	0.4	0.1	2.0
	Decubitus ulcer	n/a	281	100.0	1	0.4	0.1	2.0
	Dermal cyst	n/a	281	100.0	1	0.4	0.1	2.0
	Dermatitis	n/a	281	100.0	1	0.4	0.1	2.0
	Dermatitis acneiform	n/a	281	100.0	7	2.5	1.2	5.1
	Dermatitis allergic	n/a	281	100.0	1	0.4	0.1	2.0
	Dermatitis bullous	n/a	281	100.0	2	0.7	0.2	2.6
	Dry skin	n/a	281	100.0	12	4.3	2.5	7.3
	Ecchymosis	n/a	281	100.0	1	0.4	0.1	2.0
	Eczema	n/a	281	100.0	2	0.7	0.2	2.6
	Erythema	n/a	281	100.0	4	1.4	0.6	3.6
	Hair growth abnormal	n/a	281	100.0	6	2.1	1.0	4.6
	Hair texture abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Hirsutism	n/a	281	100.0	7	2.5	1.2	5.1
	Hyperhidrosis	n/a	281	100.0	2	0.7	0.2	2.6

	Hyperkeratosis	n/a	281	100.0	1	0.4	0.1	2.0
	Hypertrichosis	n/a	281	100.0	6	2.1	1.0	4.6
	Madarosis	n/a	281	100.0	1	0.4	0.1	2.0
	Nail discolouration	n/a	281	100.0	1	0.4	0.1	2.0
	Nail disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Night sweats	n/a	281	100.0	2	0.7	0.2	2.6
	Onychalgia	n/a	281	100.0	1	0.4	0.1	2.0
	Onycholysis	n/a	281	100.0	1	0.4	0.1	2.0
	Onychomadesis	n/a	281	100.0	3	1.1	0.4	3.1
	Pain of skin	n/a	281	100.0	1	0.4	0.1	2.0
	Palmar-plantar erythrodysaesthesia syndrome	n/a	281	100.0	5	1.8	0.8	4.1
	Photosensitivity reaction	n/a	281	100.0	1	0.4	0.1	2.0
	Pruritus	n/a	281	100.0	7	2.5	1.2	5.1
	Pruritus generalised	n/a	281	100.0	1	0.4	0.1	2.0
	Purpura	n/a	281	100.0	1	0.4	0.1	2.0
	Rash	n/a	281	100.0	23	8.2	5.5	12.0
	Rash erythematous	n/a	281	100.0	2	0.7	0.2	2.6
	Rash macular	n/a	281	100.0	4	1.4	0.6	3.6
	Rash maculo-papular	n/a	281	100.0	2	0.7	0.2	2.6
	Rash papular	n/a	281	100.0	1	0.4	0.1	2.0
	Scab	n/a	281	100.0	2	0.7	0.2	2.6
	Scar pain	n/a	281	100.0	1	0.4	0.1	2.0
	Skin discolouration	n/a	281	100.0	1	0.4	0.1	2.0
	Skin hyperpigmentation	n/a	281	100.0	1	0.4	0.1	2.0
	Skin lesion	n/a	281	100.0	1	0.4	0.1	2.0
	Swelling face	n/a	281	100.0	6	2.1	1.0	4.6
	Urticaria	n/a	281	100.0	2	0.7	0.2	2.6
Surgical and medical procedures	-Total	n/a	281	100.0	6	2.1	1.0	4.6
	Astringent therapy	n/a	281	100.0	5	1.8	0.8	4.1
	Therapy cessation	n/a	281	100.0	1	0.4	0.1	2.0
Vascular disorders	-Total	n/a	281	100.0	72	25.6	20.9	31.0

	Aortic dissection	n/a	281	100.0	1	0.4	0.1	2.0
	Circulatory collapse	n/a	281	100.0	1	0.4	0.1	2.0
	Deep vein thrombosis	n/a	281	100.0	2	0.7	0.2	2.6
	Embolism	n/a	281	100.0	3	1.1	0.4	3.1
	Flushing	n/a	281	100.0	1	0.4	0.1	2.0
	Haematoma	n/a	281	100.0	3	1.1	0.4	3.1
	Hot flush	n/a	281	100.0	3	1.1	0.4	3.1
	Hypertension	n/a	281	100.0	51	18.1	14.1	23.1
	Hypotension	n/a	281	100.0	4	1.4	0.6	3.6
	Lymphoedema	n/a	281	100.0	2	0.7	0.2	2.6
	Orthostatic hypotension	n/a	281	100.0	2	0.7	0.2	2.6
	Pallor	n/a	281	100.0	1	0.4	0.1	2.0
	Phlebitis	n/a	281	100.0	1	0.4	0.1	2.0
	Raynaud's phenomenon	n/a	281	100.0	1	0.4	0.1	2.0
	Superior vena cava syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombophlebitis superficial	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombosis	n/a	281	100.0	2	0.7	0.2	2.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR12_SG.xls
26MAR2021 13:42

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1-2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	< 65	176	62.6	73	41.5	34.5	48.9
		>= 65	105	37.4	52	49.5	40.1	58.9
	Anaemia	< 65	176	62.6	50	28.4	22.3	35.5
		>= 65	105	37.4	33	31.4	23.3	40.8
	Aplastic anaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bone marrow oedema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cytopenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Febrile neutropenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperfibrinogenaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Leukocytosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Leukopenia	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	5	4.8	2.1	10.7
	Lymph node pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lymphadenopathy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymphopenia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	4	3.8	1.5	9.4
	Neutropenia	< 65	176	62.6	20	11.4	7.5	16.9
		>= 65	105	37.4	11	10.5	6.0	17.8
	Neutrophilia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pancytopenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Thrombocytopenia	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	7	6.7	3.3	13.1
	Thrombocytosis	< 65	176	62.6	2	1.1	0.3	4.0

		>= 65	105	37.4	3	2.9	1.0	8.1
Cardiac disorders	-Total	< 65	176	62.6	20	11.4	7.5	16.9
		>= 65	105	37.4	14	13.3	8.1	21.1
	Acute coronary syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Angina pectoris	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Aortic valve calcification	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Atrial fibrillation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Atrial flutter	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bradycardia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bundle branch block right	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cardiac failure	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Extrasystoles	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Myocardial ischaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nodal arrhythmia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Palpitations	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pericardial effusion	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sinus bradycardia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sinus tachycardia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tachycardia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Ventricular extrasystoles	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ventricular pre-excitation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Congenital, familial and genetic disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Gilbert's syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hydrocele	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Ear and labyrinth disorders	-Total	< 65	176	62.6	14	8.0	4.8	12.9
		>= 65	105	37.4	6	5.7	2.6	11.9
	Ear congestion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ear discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ear pain	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tinnitus	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Vertigo	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	3	2.9	1.0	8.1
Endocrine disorders	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperthyroidism	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypothyroidism	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
Eye disorders	-Total	< 65	176	62.6	29	16.5	11.7	22.7
		>= 65	105	37.4	9	8.6	4.6	15.5
	Abnormal sensation in eye	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blepharitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Chalazion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Conjunctival cyst	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Conjunctival haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diplopia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dry eye	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eye swelling	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

	Eyelid oedema	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Eyelid ptosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Keratitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ocular discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Periorbital oedema	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Photophobia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Photopsia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ulcerative keratitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vision blurred	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Visual acuity reduced	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Gastrointestinal disorders	-Total	< 65	176	62.6	121	68.8	61.6	75.1
		>= 65	105	37.4	78	74.3	65.2	81.7
	Abdominal discomfort	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Abdominal distension	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
	Abdominal pain	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	5	4.8	2.1	10.7
	Abdominal pain lower	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Abdominal pain upper	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	5	4.8	2.1	10.7
	Abdominal symptom	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Anal incontinence	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Aphthous ulcer	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ascites	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Constipation	< 65	176	62.6	71	40.3	33.4	47.7

		>= 65	105	37.4	45	42.9	33.8	52.4
	Dental dysaesthesia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diarrhoea	< 65	176	62.6	38	21.6	16.2	28.2
		>= 65	105	37.4	27	25.7	18.3	34.8
	Dry mouth	< 65	176	62.6	23	13.1	8.9	18.8
		>= 65	105	37.4	24	22.9	15.9	31.8
	Dyspepsia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	3	2.9	1.0	8.1
	Dysphagia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	14	13.3	8.1	21.1
	Enteritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Epigastric discomfort	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eructation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Faeces soft	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Flatulence	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Frequent bowel movements	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastric ulcer	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastritis	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastritis erosive	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastrointestinal haemorrhage	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastrointestinal inflammation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrointestinal oedema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrointestinal wall thickening	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrooesophageal reflux disease	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	5	4.8	2.1	10.7
	Gingival bleeding	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2

	Gingival swelling	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Glossitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Glossodynia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haematochezia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Haemorrhoids	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	4	3.8	1.5	9.4
	Hypoaesthesia oral	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	0	0.0	0.0	3.5
	Impaired gastric emptying	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Irritable bowel syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Melaena	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mouth ulceration	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	6	5.7	2.6	11.9
	Nausea	< 65	176	62.6	24	13.6	9.3	19.5
		>= 65	105	37.4	18	17.1	11.1	25.5
	Odynophagia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oesophageal irritation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oesophagitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oral disorder	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oral dysaesthesia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oral mucosal erythema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oral pain	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	3	2.9	1.0	8.1
	Pancreatitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Paraesthesia oral	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Rectal prolapse	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Regurgitation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sensitivity of teeth	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Stomatitis	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Swollen tongue	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tongue coated	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tongue discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tongue ulceration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tooth discolouration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Toothache	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Vomiting	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	13	12.4	7.4	20.0
General disorders and administration site conditions	-Total	< 65	176	62.6	119	67.6	60.4	74.1
		>= 65	105	37.4	74	70.5	61.2	78.4
	Asthenia	< 65	176	62.6	24	13.6	9.3	19.5
		>= 65	105	37.4	13	12.4	7.4	20.0
	Axillary pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Catheter site pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Chest discomfort	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	4	3.8	1.5	9.4
	Chest pain	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
	Chills	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Disease progression	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Face oedema	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	5	4.8	2.1	10.7
	Facial pain	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Fatigue	< 65	176	62.6	30	17.0	12.2	23.3
		>= 65	105	37.4	31	29.5	21.6	38.8
	Feeling abnormal	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Feeling cold	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Feeling hot	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gait disturbance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	6	5.7	2.6	11.9
	General physical health deterioration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Generalised oedema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Impaired healing	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Influenza like illness	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Injection site bruising	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Localised oedema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Malaise	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Mucosal dryness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mucosal inflammation	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	9	8.6	4.6	15.5
	Non-cardiac chest pain	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	3	2.9	1.0	8.1
	Oedema	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oedema peripheral	< 65	176	62.6	19	10.8	7.0	16.2
		>= 65	105	37.4	23	21.9	15.1	30.7
	Pain	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Peripheral swelling	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
	Pyrexia	< 65	176	62.6	43	24.4	18.7	31.3
		>= 65	105	37.4	28	26.7	19.1	35.8

	Swelling	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Temperature intolerance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Xerosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Hepatobiliary disorders	-Total	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	11	10.5	6.0	17.8
	Cholecystitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hepatic function abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hepatic steatosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hepatocellular injury	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperbilirubinaemia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Liver disorder	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pneumobilia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Portal vein thrombosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Immune system disorders	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Contrast media allergy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Drug hypersensitivity	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Food allergy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypersensitivity	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Seasonal allergy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Infections and infestations	-Total	< 65	176	62.6	81	46.0	38.8	53.4
		>= 65	105	37.4	41	39.0	30.3	48.6
	Abdominal abscess	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Acute sinusitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Arthritis infective	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Atypical pneumonia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bacteraemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bacterial disease carrier	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bacterial vaginosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bronchitis	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Candida infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cellulitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Chronic sinusitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Conjunctivitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Corona virus infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cystitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cystitis escherichia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ear infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Epididymitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Epstein-Barr virus infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Escherichia bacteraemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Escherichia infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Escherichia urinary tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Eye infection	< 65	176	62.6	0	0.0	0.0	2.1

		>= 65	105	37.4	1	1.0	0.2	5.2
	Febrile infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Folliculitis	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fungal infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastroenteritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Genital candidiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Genital herpes	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gingivitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Herpes simplex	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Herpes virus infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Herpes zoster	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	2	1.9	0.5	6.7
	Infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Influenza	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lower respiratory tract infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lung infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lyme disease	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymph node tuberculosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Nasal herpes	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nasopharyngitis	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oral candidiasis	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	6	5.7	2.6	11.9
	Oral fungal infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

	Oropharyngeal candidiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Otitis externa	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Otitis media	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Paronychia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pharyngitis	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	7	6.7	3.3	13.1
	Pneumonia influenzal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia pseudomonal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia streptococcal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyelonephritis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pyuria	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory tract infection bacterial	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rhinitis	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sepsis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sinusitis	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	1	1.0	0.2	5.2
	Skin infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Staphylococcal infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Systemic infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tinea cruris	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Tinea infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tinea pedis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tonsillitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tooth infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tracheitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tuberculosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Upper respiratory tract infection	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Urethritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary tract infection	< 65	176	62.6	18	10.2	6.6	15.6
		>= 65	105	37.4	11	10.5	6.0	17.8
	Varicella	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Varicella zoster virus infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Viral hepatitis carrier	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Viral infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vulvovaginal candidiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Injury, poisoning and procedural complications	-Total	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	13	12.4	7.4	20.0
	Contusion	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Epicondylitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fall	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	6	5.7	2.6	11.9
	Incision site pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Joint dislocation	< 65	176	62.6	2	1.1	0.3	4.0

		>= 65	105	37.4	0	0.0	0.0	3.5
	Laceration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ligament sprain	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Limb injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Muscle rupture	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscle strain	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Procedural pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Procedural pneumothorax	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rib fracture	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Scar	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Skin abrasion	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Skin injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tendon rupture	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Thermal burn	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Wound	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Wound complication	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Wrist fracture	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Investigations	-Total	< 65	176	62.6	133	75.6	68.7	81.3
		>= 65	105	37.4	76	72.4	63.2	80.0
	Alanine aminotransferase increased	< 65	176	62.6	57	32.4	25.9	39.6
		>= 65	105	37.4	26	24.8	17.5	33.8
	Albumin urine present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Alpha hydroxybutyrate dehydrogenase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Amylase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Aspartate aminotransferase increased	< 65	176	62.6	72	40.9	33.9	48.3
		>= 65	105	37.4	39	37.1	28.5	46.7
	Bacterial test	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bilirubin conjugated increased	< 65	176	62.6	14	8.0	4.8	12.9
		>= 65	105	37.4	5	4.8	2.1	10.7
	Blood albumin decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood alkaline phosphatase	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood alkaline phosphatase decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood alkaline phosphatase increased	< 65	176	62.6	21	11.9	7.9	17.6
		>= 65	105	37.4	10	9.5	5.3	16.6
	Blood bilirubin increased	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	12	11.4	6.7	18.9
	Blood bilirubin unconjugated increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood calcium decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood calcium increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood chloride increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood cholesterol increased	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood creatine increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood creatine phosphokinase MB increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood creatine phosphokinase increased	< 65	176	62.6	27	15.3	10.8	21.4
		>= 65	105	37.4	7	6.7	3.3	13.1
	Blood creatinine	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood creatinine increased	< 65	176	62.6	38	21.6	16.2	28.2
		>= 65	105	37.4	22	21.0	14.3	29.7
	Blood fibrinogen increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Blood glucose increased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood iron decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood ketone body increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood lactate dehydrogenase increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	4	3.8	1.5	9.4
	Blood magnesium decreased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood phosphorus increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood potassium decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood potassium increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood pressure increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood sodium decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood thyroid stimulating hormone increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood triglycerides increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood urea increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood uric acid decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood uric acid increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood urine	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood urine present	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	C-reactive protein increased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Carbon dioxide decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Complement factor C1 decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Computerised tomogram thorax abnormal	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	1	1.0	0.2	5.2
	Crystal urine present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cystatin C increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Electrocardiogram QT prolonged	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	5	4.8	2.1	10.7
	Electrocardiogram ST-T change	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Fibrin D dimer increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Fibrin degradation products increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Free fatty acids increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gamma-glutamyltransferase increased	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	2	1.9	0.5	6.7
	Glomerular filtration rate decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Glutamate dehydrogenase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Granulocyte count decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haematocrit decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haemoglobin decreased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	0	0.0	0.0	3.5
	Heart rate increased	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hepatic enzyme increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	International normalised ratio increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Intraocular pressure increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Laboratory test abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lipase increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Liver function test increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Lymphocyte count decreased	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Lymphocyte count increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mean cell volume increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Myoglobin blood increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neutrophil count decreased	< 65	176	62.6	35	19.9	14.7	26.4
		>= 65	105	37.4	10	9.5	5.3	16.6
	Neutrophil count increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neutrophil percentage increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Occult blood positive	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Platelet count decreased	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	8	7.6	3.9	14.3
	Platelet count increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Procalcitonin increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Protein total decreased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Protein total increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Protein urine present	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Prothrombin time prolonged	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Red blood cell count decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Serum amyloid A protein increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Thrombin time prolonged	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Total bile acids increased	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Transaminases increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7

	Transferrin increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Troponin T increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Troponin increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary sediment present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urine ketone body present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Urine leukocyte esterase positive	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urobilinogen urine increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Weight decreased	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	10	9.5	5.3	16.6
	Weight increased	< 65	176	62.6	18	10.2	6.6	15.6
		>= 65	105	37.4	6	5.7	2.6	11.9
	White blood cell count decreased	< 65	176	62.6	43	24.4	18.7	31.3
		>= 65	105	37.4	14	13.3	8.1	21.1
	White blood cells urine positive	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
Metabolism and nutrition disorders	-Total	< 65	176	62.6	81	46.0	38.8	53.4
		>= 65	105	37.4	57	54.3	44.8	63.5
	Abnormal loss of weight	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Alkalosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cell death	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Decreased appetite	< 65	176	62.6	18	10.2	6.6	15.6
		>= 65	105	37.4	18	17.1	11.1	25.5
	Dehydration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Electrolyte imbalance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fluid retention	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypercalcaemia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypercholesterolaemia	< 65	176	62.6	4	2.3	0.9	5.7

		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperglycaemia	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	8	7.6	3.9	14.3
	Hyperkalaemia	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Hyperlipidaemia	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypermagnesaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hypernatraemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperphosphataemia	< 65	176	62.6	23	13.1	8.9	18.8
		>= 65	105	37.4	8	7.6	3.9	14.3
	Hypertriglyceridaemia	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hyperuricaemia	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypoalbuminaemia	< 65	176	62.6	29	16.5	11.7	22.7
		>= 65	105	37.4	8	7.6	3.9	14.3
	Hypocalcaemia	< 65	176	62.6	20	11.4	7.5	16.9
		>= 65	105	37.4	11	10.5	6.0	17.8
	Hypochloraemia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hypoglycaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypokalaemia	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	16	15.2	9.6	23.3
	Hypomagnesaemia	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	5	4.8	2.1	10.7
	Hyponatraemia	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	5	4.8	2.1	10.7
	Hypophosphataemia	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	5	4.8	2.1	10.7
	Hypoproteinaemia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Increased appetite	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vitamin D deficiency	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Musculoskeletal and connective tissue disorders	-Total	< 65	176	62.6	77	43.8	36.6	51.1
		>= 65	105	37.4	42	40.0	31.1	49.6

	Arthralgia	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Arthropathy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Back pain	< 65	176	62.6	22	12.5	8.4	18.2
		>= 65	105	37.4	13	12.4	7.4	20.0
	Bone pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Bursitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Coccydynia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Costochondritis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Flank pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Groin pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypercreatinaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Intervertebral disc protrusion	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Joint range of motion decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Joint stiffness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Joint swelling	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Muscle fatigue	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscle spasms	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	9	8.6	4.6	15.5
	Muscular weakness	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	5	4.8	2.1	10.7
	Musculoskeletal chest pain	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Musculoskeletal pain	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	7	6.7	3.3	13.1
	Musculoskeletal stiffness	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Myalgia	< 65	176	62.6	18	10.2	6.6	15.6
		>= 65	105	37.4	5	4.8	2.1	10.7
	Myopathy	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neck pain	< 65	176	62.6	11	6.3	3.5	10.8
		>= 65	105	37.4	3	2.9	1.0	8.1
	Osteopenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pain in extremity	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	10	9.5	5.3	16.6
	Pain in jaw	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rotator cuff syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Spinal column stenosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Spinal osteoarthritis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tendon disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tendon pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	5	4.8	2.1	10.7
	Anogenital warts	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Basal cell carcinoma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bowen's disease	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Metastases to central nervous system	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Renal cell carcinoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Squamous cell carcinoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Squamous cell carcinoma of skin	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tumour pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Nervous system disorders	-Total	< 65	176	62.6	80	45.5	38.3	52.8

		>= 65	105	37.4	61	58.1	48.5	67.1
	Ageusia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Aphasia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ataxia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Balance disorder	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Brain oedema	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cerebellar haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Disturbance in attention	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dizziness	< 65	176	62.6	20	11.4	7.5	16.9
		>= 65	105	37.4	17	16.2	10.4	24.4
	Dizziness postural	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dysarthria	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dysgeusia	< 65	176	62.6	18	10.2	6.6	15.6
		>= 65	105	37.4	24	22.9	15.9	31.8
	Dyskinesia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Headache	< 65	176	62.6	25	14.2	9.8	20.1
		>= 65	105	37.4	7	6.7	3.3	13.1
	Hemiplegia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperaesthesia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypersomnia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypoaesthesia	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	9	8.6	4.6	15.5
	Hypotonia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lethargy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lumbar radiculopathy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Memory impairment	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Migraine with aura	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neuralgia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neuropathy peripheral	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Paraesthesia	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Paralysis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Parosmia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Peripheral sensory neuropathy	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Polyneuropathy chronic	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Post herpetic neuralgia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Presyncope	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Psychomotor skills impaired	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Restless legs syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sciatica	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Seizure	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Sensory disturbance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Slow speech	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Somnolence	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Syncope	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Tension headache	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Tremor	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Visual field defect	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
Product issues	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Device dislocation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Psychiatric disorders	-Total	< 65	176	62.6	36	20.5	15.2	27.0
		>= 65	105	37.4	18	17.1	11.1	25.5
	Abnormal behaviour	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Abnormal dreams	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Adjustment disorder with mixed anxiety and depressed mood	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Anxiety	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	3	2.9	1.0	8.1
	Bradyphrenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Confusional state	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Delirium	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Depressed mood	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Depression	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Fear of falling	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Insomnia	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	4	3.8	1.5	9.4
	Irritability	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Libido decreased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mental status changes	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Mood altered	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Psychomotor retardation	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	1	1.0	0.2	5.2
	Restlessness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Sleep disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Renal and urinary disorders	-Total	< 65	176	62.6	22	12.5	8.4	18.2
		>= 65	105	37.4	19	18.1	11.9	26.5
	Acute kidney injury	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Azotaemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cystitis haemorrhagic	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dysuria	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	4	3.8	1.5	9.4
	Haematuria	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haemorrhage urinary tract	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Micturition urgency	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nephritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nocturia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pollakiuria	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Proteinuria	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Renal colic	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Renal disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Renal failure	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Renal impairment	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Strangury	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary incontinence	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7

	Urinary retention	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Urinary tract pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urine flow decreased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Reproductive system and breast disorders	-Total	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	6	5.7	2.6	11.9
	Benign prostatic hyperplasia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Breast discharge	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Erectile dysfunction	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Galactorrhoea	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Genital ulceration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Metrorrhagia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pelvic discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pelvic fluid collection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Perineal pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Postmenopausal haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Prostatitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Uterine polyp	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vaginal haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vulvovaginal dryness	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Vulvovaginal erythema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Respiratory, thoracic and mediastinal disorders	-Total	< 65	176	62.6	98	55.7	48.3	62.8
		>= 65	105	37.4	55	52.4	42.9	61.7

	Aspiration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bronchospasm	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Choking	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cough	< 65	176	62.6	41	23.3	17.7	30.1
		>= 65	105	37.4	23	21.9	15.1	30.7
	Dry throat	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dysphonia	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Dyspnoea	< 65	176	62.6	24	13.6	9.3	19.5
		>= 65	105	37.4	15	14.3	8.9	22.2
	Dyspnoea exertional	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	6	5.7	2.6	11.9
	Epistaxis	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	6	5.7	2.6	11.9
	Haemoptysis	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hiccups	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hypoxia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Interstitial lung disease	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Laryngeal haemorrhage	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nasal congestion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Nasal dryness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Nasal polyps	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oropharyngeal discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oropharyngeal pain	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	6	5.7	2.6	11.9
	Paranasal sinus discomfort	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pharyngeal disorder	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Pleural effusion	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pleural thickening	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pleuritic pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pneumonitis	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	9	8.6	4.6	15.5
	Pneumothorax	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Productive cough	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	6	5.7	2.6	11.9
	Pulmonary embolism	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pulmonary mass	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pulmonary pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiration abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rhinalgia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rhinitis allergic	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rhinorrhoea	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sinus congestion	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sleep apnoea syndrome	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sputum discoloured	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Throat irritation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Upper-airway cough syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Vocal cord leukoplakia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Wheezing	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

Skin and subcutaneous tissue disorders	-Total	< 65	176	62.6	63	35.8	29.1	43.1
		>= 65	105	37.4	37	35.2	26.8	44.7
	Acne	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Alopecia	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Chloasma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Decubitus ulcer	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermal cyst	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermatitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermatitis acneiform	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermatitis allergic	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dermatitis bullous	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Dry skin	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Ecchymosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eczema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Erythema	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hair growth abnormal	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hair texture abnormal	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hirsutism	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperhidrosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hyperkeratosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypertrichosis	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	0	0.0	0.0	3.5

	Madarosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nail discolouration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nail disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Night sweats	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Onychalgia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Onycholysis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Onychomadesis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pain of skin	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Palmar-plantar erythrodysaesthesia syndrome	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Photosensitivity reaction	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pruritus	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	4	3.8	1.5	9.4
	Pruritus generalised	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Purpura	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rash	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	7	6.7	3.3	13.1
	Rash erythematous	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rash macular	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Rash maculo-papular	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rash papular	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Scab	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Scar pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Skin discolouration	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Skin hyperpigmentation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Skin lesion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Swelling face	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Urticaria	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Surgical and medical procedures	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Astringent therapy	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Therapy cessation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Vascular disorders	-Total	< 65	176	62.6	43	24.4	18.7	31.3
		>= 65	105	37.4	29	27.6	20.0	36.8
	Aortic dissection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Circulatory collapse	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Deep vein thrombosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Embolism	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Flushing	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haematoma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hot flush	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hypertension	< 65	176	62.6	31	17.6	12.7	23.9
		>= 65	105	37.4	20	19.0	12.7	27.6
	Hypotension	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Lymphoedema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Orthostatic hypotension	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pallor	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Phlebitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Raynaud's phenomenon	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Superior vena cava syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Thrombophlebitis superficial	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Thrombosis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR12_SG.xls
26MAR2021 13:42

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1-2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	84	29.9	36	42.9	32.8	53.5
		1	190	67.6	87	45.8	38.9	52.9
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia	0	84	29.9	23	27.4	19.0	37.7
		1	190	67.6	59	31.1	24.9	38.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Aplastic anaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bone marrow oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Febrile neutropenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperfibrinogenaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Leukocytosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Leukopenia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymph node pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Lymphadenopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphopenia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutropenia	0	84	29.9	14	16.7	10.2	26.1
		1	190	67.6	17	8.9	5.7	13.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophilia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytopenia	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytosis	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Cardiac disorders	-Total	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	28	14.7	10.4	20.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute coronary syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Angina pectoris	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aortic valve calcification	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Atrial fibrillation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Atrial flutter	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bradycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bundle branch block right	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cardiac failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Extrasystoles	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myocardial ischaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nodal arrhythmia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Palpitations	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pericardial effusion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinus bradycardia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinus tachycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tachycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Ventricular extrasystoles	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ventricular pre-excitation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Congenital, familial and genetic disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gilbert's syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hydrocele	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Ear and labyrinth disorders	-Total	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear congestion	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear pain	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tinnitus	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Vertigo	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Endocrine disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperthyroidism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypothyroidism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Eye disorders	-Total	0	84	29.9	15	17.9	11.1	27.4
		1	190	67.6	22	11.6	7.8	16.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal sensation in eye	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blepharitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chalazion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Conjunctival cyst	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Conjunctival haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diplopia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry eye	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eye swelling	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eyelid oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eyelid ptosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Keratitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ocular discomfort	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Periorbital oedema	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Photophobia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Photopsia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ulcerative keratitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vision blurred	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Visual acuity reduced	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Gastrointestinal disorders	-Total	0	84	29.9	65	77.4	67.4	85.0
		1	190	67.6	128	67.4	60.4	73.6
		2	6	2.1	5	83.3	43.6	97.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Abdominal discomfort	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal distension	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Abdominal pain lower	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain upper	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal symptom	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anal incontinence	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aphthous ulcer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ascites	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Constipation	0	84	29.9	42	50.0	39.5	60.5
		1	190	67.6	71	37.4	30.8	44.4
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Dental dysaesthesia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diarrhoea	0	84	29.9	21	25.0	17.0	35.2
		1	190	67.6	41	21.6	16.3	28.0
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry mouth	0	84	29.9	20	23.8	16.0	33.9
		1	190	67.6	26	13.7	9.5	19.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspepsia	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysphagia	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Enteritis	0	84	29.9	1	1.2		0.2	6.4
		1	190	67.6	0	0.0		0.0	2.0
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Epigastric discomfort	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Eructation	0	84	29.9	1	1.2		0.2	6.4
		1	190	67.6	0	0.0		0.0	2.0
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Faeces soft	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Flatulence	0	84	29.9	1	1.2		0.2	6.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Frequent bowel movements	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Gastric ulcer	0	84	29.9	1	1.2		0.2	6.4
		1	190	67.6	0	0.0		0.0	2.0
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Gastritis	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	3	1.6		0.5	4.5
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Gastritis erosive	0	84	29.9	1	1.2		0.2	6.4
		1	190	67.6	0	0.0		0.0	2.0
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Gastrointestinal haemorrhage	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Gastrointestinal inflammation	0	84	29.9	1	1.2		0.2	6.4
		1	190	67.6	0	0.0		0.0	2.0
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Gastrointestinal oedema	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Gastrointestinal wall thickening	0	84	29.9	1	1.2		0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrooesophageal reflux disease	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gingival bleeding	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gingival swelling	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glossitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glossodynia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematochezia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhoids	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoaesthesia oral	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Impaired gastric emptying	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Irritable bowel syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Melaena	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Mouth ulceration	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	7	3.7	1.8	7.4

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nausea	0	84	29.9	13	15.5	9.3	24.7
		1	190	67.6	27	14.2	10.0	19.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	1	100.0	20.7	100.0
	Odynophagia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oesophageal irritation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oesophagitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral dysaesthesia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral mucosal erythema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancreatitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paraesthesia oral	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rectal prolapse	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Regurgitation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Sensitivity of teeth	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Stomatitis	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Swollen tongue	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tongue coated	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tongue discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tongue ulceration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tooth discolouration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Toothache	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vomiting	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	17	8.9	5.7	13.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
General disorders and administration site conditions	-Total	0	84	29.9	57	67.9	57.3	76.9
		1	190	67.6	129	67.9	61.0	74.1
		2	6	2.1	6	100.0	61.0	100.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Asthenia	0	84	29.9	14	16.7	10.2	26.1
		1	190	67.6	22	11.6	7.8	16.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Axillary pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Catheter site pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chills	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disease progression	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Face oedema	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Facial pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fatigue	0	84	29.9	17	20.2	13.0	30.0
		1	190	67.6	41	21.6	16.3	28.0
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Feeling abnormal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Feeling cold	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Feeling hot	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gait disturbance	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	General physical health deterioration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Generalised oedema	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Impaired healing	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Influenza like illness	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Injection site bruising	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Localised oedema	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Malaise	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mucosal dryness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mucosal inflammation	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Non-cardiac chest pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oedema peripheral	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	30	15.8	11.3	21.6
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain	0	84	29.9	3	3.6	1.2	10.0

		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Peripheral swelling	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyrexia	0	84	29.9	25	29.8	21.0	40.2
		1	190	67.6	42	22.1	16.8	28.5
		2	6	2.1	4	66.7	30.0	90.3
		Missing	1	0.4	0	0.0	0.0	79.3
	Swelling	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Temperature intolerance	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Xerosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Hepatobiliary disorders	-Total	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Cholecystitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic function abnormal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic steatosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatocellular injury	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperbilirubinaemia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Liver disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumobilia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Portal vein thrombosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
Immune system disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Contrast media allergy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Drug hypersensitivity	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Food allergy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypersensitivity	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Seasonal allergy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Infections and infestations	-Total	0	84	29.9	44	52.4	41.8	62.7
		1	190	67.6	77	40.5	33.8	47.6
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal abscess	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute sinusitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Arthritis infective	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Atypical pneumonia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacterial disease carrier	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacterial vaginosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bronchitis	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Candida infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cellulitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chronic sinusitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Conjunctivitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Corona virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis escherichia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Ear infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epididymitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epstein-Barr virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Escherichia bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Escherichia infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Escherichia urinary tract infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eye infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Febrile infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Folliculitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fungal infection	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastroenteritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Genital candidiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Genital herpes	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gingivitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Herpes simplex	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Herpes virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Herpes zoster	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Influenza	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lower respiratory tract infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lung infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lyme disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymph node tuberculosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasal herpes	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasopharyngitis	0	84	29.9	7	8.3	4.1	16.2

		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral candidiasis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral fungal infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oropharyngeal candidiasis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Otitis externa	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Otitis media	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paronychia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pharyngitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia influenzal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia pseudomonal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia streptococcal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyelonephritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory tract infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory tract infection bacterial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinitis	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sepsis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinusitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Staphylococcal infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Systemic infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tinea cruris	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tinea infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tinea pedis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Tonsillitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tooth infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tracheitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tuberculosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Upper respiratory tract infection	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urethritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary tract infection	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	17	8.9	5.7	13.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Varicella	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Varicella zoster virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Viral hepatitis carrier	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Viral infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vulvovaginal candidiasis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

Injury, poisoning and procedural complications	-Total	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	18	9.5	6.1	14.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Contusion	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epicondylitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fall	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Incision site pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint dislocation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Laceration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ligament sprain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Limb injury	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle rupture	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle strain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Procedural pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Procedural pneumothorax	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rib fracture	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Scar	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin abrasion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tendon rupture	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thermal burn	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wound	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wound complication	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wrist fracture	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Investigations	-Total	0	84	29.9	59	70.2	59.8	79.0
		1	190	67.6	147	77.4	70.9	82.7
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Alanine aminotransferase increased	0	84	29.9	20	23.8	16.0	33.9

		1	190	67.6	61	32.1	25.9	39.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	1	100.0	20.7	100.0
	Albumin urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alpha hydroxybutyrate dehydrogenase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Amylase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aspartate aminotransferase increased	0	84	29.9	27	32.1	23.1	42.7
		1	190	67.6	82	43.2	36.3	50.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	1	100.0	20.7	100.0
	Bacterial test	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bilirubin conjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood albumin decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase increased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	28	14.7	10.4	20.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin increased	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin unconjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	8	4.2	2.1	8.1

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood calcium decreased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood calcium increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood chloride increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood cholesterol increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine increased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase MB increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase increased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	30	15.8	11.3	21.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatinine	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatinine increased	0	84	29.9	17	20.2	13.0	30.0
		1	190	67.6	42	22.1	16.8	28.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood fibrinogen increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood glucose increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood iron decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Blood ketone body increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood lactate dehydrogenase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood magnesium decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood phosphorus increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood potassium decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood potassium increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood pressure increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood sodium decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood thyroid stimulating hormone increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood triglycerides increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood urea increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood uric acid decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Blood uric acid increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood urine	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	C-reactive protein increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Carbon dioxide decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Complement factor C1 decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Computerised tomogram thorax abnormal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Crystal urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystatin C increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrocardiogram QT prolonged	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrocardiogram ST-T change	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fibrin D dimer increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Fibrin degradation products increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Free fatty acids increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gamma-glutamyltransferase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	17	8.9	5.7	13.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glomerular filtration rate decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glutamate dehydrogenase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Granulocyte count decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematocrit decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemoglobin decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Heart rate increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic enzyme increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	International normalised ratio increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intraocular pressure increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Laboratory test abnormal	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lipase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Liver function test increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphocyte count decreased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphocyte count increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mean cell volume increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myoglobin blood increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil count decreased	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	33	17.4	12.6	23.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil count increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil percentage increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Occult blood positive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count decreased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	22	11.6	7.8	16.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5

		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Procalcitonin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Protein total decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Protein total increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Protein urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Prothrombin time prolonged	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Red blood cell count decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Serum amyloid A protein increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombin time prolonged	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Total bile acids increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Transaminases increased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Transferrin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Troponin T increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Troponin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary sediment present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urine ketone body present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urine leukocyte esterase positive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urobilinogen urine increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Weight decreased	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Weight increased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	White blood cell count decreased	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	47	24.7	19.1	31.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	White blood cells urine positive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Metabolism and nutrition disorders	-Total	0	84	29.9	40	47.6	37.3	58.2
		1	190	67.6	98	51.6	44.5	58.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal loss of weight	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alkalosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Cell death	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Decreased appetite	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	28	14.7	10.4	20.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dehydration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrolyte imbalance	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fluid retention	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercalcaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercholesterolaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperglycaemia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperkalaemia	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperlipidaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypermagnesaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypernatraemia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Hyperphosphataemia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	24	12.6	8.6	18.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertriglyceridaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperuricaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoalbuminaemia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	29	15.3	10.8	21.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypocalcaemia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	27	14.2	10.0	19.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypochloraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoglycaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypokalaemia	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypomagnesaemia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyponatraemia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypophosphataemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoproteinaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Increased appetite	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vitamin D deficiency	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Musculoskeletal and connective tissue disorders	-Total	0	84	29.9	41	48.8	38.4	59.3
		1	190	67.6	75	39.5	32.8	46.6
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Arthralgia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Arthropathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Back pain	0	84	29.9	14	16.7	10.2	26.1
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bone pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bursitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Coccydynia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Costochondritis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Flank pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Groin pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercreatinaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intervertebral disc protrusion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint range of motion decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint stiffness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint swelling	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle fatigue	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle spasms	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	16	8.4	5.2	13.2
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscular weakness	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal chest pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal pain	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	16	8.4	5.2	13.2
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal stiffness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myalgia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Neck pain	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Osteopenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain in extremity	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	18	9.5	6.1	14.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain in jaw	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rotator cuff syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Spinal column stenosis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Spinal osteoarthritis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tendon disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tendon pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anogenital warts	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Basal cell carcinoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Bowen's disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Metastases to central nervous system	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal cell carcinoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Squamous cell carcinoma	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Squamous cell carcinoma of skin	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tumour pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Nervous system disorders	-Total	0	84	29.9	37	44.0	33.9	54.7
		1	190	67.6	100	52.6	45.6	59.6
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	1	100.0	20.7	100.0
	Ageusia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aphasia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ataxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Balance disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Brain oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Cerebellar haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disturbance in attention	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dizziness	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	28	14.7	10.4	20.5
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dizziness postural	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysarthria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysgeusia	0	84	29.9	13	15.5	9.3	24.7
		1	190	67.6	28	14.7	10.4	20.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyskinesia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Headache	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	22	11.6	7.8	16.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	1	100.0	20.7	100.0
	Hemiplegia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperaesthesia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypersomnia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoaesthesia	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypotonia	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lethargy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lumbar radiculopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Memory impairment	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Migraine with aura	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neuralgia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neuropathy peripheral	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paraesthesia	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paralysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Parosmia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Peripheral sensory neuropathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Polyneuropathy chronic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Post herpetic neuralgia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Presyncope	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Psychomotor skills impaired	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Restless legs syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sciatica	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Seizure	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Sensory disturbance	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Slow speech	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Somnolence	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Syncope	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tension headache	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tremor	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Visual field defect	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
Product issues	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Device dislocation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Psychiatric disorders	-Total	0	84	29.9	16	19.0	12.1	28.7
		1	190	67.6	36	18.9	14.0	25.1
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal behaviour	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal dreams	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Adjustment disorder with mixed anxiety and depressed mood	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anxiety	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Bradyphrenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Confusional state	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Delirium	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Depressed mood	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Depression	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Fear of falling	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Insomnia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	18	9.5	6.1	14.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Irritability	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Libido decreased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mental status changes	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mood altered	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Psychomotor retardation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Restlessness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sleep disorder	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Renal and urinary disorders	-Total	0	84	29.9	14	16.7	10.2	26.1
		1	190	67.6	24	12.6	8.6	18.1
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute kidney injury	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Azotaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Cystitis haemorrhagic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysuria	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhage urinary tract	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Micturition urgency	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Nephritis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nocturia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pollakiuria	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Proteinuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal colic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal disorder	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal failure	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal impairment	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Strangury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary incontinence	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary retention	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary tract pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urine flow decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Reproductive system and breast disorders	-Total	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Benign prostatic hyperplasia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Breast discharge	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Erectile dysfunction	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Galactorrhoea	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Genital ulceration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Metrorrhagia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pelvic discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pelvic fluid collection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Perineal pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Postmenopausal haemorrhage	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Prostatitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Uterine polyp	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vaginal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vulvovaginal dryness	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vulvovaginal erythema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Respiratory, thoracic and mediastinal disorders	-Total	0	84	29.9	51	60.7	50.0	70.5
		1	190	67.6	99	52.1	45.0	59.1
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Aspiration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bronchospasm	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Choking	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cough	0	84	29.9	23	27.4	19.0	37.7
		1	190	67.6	39	20.5	15.4	26.8
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry throat	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysphonia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	29	15.3	10.8	21.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea exertional	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epistaxis	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemoptysis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hiccups	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Interstitial lung disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Laryngeal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Nasal congestion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasal dryness	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasal polyps	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oropharyngeal discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oropharyngeal pain	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paranasal sinus discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pharyngeal disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural effusion	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural thickening	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleuritic pain	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonitis	0	84	29.9	14	16.7	10.2	26.1
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumothorax	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Productive cough	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary embolism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary mass	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiration abnormal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinalgia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinitis allergic	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinorrhoea	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinus congestion	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sleep apnoea syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sputum discoloured	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Throat irritation	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Upper-airway cough syndrome	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vocal cord leukoplakia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wheezing	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Skin and subcutaneous tissue disorders	-Total	0	84	29.9	37	44.0	33.9	54.7
		1	190	67.6	59	31.1	24.9	38.0
		2	6	2.1	4	66.7	30.0	90.3
		Missing	1	0.4	0	0.0	0.0	79.3
	Acne	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alopecia	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chloasma	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Decubitus ulcer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermal cyst	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis acneiform	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis allergic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis bullous	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry skin	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Ecchymosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eczema	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Erythema	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hair growth abnormal	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hair texture abnormal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hirsutism	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperhidrosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperkeratosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertrichosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Madarosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nail discolouration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Nail disorder	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Night sweats	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Onychalgia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Onycholysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Onychomadesis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain of skin	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Palmar-plantar erythrodysaesthesia syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Photosensitivity reaction	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pruritus	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pruritus generalised	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Purpura	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Rash erythematous	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash macular	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash maculo-papular	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash papular	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Scab	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Scar pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin discolouration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin hyperpigmentation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin lesion	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Swelling face	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urticaria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Surgical and medical procedures	-Total	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Astringent therapy	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Therapy cessation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Vascular disorders	-Total	0	84	29.9	17	20.2	13.0	30.0
		1	190	67.6	54	28.4	22.5	35.2
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Aortic dissection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Circulatory collapse	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Deep vein thrombosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Flushing	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hot flush	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertension	0	84	29.9	12	14.3	8.4	23.3
		1	190	67.6	38	20.0	14.9	26.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypotension	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphoedema	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Orthostatic hypotension	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pallor	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Phlebitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Raynaud's phenomenon	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Superior vena cava syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombophlebitis superficial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR12_SG.xls
26MAR2021 13:42

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1-2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	USA	64	22.8	30	46.9	35.2	58.9
		Europe (EU)	95	33.8	39	41.1	31.7	51.1
		Asia (AS)	122	43.4	56	45.9	37.3	54.7
	Anaemia	USA	64	22.8	18	28.1	18.6	40.1
		Europe (EU)	95	33.8	27	28.4	20.3	38.2
		Asia (AS)	122	43.4	38	31.1	23.6	39.8
	Aplastic anaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bone marrow oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cytopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Febrile neutropenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyperfibrinogenaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Leukocytosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Leukopenia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	10	10.5	5.8	18.3
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Lymph node pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lymphadenopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lymphopenia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neutropenia	USA	64	22.8	13	20.3	12.3	31.7

		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Neutrophilia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pancytopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thrombocytopenia	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Thrombocytosis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Cardiac disorders	-Total	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	18	14.8	9.5	22.1
	Acute coronary syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Angina pectoris	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aortic valve calcification	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Atrial fibrillation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Atrial flutter	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Bradycardia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bundle branch block right	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cardiac failure	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Extrasystoles	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Myocardial ischaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nodal arrhythmia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Palpitations	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pericardial effusion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinus bradycardia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinus tachycardia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Tachycardia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Ventricular extrasystoles	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Ventricular pre-excitation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Congenital, familial and genetic disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gilbert's syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hydrocele	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Ear and labyrinth disorders	-Total	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Ear congestion	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ear discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ear pain	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Tinnitus	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Vertigo	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
Endocrine disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperthyroidism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypothyroidism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Eye disorders	-Total	USA	64	22.8	16	25.0	16.0	36.8
		Europe (EU)	95	33.8	13	13.7	8.2	22.0
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Abnormal sensation in eye	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blepharitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Chalazion	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Conjunctival cyst	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Conjunctival haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Diplopia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dry eye	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eye swelling	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eyelid oedema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1

	Eyelid ptosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Keratitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ocular discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Periorbital oedema	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Photophobia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Photopsia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ulcerative keratitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vision blurred	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Visual acuity reduced	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Gastrointestinal disorders	-Total	USA	64	22.8	51	79.7	68.3	87.7
		Europe (EU)	95	33.8	71	74.7	65.2	82.4
		Asia (AS)	122	43.4	77	63.1	54.3	71.2
	Abdominal discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Abdominal distension	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Abdominal pain	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Abdominal pain lower	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Abdominal pain upper	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Abdominal symptom	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Anal incontinence	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Aphthous ulcer	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ascites	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Constipation	USA	64	22.8	25	39.1	28.1	51.3
		Europe (EU)	95	33.8	39	41.1	31.7	51.1
		Asia (AS)	122	43.4	52	42.6	34.2	51.5
	Dental dysaesthesia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Diarrhoea	USA	64	22.8	18	28.1	18.6	40.1
		Europe (EU)	95	33.8	25	26.3	18.5	36.0
		Asia (AS)	122	43.4	22	18.0	12.2	25.8
	Dry mouth	USA	64	22.8	19	29.7	19.9	41.8
		Europe (EU)	95	33.8	18	18.9	12.3	28.0
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Dyspepsia	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Dysphagia	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Enteritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epigastric discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eructation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Faeces soft	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Flatulence	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Frequent bowel movements	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastric ulcer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastritis erosive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastrointestinal inflammation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal wall thickening	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrooesophageal reflux disease	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gingival bleeding	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Gingival swelling	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Glossitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Glossodynia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haematochezia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haemorrhoids	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hypoaesthesia oral	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0

	Impaired gastric emptying	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Irritable bowel syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Melaena	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Mouth ulceration	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Nausea	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	17	17.9	11.5	26.8
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Odynophagia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oesophageal irritation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oesophagitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oral disorder	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oral dysaesthesia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oral mucosal erythema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oral pain	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pancreatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Paraesthesia oral	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rectal prolapse	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Regurgitation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sensitivity of teeth	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Stomatitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Swollen tongue	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tongue coated	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tongue discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tongue ulceration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tooth discolouration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Toothache	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Vomiting	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	13	13.7	8.2	22.0
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
General disorders and administration site conditions	-Total	USA	64	22.8	48	75.0	63.2	84.0
		Europe (EU)	95	33.8	66	69.5	59.6	77.8
		Asia (AS)	122	43.4	79	64.8	55.9	72.7
	Asthenia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	25	26.3	18.5	36.0
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Axillary pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Catheter site pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Chest discomfort	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Chest pain	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Chills	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Disease progression	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Face oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	17	13.9	8.9	21.2
	Facial pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fatigue	USA	64	22.8	26	40.6	29.5	52.9
		Europe (EU)	95	33.8	19	20.0	13.2	29.1
		Asia (AS)	122	43.4	16	13.1	8.2	20.2
	Feeling abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Feeling cold	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Feeling hot	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gait disturbance	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	General physical health deterioration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Generalised oedema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Impaired healing	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Influenza like illness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Injection site bruising	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Localised oedema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Malaise	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	17	13.9	8.9	21.2
	Mucosal dryness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Mucosal inflammation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	18	18.9	12.3	28.0
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Non-cardiac chest pain	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Oedema	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oedema peripheral	USA	64	22.8	19	29.7	19.9	41.8
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Pain	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Peripheral swelling	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Pyrexia	USA	64	22.8	10	15.6	8.7	26.4
		Europe (EU)	95	33.8	27	28.4	20.3	38.2
		Asia (AS)	122	43.4	34	27.9	20.7	36.4
	Swelling	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Temperature intolerance	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Xerosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Hepatobiliary disorders	-Total	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Cholecystitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hepatic function abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0

	Hepatic steatosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hepatocellular injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperbilirubinaemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Liver disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumobilia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Portal vein thrombosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Immune system disorders	-Total	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Contrast media allergy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Drug hypersensitivity	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Food allergy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypersensitivity	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Seasonal allergy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Infections and infestations	-Total	USA	64	22.8	30	46.9	35.2	58.9
		Europe (EU)	95	33.8	51	53.7	43.7	63.4
		Asia (AS)	122	43.4	41	33.6	25.8	42.4
	Abdominal abscess	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Acute sinusitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Arthritis infective	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Atypical pneumonia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacteraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacterial disease carrier	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacterial vaginosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bronchitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Candida infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cellulitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Chronic sinusitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Conjunctivitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Corona virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cystitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cystitis escherichia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ear infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epididymitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epstein-Barr virus infection	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Escherichia bacteraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Escherichia infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Escherichia urinary tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eye infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Febrile infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Folliculitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fungal infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Gastroenteritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Genital candidiasis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Genital herpes	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gingivitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Herpes simplex	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Herpes virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Herpes zoster	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Influenza	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lower respiratory tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lung infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lyme disease	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymph node tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nasal herpes	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasopharyngitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Oral candidiasis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oral fungal infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oropharyngeal candidiasis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Otitis externa	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Otitis media	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Paronychia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Pharyngitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	9	7.4	3.9	13.4

	Pneumonia influenzal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonia pseudomonal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonia streptococcal	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pyelonephritis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pyuria	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory tract infection bacterial	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhinitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Sepsis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinusitis	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Skin infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Staphylococcal infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Systemic infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tinea cruris	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tinea infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Tinea pedis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tonsillitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tooth infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tracheitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Upper respiratory tract infection	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Urethritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary tract infection	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Varicella	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Varicella zoster virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Viral hepatitis carrier	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Viral infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vulvovaginal candidiasis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Injury, poisoning and procedural complications	-Total	USA	64	22.8	13	20.3	12.3	31.7
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Contusion	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epicondylitis	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fall	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Incision site pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Joint dislocation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Laceration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ligament sprain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Limb injury	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle rupture	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle strain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Procedural pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Procedural pneumothorax	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rib fracture	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Scar	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin abrasion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tendon rupture	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thermal burn	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Wound	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Wound complication	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Wrist fracture	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Investigations	-Total	USA	64	22.8	49	76.6	64.9	85.3
		Europe (EU)	95	33.8	60	63.2	53.1	72.2
		Asia (AS)	122	43.4	100	82.0	74.2	87.8
	Alanine aminotransferase increased	USA	64	22.8	18	28.1	18.6	40.1
		Europe (EU)	95	33.8	16	16.8	10.6	25.6
		Asia (AS)	122	43.4	49	40.2	31.9	49.0
	Albumin urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Alpha hydroxybutyrate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Amylase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Aspartate aminotransferase increased	USA	64	22.8	25	39.1	28.1	51.3
		Europe (EU)	95	33.8	25	26.3	18.5	36.0
		Asia (AS)	122	43.4	61	50.0	41.3	58.7
	Bacterial test	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bilirubin conjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	19	15.6	10.2	23.0
	Blood albumin decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood alkaline phosphatase	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Blood alkaline phosphatase decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood alkaline phosphatase increased	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	21	17.2	11.5	24.9
	Blood bilirubin increased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	17	13.9	8.9	21.2
	Blood bilirubin unconjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Blood calcium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood calcium increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood chloride increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood cholesterol increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Blood creatine increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood creatine phosphokinase MB increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Blood creatine phosphokinase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	25	20.5	14.3	28.5
	Blood creatinine	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood creatinine increased	USA	64	22.8	17	26.6	17.3	38.5
		Europe (EU)	95	33.8	20	21.1	14.1	30.3
		Asia (AS)	122	43.4	23	18.9	12.9	26.7
	Blood fibrinogen increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood glucose increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

	Blood iron decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood ketone body increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood lactate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Blood magnesium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood phosphorus increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Blood potassium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood potassium increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood pressure increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Blood sodium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood thyroid stimulating hormone increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood triglycerides increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Blood urea increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Blood uric acid decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood uric acid increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Blood urine	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Blood urine present	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	C-reactive protein increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Carbon dioxide decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Complement factor C1 decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Computerised tomogram thorax abnormal	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Crystal urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cystatin C increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Electrocardiogram QT prolonged	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Electrocardiogram ST-T change	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Fibrin D dimer increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Fibrin degradation products increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Free fatty acids increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gamma-glutamyltransferase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	16	13.1	8.2	20.2
	Glomerular filtration rate decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Glutamate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Granulocyte count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haematocrit decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haemoglobin decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Heart rate increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Hepatic enzyme increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	International normalised ratio increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Intraocular pressure increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Laboratory test abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lipase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Liver function test increased	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymphocyte count decreased	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Lymphocyte count increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Mean cell volume increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Myoglobin blood increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Neutrophil count decreased	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	36	29.5	22.1	38.1
	Neutrophil count increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Neutrophil percentage increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Occult blood positive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Platelet count decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	18	14.8	9.5	22.1
	Platelet count increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Procalcitonin increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Protein total decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Protein total increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Protein urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Prothrombin time prolonged	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Red blood cell count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Serum amyloid A protein increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Thrombin time prolonged	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Total bile acids increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Transaminases increased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Transferrin increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Troponin T increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Troponin increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary sediment present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urine ketone body present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Urine leukocyte esterase positive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urobilinogen urine increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Weight decreased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
	Weight increased	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	17	13.9	8.9	21.2
	White blood cell count decreased	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	10	10.5	5.8	18.3
		Asia (AS)	122	43.4	32	26.2	19.2	34.7
	White blood cells urine positive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
Metabolism and nutrition disorders	-Total	USA	64	22.8	27	42.2	30.9	54.4
		Europe (EU)	95	33.8	42	44.2	34.6	54.2
		Asia (AS)	122	43.4	69	56.6	47.7	65.0
	Abnormal loss of weight	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Alkalosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cell death	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Decreased appetite	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	23	18.9	12.9	26.7
	Dehydration	USA	64	22.8	4	6.3	2.5	15.0

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Electrolyte imbalance	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Fluid retention	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypercalcaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hypercholesterolaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hyperglycaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
	Hyperkalaemia	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hyperlipidaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Hypermagnesaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hypernatraemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hyperphosphataemia	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Hypertriglyceridaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Hyperuricaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Hypoalbuminaemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	32	26.2	19.2	34.7
	Hypocalcaemia	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	17	13.9	8.9	21.2
	Hypochloraemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Hypoglycaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypokalaemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	13	13.7	8.2	22.0
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Hypomagnesaemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Hyponatraemia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	12	9.8	5.7	16.4
	Hypophosphataemia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Hypoproteinaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Increased appetite	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vitamin D deficiency	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Musculoskeletal and connective tissue disorders	-Total	USA	64	22.8	38	59.4	47.1	70.5
		Europe (EU)	95	33.8	38	40.0	30.7	50.1
		Asia (AS)	122	43.4	43	35.2	27.3	44.1
	Arthralgia	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Arthropathy	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Back pain	USA	64	22.8	13	20.3	12.3	31.7
		Europe (EU)	95	33.8	10	10.5	5.8	18.3
		Asia (AS)	122	43.4	12	9.8	5.7	16.4
	Bone pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Bursitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Coccydynia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Costochondritis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Flank pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Groin pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypercreatinaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Intervertebral disc protrusion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Joint range of motion decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Joint stiffness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Joint swelling	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle fatigue	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Muscle spasms	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Muscular weakness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Musculoskeletal chest pain	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Musculoskeletal pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	12	12.6	7.4	20.8
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Musculoskeletal stiffness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Myalgia	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	7	5.7	2.8	11.4

	Myopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neck pain	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Osteopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pain in extremity	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Pain in jaw	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rotator cuff syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Spinal column stenosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Spinal osteoarthritis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tendon disorder	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tendon pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Anogenital warts	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Basal cell carcinoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bowen's disease	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Metastases to central nervous system	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal cell carcinoma	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Squamous cell carcinoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Squamous cell carcinoma of skin	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tumour pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Nervous system disorders	-Total	USA	64	22.8	41	64.1	51.8	74.7
		Europe (EU)	95	33.8	46	48.4	38.6	58.3
		Asia (AS)	122	43.4	54	44.3	35.8	53.1
	Ageusia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aphasia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ataxia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Balance disorder	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Brain oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebellar haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Disturbance in attention	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dizziness	USA	64	22.8	13	20.3	12.3	31.7
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Dizziness postural	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dysarthria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dysgeusia	USA	64	22.8	14	21.9	13.5	33.4
		Europe (EU)	95	33.8	20	21.1	14.1	30.3

		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Dyskinesia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Headache	USA	64	22.8	14	21.9	13.5	33.4
		Europe (EU)	95	33.8	12	12.6	7.4	20.8
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Hemiplegia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyperaesthesia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypersomnia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypoaesthesia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	16	13.1	8.2	20.2
	Hypotonia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lethargy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lumbar radiculopathy	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Memory impairment	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Migraine with aura	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neuralgia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neuropathy peripheral	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Paraesthesia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Paralysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Parosmia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Peripheral sensory neuropathy	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Polyneuropathy chronic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Post herpetic neuralgia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Presyncope	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Psychomotor skills impaired	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Restless legs syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sciatica	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Seizure	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Sensory disturbance	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Slow speech	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Somnolence	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Syncope	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tension headache	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tremor	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Visual field defect	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Product issues	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Device dislocation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Psychiatric disorders	-Total	USA	64	22.8	14	21.9	13.5	33.4
		Europe (EU)	95	33.8	17	17.9	11.5	26.8
		Asia (AS)	122	43.4	23	18.9	12.9	26.7
	Abnormal behaviour	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Abnormal dreams	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Adjustment disorder with mixed anxiety and depressed mood	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Anxiety	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Bradyphrenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Confusional state	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Delirium	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Depressed mood	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Depression	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fear of falling	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Insomnia	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Irritability	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Libido decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Mental status changes	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Mood altered	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Psychomotor retardation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Restlessness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Sleep disorder	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Renal and urinary disorders	-Total	USA	64	22.8	18	28.1	18.6	40.1
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Acute kidney injury	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Azotaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Cystitis haemorrhagic	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dysuria	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Haematuria	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Haemorrhage urinary tract	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Micturition urgency	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nephritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nocturia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pollakiuria	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Proteinuria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Renal colic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal failure	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal impairment	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Strangury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urinary incontinence	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary retention	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urinary tract pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urine flow decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Reproductive system and breast disorders	-Total	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	10	10.5	5.8	18.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Benign prostatic hyperplasia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Breast discharge	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Erectile dysfunction	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Galactorrhoea	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Genital ulceration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Metrorrhagia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pelvic discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pelvic fluid collection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Perineal pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Postmenopausal haemorrhage	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Prostatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Uterine polyp	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vaginal haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vulvovaginal dryness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vulvovaginal erythema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Respiratory, thoracic and mediastinal disorders	-Total	USA	64	22.8	38	59.4	47.1	70.5
		Europe (EU)	95	33.8	51	53.7	43.7	63.4
		Asia (AS)	122	43.4	64	52.5	43.7	61.1
	Aspiration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Bronchospasm	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Choking	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cough	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	23	24.2	16.7	33.7
		Asia (AS)	122	43.4	26	21.3	15.0	29.4
	Dry throat	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dysphonia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Dyspnoea	USA	64	22.8	10	15.6	8.7	26.4
		Europe (EU)	95	33.8	13	13.7	8.2	22.0
		Asia (AS)	122	43.4	16	13.1	8.2	20.2
	Dyspnoea exertional	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Epistaxis	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Haemoptysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Hiccups	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypoxia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Interstitial lung disease	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Laryngeal haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nasal congestion	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasal dryness	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasal polyps	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oropharyngeal discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oropharyngeal pain	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Paranasal sinus discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pharyngeal disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pleural effusion	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pleural thickening	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pleuritic pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonitis	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Pneumothorax	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Productive cough	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Pulmonary embolism	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pulmonary mass	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pulmonary pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiration abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rhinalgia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhinitis allergic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rhinorrhoea	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinus congestion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sleep apnoea syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Sputum discoloured	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Throat irritation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Upper-airway cough syndrome	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vocal cord leukoplakia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Wheezing	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Skin and subcutaneous tissue disorders	-Total	USA	64	22.8	32	50.0	38.1	61.9
		Europe (EU)	95	33.8	29	30.5	22.2	40.4
		Asia (AS)	122	43.4	39	32.0	24.4	40.7
	Acne	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Alopecia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Chloasma	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Decubitus ulcer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dermal cyst	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Dermatitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dermatitis acneiform	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Dermatitis allergic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dermatitis bullous	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dry skin	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Ecchymosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Eczema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Erythema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hair growth abnormal	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hair texture abnormal	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hirsutism	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperhidrosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperkeratosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypertrichosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Madarosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Nail discolouration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nail disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Night sweats	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Onychalgia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Onycholysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Onychomadesis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Pain of skin	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Palmar-plantar erythrodysaesthesia syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Photosensitivity reaction	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pruritus	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Pruritus generalised	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Purpura	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rash	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Rash erythematous	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rash macular	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rash maculo-papular	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rash papular	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Scab	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Scar pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Skin discolouration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin hyperpigmentation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin lesion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Swelling face	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Urticaria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Surgical and medical procedures	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Astringent therapy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Therapy cessation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Vascular disorders	-Total	USA	64	22.8	17	26.6	17.3	38.5
		Europe (EU)	95	33.8	23	24.2	16.7	33.7
		Asia (AS)	122	43.4	32	26.2	19.2	34.7
	Aortic dissection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Circulatory collapse	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Deep vein thrombosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Embolism	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Flushing	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haematoma	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hot flush	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypertension	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	14	14.7	9.0	23.2
		Asia (AS)	122	43.4	28	23.0	16.4	31.2
	Hypotension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lymphoedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Orthostatic hypotension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pallor	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Phlebitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Raynaud's phenomenon	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Superior vena cava syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Thrombophlebitis superficial	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thrombosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR12_SG.xls
26MAR2021 13:42

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1-2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	116	41.3	48	41.4	32.8	50.5
		1	77	27.4	34	44.2	33.6	55.3
		>= 2	88	31.3	43	48.9	38.7	59.1
	Anaemia	0	116	41.3	32	27.6	20.3	36.3
		1	77	27.4	23	29.9	20.8	40.8
		>= 2	88	31.3	28	31.8	23.0	42.1
	Aplastic anaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bone marrow oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cytopenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Febrile neutropenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperfibrinogenaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Leukocytosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Leukopenia	0	116	41.3	14	12.1	7.3	19.2
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	3	3.4	1.2	9.5
	Lymph node pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymphadenopathy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymphopenia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Neutropenia	0	116	41.3	11	9.5	5.4	16.2

		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	7	8.0	3.9	15.5
	Neutrophilia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pancytopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Thrombocytopenia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Thrombocytosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
Cardiac disorders	-Total	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	15	17.0	10.6	26.2
	Acute coronary syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Angina pectoris	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Aortic valve calcification	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Atrial fibrillation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Atrial flutter	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bradycardia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bundle branch block right	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cardiac failure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Extrasystoles	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Myocardial ischaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Nodal arrhythmia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Palpitations	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pericardial effusion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Sinus bradycardia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Sinus tachycardia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Tachycardia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Ventricular extrasystoles	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ventricular pre-excitation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Congenital, familial and genetic disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gilbert's syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hydrocele	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Ear and labyrinth disorders	-Total	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	8	9.1	4.7	16.9
	Ear congestion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ear discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ear pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9

	Tinnitus	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vertigo	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	5	5.7	2.5	12.6
Endocrine disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hyperthyroidism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypothyroidism	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
Eye disorders	-Total	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	17	22.1	14.3	32.5
		>= 2	88	31.3	13	14.8	8.8	23.7
	Abnormal sensation in eye	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blepharitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Chalazion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Conjunctival cyst	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Conjunctival haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Diplopia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dry eye	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Eye swelling	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eyelid oedema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9

	Eyelid ptosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Keratitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ocular discomfort	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Periorbital oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	1	1.1	0.2	6.2
	Photophobia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Photopsia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ulcerative keratitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vision blurred	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	5	5.7	2.5	12.6
	Visual acuity reduced	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Gastrointestinal disorders	-Total	0	116	41.3	79	68.1	59.2	75.9
		1	77	27.4	55	71.4	60.5	80.3
		>= 2	88	31.3	65	73.9	63.8	81.9
	Abdominal discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Abdominal distension	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Abdominal pain	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Abdominal pain lower	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Abdominal pain upper	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Abdominal symptom	0	116	41.3	1	0.9	0.2	4.7

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Anal incontinence	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Aphthous ulcer	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ascites	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Constipation	0	116	41.3	51	44.0	35.3	53.0
		1	77	27.4	32	41.6	31.2	52.7
		>= 2	88	31.3	33	37.5	28.1	47.9
	Dental dysaesthesia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Diarrhoea	0	116	41.3	24	20.7	14.3	28.9
		1	77	27.4	21	27.3	18.6	38.1
		>= 2	88	31.3	20	22.7	15.2	32.5
	Dry mouth	0	116	41.3	14	12.1	7.3	19.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	20	22.7	15.2	32.5
	Dyspepsia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Dysphagia	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	9	10.2	5.5	18.3
	Enteritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Epigastric discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Eructation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Faeces soft	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Flatulence	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Frequent bowel movements	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastric ulcer	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastritis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Gastritis erosive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrointestinal haemorrhage	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrointestinal inflammation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrointestinal oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastrointestinal wall thickening	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrooesophageal reflux disease	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Gingival bleeding	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Gingival swelling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Glossitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Glossodynia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haematochezia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemorrhoids	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypoaesthesia oral	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2

	Impaired gastric emptying	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Irritable bowel syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Melaena	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Mouth ulceration	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Nausea	0	116	41.3	18	15.5	10.0	23.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	11	12.5	7.1	21.0
	Odynophagia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oesophageal irritation	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oesophagitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oral disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Oral dysaesthesia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oral mucosal erythema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Oral pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Pancreatitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Paraesthesia oral	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rectal prolapse	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Regurgitation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sensitivity of teeth	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Stomatitis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Swollen tongue	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tongue coated	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tongue discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tongue ulceration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tooth discolouration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Toothache	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Vomiting	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	9	10.2	5.5	18.3
General disorders and administration site conditions	-Total	0	116	41.3	71	61.2	52.1	69.6
		1	77	27.4	53	68.8	57.8	78.1
		>= 2	88	31.3	69	78.4	68.7	85.7
	Asthenia	0	116	41.3	18	15.5	10.0	23.2
		1	77	27.4	11	14.3	8.2	23.8
		>= 2	88	31.3	8	9.1	4.7	16.9
	Axillary pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Catheter site pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Chest discomfort	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Chest pain	0	116	41.3	6	5.2	2.4	10.8

		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Chills	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Disease progression	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Face oedema	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	8	9.1	4.7	16.9
	Facial pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fatigue	0	116	41.3	24	20.7	14.3	28.9
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	24	27.3	19.1	37.4
	Feeling abnormal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Feeling cold	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Feeling hot	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gait disturbance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	General physical health deterioration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Generalised oedema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Impaired healing	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Influenza like illness	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Injection site bruising	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Localised oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	2	2.3	0.6	7.9
	Malaise	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	6	6.8	3.2	14.1
	Mucosal dryness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Mucosal inflammation	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Non-cardiac chest pain	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oedema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oedema peripheral	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	19	21.6	14.3	31.3
	Pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Peripheral swelling	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pyrexia	0	116	41.3	23	19.8	13.6	28.0
		1	77	27.4	22	28.6	19.7	39.5
		>= 2	88	31.3	26	29.5	21.0	39.8
	Swelling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Temperature intolerance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Xerosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Hepatobiliary disorders	-Total	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	5	5.7	2.5	12.6
	Cholecystitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hepatic function abnormal	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Hepatic steatosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hepatocellular injury	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hyperbilirubinaemia	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Liver disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumobilia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Portal vein thrombosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
Immune system disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Contrast media allergy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Drug hypersensitivity	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Food allergy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypersensitivity	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Seasonal allergy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
Infections and infestations	-Total	0	116	41.3	39	33.6	25.7	42.6
		1	77	27.4	37	48.1	37.3	59.0
		>= 2	88	31.3	46	52.3	42.0	62.4
	Abdominal abscess	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Acute sinusitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Arthritis infective	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Atypical pneumonia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bacteraemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bacterial disease carrier	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bacterial vaginosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bronchitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	2	2.3	0.6	7.9
	Candida infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cellulitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Chronic sinusitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Conjunctivitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Corona virus infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cystitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cystitis escherichia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ear infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Epididymitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Epstein-Barr virus infection	0	116	41.3	1	0.9	0.2	4.7

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Escherichia bacteraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Escherichia infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Escherichia urinary tract infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eye infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Febrile infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Folliculitis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fungal infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastroenteritis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Genital candidiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Genital herpes	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gingivitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Herpes simplex	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Herpes virus infection	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Herpes zoster	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1	0.2	6.2
	Influenza	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lower respiratory tract infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lung infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lyme disease	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lymph node tuberculosis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasal herpes	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasopharyngitis	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Oral candidiasis	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Oral fungal infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oropharyngeal candidiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Otitis externa	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Otitis media	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Paronychia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pharyngitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	8	9.1	4.7	16.9

	Pneumonia influenzal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonia pseudomonal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia streptococcal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pyelonephritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pyuria	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Respiratory tract infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiratory tract infection bacterial	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Sepsis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sinusitis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Skin infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Staphylococcal infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Systemic infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tinea cruris	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tinea infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Tinea pedis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Tonsillitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tooth infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tracheitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tuberculosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Upper respiratory tract infection	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	7	8.0	3.9	15.5
	Urethritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urinary tract infection	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	13	14.8	8.8	23.7
	Varicella	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Varicella zoster virus infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Viral hepatitis carrier	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Viral infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vulvovaginal candidiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Injury, poisoning and procedural complications	-Total	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	14	15.9	9.7	25.0
	Contusion	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Epicondylitis	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Fall	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Incision site pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Joint dislocation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Laceration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ligament sprain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Limb injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Muscle rupture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Muscle strain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Procedural pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Procedural pneumothorax	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rib fracture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Scar	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Skin abrasion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Skin injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Tendon rupture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Thermal burn	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Wound	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Wound complication	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Wrist fracture	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Investigations	-Total	0	116	41.3	85	73.3	64.6	80.5
		1	77	27.4	58	75.3	64.6	83.6
		>= 2	88	31.3	66	75.0	65.0	82.9
	Alanine aminotransferase increased	0	116	41.3	39	33.6	25.7	42.6
		1	77	27.4	16	20.8	13.2	31.1
		>= 2	88	31.3	28	31.8	23.0	42.1
	Albumin urine present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Alpha hydroxybutyrate dehydrogenase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Amylase increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Aspartate aminotransferase increased	0	116	41.3	46	39.7	31.2	48.8
		1	77	27.4	29	37.7	27.7	48.8
		>= 2	88	31.3	36	40.9	31.2	51.4
	Bacterial test	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bilirubin conjugated increased	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Blood albumin decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood alkaline phosphatase	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Blood alkaline phosphatase decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood alkaline phosphatase increased	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	13	14.8	8.8	23.7
	Blood bilirubin increased	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	7	8.0	3.9	15.5
	Blood bilirubin unconjugated increased	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood calcium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood calcium increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood chloride increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood cholesterol increased	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Blood creatine increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood creatine phosphokinase MB increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood creatine phosphokinase increased	0	116	41.3	17	14.7	9.4	22.2
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	11	12.5	7.1	21.0
	Blood creatinine	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood creatinine increased	0	116	41.3	17	14.7	9.4	22.2
		1	77	27.4	19	24.7	16.4	35.4
		>= 2	88	31.3	24	27.3	19.1	37.4
	Blood fibrinogen increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood glucose increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5

	Blood iron decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood ketone body increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood lactate dehydrogenase increased	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood magnesium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood phosphorus increased	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood potassium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood potassium increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood pressure increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood sodium decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood thyroid stimulating hormone increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood triglycerides increased	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood urea increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood uric acid decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood uric acid increased	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Blood urine	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood urine present	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	C-reactive protein increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Carbon dioxide decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Complement factor C1 decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Computerised tomogram thorax abnormal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Crystal urine present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cystatin C increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Electrocardiogram QT prolonged	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	7	8.0	3.9	15.5
	Electrocardiogram ST-T change	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Fibrin D dimer increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Fibrin degradation products increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Free fatty acids increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gamma-glutamyltransferase increased	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	7	8.0	3.9	15.5
	Glomerular filtration rate decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Glutamate dehydrogenase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Granulocyte count decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Haematocrit decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemoglobin decreased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Heart rate increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hepatic enzyme increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	International normalised ratio increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intraocular pressure increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Laboratory test abnormal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lipase increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Liver function test increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lymphocyte count decreased	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	4	4.5	1.8	11.1
	Lymphocyte count increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Mean cell volume increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Myoglobin blood increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neutrophil count decreased	0	116	41.3	19	16.4	10.7	24.2
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	17	19.3	12.4	28.8
	Neutrophil count increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2

	Neutrophil percentage increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Occult blood positive	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Platelet count decreased	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	9	10.2	5.5	18.3
	Platelet count increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Procalcitonin increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Protein total decreased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Protein total increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Protein urine present	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Prothrombin time prolonged	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Red blood cell count decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Serum amyloid A protein increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Thrombin time prolonged	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Total bile acids increased	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Transaminases increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Transferrin increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Troponin T increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Troponin increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Urinary sediment present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urine ketone body present	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Urine leukocyte esterase positive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urobilinogen urine increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Weight decreased	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	7	8.0	3.9	15.5
	Weight increased	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	9	10.2	5.5	18.3
	White blood cell count decreased	0	116	41.3	23	19.8	13.6	28.0
		1	77	27.4	15	19.5	12.2	29.7
		>= 2	88	31.3	19	21.6	14.3	31.3
	White blood cells urine positive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
Metabolism and nutrition disorders	-Total	0	116	41.3	57	49.1	40.2	58.1
		1	77	27.4	34	44.2	33.6	55.3
		>= 2	88	31.3	47	53.4	43.1	63.5
	Abnormal loss of weight	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Alkalosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cell death	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Decreased appetite	0	116	41.3	12	10.3	6.0	17.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	11	12.5	7.1	21.0
	Dehydration	0	116	41.3	2	1.7	0.5	6.1

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Electrolyte imbalance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Fluid retention	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypercalcaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hypercholesterolaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperglycaemia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	7	8.0	3.9	15.5
	Hyperkalaemia	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hyperlipidaemia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypermagnesaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypernatraemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperphosphataemia	0	116	41.3	15	12.9	8.0	20.2
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	10	11.4	6.3	19.7
	Hypertriglyceridaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Hyperuricaemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hypoalbuminaemia	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	17	19.3	12.4	28.8
	Hypocalcaemia	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	12	13.6	8.0	22.3
	Hypochloraemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	2	2.3	0.6	7.9
	Hypoglycaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypokalaemia	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	11	12.5	7.1	21.0
	Hypomagnesaemia	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	10	11.4	6.3	19.7
	Hyponatraemia	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	5	5.7	2.5	12.6
	Hypophosphataemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	6	6.8	3.2	14.1
	Hypoproteinaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Increased appetite	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vitamin D deficiency	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Musculoskeletal and connective tissue disorders	-Total	0	116	41.3	45	38.8	30.4	47.9
		1	77	27.4	35	45.5	34.8	56.5
		>= 2	88	31.3	39	44.3	34.4	54.7
	Arthralgia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Arthropathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Back pain	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	15	17.0	10.6	26.2
	Bone pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bursitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Coccydynia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Costochondritis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Flank pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Groin pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypercreatinaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intervertebral disc protrusion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Joint range of motion decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Joint stiffness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Joint swelling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Muscle fatigue	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Muscle spasms	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	10	11.4	6.3	19.7
	Muscular weakness	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Musculoskeletal chest pain	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Musculoskeletal pain	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	8	9.1	4.7	16.9
	Musculoskeletal stiffness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Myalgia	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	3	3.4	1.2	9.5

	Myopathy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neck pain	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	6	6.8	3.2	14.1
	Osteopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pain in extremity	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	10	11.4	6.3	19.7
	Pain in jaw	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rotator cuff syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Spinal column stenosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Spinal osteoarthritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tendon disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tendon pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Anogenital warts	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Basal cell carcinoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bowen's disease	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Metastases to central nervous system	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal cell carcinoma	0	116	41.3	1	0.9	0.2	4.7

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Squamous cell carcinoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Squamous cell carcinoma of skin	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tumour pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Nervous system disorders	-Total	0	116	41.3	52	44.8	36.1	53.9
		1	77	27.4	44	57.1	46.0	67.6
		>= 2	88	31.3	45	51.1	40.9	61.3
	Ageusia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Aphasia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ataxia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Balance disorder	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Brain oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Cerebellar haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Disturbance in attention	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dizziness	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	12	15.6	9.1	25.3
		>= 2	88	31.3	12	13.6	8.0	22.3
	Dizziness postural	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dysarthria	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dysgeusia	0	116	41.3	20	17.2	11.4	25.1
		1	77	27.4	14	18.2	11.2	28.2

		>= 2	88	31.3	8	9.1	4.7	16.9
	Dyskinesia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Headache	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	9	10.2	5.5	18.3
	Hemiplegia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperaesthesia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypersomnia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypoaesthesia	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	7	8.0	3.9	15.5
	Hypotonia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lethargy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lumbar radiculopathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Memory impairment	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Migraine with aura	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Neuralgia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neuropathy peripheral	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	3	3.4	1.2	9.5
	Paraesthesia	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	4	4.5	1.8	11.1
	Paralysis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Parosmia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Peripheral sensory neuropathy	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Polyneuropathy chronic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Post herpetic neuralgia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Presyncope	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Psychomotor skills impaired	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Restless legs syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sciatica	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Seizure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Sensory disturbance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Slow speech	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Somnolence	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Syncope	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Tension headache	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tremor	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Visual field defect	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Product issues	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Device dislocation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Psychiatric disorders	-Total	0	116	41.3	19	16.4	10.7	24.2
		1	77	27.4	15	19.5	12.2	29.7
		>= 2	88	31.3	20	22.7	15.2	32.5
	Abnormal behaviour	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Abnormal dreams	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Adjustment disorder with mixed anxiety and depressed mood	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Anxiety	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Bradyphrenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Confusional state	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Delirium	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Depressed mood	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Depression	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fear of falling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Insomnia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	9	10.2	5.5	18.3
	Irritability	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Libido decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Mental status changes	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Mood altered	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Psychomotor retardation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Restlessness	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sleep disorder	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Renal and urinary disorders	-Total	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	18	20.5	13.3	30.0
	Acute kidney injury	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Azotaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Cystitis haemorrhagic	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dysuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	8	9.1	4.7	16.9
	Haematuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemorrhage urinary tract	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Micturition urgency	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Nephritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Nocturia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pollakiuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Proteinuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Renal colic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal failure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal impairment	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Strangury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Urinary incontinence	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urinary retention	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Urinary tract pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urine flow decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Reproductive system and breast disorders	-Total	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	7	8.0	3.9	15.5
	Benign prostatic hyperplasia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Breast discharge	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Erectile dysfunction	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Galactorrhoea	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Genital ulceration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Metrorrhagia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pelvic discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pelvic fluid collection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Perineal pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Postmenopausal haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Prostatitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Uterine polyp	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vaginal haemorrhage	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vulvovaginal dryness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vulvovaginal erythema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Respiratory, thoracic and mediastinal disorders	-Total	0	116	41.3	56	48.3	39.4	57.3
		1	77	27.4	46	59.7	48.6	70.0
		>= 2	88	31.3	51	58.0	47.5	67.7
	Aspiration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Bronchospasm	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Choking	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cough	0	116	41.3	18	15.5	10.0	23.2
		1	77	27.4	26	33.8	24.2	44.9
		>= 2	88	31.3	20	22.7	15.2	32.5
	Dry throat	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dysphonia	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Dyspnoea	0	116	41.3	12	10.3	6.0	17.2
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	17	19.3	12.4	28.8
	Dyspnoea exertional	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Epistaxis	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	3	3.4	1.2	9.5
	Haemoptysis	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Hiccups	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypoxia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Interstitial lung disease	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Laryngeal haemorrhage	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasal congestion	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Nasal dryness	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasal polyps	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oropharyngeal discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oropharyngeal pain	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	5	5.7	2.5	12.6
	Paranasal sinus discomfort	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pharyngeal disorder	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pleural effusion	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pleural thickening	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pleuritic pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonitis	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	11	12.5	7.1	21.0
	Pneumothorax	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Productive cough	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	6	6.8	3.2	14.1
	Pulmonary embolism	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pulmonary mass	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pulmonary pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiration abnormal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinalgia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinitis allergic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinorrhoea	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sinus congestion	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sleep apnoea syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sputum discoloured	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Throat irritation	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Upper-airway cough syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Vocal cord leukoplakia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Wheezing	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Skin and subcutaneous tissue disorders	-Total	0	116	41.3	32	27.6	20.3	36.3
		1	77	27.4	35	45.5	34.8	56.5
		>= 2	88	31.3	33	37.5	28.1	47.9
	Acne	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Alopecia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	4	4.5	1.8	11.1
	Chloasma	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Decubitus ulcer	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dermal cyst	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Dermatitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dermatitis acneiform	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Dermatitis allergic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dermatitis bullous	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dry skin	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Ecchymosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eczema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Erythema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hair growth abnormal	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Hair texture abnormal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hirsutism	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hyperhidrosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperkeratosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypertrichosis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	0	0.0	0.0	4.2
	Madarosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Nail discolouration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nail disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Night sweats	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Onychalgia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Onycholysis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Onychomadesis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pain of skin	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Palmar-plantar erythrodysaesthesia syndrome	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Photosensitivity reaction	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pruritus	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Pruritus generalised	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Purpura	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rash	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	10	11.4	6.3	19.7
	Rash erythematous	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Rash macular	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Rash maculo-papular	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rash papular	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Scab	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Scar pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Skin discolouration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Skin hyperpigmentation	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Skin lesion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Swelling face	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urticaria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Surgical and medical procedures	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Astringent therapy	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Therapy cessation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Vascular disorders	-Total	0	116	41.3	20	17.2	11.4	25.1
		1	77	27.4	19	24.7	16.4	35.4
		>= 2	88	31.3	33	37.5	28.1	47.9
	Aortic dissection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Circulatory collapse	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Deep vein thrombosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	1	1.1	0.2	6.2
	Embolism	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Flushing	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haematoma	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hot flush	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypertension	0	116	41.3	16	13.8	8.7	21.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	22	25.0	17.1	35.0
	Hypotension	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Lymphoedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Orthostatic hypotension	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pallor	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Phlebitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Raynaud's phenomenon	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Superior vena cava syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Thrombophlebitis superficial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Thrombosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR12_SG.xls
26MAR2021 13:42

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1-2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Asian	128	45.6	59	46.1	37.7	54.7
		Non-Asian	135	48.0	59	43.7	35.6	52.1
		Unknown	18	6.4	7	38.9	20.3	61.4
	Anaemia	Asian	128	45.6	40	31.3	23.9	39.7
		Non-Asian	135	48.0	38	28.1	21.2	36.3
		Unknown	18	6.4	5	27.8	12.5	50.9
	Aplastic anaemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bone marrow oedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cytopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Febrile neutropenia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperfibrinogenaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Leukocytosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Leukopenia	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	13	9.6	5.7	15.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymph node pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphadenopathy	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutropenia	Asian	128	45.6	8	6.3	3.2	11.8

		Non-Asian	135	48.0	20	14.8	9.8	21.8
		Unknown	18	6.4	3	16.7	5.8	39.2
	Neutrophilia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancytopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytopenia	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
Cardiac disorders	-Total	Asian	128	45.6	19	14.8	9.7	22.0
		Non-Asian	135	48.0	13	9.6	5.7	15.8
		Unknown	18	6.4	2	11.1	3.1	32.8
	Acute coronary syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Angina pectoris	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aortic valve calcification	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Atrial fibrillation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Atrial flutter	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bradycardia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bundle branch block right	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cardiac failure	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Extrasystoles	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Myocardial ischaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Nodal arrhythmia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Palpitations	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pericardial effusion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinus bradycardia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Sinus tachycardia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tachycardia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ventricular extrasystoles	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ventricular pre-excitation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Congenital, familial and genetic disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gilbert's syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hydrocele	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Ear and labyrinth disorders	-Total	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Ear congestion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ear discomfort	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ear pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6

	Tinnitus	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vertigo	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	2	11.1	3.1	32.8
Endocrine disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyperthyroidism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypothyroidism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Eye disorders	-Total	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	25	18.5	12.9	25.9
		Unknown	18	6.4	3	16.7	5.8	39.2
	Abnormal sensation in eye	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blepharitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chalazion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Conjunctival cyst	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Conjunctival haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diplopia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dry eye	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Eye swelling	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eyelid oedema	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Eyelid ptosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Keratitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ocular discomfort	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Periorbital oedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Photophobia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Photopsia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ulcerative keratitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vision blurred	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Visual acuity reduced	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Gastrointestinal disorders	-Total	Asian	128	45.6	82	64.1	55.5	71.9
		Non-Asian	135	48.0	103	76.3	68.5	82.7
		Unknown	18	6.4	14	77.8	54.8	91.0
	Abdominal discomfort	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal distension	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal pain	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	1	5.6	1.0	25.8
	Abdominal pain lower	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal pain upper	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Abdominal symptom	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anal incontinence	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aphthous ulcer	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ascites	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Constipation	Asian	128	45.6	54	42.2	34.0	50.8
		Non-Asian	135	48.0	54	40.0	32.1	48.4
		Unknown	18	6.4	8	44.4	24.6	66.3
	Dental dysaesthesia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diarrhoea	Asian	128	45.6	23	18.0	12.3	25.5
		Non-Asian	135	48.0	38	28.1	21.2	36.3
		Unknown	18	6.4	4	22.2	9.0	45.2
	Dry mouth	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	32	23.7	17.3	31.5
		Unknown	18	6.4	4	22.2	9.0	45.2
	Dyspepsia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	3	16.7	5.8	39.2
	Dysphagia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	15	11.1	6.9	17.5
		Unknown	18	6.4	1	5.6	1.0	25.8
	Enteritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epigastric discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eructation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Faeces soft	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Flatulence	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Frequent bowel movements	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastric ulcer	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastritis erosive	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal haemorrhage	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal inflammation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal oedema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal wall thickening	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrooesophageal reflux disease	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Gingival bleeding	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gingival swelling	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Glossitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Glossodynia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematochezia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhoids	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoaesthesia oral	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

	Impaired gastric emptying	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Irritable bowel syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Melaena	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mouth ulceration	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nausea	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	23	17.0	11.6	24.3
		Unknown	18	6.4	3	16.7	5.8	39.2
	Odynophagia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oesophageal irritation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oesophagitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral dysaesthesia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral mucosal erythema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancreatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Paraesthesia oral	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rectal prolapse	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Regurgitation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sensitivity of teeth	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Stomatitis	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Swollen tongue	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tongue coated	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tongue discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tongue ulceration	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tooth discolouration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Toothache	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vomiting	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	2	11.1	3.1	32.8
General disorders and administration site conditions	-Total	Asian	128	45.6	83	64.8	56.2	72.6
		Non-Asian	135	48.0	99	73.3	65.3	80.1
		Unknown	18	6.4	11	61.1	38.6	79.7
	Asthenia	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	22	16.3	11.0	23.4
		Unknown	18	6.4	5	27.8	12.5	50.9
	Axillary pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Catheter site pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chest discomfort	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chest pain	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chills	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Disease progression	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Face oedema	Asian	128	45.6	17	13.3	8.5	20.2
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Facial pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fatigue	Asian	128	45.6	18	14.1	9.1	21.1
		Non-Asian	135	48.0	40	29.6	22.6	37.8
		Unknown	18	6.4	3	16.7	5.8	39.2
	Feeling abnormal	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Feeling cold	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Feeling hot	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gait disturbance	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	General physical health deterioration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Generalised oedema	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Impaired healing	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Influenza like illness	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Injection site bruising	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Localised oedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Malaise	Asian	128	45.6	18	14.1	9.1	21.1
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Mucosal dryness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mucosal inflammation	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Non-cardiac chest pain	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Oedema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oedema peripheral	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	25	18.5	12.9	25.9
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pain	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Peripheral swelling	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pyrexia	Asian	128	45.6	36	28.1	21.1	36.5
		Non-Asian	135	48.0	31	23.0	16.7	30.7
		Unknown	18	6.4	4	22.2	9.0	45.2
	Swelling	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Temperature intolerance	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Xerosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Hepatobiliary disorders	-Total	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	3	16.7	5.8	39.2
	Cholecystitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatic function abnormal	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Hepatic steatosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatocellular injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	3	16.7	5.8	39.2
	Hyperbilirubinaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Liver disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumobilia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Portal vein thrombosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Immune system disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Contrast media allergy	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Drug hypersensitivity	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Food allergy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypersensitivity	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Seasonal allergy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Infections and infestations	-Total	Asian	128	45.6	44	34.4	26.7	43.0
		Non-Asian	135	48.0	71	52.6	44.2	60.8
		Unknown	18	6.4	7	38.9	20.3	61.4
	Abdominal abscess	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Acute sinusitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Arthritis infective	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Atypical pneumonia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Bacterial disease carrier	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bacterial vaginosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bronchitis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Candida infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cellulitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chronic sinusitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Conjunctivitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Corona virus infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis escherichia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ear infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Epididymitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epstein-Barr virus infection	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Escherichia bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Escherichia infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Escherichia urinary tract infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eye infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Febrile infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Folliculitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fungal infection	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastroenteritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Genital candidiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Genital herpes	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gingivitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Herpes simplex	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Herpes virus infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Herpes zoster	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Influenza	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lower respiratory tract infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lung infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Lyme disease	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymph node tuberculosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal herpes	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasopharyngitis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral candidiasis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral fungal infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oropharyngeal candidiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Otitis externa	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Otitis media	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Paronychia	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pharyngitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	0	0.0	0.0	17.6

	Pneumonia influenzal	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia pseudomonal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumonia streptococcal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyelonephritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyuria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory tract infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory tract infection bacterial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sepsis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinusitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Skin infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Staphylococcal infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Systemic infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinea cruris	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinea infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Tinea pedis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tonsillitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tooth infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tracheitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tuberculosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Upper respiratory tract infection	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urethritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary tract infection	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	21	15.6	10.4	22.6
		Unknown	18	6.4	1	5.6	1.0	25.8
	Varicella	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Varicella zoster virus infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Viral hepatitis carrier	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Viral infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vulvovaginal candidiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Injury, poisoning and procedural complications	-Total	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	18	13.3	8.6	20.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Contusion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epicondylitis	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fall	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Incision site pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint dislocation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Laceration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ligament sprain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Limb injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle rupture	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle strain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Procedural pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Procedural pneumothorax	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rib fracture	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Scar	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin abrasion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Tendon rupture	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thermal burn	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wound	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wound complication	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wrist fracture	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Investigations	-Total	Asian	128	45.6	103	80.5	72.8	86.4
		Non-Asian	135	48.0	93	68.9	60.6	76.1
		Unknown	18	6.4	13	72.2	49.1	87.5
	Alanine aminotransferase increased	Asian	128	45.6	49	38.3	30.3	46.9
		Non-Asian	135	48.0	32	23.7	17.3	31.5
		Unknown	18	6.4	2	11.1	3.1	32.8
	Albumin urine present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alpha hydroxybutyrate dehydrogenase increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Amylase increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aspartate aminotransferase increased	Asian	128	45.6	63	49.2	40.7	57.8
		Non-Asian	135	48.0	44	32.6	25.3	40.9
		Unknown	18	6.4	4	22.2	9.0	45.2
	Bacterial test	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bilirubin conjugated increased	Asian	128	45.6	19	14.8	9.7	22.0
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood albumin decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood alkaline phosphatase	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Blood alkaline phosphatase decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood alkaline phosphatase increased	Asian	128	45.6	21	16.4	11.0	23.8
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood bilirubin increased	Asian	128	45.6	17	13.3	8.5	20.2
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Blood bilirubin unconjugated increased	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood calcium decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood calcium increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood chloride increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood cholesterol increased	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine phosphokinase MB increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine phosphokinase increased	Asian	128	45.6	25	19.5	13.6	27.2
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	3	16.7	5.8	39.2
	Blood creatinine	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatinine increased	Asian	128	45.6	23	18.0	12.3	25.5
		Non-Asian	135	48.0	33	24.4	18.0	32.3
		Unknown	18	6.4	4	22.2	9.0	45.2
	Blood fibrinogen increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood glucose increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Blood iron decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood ketone body increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood lactate dehydrogenase increased	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood magnesium decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood phosphorus increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood potassium decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood potassium increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood pressure increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood sodium decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood thyroid stimulating hormone increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood triglycerides increased	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood urea increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood uric acid decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood uric acid increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood urine	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood urine present	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	C-reactive protein increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Carbon dioxide decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Complement factor C1 decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Computerised tomogram thorax abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Crystal urine present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystatin C increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrocardiogram QT prolonged	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrocardiogram ST-T change	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fibrin D dimer increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fibrin degradation products increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Free fatty acids increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gamma-glutamyltransferase increased	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Glomerular filtration rate decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Glutamate dehydrogenase increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Granulocyte count decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematocrit decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemoglobin decreased	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Heart rate increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatic enzyme increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	International normalised ratio increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intraocular pressure increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Laboratory test abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Lipase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Liver function test increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphocyte count decreased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphocyte count increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mean cell volume increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Myoglobin blood increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutrophil count decreased	Asian	128	45.6	36	28.1	21.1	36.5
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Neutrophil count increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Neutrophil percentage increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Occult blood positive	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Platelet count decreased	Asian	128	45.6	18	14.1	9.1	21.1
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Platelet count increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Procalcitonin increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Protein total decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Protein total increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Protein urine present	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Prothrombin time prolonged	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Red blood cell count decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Serum amyloid A protein increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombin time prolonged	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Total bile acids increased	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Transaminases increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Transferrin increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Troponin T increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Troponin increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary sediment present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urine ketone body present	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urine leukocyte esterase positive	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urobilinogen urine increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Weight decreased	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Weight increased	Asian	128	45.6	17	13.3	8.5	20.2
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	White blood cell count decreased	Asian	128	45.6	34	26.6	19.7	34.8
		Non-Asian	135	48.0	20	14.8	9.8	21.8
		Unknown	18	6.4	3	16.7	5.8	39.2
	White blood cells urine positive	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Metabolism and nutrition disorders	-Total	Asian	128	45.6	73	57.0	48.4	65.3
		Non-Asian	135	48.0	58	43.0	34.9	51.4
		Unknown	18	6.4	7	38.9	20.3	61.4
	Abnormal loss of weight	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alkalosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cell death	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Decreased appetite	Asian	128	45.6	24	18.8	12.9	26.4
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dehydration	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Electrolyte imbalance	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fluid retention	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercalcaemia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercholesterolaemia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperglycaemia	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperkalaemia	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyperlipidaemia	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypermagnesaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypernatraemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperphosphataemia	Asian	128	45.6	15	11.7	7.2	18.4
		Non-Asian	135	48.0	16	11.9	7.4	18.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypertriglyceridaemia	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperuricaemia	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoalbuminaemia	Asian	128	45.6	32	25.0	18.3	33.2
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypocalcaemia	Asian	128	45.6	18	14.1	9.1	21.1
		Non-Asian	135	48.0	12	8.9	5.2	14.9
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypochloraemia	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoglycaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypokalaemia	Asian	128	45.6	14	10.9	6.6	17.5
		Non-Asian	135	48.0	15	11.1	6.9	17.5
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypomagnesaemia	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyponatraemia	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypophosphataemia	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypoproteinaemia	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Increased appetite	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vitamin D deficiency	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Musculoskeletal and connective tissue disorders	-Total	Asian	128	45.6	47	36.7	28.9	45.3
		Non-Asian	135	48.0	63	46.7	38.5	55.1
		Unknown	18	6.4	9	50.0	29.0	71.0
	Arthralgia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Arthropathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Back pain	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	21	15.6	10.4	22.6
		Unknown	18	6.4	2	11.1	3.1	32.8
	Bone pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bursitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Coccydynia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Costochondritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Flank pain	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Groin pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercreatinaemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intervertebral disc protrusion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint range of motion decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint stiffness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint swelling	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Muscle fatigue	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle spasms	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	3	16.7	5.8	39.2
	Muscular weakness	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Musculoskeletal chest pain	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Musculoskeletal pain	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	2	11.1	3.1	32.8
	Musculoskeletal stiffness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Myalgia	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	2	11.1	3.1	32.8

	Myopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neck pain	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Osteopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain in extremity	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain in jaw	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Rotator cuff syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Spinal column stenosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Spinal osteoarthritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tendon disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tendon pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anogenital warts	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Basal cell carcinoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bowen's disease	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Metastases to central nervous system	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal cell carcinoma	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Squamous cell carcinoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Squamous cell carcinoma of skin	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tumour pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Nervous system disorders	-Total	Asian	128	45.6	58	45.3	37.0	53.9
		Non-Asian	135	48.0	75	55.6	47.1	63.7
		Unknown	18	6.4	8	44.4	24.6	66.3
	Ageusia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aphasia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ataxia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Balance disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Brain oedema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebellar haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Disturbance in attention	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dizziness	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	19	14.1	9.2	20.9
		Unknown	18	6.4	2	11.1	3.1	32.8
	Dizziness postural	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysarthria	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysgeusia	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	29	21.5	15.4	29.1

		Unknown	18	6.4	3	16.7	5.8	39.2
	Dyskinesia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Headache	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	20	14.8	9.8	21.8
		Unknown	18	6.4	4	22.2	9.0	45.2
	Hemiplegia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperaesthesia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Hypersomnia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoaesthesia	Asian	128	45.6	17	13.3	8.5	20.2
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypotonia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lethargy	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lumbar radiculopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Memory impairment	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Migraine with aura	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Neuralgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neuropathy peripheral	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Paraesthesia	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	Paralysis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Parosmia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Peripheral sensory neuropathy	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Polyneuropathy chronic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Post herpetic neuralgia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Presyncope	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Psychomotor skills impaired	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Restless legs syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sciatica	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Seizure	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sensory disturbance	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Slow speech	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Somnolence	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Syncope	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tension headache	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tremor	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Visual field defect	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Product issues	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Device dislocation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Psychiatric disorders	-Total	Asian	128	45.6	26	20.3	14.3	28.1
		Non-Asian	135	48.0	24	17.8	12.2	25.1
		Unknown	18	6.4	4	22.2	9.0	45.2
	Abnormal behaviour	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abnormal dreams	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Adjustment disorder with mixed anxiety and depressed mood	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anxiety	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bradyphrenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Confusional state	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Delirium	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Depressed mood	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Depression	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Fear of falling	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Insomnia	Asian	128	45.6	17	13.3	8.5	20.2
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Irritability	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Libido decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mental status changes	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mood altered	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Psychomotor retardation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Restlessness	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sleep disorder	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Renal and urinary disorders	-Total	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	24	17.8	12.2	25.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Acute kidney injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Azotaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis haemorrhagic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysuria	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematuria	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhage urinary tract	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Micturition urgency	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nephritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Nocturia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pollakiuria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Proteinuria	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal colic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal impairment	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Strangury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary incontinence	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary retention	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Urinary tract pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urine flow decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Reproductive system and breast disorders	-Total	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	Benign prostatic hyperplasia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Breast discharge	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Erectile dysfunction	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Galactorrhoea	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Genital ulceration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Metrorrhagia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pelvic discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pelvic fluid collection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Perineal pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Postmenopausal haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Prostatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Uterine polyp	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vaginal haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vulvovaginal dryness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vulvovaginal erythema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Respiratory, thoracic and mediastinal disorders	-Total	Asian	128	45.6	67	52.3	43.7	60.8
		Non-Asian	135	48.0	78	57.8	49.3	65.8
		Unknown	18	6.4	8	44.4	24.6	66.3
	Aspiration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Bronchospasm	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Choking	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cough	Asian	128	45.6	29	22.7	16.3	30.6
		Non-Asian	135	48.0	31	23.0	16.7	30.7
		Unknown	18	6.4	4	22.2	9.0	45.2
	Dry throat	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysphonia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dyspnoea	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	21	15.6	10.4	22.6
		Unknown	18	6.4	2	11.1	3.1	32.8
	Dyspnoea exertional	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epistaxis	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Haemoptysis	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hiccups	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoxia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Interstitial lung disease	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Laryngeal haemorrhage	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal congestion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal dryness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal polyps	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oropharyngeal discomfort	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oropharyngeal pain	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	0	0.0	0.0	17.6
	Paranasal sinus discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pharyngeal disorder	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleural effusion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pleural thickening	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleuritic pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonitis	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumothorax	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Productive cough	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary embolism	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary mass	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiration abnormal	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinalgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinitis allergic	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinorrhoea	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinus congestion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sleep apnoea syndrome	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sputum discoloured	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Throat irritation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Upper-airway cough syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Vocal cord leukoplakia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wheezing	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Skin and subcutaneous tissue disorders	-Total	Asian	128	45.6	42	32.8	25.3	41.3
		Non-Asian	135	48.0	50	37.0	29.4	45.4
		Unknown	18	6.4	8	44.4	24.6	66.3
	Acne	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alopecia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chloasma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Decubitus ulcer	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermal cyst	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Dermatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermatitis acneiform	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dermatitis allergic	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermatitis bullous	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dry skin	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Ecchymosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eczema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Erythema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hair growth abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hair texture abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hirsutism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyperhidrosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyperkeratosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypertrichosis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Madarosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Nail discolouration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nail disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Night sweats	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Onychalgia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Onycholysis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Onychomadesis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain of skin	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Palmar-plantar erythrodysaesthesia syndrome	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Photosensitivity reaction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pruritus	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pruritus generalised	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Purpura	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rash	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Rash erythematous	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rash macular	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Rash maculo-papular	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rash papular	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Scab	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Scar pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin discolouration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin hyperpigmentation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin lesion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Swelling face	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Urticaria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Surgical and medical procedures	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Astringent therapy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Therapy cessation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Vascular disorders	-Total	Asian	128	45.6	34	26.6	19.7	34.8
		Non-Asian	135	48.0	33	24.4	18.0	32.3
		Unknown	18	6.4	5	27.8	12.5	50.9
	Aortic dissection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Circulatory collapse	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Deep vein thrombosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Embolism	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Flushing	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hot flush	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypertension	Asian	128	45.6	30	23.4	16.9	31.5
		Non-Asian	135	48.0	18	13.3	8.6	20.1
		Unknown	18	6.4	3	16.7	5.8	39.2
	Hypotension	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphoedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Orthostatic hypotension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pallor	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Phlebitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Raynaud's phenomenon	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Superior vena cava syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombophlebitis superficial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR12_SG.xls
26MAR2021 13:42

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1-2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Female	152	54.1	77	50.7	42.8	58.5
		Male	129	45.9	48	37.2	29.4	45.8
	Anaemia	Female	152	54.1	51	33.6	26.5	41.4
		Male	129	45.9	32	24.8	18.2	32.9
	Aplastic anaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bone marrow oedema	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cytopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Febrile neutropenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hyperfibrinogenaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Leukocytosis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Leukopenia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	10	7.8	4.3	13.7
	Lymph node pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lymphadenopathy	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Lymphopenia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Neutropenia	Female	152	54.1	21	13.8	9.2	20.2
		Male	129	45.9	10	7.8	4.3	13.7
	Neutrophilia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pancytopenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Thrombocytopenia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	4	3.1	1.2	7.7
	Thrombocytosis	Female	152	54.1	5	3.3	1.4	7.5

		Male	129	45.9	0	0.0	0.0	2.9
Cardiac disorders	-Total	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	18	14.0	9.0	21.0
	Acute coronary syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Angina pectoris	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Aortic valve calcification	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Atrial fibrillation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Atrial flutter	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Bradycardia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Bundle branch block right	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cardiac failure	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Extrasystoles	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Myocardial ischaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Nodal arrhythmia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Palpitations	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Pericardial effusion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Sinus bradycardia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Sinus tachycardia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Tachycardia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Ventricular extrasystoles	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Ventricular pre-excitation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Congenital, familial and genetic disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5

	Gilbert's syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hydrocele	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Ear and labyrinth disorders	-Total	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	9	7.0	3.7	12.7
	Ear congestion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Ear discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Ear pain	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Tinnitus	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Vertigo	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	3	2.3	0.8	6.6
Endocrine disorders	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperthyroidism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypothyroidism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Eye disorders	-Total	Female	152	54.1	29	19.1	13.6	26.1
		Male	129	45.9	9	7.0	3.7	12.7
	Abnormal sensation in eye	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blepharitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Chalazion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Conjunctival cyst	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Conjunctival haemorrhage	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Diplopia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dry eye	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Eye swelling	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9

	Eyelid oedema	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	0	0.0	0.0	2.9
	Eyelid ptosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Keratitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ocular discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Periorbital oedema	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Photophobia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Photopsia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Ulcerative keratitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vision blurred	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	1	0.8	0.1	4.3
	Visual acuity reduced	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Gastrointestinal disorders	-Total	Female	152	54.1	116	76.3	69.0	82.4
		Male	129	45.9	83	64.3	55.8	72.1
	Abdominal discomfort	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Abdominal distension	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	2	1.6	0.4	5.5
	Abdominal pain	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	5	3.9	1.7	8.8
	Abdominal pain lower	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Abdominal pain upper	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	8	6.2	3.2	11.8
	Abdominal symptom	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Anal incontinence	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Aphthous ulcer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ascites	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Constipation	Female	152	54.1	70	46.1	38.3	54.0

		Male	129	45.9	46	35.7	27.9	44.2
	Dental dysaesthesia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Diarrhoea	Female	152	54.1	38	25.0	18.8	32.4
		Male	129	45.9	27	20.9	14.8	28.7
	Dry mouth	Female	152	54.1	28	18.4	13.1	25.3
		Male	129	45.9	19	14.7	9.6	21.9
	Dyspepsia	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	3	2.3	0.8	6.6
	Dysphagia	Female	152	54.1	15	9.9	6.1	15.6
		Male	129	45.9	5	3.9	1.7	8.8
	Enteritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Epigastric discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Eructation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Faeces soft	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Flatulence	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Frequent bowel movements	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastric ulcer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastritis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastritis erosive	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrointestinal haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrointestinal inflammation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrointestinal oedema	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gastrointestinal wall thickening	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrooesophageal reflux disease	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	4	3.1	1.2	7.7
	Gingival bleeding	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3

	Gingival swelling	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Glossitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Glossodynia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haematochezia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Haemorrhoids	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hypoaesthesia oral	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Impaired gastric emptying	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Irritable bowel syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Melaena	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Mouth ulceration	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	3	2.3	0.8	6.6
	Nausea	Female	152	54.1	31	20.4	14.8	27.5
		Male	129	45.9	11	8.5	4.8	14.6
	Odynophagia	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	0	0.0	0.0	2.9
	Oesophageal irritation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oesophagitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Oral disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Oral dysaesthesia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oral mucosal erythema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Oral pain	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	1	0.8	0.1	4.3
	Pancreatitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Paraesthesia oral	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Rectal prolapse	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Regurgitation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Sensitivity of teeth	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Stomatitis	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	2	1.6	0.4	5.5
	Swollen tongue	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tongue coated	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tongue discomfort	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tongue ulceration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tooth discolouration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Toothache	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	5	3.9	1.7	8.8
	Vomiting	Female	152	54.1	19	12.5	8.2	18.7
		Male	129	45.9	10	7.8	4.3	13.7
General disorders and administration site conditions	-Total	Female	152	54.1	111	73.0	65.5	79.4
		Male	129	45.9	82	63.6	55.0	71.4
	Asthenia	Female	152	54.1	25	16.4	11.4	23.2
		Male	129	45.9	12	9.3	5.4	15.6
	Axillary pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Catheter site pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Chest discomfort	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	2	1.6	0.4	5.5
	Chest pain	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	5	3.9	1.7	8.8
	Chills	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Disease progression	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Face oedema	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	5	3.9	1.7	8.8
	Facial pain	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Fatigue	Female	152	54.1	29	19.1	13.6	26.1
		Male	129	45.9	32	24.8	18.2	32.9
	Feeling abnormal	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Feeling cold	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Feeling hot	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gait disturbance	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	General physical health deterioration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Generalised oedema	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Impaired healing	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Influenza like illness	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Injection site bruising	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Localised oedema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Malaise	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	9	7.0	3.7	12.7
	Mucosal dryness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Mucosal inflammation	Female	152	54.1	18	11.8	7.6	17.9
		Male	129	45.9	3	2.3	0.8	6.6
	Non-cardiac chest pain	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	4	3.1	1.2	7.7
	Oedema	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Oedema peripheral	Female	152	54.1	26	17.1	11.9	23.9
		Male	129	45.9	16	12.4	7.8	19.2
	Pain	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Peripheral swelling	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Pyrexia	Female	152	54.1	41	27.0	20.6	34.5
		Male	129	45.9	30	23.3	16.8	31.3

	Swelling	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Temperature intolerance	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Xerosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Hepatobiliary disorders	-Total	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	13	10.1	6.0	16.5
	Cholecystitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Hepatic function abnormal	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hepatic steatosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hepatocellular injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Hyperbilirubinaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	5	3.9	1.7	8.8
	Liver disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumobilia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Portal vein thrombosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Immune system disorders	-Total	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Contrast media allergy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Drug hypersensitivity	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Food allergy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypersensitivity	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Seasonal allergy	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
Infections and infestations	-Total	Female	152	54.1	73	48.0	40.2	55.9
		Male	129	45.9	49	38.0	30.1	46.6
	Abdominal abscess	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Acute sinusitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Arthritis infective	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Atypical pneumonia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bacteraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Bacterial disease carrier	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Bacterial vaginosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bronchitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	Candida infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cellulitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Chronic sinusitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Conjunctivitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Corona virus infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cystitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Cystitis escherichia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ear infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Epididymitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Epstein-Barr virus infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Escherichia bacteraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Escherichia infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Escherichia urinary tract infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Eye infection	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Febrile infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Folliculitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Fungal infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Gastroenteritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Genital candidiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Genital herpes	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Gingivitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Herpes simplex	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Herpes virus infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Herpes zoster	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	4	3.1	1.2	7.7
	Infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Influenza	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lower respiratory tract infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lung infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lyme disease	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lymph node tuberculosis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Nasal herpes	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nasopharyngitis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	5	3.9	1.7	8.8
	Oral candidiasis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	5	3.9	1.7	8.8
	Oral fungal infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9

	Oropharyngeal candidiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Otitis externa	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Otitis media	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Paronychia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Pharyngitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Pneumonia	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	9	7.0	3.7	12.7
	Pneumonia influenzal	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonia pseudomonal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pneumonia streptococcal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pyelonephritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pyuria	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Respiratory tract infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Respiratory tract infection bacterial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rhinitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Sepsis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sinusitis	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	1	0.8	0.1	4.3
	Skin infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Staphylococcal infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Systemic infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tinea cruris	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Tinea infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tinea pedis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Tonsillitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tooth infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tracheitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tuberculosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Upper respiratory tract infection	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	4	3.1	1.2	7.7
	Urethritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urinary tract infection	Female	152	54.1	23	15.1	10.3	21.7
		Male	129	45.9	6	4.7	2.1	9.8
	Varicella	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Varicella zoster virus infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Viral hepatitis carrier	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Viral infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Vulvovaginal candidiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Injury, poisoning and procedural complications	-Total	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	14	10.9	6.6	17.4
	Contusion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	4	3.1	1.2	7.7
	Epicondylitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Fall	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	6	4.7	2.1	9.8
	Incision site pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Joint dislocation	Female	152	54.1	2	1.3	0.4	4.7

		Male	129	45.9	0	0.0	0.0	2.9
	Laceration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ligament sprain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Limb injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Muscle rupture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Muscle strain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Procedural pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Procedural pneumothorax	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rib fracture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Scar	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin abrasion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tendon rupture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Thermal burn	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Wound	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Wound complication	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Wrist fracture	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Investigations	-Total	Female	152	54.1	118	77.6	70.4	83.5
		Male	129	45.9	91	70.5	62.2	77.7
	Alanine aminotransferase increased	Female	152	54.1	50	32.9	25.9	40.7
		Male	129	45.9	33	25.6	18.8	33.7
	Albumin urine present	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Alpha hydroxybutyrate dehydrogenase increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9

	Amylase increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Aspartate aminotransferase increased	Female	152	54.1	65	42.8	35.2	50.7
		Male	129	45.9	46	35.7	27.9	44.2
	Bacterial test	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bilirubin conjugated increased	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	6	4.7	2.1	9.8
	Blood albumin decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood alkaline phosphatase	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood alkaline phosphatase decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood alkaline phosphatase increased	Female	152	54.1	21	13.8	9.2	20.2
		Male	129	45.9	10	7.8	4.3	13.7
	Blood bilirubin increased	Female	152	54.1	18	11.8	7.6	17.9
		Male	129	45.9	7	5.4	2.7	10.8
	Blood bilirubin unconjugated increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	4	3.1	1.2	7.7
	Blood calcium decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Blood calcium increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood chloride increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood cholesterol increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	4	3.1	1.2	7.7
	Blood creatine increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Blood creatine phosphokinase MB increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Blood creatine phosphokinase increased	Female	152	54.1	26	17.1	11.9	23.9
		Male	129	45.9	8	6.2	3.2	11.8
	Blood creatinine	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood creatinine increased	Female	152	54.1	26	17.1	11.9	23.9
		Male	129	45.9	34	26.4	19.5	34.6
	Blood fibrinogen increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Blood glucose increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Blood iron decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood ketone body increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood lactate dehydrogenase increased	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	2	1.6	0.4	5.5
	Blood magnesium decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood phosphorus increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Blood potassium decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood potassium increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood pressure increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Blood sodium decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood thyroid stimulating hormone increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood triglycerides increased	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Blood urea increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Blood uric acid decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood uric acid increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Blood urine	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Blood urine present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	C-reactive protein increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Carbon dioxide decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Complement factor C1 decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Computerised tomogram thorax abnormal	Female	152	54.1	2	1.3	0.4	4.7

		Male	129	45.9	0	0.0	0.0	2.9
	Crystal urine present	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cystatin C increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Electrocardiogram QT prolonged	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	2	1.6	0.4	5.5
	Electrocardiogram ST-T change	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Fibrin D dimer increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Fibrin degradation products increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Free fatty acids increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gamma-glutamyltransferase increased	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	4	3.1	1.2	7.7
	Glomerular filtration rate decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Glutamate dehydrogenase increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Granulocyte count decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haematocrit decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haemoglobin decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Heart rate increased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hepatic enzyme increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	International normalised ratio increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Intraocular pressure increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Laboratory test abnormal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lipase increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Liver function test increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3

	Lymphocyte count decreased	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	4	3.1	1.2	7.7
	Lymphocyte count increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Mean cell volume increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Myoglobin blood increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Neutrophil count decreased	Female	152	54.1	27	17.8	12.5	24.6
		Male	129	45.9	18	14.0	9.0	21.0
	Neutrophil count increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Neutrophil percentage increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Occult blood positive	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Platelet count decreased	Female	152	54.1	19	12.5	8.2	18.7
		Male	129	45.9	6	4.7	2.1	9.8
	Platelet count increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Procalcitonin increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Protein total decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Protein total increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Protein urine present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Prothrombin time prolonged	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Red blood cell count decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Serum amyloid A protein increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombin time prolonged	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Total bile acids increased	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	4	3.1	1.2	7.7
	Transaminases increased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7

	Transferrin increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Troponin T increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Troponin increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urinary sediment present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urine ketone body present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Urine leukocyte esterase positive	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urobilinogen urine increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Weight decreased	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	4	3.1	1.2	7.7
	Weight increased	Female	152	54.1	15	9.9	6.1	15.6
		Male	129	45.9	9	7.0	3.7	12.7
	White blood cell count decreased	Female	152	54.1	34	22.4	16.5	29.6
		Male	129	45.9	23	17.8	12.2	25.3
	White blood cells urine positive	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
Metabolism and nutrition disorders	-Total	Female	152	54.1	83	54.6	46.7	62.3
		Male	129	45.9	55	42.6	34.4	51.3
	Abnormal loss of weight	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Alkalosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cell death	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Decreased appetite	Female	152	54.1	20	13.2	8.7	19.5
		Male	129	45.9	16	12.4	7.8	19.2
	Dehydration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	4	3.1	1.2	7.7
	Electrolyte imbalance	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Fluid retention	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypercalcaemia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Hypercholesterolaemia	Female	152	54.1	2	1.3	0.4	4.7

		Male	129	45.9	3	2.3	0.8	6.6
	Hyperglycaemia	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	7	5.4	2.7	10.8
	Hyperkalaemia	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	7	5.4	2.7	10.8
	Hyperlipidaemia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hypermagnesaemia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hypernatraemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Hyperphosphataemia	Female	152	54.1	23	15.1	10.3	21.7
		Male	129	45.9	8	6.2	3.2	11.8
	Hypertriglyceridaemia	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Hyperuricaemia	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	4	3.1	1.2	7.7
	Hypoalbuminaemia	Female	152	54.1	25	16.4	11.4	23.2
		Male	129	45.9	12	9.3	5.4	15.6
	Hypocalcaemia	Female	152	54.1	21	13.8	9.2	20.2
		Male	129	45.9	10	7.8	4.3	13.7
	Hypochloraemia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Hypoglycaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypokalaemia	Female	152	54.1	18	11.8	7.6	17.9
		Male	129	45.9	11	8.5	4.8	14.6
	Hypomagnesaemia	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	8	6.2	3.2	11.8
	Hyponatraemia	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	7	5.4	2.7	10.8
	Hypophosphataemia	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	7	5.4	2.7	10.8
	Hypoproteinaemia	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	1	0.8	0.1	4.3
	Increased appetite	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Vitamin D deficiency	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Musculoskeletal and connective tissue disorders	-Total	Female	152	54.1	69	45.4	37.7	53.3
		Male	129	45.9	50	38.8	30.8	47.4

	Arthralgia	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	5	3.9	1.7	8.8
	Arthropathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Back pain	Female	152	54.1	19	12.5	8.2	18.7
		Male	129	45.9	16	12.4	7.8	19.2
	Bone pain	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Bursitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Coccydynia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Costochondritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Flank pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Groin pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypercreatinaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Intervertebral disc protrusion	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Joint range of motion decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Joint stiffness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Joint swelling	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Muscle fatigue	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Muscle spasms	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	8	6.2	3.2	11.8
	Muscular weakness	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	2	1.6	0.4	5.5
	Musculoskeletal chest pain	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	4	3.1	1.2	7.7
	Musculoskeletal pain	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	11	8.5	4.8	14.6
	Musculoskeletal stiffness	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Myalgia	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	7	5.4	2.7	10.8
	Myopathy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Neck pain	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	5	3.9	1.7	8.8
	Osteopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pain in extremity	Female	152	54.1	17	11.2	7.1	17.2
		Male	129	45.9	8	6.2	3.2	11.8
	Pain in jaw	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Rotator cuff syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Spinal column stenosis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Spinal osteoarthritis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tendon disorder	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tendon pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	4	3.1	1.2	7.7
	Anogenital warts	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Basal cell carcinoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Bowen's disease	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Metastases to central nervous system	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Renal cell carcinoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Squamous cell carcinoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Squamous cell carcinoma of skin	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tumour pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Nervous system disorders	-Total	Female	152	54.1	79	52.0	44.1	59.8

		Male	129	45.9	62	48.1	39.6	56.6
	Ageusia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Aphasia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Ataxia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Balance disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Brain oedema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cerebellar haemorrhage	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Disturbance in attention	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Dizziness	Female	152	54.1	20	13.2	8.7	19.5
		Male	129	45.9	17	13.2	8.4	20.1
	Dizziness postural	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dysarthria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dysgeusia	Female	152	54.1	24	15.8	10.8	22.4
		Male	129	45.9	18	14.0	9.0	21.0
	Dyskinesia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Headache	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	16	12.4	7.8	19.2
	Hemiplegia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperaesthesia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypersomnia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypoaesthesia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	6	4.7	2.1	9.8
	Hypotonia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lethargy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lumbar radiculopathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Memory impairment	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Migraine with aura	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neuralgia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neuropathy peripheral	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	5	3.9	1.7	8.8
	Paraesthesia	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	6	4.7	2.1	9.8
	Paralysis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Parosmia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Peripheral sensory neuropathy	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	3	2.3	0.8	6.6
	Polyneuropathy chronic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Post herpetic neuralgia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Presyncope	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Psychomotor skills impaired	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Restless legs syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Sciatica	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Seizure	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Sensory disturbance	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Slow speech	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Somnolence	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Syncope	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Tension headache	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Tremor	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Visual field defect	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
Product issues	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Device dislocation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Psychiatric disorders	-Total	Female	152	54.1	29	19.1	13.6	26.1
		Male	129	45.9	25	19.4	13.5	27.0
	Abnormal behaviour	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Abnormal dreams	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Adjustment disorder with mixed anxiety and depressed mood	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Anxiety	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	4	3.1	1.2	7.7
	Bradyphrenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Confusional state	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	4	3.1	1.2	7.7
	Delirium	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Depressed mood	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Depression	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Fear of falling	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Insomnia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	8	6.2	3.2	11.8
	Irritability	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Libido decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Mental status changes	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Mood altered	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Psychomotor retardation	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	2	1.6	0.4	5.5
	Restlessness	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Sleep disorder	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Renal and urinary disorders	-Total	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	25	19.4	13.5	27.0
	Acute kidney injury	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Azotaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cystitis haemorrhagic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dysuria	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	6	4.7	2.1	9.8
	Haematuria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Haemorrhage urinary tract	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Micturition urgency	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Nephritis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Nocturia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Pollakiuria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Proteinuria	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Renal colic	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Renal disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Renal failure	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Renal impairment	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Strangury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urinary incontinence	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5

	Urinary retention	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	4	3.1	1.2	7.7
	Urinary tract pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urine flow decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Reproductive system and breast disorders	-Total	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	14	10.9	6.6	17.4
	Benign prostatic hyperplasia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Breast discharge	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Erectile dysfunction	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	9	7.0	3.7	12.7
	Galactorrhoea	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Genital ulceration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Metrorrhagia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pelvic discomfort	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pelvic fluid collection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Perineal pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Postmenopausal haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Prostatitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Uterine polyp	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vaginal haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vulvovaginal dryness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vulvovaginal erythema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Respiratory, thoracic and mediastinal disorders	-Total	Female	152	54.1	86	56.6	48.6	64.2
		Male	129	45.9	67	51.9	43.4	60.4

	Aspiration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Bronchospasm	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Choking	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cough	Female	152	54.1	34	22.4	16.5	29.6
		Male	129	45.9	30	23.3	16.8	31.3
	Dry throat	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Dysphonia	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	5	3.9	1.7	8.8
	Dyspnoea	Female	152	54.1	21	13.8	9.2	20.2
		Male	129	45.9	18	14.0	9.0	21.0
	Dyspnoea exertional	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	8	6.2	3.2	11.8
	Epistaxis	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	6	4.7	2.1	9.8
	Haemoptysis	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	5	3.9	1.7	8.8
	Hiccups	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hypoxia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Interstitial lung disease	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Laryngeal haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nasal congestion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Nasal dryness	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Nasal polyps	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oropharyngeal discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oropharyngeal pain	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	5	3.9	1.7	8.8
	Paranasal sinus discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pharyngeal disorder	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
	Pleural effusion	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Pleural thickening	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pleuritic pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonitis	Female	152	54.1	18	11.8	7.6	17.9
		Male	129	45.9	8	6.2	3.2	11.8
	Pneumothorax	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Productive cough	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	7	5.4	2.7	10.8
	Pulmonary embolism	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pulmonary mass	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pulmonary pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Respiration abnormal	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rhinalgia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rhinitis allergic	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Rhinorrhoea	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Sinus congestion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sleep apnoea syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Sputum discoloured	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Throat irritation	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Upper-airway cough syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Vocal cord leukoplakia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Wheezing	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9

Skin and subcutaneous tissue disorders	-Total	Female	152	54.1	63	41.4	33.9	49.4
		Male	129	45.9	37	28.7	21.6	37.0
	Acne	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Alopecia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	2	1.6	0.4	5.5
	Chloasma	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Decubitus ulcer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dermal cyst	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dermatitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dermatitis acneiform	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Dermatitis allergic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dermatitis bullous	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Dry skin	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	6	4.7	2.1	9.8
	Ecchymosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Eczema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Erythema	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Hair growth abnormal	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hair texture abnormal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hirsutism	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Hyperhidrosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Hyperkeratosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypertrichosis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5

	Madarosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nail discolouration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nail disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Night sweats	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Onychalgia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Onycholysis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Onychomadesis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Pain of skin	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Palmar-plantar erythrodysaesthesia syndrome	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	0	0.0	0.0	2.9
	Photosensitivity reaction	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pruritus	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	Pruritus generalised	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Purpura	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rash	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	7	5.4	2.7	10.8
	Rash erythematous	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Rash macular	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Rash maculo-papular	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Rash papular	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Scab	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Scar pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin discolouration	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Skin hyperpigmentation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Skin lesion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Swelling face	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urticaria	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Surgical and medical procedures	-Total	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Astringent therapy	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Therapy cessation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Vascular disorders	-Total	Female	152	54.1	39	25.7	19.4	33.1
		Male	129	45.9	33	25.6	18.8	33.7
	Aortic dissection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Circulatory collapse	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Deep vein thrombosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Embolism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Flushing	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Haematoma	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hot flush	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hypertension	Female	152	54.1	24	15.8	10.8	22.4
		Male	129	45.9	27	20.9	14.8	28.7
	Hypotension	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lymphoedema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Orthostatic hypotension	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pallor	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Phlebitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Raynaud's phenomenon	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Superior vena cava syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombophlebitis superficial	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR12_SG.xls
26MAR2021 13:42

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	11	3.9	2.2	6.9
Sex	Female	152	54.1	6	3.9	1.8	8.3
	Male	129	45.9	5	3.9	1.7	8.8
Age	< 65	176	62.6	9	5.1	2.7	9.4
	>= 65	105	37.4	2	1.9	0.5	6.7
ECOG performance status	0	84	29.9	3	3.6	1.2	10.0
	1	190	67.6	8	4.2	2.1	8.1
	2	6	2.1	0	0.0	0.0	39.0
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	1	1.6	0.3	8.3
	Europe (EU)	95	33.8	5	5.3	2.3	11.7
	Asia (AS)	122	43.4	5	4.1	1.8	9.2
Race/ethnicity	Asian	128	45.6	5	3.9	1.7	8.8
	Non-Asian	135	48.0	3	2.2	0.8	6.3
	Unknown	18	6.4	3	16.7	5.8	39.2
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	6	5.2	2.4	10.8
	1	77	27.4	2	2.6	0.7	9.0
	>= 2	88	31.3	3	3.4	1.2	9.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AEGR1_SG.xls
26MAR2021 10:17

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	10	3.6	1.9	6.4
Sex	Female	152	54.1	5	3.3	1.4	7.5
	Male	129	45.9	5	3.9	1.7	8.8
Age	< 65	176	62.6	8	4.5	2.3	8.7
	>= 65	105	37.4	2	1.9	0.5	6.7
ECOG performance status	0	84	29.9	3	3.6	1.2	10.0
	1	190	67.6	7	3.7	1.8	7.4
	2	6	2.1	0	0.0	0.0	39.0
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	1	1.6	0.3	8.3
	Europe (EU)	95	33.8	5	5.3	2.3	11.7
	Asia (AS)	122	43.4	4	3.3	1.3	8.1
Race/ethnicity	Asian	128	45.6	4	3.1	1.2	7.8
	Non-Asian	135	48.0	3	2.2	0.8	6.3
	Unknown	18	6.4	3	16.7	5.8	39.2
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	6	5.2	2.4	10.8
	1	77	27.4	2	2.6	0.7	9.0
	>= 2	88	31.3	2	2.3	0.6	7.9

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw_B63_06NOV2020_SE_TO_AEGR1_SG.xls
26MAR2021 9:55

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	n/a	281	100.0	59	21.0	16.6	26.1
	Anaemia	n/a	281	100.0	28	10.0	7.0	14.0
	Cytopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Febrile neutropenia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperfibrinogenaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Leukocytosis	n/a	281	100.0	3	1.1	0.4	3.1
	Leukopenia	n/a	281	100.0	8	2.8	1.4	5.5
	Lymph node pain	n/a	281	100.0	1	0.4	0.1	2.0
	Lymphadenopathy	n/a	281	100.0	2	0.7	0.2	2.6
	Lymphopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Neutropenia	n/a	281	100.0	7	2.5	1.2	5.1
	Neutrophilia	n/a	281	100.0	1	0.4	0.1	2.0
	Pancytopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombocytopenia	n/a	281	100.0	12	4.3	2.5	7.3
	Thrombocytosis	n/a	281	100.0	4	1.4	0.6	3.6
Cardiac disorders	-Total	n/a	281	100.0	25	8.9	6.1	12.8
	Aortic valve calcification	n/a	281	100.0	1	0.4	0.1	2.0
	Atrial flutter	n/a	281	100.0	2	0.7	0.2	2.6
	Bradycardia	n/a	281	100.0	1	0.4	0.1	2.0
	Bundle branch block right	n/a	281	100.0	1	0.4	0.1	2.0
	Extrasystoles	n/a	281	100.0	1	0.4	0.1	2.0
	Myocardial ischaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Nodal arrhythmia	n/a	281	100.0	2	0.7	0.2	2.6

	Palpitations	n/a	281	100.0	4	1.4	0.6	3.6
	Pericardial effusion	n/a	281	100.0	2	0.7	0.2	2.6
	Sinus bradycardia	n/a	281	100.0	4	1.4	0.6	3.6
	Sinus tachycardia	n/a	281	100.0	2	0.7	0.2	2.6
	Tachycardia	n/a	281	100.0	4	1.4	0.6	3.6
	Ventricular extrasystoles	n/a	281	100.0	1	0.4	0.1	2.0
	Ventricular pre-excitation	n/a	281	100.0	1	0.4	0.1	2.0
Congenital, familial and genetic disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Hydrocele	n/a	281	100.0	1	0.4	0.1	2.0
Ear and labyrinth disorders	-Total	n/a	281	100.0	17	6.0	3.8	9.5
	Ear congestion	n/a	281	100.0	2	0.7	0.2	2.6
	Ear discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Ear pain	n/a	281	100.0	3	1.1	0.4	3.1
	Tinnitus	n/a	281	100.0	3	1.1	0.4	3.1
	Vertigo	n/a	281	100.0	9	3.2	1.7	6.0
Endocrine disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Hyperthyroidism	n/a	281	100.0	1	0.4	0.1	2.0
	Hypothyroidism	n/a	281	100.0	2	0.7	0.2	2.6
Eye disorders	-Total	n/a	281	100.0	32	11.4	8.2	15.6
	Abnormal sensation in eye	n/a	281	100.0	1	0.4	0.1	2.0
	Blepharitis	n/a	281	100.0	1	0.4	0.1	2.0
	Conjunctival haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Diplopia	n/a	281	100.0	1	0.4	0.1	2.0
	Dry eye	n/a	281	100.0	7	2.5	1.2	5.1
	Eye swelling	n/a	281	100.0	2	0.7	0.2	2.6
	Eyelid oedema	n/a	281	100.0	5	1.8	0.8	4.1
	Eyelid ptosis	n/a	281	100.0	1	0.4	0.1	2.0
	Periorbital oedema	n/a	281	100.0	5	1.8	0.8	4.1
	Photophobia	n/a	281	100.0	1	0.4	0.1	2.0

	Photopsia	n/a	281	100.0	1	0.4	0.1	2.0
	Vision blurred	n/a	281	100.0	12	4.3	2.5	7.3
	Visual acuity reduced	n/a	281	100.0	1	0.4	0.1	2.0
Gastrointestinal disorders	-Total	n/a	281	100.0	173	61.6	55.8	67.1
	Abdominal discomfort	n/a	281	100.0	4	1.4	0.6	3.6
	Abdominal distension	n/a	281	100.0	7	2.5	1.2	5.1
	Abdominal pain	n/a	281	100.0	10	3.6	1.9	6.4
	Abdominal pain lower	n/a	281	100.0	2	0.7	0.2	2.6
	Abdominal pain upper	n/a	281	100.0	9	3.2	1.7	6.0
	Abdominal symptom	n/a	281	100.0	1	0.4	0.1	2.0
	Anal incontinence	n/a	281	100.0	2	0.7	0.2	2.6
	Aphthous ulcer	n/a	281	100.0	1	0.4	0.1	2.0
	Ascites	n/a	281	100.0	2	0.7	0.2	2.6
	Constipation	n/a	281	100.0	93	33.1	27.9	38.8
	Dental dysaesthesia	n/a	281	100.0	1	0.4	0.1	2.0
	Diarrhoea	n/a	281	100.0	53	18.9	14.7	23.8
	Dry mouth	n/a	281	100.0	43	15.3	11.6	20.0
	Dyspepsia	n/a	281	100.0	7	2.5	1.2	5.1
	Dysphagia	n/a	281	100.0	16	5.7	3.5	9.0
	Epigastric discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Eructation	n/a	281	100.0	1	0.4	0.1	2.0
	Faeces soft	n/a	281	100.0	1	0.4	0.1	2.0
	Flatulence	n/a	281	100.0	2	0.7	0.2	2.6
	Frequent bowel movements	n/a	281	100.0	1	0.4	0.1	2.0
	Gastritis	n/a	281	100.0	2	0.7	0.2	2.6
	Gastrointestinal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal inflammation	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal oedema	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal wall thickening	n/a	281	100.0	1	0.4	0.1	2.0

	Gastrooesophageal reflux disease	n/a	281	100.0	4	1.4	0.6	3.6
	Gingival bleeding	n/a	281	100.0	3	1.1	0.4	3.1
	Gingival swelling	n/a	281	100.0	1	0.4	0.1	2.0
	Glossitis	n/a	281	100.0	1	0.4	0.1	2.0
	Glossodynia	n/a	281	100.0	1	0.4	0.1	2.0
	Haematochezia	n/a	281	100.0	1	0.4	0.1	2.0
	Haemorrhoids	n/a	281	100.0	3	1.1	0.4	3.1
	Hypoaesthesia oral	n/a	281	100.0	5	1.8	0.8	4.1
	Impaired gastric emptying	n/a	281	100.0	1	0.4	0.1	2.0
	Melaena	n/a	281	100.0	1	0.4	0.1	2.0
	Mouth ulceration	n/a	281	100.0	8	2.8	1.4	5.5
	Nausea	n/a	281	100.0	27	9.6	6.7	13.6
	Odynophagia	n/a	281	100.0	4	1.4	0.6	3.6
	Oesophageal irritation	n/a	281	100.0	1	0.4	0.1	2.0
	Oesophagitis	n/a	281	100.0	2	0.7	0.2	2.6
	Oral disorder	n/a	281	100.0	2	0.7	0.2	2.6
	Oral dysaesthesia	n/a	281	100.0	1	0.4	0.1	2.0
	Oral mucosal erythema	n/a	281	100.0	1	0.4	0.1	2.0
	Oral pain	n/a	281	100.0	5	1.8	0.8	4.1
	Paraesthesia oral	n/a	281	100.0	1	0.4	0.1	2.0
	Regurgitation	n/a	281	100.0	1	0.4	0.1	2.0
	Sensitivity of teeth	n/a	281	100.0	1	0.4	0.1	2.0
	Stomatitis	n/a	281	100.0	4	1.4	0.6	3.6
	Swollen tongue	n/a	281	100.0	1	0.4	0.1	2.0
	Tongue coated	n/a	281	100.0	1	0.4	0.1	2.0
	Tongue discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Tongue ulceration	n/a	281	100.0	1	0.4	0.1	2.0
	Tooth discolouration	n/a	281	100.0	1	0.4	0.1	2.0
	Toothache	n/a	281	100.0	5	1.8	0.8	4.1

	Vomiting	n/a	281	100.0	18	6.4	4.1	9.9
General disorders and administration site conditions	-Total	n/a	281	100.0	159	56.6	50.7	62.3
	Asthenia	n/a	281	100.0	18	6.4	4.1	9.9
	Axillary pain	n/a	281	100.0	1	0.4	0.1	2.0
	Catheter site pain	n/a	281	100.0	1	0.4	0.1	2.0
	Chest discomfort	n/a	281	100.0	9	3.2	1.7	6.0
	Chest pain	n/a	281	100.0	6	2.1	1.0	4.6
	Chills	n/a	281	100.0	4	1.4	0.6	3.6
	Face oedema	n/a	281	100.0	14	5.0	3.0	8.2
	Fatigue	n/a	281	100.0	33	11.7	8.5	16.0
	Feeling abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Feeling cold	n/a	281	100.0	1	0.4	0.1	2.0
	Feeling hot	n/a	281	100.0	1	0.4	0.1	2.0
	Gait disturbance	n/a	281	100.0	4	1.4	0.6	3.6
	General physical health deterioration	n/a	281	100.0	1	0.4	0.1	2.0
	Generalised oedema	n/a	281	100.0	3	1.1	0.4	3.1
	Impaired healing	n/a	281	100.0	4	1.4	0.6	3.6
	Influenza like illness	n/a	281	100.0	1	0.4	0.1	2.0
	Injection site bruising	n/a	281	100.0	1	0.4	0.1	2.0
	Localised oedema	n/a	281	100.0	2	0.7	0.2	2.6
	Malaise	n/a	281	100.0	17	6.0	3.8	9.5
	Mucosal dryness	n/a	281	100.0	1	0.4	0.1	2.0
	Mucosal inflammation	n/a	281	100.0	12	4.3	2.5	7.3
	Non-cardiac chest pain	n/a	281	100.0	10	3.6	1.9	6.4
	Oedema	n/a	281	100.0	4	1.4	0.6	3.6
	Oedema peripheral	n/a	281	100.0	33	11.7	8.5	16.0
	Pain	n/a	281	100.0	4	1.4	0.6	3.6
	Peripheral swelling	n/a	281	100.0	6	2.1	1.0	4.6
	Pyrexia	n/a	281	100.0	48	17.1	13.1	21.9

	Swelling	n/a	281	100.0	1	0.4	0.1	2.0
	Temperature intolerance	n/a	281	100.0	3	1.1	0.4	3.1
	Xerosis	n/a	281	100.0	1	0.4	0.1	2.0
Hepatobiliary disorders	-Total	n/a	281	100.0	15	5.3	3.3	8.6
	Cholecystitis	n/a	281	100.0	2	0.7	0.2	2.6
	Hepatic function abnormal	n/a	281	100.0	3	1.1	0.4	3.1
	Hepatic steatosis	n/a	281	100.0	1	0.4	0.1	2.0
	Hepatocellular injury	n/a	281	100.0	3	1.1	0.4	3.1
	Hyperbilirubinaemia	n/a	281	100.0	3	1.1	0.4	3.1
	Liver disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumobilia	n/a	281	100.0	1	0.4	0.1	2.0
	Portal vein thrombosis	n/a	281	100.0	1	0.4	0.1	2.0
Immune system disorders	-Total	n/a	281	100.0	4	1.4	0.6	3.6
	Drug hypersensitivity	n/a	281	100.0	1	0.4	0.1	2.0
	Food allergy	n/a	281	100.0	1	0.4	0.1	2.0
	Hypersensitivity	n/a	281	100.0	1	0.4	0.1	2.0
	Seasonal allergy	n/a	281	100.0	1	0.4	0.1	2.0
Infections and infestations	-Total	n/a	281	100.0	63	22.4	17.9	27.6
	Acute sinusitis	n/a	281	100.0	1	0.4	0.1	2.0
	Bacterial disease carrier	n/a	281	100.0	1	0.4	0.1	2.0
	Bronchitis	n/a	281	100.0	5	1.8	0.8	4.1
	Candida infection	n/a	281	100.0	1	0.4	0.1	2.0
	Chronic sinusitis	n/a	281	100.0	1	0.4	0.1	2.0
	Cystitis	n/a	281	100.0	1	0.4	0.1	2.0
	Ear infection	n/a	281	100.0	1	0.4	0.1	2.0
	Epstein-Barr virus infection	n/a	281	100.0	1	0.4	0.1	2.0
	Escherichia bacteraemia	n/a	281	100.0	1	0.4	0.1	2.0
	Eye infection	n/a	281	100.0	1	0.4	0.1	2.0
	Folliculitis	n/a	281	100.0	3	1.1	0.4	3.1

	Fungal infection	n/a	281	100.0	2	0.7	0.2	2.6
	Gastroenteritis	n/a	281	100.0	1	0.4	0.1	2.0
	Genital candidiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Herpes simplex	n/a	281	100.0	1	0.4	0.1	2.0
	Herpes virus infection	n/a	281	100.0	1	0.4	0.1	2.0
	Herpes zoster	n/a	281	100.0	2	0.7	0.2	2.6
	Infection	n/a	281	100.0	1	0.4	0.1	2.0
	Influenza	n/a	281	100.0	2	0.7	0.2	2.6
	Lower respiratory tract infection	n/a	281	100.0	1	0.4	0.1	2.0
	Lymph node tuberculosis	n/a	281	100.0	1	0.4	0.1	2.0
	Nasal herpes	n/a	281	100.0	1	0.4	0.1	2.0
	Nasopharyngitis	n/a	281	100.0	7	2.5	1.2	5.1
	Oral candidiasis	n/a	281	100.0	3	1.1	0.4	3.1
	Otitis externa	n/a	281	100.0	1	0.4	0.1	2.0
	Otitis media	n/a	281	100.0	1	0.4	0.1	2.0
	Paronychia	n/a	281	100.0	6	2.1	1.0	4.6
	Pharyngitis	n/a	281	100.0	2	0.7	0.2	2.6
	Pneumonia	n/a	281	100.0	4	1.4	0.6	3.6
	Pyelonephritis	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory tract infection	n/a	281	100.0	1	0.4	0.1	2.0
	Rhinitis	n/a	281	100.0	1	0.4	0.1	2.0
	Sinusitis	n/a	281	100.0	4	1.4	0.6	3.6
	Skin infection	n/a	281	100.0	1	0.4	0.1	2.0
	Tinea infection	n/a	281	100.0	1	0.4	0.1	2.0
	Tinea pedis	n/a	281	100.0	2	0.7	0.2	2.6
	Tooth infection	n/a	281	100.0	1	0.4	0.1	2.0
	Tracheitis	n/a	281	100.0	1	0.4	0.1	2.0
	Tuberculosis	n/a	281	100.0	1	0.4	0.1	2.0
	Upper respiratory tract infection	n/a	281	100.0	5	1.8	0.8	4.1

	Urinary tract infection	n/a	281	100.0	6	2.1	1.0	4.6
	Viral infection	n/a	281	100.0	1	0.4	0.1	2.0
Injury, poisoning and procedural complications	-Total	n/a	281	100.0	17	6.0	3.8	9.5
	Contusion	n/a	281	100.0	5	1.8	0.8	4.1
	Epicondylitis	n/a	281	100.0	1	0.4	0.1	2.0
	Fall	n/a	281	100.0	3	1.1	0.4	3.1
	Incision site pain	n/a	281	100.0	1	0.4	0.1	2.0
	Injury	n/a	281	100.0	1	0.4	0.1	2.0
	Joint dislocation	n/a	281	100.0	1	0.4	0.1	2.0
	Laceration	n/a	281	100.0	1	0.4	0.1	2.0
	Ligament sprain	n/a	281	100.0	2	0.7	0.2	2.6
	Limb injury	n/a	281	100.0	2	0.7	0.2	2.6
	Muscle strain	n/a	281	100.0	2	0.7	0.2	2.6
	Procedural pain	n/a	281	100.0	2	0.7	0.2	2.6
	Rib fracture	n/a	281	100.0	1	0.4	0.1	2.0
	Scar	n/a	281	100.0	1	0.4	0.1	2.0
	Skin abrasion	n/a	281	100.0	1	0.4	0.1	2.0
	Skin injury	n/a	281	100.0	1	0.4	0.1	2.0
	Tendon rupture	n/a	281	100.0	1	0.4	0.1	2.0
	Wound	n/a	281	100.0	1	0.4	0.1	2.0
Investigations	-Total	n/a	281	100.0	186	66.2	60.5	71.5
	Alanine aminotransferase increased	n/a	281	100.0	71	25.3	20.5	30.7
	Albumin urine present	n/a	281	100.0	1	0.4	0.1	2.0
	Alpha hydroxybutyrate dehydrogenase increased	n/a	281	100.0	2	0.7	0.2	2.6
	Aspartate aminotransferase increased	n/a	281	100.0	98	34.9	29.5	40.6
	Bacterial test	n/a	281	100.0	1	0.4	0.1	2.0
	Bilirubin conjugated increased	n/a	281	100.0	13	4.6	2.7	7.8
	Blood albumin decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood alkaline phosphatase	n/a	281	100.0	1	0.4	0.1	2.0

	Blood alkaline phosphatase decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood alkaline phosphatase increased	n/a	281	100.0	23	8.2	5.5	12.0
	Blood bilirubin increased	n/a	281	100.0	19	6.8	4.4	10.3
	Blood bilirubin unconjugated increased	n/a	281	100.0	6	2.1	1.0	4.6
	Blood calcium decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood calcium increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood chloride increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood cholesterol increased	n/a	281	100.0	7	2.5	1.2	5.1
	Blood creatine increased	n/a	281	100.0	3	1.1	0.4	3.1
	Blood creatine phosphokinase MB increased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood creatine phosphokinase increased	n/a	281	100.0	16	5.7	3.5	9.0
	Blood creatinine	n/a	281	100.0	1	0.4	0.1	2.0
	Blood creatinine increased	n/a	281	100.0	51	18.1	14.1	23.1
	Blood fibrinogen increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood glucose increased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood ketone body increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood lactate dehydrogenase increased	n/a	281	100.0	10	3.6	1.9	6.4
	Blood magnesium decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood phosphorus increased	n/a	281	100.0	7	2.5	1.2	5.1
	Blood potassium increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood pressure increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood sodium decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood thyroid stimulating hormone increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood triglycerides increased	n/a	281	100.0	8	2.8	1.4	5.5
	Blood urea increased	n/a	281	100.0	6	2.1	1.0	4.6
	Blood uric acid decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood uric acid increased	n/a	281	100.0	7	2.5	1.2	5.1
	Blood urine	n/a	281	100.0	3	1.1	0.4	3.1
	Blood urine present	n/a	281	100.0	1	0.4	0.1	2.0

	C-reactive protein increased	n/a	281	100.0	2	0.7	0.2	2.6
	Carbon dioxide decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Complement factor C1 decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Computerised tomogram thorax abnormal	n/a	281	100.0	2	0.7	0.2	2.6
	Crystal urine present	n/a	281	100.0	1	0.4	0.1	2.0
	Cystatin C increased	n/a	281	100.0	1	0.4	0.1	2.0
	Electrocardiogram QT prolonged	n/a	281	100.0	13	4.6	2.7	7.8
	Electrocardiogram ST-T change	n/a	281	100.0	2	0.7	0.2	2.6
	Fibrin D dimer increased	n/a	281	100.0	2	0.7	0.2	2.6
	Fibrin degradation products increased	n/a	281	100.0	1	0.4	0.1	2.0
	Free fatty acids increased	n/a	281	100.0	1	0.4	0.1	2.0
	Gamma-glutamyltransferase increased	n/a	281	100.0	13	4.6	2.7	7.8
	Glomerular filtration rate decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Glutamate dehydrogenase increased	n/a	281	100.0	2	0.7	0.2	2.6
	Haematocrit decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Haemoglobin decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Heart rate increased	n/a	281	100.0	6	2.1	1.0	4.6
	Hepatic enzyme increased	n/a	281	100.0	2	0.7	0.2	2.6
	International normalised ratio increased	n/a	281	100.0	2	0.7	0.2	2.6
	Intraocular pressure increased	n/a	281	100.0	1	0.4	0.1	2.0
	Laboratory test abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Lipase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Liver function test increased	n/a	281	100.0	1	0.4	0.1	2.0
	Lymphocyte count decreased	n/a	281	100.0	6	2.1	1.0	4.6
	Mean cell volume increased	n/a	281	100.0	1	0.4	0.1	2.0
	Myoglobin blood increased	n/a	281	100.0	1	0.4	0.1	2.0
	Neutrophil count decreased	n/a	281	100.0	16	5.7	3.5	9.0
	Neutrophil count increased	n/a	281	100.0	2	0.7	0.2	2.6
	Occult blood positive	n/a	281	100.0	3	1.1	0.4	3.1

	Platelet count decreased	n/a	281	100.0	17	6.0	3.8	9.5	
	Platelet count increased	n/a	281	100.0	4	1.4	0.6	3.6	
	Protein total decreased	n/a	281	100.0	3	1.1	0.4	3.1	
	Protein total increased	n/a	281	100.0	1	0.4	0.1	2.0	
	Protein urine present	n/a	281	100.0	2	0.7	0.2	2.6	
	Prothrombin time prolonged	n/a	281	100.0	1	0.4	0.1	2.0	
	Red blood cell count decreased	n/a	281	100.0	1	0.4	0.1	2.0	
	Thrombin time prolonged	n/a	281	100.0	1	0.4	0.1	2.0	
	Total bile acids increased	n/a	281	100.0	8	2.8	1.4	5.5	
	Transaminases increased	n/a	281	100.0	7	2.5	1.2	5.1	
	Transferrin increased	n/a	281	100.0	1	0.4	0.1	2.0	
	Troponin T increased	n/a	281	100.0	1	0.4	0.1	2.0	
	Troponin increased	n/a	281	100.0	1	0.4	0.1	2.0	
	Urinary sediment present	n/a	281	100.0	1	0.4	0.1	2.0	
	Urine ketone body present	n/a	281	100.0	3	1.1	0.4	3.1	
	Urine leukocyte esterase positive	n/a	281	100.0	1	0.4	0.1	2.0	
	Urobilinogen urine increased	n/a	281	100.0	2	0.7	0.2	2.6	
	Weight decreased	n/a	281	100.0	14	5.0	3.0	8.2	
	Weight increased	n/a	281	100.0	14	5.0	3.0	8.2	
	White blood cell count decreased	n/a	281	100.0	23	8.2	5.5	12.0	
	White blood cells urine positive	n/a	281	100.0	3	1.1	0.4	3.1	
Metabolism and nutrition disorders	-Total	n/a	281	100.0	111	39.5	34.0	45.3	
	Alkalosis	n/a	281	100.0	1	0.4	0.1	2.0	
	Cell death	n/a	281	100.0	1	0.4	0.1	2.0	
	Decreased appetite	n/a	281	100.0	24	8.5	5.8	12.4	
	Dehydration	n/a	281	100.0	1	0.4	0.1	2.0	
	Fluid retention	n/a	281	100.0	1	0.4	0.1	2.0	
	Hypercalcaemia	n/a	281	100.0	5	1.8	0.8	4.1	
	Hypercholesterolaemia	n/a	281	100.0	5	1.8	0.8	4.1	

	Hyperglycaemia	n/a	281	100.0	16	5.7	3.5	9.0
	Hyperkalaemia	n/a	281	100.0	8	2.8	1.4	5.5
	Hyperlipidaemia	n/a	281	100.0	6	2.1	1.0	4.6
	Hypermagnesaemia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypernatraemia	n/a	281	100.0	2	0.7	0.2	2.6
	Hyperphosphataemia	n/a	281	100.0	28	10.0	7.0	14.0
	Hypertriglyceridaemia	n/a	281	100.0	5	1.8	0.8	4.1
	Hyperuricaemia	n/a	281	100.0	10	3.6	1.9	6.4
	Hypoalbuminaemia	n/a	281	100.0	17	6.0	3.8	9.5
	Hypocalcaemia	n/a	281	100.0	19	6.8	4.4	10.3
	Hypochloraemia	n/a	281	100.0	4	1.4	0.6	3.6
	Hypoglycaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypokalaemia	n/a	281	100.0	21	7.5	4.9	11.2
	Hypomagnesaemia	n/a	281	100.0	20	7.1	4.7	10.7
	Hyponatraemia	n/a	281	100.0	17	6.0	3.8	9.5
	Hypophosphataemia	n/a	281	100.0	8	2.8	1.4	5.5
	Hypoproteinaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Increased appetite	n/a	281	100.0	1	0.4	0.1	2.0
	Vitamin D deficiency	n/a	281	100.0	1	0.4	0.1	2.0
Musculoskeletal and connective tissue disorders	-Total	n/a	281	100.0	92	32.7	27.5	38.4
	Arthralgia	n/a	281	100.0	11	3.9	2.2	6.9
	Arthropathy	n/a	281	100.0	1	0.4	0.1	2.0
	Back pain	n/a	281	100.0	22	7.8	5.2	11.6
	Bone pain	n/a	281	100.0	2	0.7	0.2	2.6
	Coccydynia	n/a	281	100.0	1	0.4	0.1	2.0
	Costochondritis	n/a	281	100.0	2	0.7	0.2	2.6
	Flank pain	n/a	281	100.0	2	0.7	0.2	2.6
	Groin pain	n/a	281	100.0	1	0.4	0.1	2.0
	Hypercreatinaemia	n/a	281	100.0	1	0.4	0.1	2.0

	Intervertebral disc protrusion	n/a	281	100.0	2	0.7	0.2	2.6
	Joint stiffness	n/a	281	100.0	1	0.4	0.1	2.0
	Joint swelling	n/a	281	100.0	2	0.7	0.2	2.6
	Muscle fatigue	n/a	281	100.0	1	0.4	0.1	2.0
	Muscle spasms	n/a	281	100.0	20	7.1	4.7	10.7
	Muscular weakness	n/a	281	100.0	6	2.1	1.0	4.6
	Musculoskeletal chest pain	n/a	281	100.0	5	1.8	0.8	4.1
	Musculoskeletal pain	n/a	281	100.0	15	5.3	3.3	8.6
	Musculoskeletal stiffness	n/a	281	100.0	1	0.4	0.1	2.0
	Myalgia	n/a	281	100.0	21	7.5	4.9	11.2
	Myopathy	n/a	281	100.0	2	0.7	0.2	2.6
	Neck pain	n/a	281	100.0	9	3.2	1.7	6.0
	Osteopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Pain in extremity	n/a	281	100.0	17	6.0	3.8	9.5
	Pain in jaw	n/a	281	100.0	2	0.7	0.2	2.6
	Rotator cuff syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Spinal column stenosis	n/a	281	100.0	1	0.4	0.1	2.0
	Tendon pain	n/a	281	100.0	1	0.4	0.1	2.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	281	100.0	7	2.5	1.2	5.1
	Anogenital warts	n/a	281	100.0	1	0.4	0.1	2.0
	Basal cell carcinoma	n/a	281	100.0	1	0.4	0.1	2.0
	Bowen's disease	n/a	281	100.0	1	0.4	0.1	2.0
	Renal cell carcinoma	n/a	281	100.0	1	0.4	0.1	2.0
	Squamous cell carcinoma	n/a	281	100.0	1	0.4	0.1	2.0
	Squamous cell carcinoma of skin	n/a	281	100.0	1	0.4	0.1	2.0
	Tumour pain	n/a	281	100.0	1	0.4	0.1	2.0
Nervous system disorders	-Total	n/a	281	100.0	121	43.1	37.4	48.9
	Ageusia	n/a	281	100.0	2	0.7	0.2	2.6
	Aphasia	n/a	281	100.0	1	0.4	0.1	2.0

	Ataxia	n/a	281	100.0	1	0.4	0.1	2.0
	Brain oedema	n/a	281	100.0	2	0.7	0.2	2.6
	Cerebellar haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Disturbance in attention	n/a	281	100.0	2	0.7	0.2	2.6
	Dizziness	n/a	281	100.0	28	10.0	7.0	14.0
	Dizziness postural	n/a	281	100.0	1	0.4	0.1	2.0
	Dysarthria	n/a	281	100.0	1	0.4	0.1	2.0
	Dysgeusia	n/a	281	100.0	37	13.2	9.7	17.6
	Dyskinesia	n/a	281	100.0	1	0.4	0.1	2.0
	Headache	n/a	281	100.0	25	8.9	6.1	12.8
	Hyperaesthesia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypersomnia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypoaesthesia	n/a	281	100.0	16	5.7	3.5	9.0
	Hypotonia	n/a	281	100.0	1	0.4	0.1	2.0
	Lethargy	n/a	281	100.0	1	0.4	0.1	2.0
	Memory impairment	n/a	281	100.0	1	0.4	0.1	2.0
	Neuralgia	n/a	281	100.0	1	0.4	0.1	2.0
	Neuropathy peripheral	n/a	281	100.0	11	3.9	2.2	6.9
	Paraesthesia	n/a	281	100.0	9	3.2	1.7	6.0
	Paralysis	n/a	281	100.0	1	0.4	0.1	2.0
	Parosmia	n/a	281	100.0	1	0.4	0.1	2.0
	Peripheral sensory neuropathy	n/a	281	100.0	9	3.2	1.7	6.0
	Post herpetic neuralgia	n/a	281	100.0	1	0.4	0.1	2.0
	Presyncope	n/a	281	100.0	1	0.4	0.1	2.0
	Psychomotor skills impaired	n/a	281	100.0	1	0.4	0.1	2.0
	Sciatica	n/a	281	100.0	4	1.4	0.6	3.6
	Seizure	n/a	281	100.0	1	0.4	0.1	2.0
	Sensory disturbance	n/a	281	100.0	1	0.4	0.1	2.0
	Slow speech	n/a	281	100.0	1	0.4	0.1	2.0

	Somnolence	n/a	281	100.0	1	0.4	0.1	2.0
	Syncope	n/a	281	100.0	1	0.4	0.1	2.0
	Tension headache	n/a	281	100.0	1	0.4	0.1	2.0
	Tremor	n/a	281	100.0	1	0.4	0.1	2.0
	Visual field defect	n/a	281	100.0	2	0.7	0.2	2.6
Product issues	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Device dislocation	n/a	281	100.0	1	0.4	0.1	2.0
Psychiatric disorders	-Total	n/a	281	100.0	45	16.0	12.2	20.8
	Abnormal dreams	n/a	281	100.0	1	0.4	0.1	2.0
	Anxiety	n/a	281	100.0	8	2.8	1.4	5.5
	Bradyphrenia	n/a	281	100.0	1	0.4	0.1	2.0
	Confusional state	n/a	281	100.0	5	1.8	0.8	4.1
	Depression	n/a	281	100.0	5	1.8	0.8	4.1
	Fear of falling	n/a	281	100.0	1	0.4	0.1	2.0
	Insomnia	n/a	281	100.0	18	6.4	4.1	9.9
	Irritability	n/a	281	100.0	1	0.4	0.1	2.0
	Libido decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Mood altered	n/a	281	100.0	1	0.4	0.1	2.0
	Psychomotor retardation	n/a	281	100.0	2	0.7	0.2	2.6
	Restlessness	n/a	281	100.0	5	1.8	0.8	4.1
	Sleep disorder	n/a	281	100.0	2	0.7	0.2	2.6
Renal and urinary disorders	-Total	n/a	281	100.0	30	10.7	7.6	14.8
	Acute kidney injury	n/a	281	100.0	3	1.1	0.4	3.1
	Azotaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Cystitis haemorrhagic	n/a	281	100.0	1	0.4	0.1	2.0
	Dysuria	n/a	281	100.0	6	2.1	1.0	4.6
	Haematuria	n/a	281	100.0	2	0.7	0.2	2.6
	Micturition urgency	n/a	281	100.0	1	0.4	0.1	2.0
	Nocturia	n/a	281	100.0	3	1.1	0.4	3.1

	Pollakiuria	n/a	281	100.0	2	0.7	0.2	2.6
	Proteinuria	n/a	281	100.0	1	0.4	0.1	2.0
	Renal colic	n/a	281	100.0	1	0.4	0.1	2.0
	Renal disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Renal failure	n/a	281	100.0	2	0.7	0.2	2.6
	Renal impairment	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary incontinence	n/a	281	100.0	2	0.7	0.2	2.6
	Urinary retention	n/a	281	100.0	5	1.8	0.8	4.1
	Urinary tract pain	n/a	281	100.0	1	0.4	0.1	2.0
	Urine flow decreased	n/a	281	100.0	1	0.4	0.1	2.0
Reproductive system and breast disorders	-Total	n/a	281	100.0	16	5.7	3.5	9.0
	Benign prostatic hyperplasia	n/a	281	100.0	2	0.7	0.2	2.6
	Breast discharge	n/a	281	100.0	1	0.4	0.1	2.0
	Erectile dysfunction	n/a	281	100.0	5	1.8	0.8	4.1
	Galactorrhoea	n/a	281	100.0	1	0.4	0.1	2.0
	Genital ulceration	n/a	281	100.0	1	0.4	0.1	2.0
	Metrorrhagia	n/a	281	100.0	1	0.4	0.1	2.0
	Pelvic discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Pelvic fluid collection	n/a	281	100.0	1	0.4	0.1	2.0
	Perineal pain	n/a	281	100.0	1	0.4	0.1	2.0
	Postmenopausal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Uterine polyp	n/a	281	100.0	1	0.4	0.1	2.0
	Vaginal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Vulvovaginal dryness	n/a	281	100.0	1	0.4	0.1	2.0
	Vulvovaginal erythema	n/a	281	100.0	1	0.4	0.1	2.0
Respiratory, thoracic and mediastinal disorders	-Total	n/a	281	100.0	116	41.3	35.7	47.1
	Aspiration	n/a	281	100.0	1	0.4	0.1	2.0
	Choking	n/a	281	100.0	1	0.4	0.1	2.0
	Cough	n/a	281	100.0	44	15.7	11.9	20.4

	Dry throat	n/a	281	100.0	2	0.7	0.2	2.6
	Dysphonia	n/a	281	100.0	12	4.3	2.5	7.3
	Dyspnoea	n/a	281	100.0	22	7.8	5.2	11.6
	Dyspnoea exertional	n/a	281	100.0	7	2.5	1.2	5.1
	Epistaxis	n/a	281	100.0	11	3.9	2.2	6.9
	Haemoptysis	n/a	281	100.0	10	3.6	1.9	6.4
	Hiccups	n/a	281	100.0	2	0.7	0.2	2.6
	Interstitial lung disease	n/a	281	100.0	1	0.4	0.1	2.0
	Laryngeal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Nasal congestion	n/a	281	100.0	4	1.4	0.6	3.6
	Nasal dryness	n/a	281	100.0	4	1.4	0.6	3.6
	Nasal polyps	n/a	281	100.0	1	0.4	0.1	2.0
	Oropharyngeal discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Oropharyngeal pain	n/a	281	100.0	16	5.7	3.5	9.0
	Paranasal sinus discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Pharyngeal disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Pleural thickening	n/a	281	100.0	2	0.7	0.2	2.6
	Pleuritic pain	n/a	281	100.0	2	0.7	0.2	2.6
	Pneumonitis	n/a	281	100.0	7	2.5	1.2	5.1
	Pneumothorax	n/a	281	100.0	2	0.7	0.2	2.6
	Productive cough	n/a	281	100.0	10	3.6	1.9	6.4
	Pulmonary embolism	n/a	281	100.0	2	0.7	0.2	2.6
	Pulmonary mass	n/a	281	100.0	1	0.4	0.1	2.0
	Pulmonary pain	n/a	281	100.0	1	0.4	0.1	2.0
	Respiration abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Rhinitis allergic	n/a	281	100.0	2	0.7	0.2	2.6
	Rhinorrhoea	n/a	281	100.0	2	0.7	0.2	2.6
	Sinus congestion	n/a	281	100.0	1	0.4	0.1	2.0
	Sleep apnoea syndrome	n/a	281	100.0	3	1.1	0.4	3.1

	Throat irritation	n/a	281	100.0	2	0.7	0.2	2.6
	Upper-airway cough syndrome	n/a	281	100.0	2	0.7	0.2	2.6
	Wheezing	n/a	281	100.0	2	0.7	0.2	2.6
Skin and subcutaneous tissue disorders	-Total	n/a	281	100.0	88	31.3	26.2	37.0
	Acne	n/a	281	100.0	1	0.4	0.1	2.0
	Alopecia	n/a	281	100.0	14	5.0	3.0	8.2
	Chloasma	n/a	281	100.0	1	0.4	0.1	2.0
	Dermal cyst	n/a	281	100.0	1	0.4	0.1	2.0
	Dermatitis	n/a	281	100.0	1	0.4	0.1	2.0
	Dermatitis acneiform	n/a	281	100.0	7	2.5	1.2	5.1
	Dermatitis bullous	n/a	281	100.0	1	0.4	0.1	2.0
	Dry skin	n/a	281	100.0	12	4.3	2.5	7.3
	Ecchymosis	n/a	281	100.0	1	0.4	0.1	2.0
	Eczema	n/a	281	100.0	1	0.4	0.1	2.0
	Erythema	n/a	281	100.0	2	0.7	0.2	2.6
	Hair growth abnormal	n/a	281	100.0	6	2.1	1.0	4.6
	Hair texture abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Hirsutism	n/a	281	100.0	6	2.1	1.0	4.6
	Hyperhidrosis	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperkeratosis	n/a	281	100.0	1	0.4	0.1	2.0
	Hypertrichosis	n/a	281	100.0	6	2.1	1.0	4.6
	Madarosis	n/a	281	100.0	1	0.4	0.1	2.0
	Nail discolouration	n/a	281	100.0	1	0.4	0.1	2.0
	Nail disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Night sweats	n/a	281	100.0	2	0.7	0.2	2.6
	Onychalgia	n/a	281	100.0	1	0.4	0.1	2.0
	Onycholysis	n/a	281	100.0	1	0.4	0.1	2.0
	Onychomadesis	n/a	281	100.0	3	1.1	0.4	3.1
	Pain of skin	n/a	281	100.0	1	0.4	0.1	2.0

	Palmar-plantar erythrodysaesthesia syndrome	n/a	281	100.0	5	1.8	0.8	4.1
	Photosensitivity reaction	n/a	281	100.0	1	0.4	0.1	2.0
	Pruritus	n/a	281	100.0	4	1.4	0.6	3.6
	Pruritus generalised	n/a	281	100.0	1	0.4	0.1	2.0
	Purpura	n/a	281	100.0	1	0.4	0.1	2.0
	Rash	n/a	281	100.0	19	6.8	4.4	10.3
	Rash erythematous	n/a	281	100.0	2	0.7	0.2	2.6
	Rash macular	n/a	281	100.0	3	1.1	0.4	3.1
	Rash maculo-papular	n/a	281	100.0	2	0.7	0.2	2.6
	Rash papular	n/a	281	100.0	1	0.4	0.1	2.0
	Scab	n/a	281	100.0	1	0.4	0.1	2.0
	Scar pain	n/a	281	100.0	1	0.4	0.1	2.0
	Skin discolouration	n/a	281	100.0	1	0.4	0.1	2.0
	Skin hyperpigmentation	n/a	281	100.0	1	0.4	0.1	2.0
	Skin lesion	n/a	281	100.0	1	0.4	0.1	2.0
	Swelling face	n/a	281	100.0	3	1.1	0.4	3.1
	Urticaria	n/a	281	100.0	2	0.7	0.2	2.6
Surgical and medical procedures	-Total	n/a	281	100.0	4	1.4	0.6	3.6
	Astringent therapy	n/a	281	100.0	4	1.4	0.6	3.6
Vascular disorders	-Total	n/a	281	100.0	22	7.8	5.2	11.6
	Circulatory collapse	n/a	281	100.0	1	0.4	0.1	2.0
	Embolism	n/a	281	100.0	1	0.4	0.1	2.0
	Flushing	n/a	281	100.0	1	0.4	0.1	2.0
	Haematoma	n/a	281	100.0	2	0.7	0.2	2.6
	Hot flush	n/a	281	100.0	3	1.1	0.4	3.1
	Hypertension	n/a	281	100.0	10	3.6	1.9	6.4
	Hypotension	n/a	281	100.0	4	1.4	0.6	3.6
	Phlebitis	n/a	281	100.0	1	0.4	0.1	2.0
	Raynaud's phenomenon	n/a	281	100.0	1	0.4	0.1	2.0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR1_SG.xls
26MAR2021 14:11

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	< 65	176	62.6	38	21.6	16.2	28.2
		>= 65	105	37.4	21	20.0	13.5	28.6
	Anaemia	< 65	176	62.6	23	13.1	8.9	18.8
		>= 65	105	37.4	5	4.8	2.1	10.7
	Cytopenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Febrile neutropenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperfibrinogenaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Leukocytosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Leukopenia	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
	Lymph node pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lymphadenopathy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymphopenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neutropenia	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Neutrophilia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pancytopenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Thrombocytopenia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	6	5.7	2.6	11.9
	Thrombocytosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
Cardiac disorders	-Total	< 65	176	62.6	15	8.5	5.2	13.6

		>= 65	105	37.4	10	9.5	5.3	16.6
	Aortic valve calcification	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Atrial flutter	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bradycardia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bundle branch block right	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Extrasystoles	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Myocardial ischaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nodal arrhythmia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Palpitations	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pericardial effusion	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sinus bradycardia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sinus tachycardia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tachycardia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Ventricular extrasystoles	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ventricular pre-excitation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Congenital, familial and genetic disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hydrocele	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Ear and labyrinth disorders	-Total	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	5	4.8	2.1	10.7
	Ear congestion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ear discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Ear pain	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tinnitus	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Vertigo	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	2	1.9	0.5	6.7
Endocrine disorders	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperthyroidism	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypothyroidism	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
Eye disorders	-Total	< 65	176	62.6	24	13.6	9.3	19.5
		>= 65	105	37.4	8	7.6	3.9	14.3
	Abnormal sensation in eye	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blepharitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Conjunctival haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diplopia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dry eye	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eye swelling	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Eyelid oedema	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Eyelid ptosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Periorbital oedema	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Photophobia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Photopsia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vision blurred	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	2	1.9	0.5	6.7

	Visual acuity reduced	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Gastrointestinal disorders	-Total	< 65	176	62.6	105	59.7	52.3	66.6
		>= 65	105	37.4	68	64.8	55.3	73.2
	Abdominal discomfort	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Abdominal distension	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Abdominal pain	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Abdominal pain lower	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Abdominal pain upper	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	3	2.9	1.0	8.1
	Abdominal symptom	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Anal incontinence	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Aphthous ulcer	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ascites	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Constipation	< 65	176	62.6	57	32.4	25.9	39.6
		>= 65	105	37.4	36	34.3	25.9	43.8
	Dental dysaesthesia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diarrhoea	< 65	176	62.6	33	18.8	13.7	25.2
		>= 65	105	37.4	20	19.0	12.7	27.6
	Dry mouth	< 65	176	62.6	22	12.5	8.4	18.2
		>= 65	105	37.4	21	20.0	13.5	28.6
	Dyspepsia	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Dysphagia	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	11	10.5	6.0	17.8
	Epigastric discomfort	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eructation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Faeces soft	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Flatulence	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Frequent bowel movements	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastritis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrointestinal haemorrhage	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastrointestinal inflammation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrointestinal oedema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrointestinal wall thickening	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrooesophageal reflux disease	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Gingival bleeding	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gingival swelling	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Glossitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Glossodynia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haematochezia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haemorrhoids	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypoaesthesia oral	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	0	0.0	0.0	3.5
	Impaired gastric emptying	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Melaena	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mouth ulceration	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	5	4.8	2.1	10.7
	Nausea	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	12	11.4	6.7	18.9

	Odynophagia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oesophageal irritation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oesophagitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oral disorder	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oral dysaesthesia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oral mucosal erythema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oral pain	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Paraesthesia oral	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Regurgitation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sensitivity of teeth	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Stomatitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Swollen tongue	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tongue coated	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tongue discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tongue ulceration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tooth discolouration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Toothache	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Vomiting	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	11	10.5	6.0	17.8
General disorders and administration site conditions	-Total	< 65	176	62.6	100	56.8	49.4	63.9
		>= 65	105	37.4	59	56.2	46.6	65.3

	Asthenia	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	5	4.8	2.1	10.7
	Axillary pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Catheter site pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Chest discomfort	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	4	3.8	1.5	9.4
	Chest pain	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Chills	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Face oedema	< 65	176	62.6	11	6.3	3.5	10.8
		>= 65	105	37.4	3	2.9	1.0	8.1
	Fatigue	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	16	15.2	9.6	23.3
	Feeling abnormal	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Feeling cold	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Feeling hot	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gait disturbance	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	General physical health deterioration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Generalised oedema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Impaired healing	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Influenza like illness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Injection site bruising	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Localised oedema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Malaise	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	1	1.0	0.2	5.2
	Mucosal dryness	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Mucosal inflammation	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Non-cardiac chest pain	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Oedema	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oedema peripheral	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	18	17.1	11.1	25.5
	Pain	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Peripheral swelling	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pyrexia	< 65	176	62.6	31	17.6	12.7	23.9
		>= 65	105	37.4	17	16.2	10.4	24.4
	Swelling	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Temperature intolerance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Xerosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Hepatobiliary disorders	-Total	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	9	8.6	4.6	15.5
	Cholecystitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hepatic function abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hepatic steatosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hepatocellular injury	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperbilirubinaemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Liver disorder	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pneumobilia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Portal vein thrombosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

Immune system disorders	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Drug hypersensitivity	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Food allergy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypersensitivity	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Seasonal allergy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Infections and infestations	-Total	< 65	176	62.6	41	23.3	17.7	30.1
		>= 65	105	37.4	22	21.0	14.3	29.7
	Acute sinusitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bacterial disease carrier	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bronchitis	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Candida infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Chronic sinusitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cystitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ear infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Epstein-Barr virus infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Escherichia bacteraemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eye infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Folliculitis	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fungal infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastroenteritis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Genital candidiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Herpes simplex	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Herpes virus infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Herpes zoster	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Influenza	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lower respiratory tract infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymph node tuberculosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nasal herpes	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nasopharyngitis	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oral candidiasis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Otitis externa	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Otitis media	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Paronychia	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pharyngitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pyelonephritis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory tract infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rhinitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sinusitis	< 65	176	62.6	4	2.3	0.9	5.7

		>= 65	105	37.4	0	0.0	0.0	3.5
	Skin infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tinea infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tinea pedis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tooth infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tracheitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tuberculosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Upper respiratory tract infection	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary tract infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	4	3.8	1.5	9.4
	Viral infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Injury, poisoning and procedural complications	-Total	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	9	8.6	4.6	15.5
	Contusion	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Epicondylitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fall	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Incision site pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Joint dislocation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Laceration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ligament sprain	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Limb injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7

	Muscle strain	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Procedural pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Rib fracture	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Scar	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Skin abrasion	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Skin injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tendon rupture	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Wound	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Investigations	-Total	< 65	176	62.6	120	68.2	61.0	74.6
		>= 65	105	37.4	66	62.9	53.3	71.5
	Alanine aminotransferase increased	< 65	176	62.6	48	27.3	21.2	34.3
		>= 65	105	37.4	23	21.9	15.1	30.7
	Albumin urine present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Alpha hydroxybutyrate dehydrogenase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Aspartate aminotransferase increased	< 65	176	62.6	66	37.5	30.7	44.8
		>= 65	105	37.4	32	30.5	22.5	39.8
	Bacterial test	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bilirubin conjugated increased	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	4	3.8	1.5	9.4
	Blood albumin decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood alkaline phosphatase	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood alkaline phosphatase decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood alkaline phosphatase increased	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	8	7.6	3.9	14.3

	Blood bilirubin increased	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	9	8.6	4.6	15.5
	Blood bilirubin unconjugated increased	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood calcium decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood calcium increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood chloride increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood cholesterol increased	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood creatine increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood creatine phosphokinase MB increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood creatine phosphokinase increased	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	4	3.8	1.5	9.4
	Blood creatinine	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood creatinine increased	< 65	176	62.6	32	18.2	13.2	24.5
		>= 65	105	37.4	19	18.1	11.9	26.5
	Blood fibrinogen increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood glucose increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood ketone body increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood lactate dehydrogenase increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	4	3.8	1.5	9.4
	Blood magnesium decreased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood phosphorus increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood potassium increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood pressure increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood sodium decreased	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood thyroid stimulating hormone increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood triglycerides increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood urea increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood uric acid decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood uric acid increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood urine	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood urine present	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	C-reactive protein increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Carbon dioxide decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Complement factor C1 decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Computerised tomogram thorax abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Crystal urine present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cystatin C increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Electrocardiogram QT prolonged	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	5	4.8	2.1	10.7
	Electrocardiogram ST-T change	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Fibrin D dimer increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Fibrin degradation products increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Free fatty acids increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gamma-glutamyltransferase increased	< 65	176	62.6	11	6.3	3.5	10.8
		>= 65	105	37.4	2	1.9	0.5	6.7

	Glomerular filtration rate decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Glutamate dehydrogenase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haematocrit decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haemoglobin decreased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Heart rate increased	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hepatic enzyme increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	International normalised ratio increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Intraocular pressure increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Laboratory test abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lipase increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Liver function test increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lymphocyte count decreased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Mean cell volume increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Myoglobin blood increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neutrophil count decreased	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	3	2.9	1.0	8.1
	Neutrophil count increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Occult blood positive	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Platelet count decreased	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	7	6.7	3.3	13.1
	Platelet count increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7

	Protein total decreased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Protein total increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Protein urine present	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Prothrombin time prolonged	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Red blood cell count decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Thrombin time prolonged	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Total bile acids increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	2	1.9	0.5	6.7
	Transaminases increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Transferrin increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Troponin T increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Troponin increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary sediment present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urine ketone body present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Urine leukocyte esterase positive	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urobilinogen urine increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Weight decreased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	8	7.6	3.9	14.3
	Weight increased	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	White blood cell count decreased	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	7	6.7	3.3	13.1
	White blood cells urine positive	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
Metabolism and nutrition disorders	-Total	< 65	176	62.6	66	37.5	30.7	44.8

		>= 65	105	37.4	45	42.9	33.8	52.4
	Alkalosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cell death	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Decreased appetite	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	11	10.5	6.0	17.8
	Dehydration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Fluid retention	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypercalcaemia	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypercholesterolaemia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperglycaemia	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	7	6.7	3.3	13.1
	Hyperkalaemia	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hyperlipidaemia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypermagnesaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hypernatraemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperphosphataemia	< 65	176	62.6	21	11.9	7.9	17.6
		>= 65	105	37.4	7	6.7	3.3	13.1
	Hypertriglyceridaemia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hyperuricaemia	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypoalbuminaemia	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	4	3.8	1.5	9.4
	Hypocalcaemia	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	6	5.7	2.6	11.9
	Hypochloraemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hypoglycaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Hypokalaemia	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	14	13.3	8.1	21.1
	Hypomagnesaemia	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	5	4.8	2.1	10.7
	Hyponatraemia	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	4	3.8	1.5	9.4
	Hypophosphataemia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Hypoproteinaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Increased appetite	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vitamin D deficiency	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Musculoskeletal and connective tissue disorders	-Total	< 65	176	62.6	60	34.1	27.5	41.4
		>= 65	105	37.4	32	30.5	22.5	39.8
	Arthralgia	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	3	2.9	1.0	8.1
	Arthropathy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Back pain	< 65	176	62.6	14	8.0	4.8	12.9
		>= 65	105	37.4	8	7.6	3.9	14.3
	Bone pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Coccydynia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Costochondritis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Flank pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Groin pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypercreatinaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Intervertebral disc protrusion	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Joint stiffness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Joint swelling	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Muscle fatigue	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscle spasms	< 65	176	62.6	11	6.3	3.5	10.8
		>= 65	105	37.4	9	8.6	4.6	15.5
	Muscular weakness	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Musculoskeletal chest pain	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Musculoskeletal pain	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	6	5.7	2.6	11.9
	Musculoskeletal stiffness	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Myalgia	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	5	4.8	2.1	10.7
	Myopathy	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neck pain	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Osteopenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pain in extremity	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	7	6.7	3.3	13.1
	Pain in jaw	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rotator cuff syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Spinal column stenosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tendon pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Anogenital warts	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Basal cell carcinoma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bowen's disease	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Renal cell carcinoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Squamous cell carcinoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Squamous cell carcinoma of skin	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tumour pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Nervous system disorders	-Total	< 65	176	62.6	70	39.8	32.8	47.1
		>= 65	105	37.4	51	48.6	39.2	58.0
	Ageusia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Aphasia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ataxia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Brain oedema	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cerebellar haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Disturbance in attention	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dizziness	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	12	11.4	6.7	18.9
	Dizziness postural	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dysarthria	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dysgeusia	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	22	21.0	14.3	29.7
	Dyskinesia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Headache	< 65	176	62.6	20	11.4	7.5	16.9
		>= 65	105	37.4	5	4.8	2.1	10.7
	Hyperaesthesia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypersomnia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Hypoaesthesia	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	7	6.7	3.3	13.1
	Hypotonia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lethargy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Memory impairment	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neuralgia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neuropathy peripheral	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	4	3.8	1.5	9.4
	Paraesthesia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	3	2.9	1.0	8.1
	Paralysis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Parosmia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Peripheral sensory neuropathy	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Post herpetic neuralgia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Presyncope	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Psychomotor skills impaired	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sciatica	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Seizure	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sensory disturbance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Slow speech	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Somnolence	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Syncope	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Tension headache	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tremor	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Visual field defect	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
Product issues	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Device dislocation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Psychiatric disorders	-Total	< 65	176	62.6	29	16.5	11.7	22.7
		>= 65	105	37.4	16	15.2	9.6	23.3
	Abnormal dreams	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Anxiety	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	2	1.9	0.5	6.7
	Bradyphrenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Confusional state	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Depression	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Fear of falling	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Insomnia	< 65	176	62.6	14	8.0	4.8	12.9
		>= 65	105	37.4	4	3.8	1.5	9.4
	Irritability	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Libido decreased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mood altered	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Psychomotor retardation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Restlessness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Sleep disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Renal and urinary disorders	-Total	< 65	176	62.6	13	7.4	4.4	12.2

		>= 65	105	37.4	17	16.2	10.4	24.4
	Acute kidney injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Azotaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cystitis haemorrhagic	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dysuria	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Haematuria	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Micturition urgency	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nocturia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pollakiuria	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Proteinuria	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Renal colic	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Renal disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Renal failure	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Renal impairment	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Urinary incontinence	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Urinary retention	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Urinary tract pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urine flow decreased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Reproductive system and breast disorders	-Total	< 65	176	62.6	11	6.3	3.5	10.8
		>= 65	105	37.4	5	4.8	2.1	10.7
	Benign prostatic hyperplasia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7

	Breast discharge	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Erectile dysfunction	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Galactorrhoea	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Genital ulceration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Metrorrhagia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pelvic discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pelvic fluid collection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Perineal pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Postmenopausal haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Uterine polyp	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vaginal haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vulvovaginal dryness	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Vulvovaginal erythema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Respiratory, thoracic and mediastinal disorders	-Total	< 65	176	62.6	76	43.2	36.1	50.6
		>= 65	105	37.4	40	38.1	29.4	47.6
	Aspiration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Choking	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cough	< 65	176	62.6	28	15.9	11.2	22.0
		>= 65	105	37.4	16	15.2	9.6	23.3
	Dry throat	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dysphonia	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	5	4.8	2.1	10.7

	Dyspnoea	< 65	176	62.6	14	8.0	4.8	12.9
		>= 65	105	37.4	8	7.6	3.9	14.3
	Dyspnoea exertional	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Epistaxis	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	5	4.8	2.1	10.7
	Haemoptysis	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hiccups	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Interstitial lung disease	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Laryngeal haemorrhage	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nasal congestion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Nasal dryness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Nasal polyps	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oropharyngeal discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oropharyngeal pain	< 65	176	62.6	11	6.3	3.5	10.8
		>= 65	105	37.4	5	4.8	2.1	10.7
	Paranasal sinus discomfort	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pharyngeal disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pleural thickening	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pleuritic pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pneumonitis	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pneumothorax	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Productive cough	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Pulmonary embolism	< 65	176	62.6	0	0.0	0.0	2.1

		>= 65	105	37.4	2	1.9	0.5	6.7
	Pulmonary mass	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pulmonary pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiration abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rhinitis allergic	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rhinorrhoea	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sinus congestion	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sleep apnoea syndrome	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Throat irritation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Upper-airway cough syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Wheezing	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
Skin and subcutaneous tissue disorders	-Total	< 65	176	62.6	62	35.2	28.6	42.5
		>= 65	105	37.4	26	24.8	17.5	33.8
	Acne	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Alopecia	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Chloasma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermal cyst	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermatitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermatitis acneiform	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermatitis bullous	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dry skin	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	4	3.8	1.5	9.4

	Ecchymosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eczema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Erythema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hair growth abnormal	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hair texture abnormal	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hirsutism	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperhidrosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperkeratosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypertrichosis	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	0	0.0	0.0	3.5
	Madarosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nail discolouration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nail disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Night sweats	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Onychalgia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Onycholysis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Onychomadesis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pain of skin	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Palmar-plantar erythrodysaesthesia syndrome	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Photosensitivity reaction	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Pruritus	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pruritus generalised	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Purpura	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rash	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	4	3.8	1.5	9.4
	Rash erythematous	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rash macular	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Rash maculo-papular	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rash papular	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Scab	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Scar pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Skin discolouration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Skin hyperpigmentation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Skin lesion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Swelling face	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urticaria	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Surgical and medical procedures	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Astringent therapy	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
Vascular disorders	-Total	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	12	11.4	6.7	18.9
	Circulatory collapse	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Embolism	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Flushing	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haematoma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hot flush	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hypertension	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	5	4.8	2.1	10.7
	Hypotension	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Phlebitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Raynaud's phenomenon	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR1_SG.xls
26MAR2021 14:11

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	84	29.9	16	19.0	12.1	28.7
		1	190	67.6	43	22.6	17.3	29.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	24	12.6	8.6	18.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Febrile neutropenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperfibrinogenaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Leukocytosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Leukopenia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymph node pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphadenopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphopenia	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutropenia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophilia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytopenia	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytosis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Cardiac disorders	-Total	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	20	10.5	6.9	15.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aortic valve calcification	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Atrial flutter	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bradycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bundle branch block right	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Extrasystoles	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Myocardial ischaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nodal arrhythmia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Palpitations	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pericardial effusion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinus bradycardia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinus tachycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tachycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ventricular extrasystoles	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ventricular pre-excitation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Congenital, familial and genetic disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hydrocele	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Ear and labyrinth disorders	-Total	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	9	4.7	2.5	8.8

		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear congestion	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear pain	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tinnitus	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Vertigo	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Endocrine disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperthyroidism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypothyroidism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Eye disorders	-Total	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	21	11.1	7.3	16.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal sensation in eye	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blepharitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Conjunctival haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diplopia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry eye	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eye swelling	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eyelid oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eyelid ptosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Periorbital oedema	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Photophobia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Photopsia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vision blurred	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Visual acuity reduced	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Gastrointestinal disorders	-Total	0	84	29.9	57	67.9	57.3	76.9
		1	190	67.6	111	58.4	51.3	65.2
		2	6	2.1	4	66.7	30.0	90.3

		Missing	1	0.4	1	100.0	20.7	100.0
	Abdominal discomfort	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal distension	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain lower	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain upper	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal symptom	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anal incontinence	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aphthous ulcer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ascites	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Constipation	0	84	29.9	35	41.7	31.7	52.3
		1	190	67.6	57	30.0	23.9	36.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Dental dysaesthesia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diarrhoea	0	84	29.9	19	22.6	15.0	32.6

		1	190	67.6	32	16.8	12.2	22.8
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry mouth	0	84	29.9	18	21.4	14.0	31.3
		1	190	67.6	24	12.6	8.6	18.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspepsia	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysphagia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Epigastric discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eructation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Faeces soft	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Flatulence	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Frequent bowel movements	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal inflammation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Gastrointestinal oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal wall thickening	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrooesophageal reflux disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gingival bleeding	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gingival swelling	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glossitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glossodynia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematochezia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhoids	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoaesthesia oral	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Impaired gastric emptying	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Melaena	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Mouth ulceration	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nausea	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	18	9.5	6.1	14.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	1	100.0	20.7	100.0
	Odynophagia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oesophageal irritation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oesophagitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral dysaesthesia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral mucosal erythema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paraesthesia oral	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Regurgitation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Sensitivity of teeth	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Stomatitis	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Swollen tongue	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tongue coated	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tongue discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tongue ulceration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tooth discolouration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Toothache	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vomiting	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
General disorders and administration site conditions	-Total	0	84	29.9	48	57.1	46.5	67.2
		1	190	67.6	106	55.8	48.7	62.7
		2	6	2.1	4	66.7	30.0	90.3
		Missing	1	0.4	1	100.0	20.7	100.0
	Asthenia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Axillary pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Catheter site pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest pain	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chills	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Face oedema	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fatigue	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	21	11.1	7.3	16.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Feeling abnormal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Feeling cold	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Feeling hot	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gait disturbance	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	General physical health deterioration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Generalised oedema	0	84	29.9	2	2.4	0.7	8.3

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Impaired healing	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Influenza like illness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Injection site bruising	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Localised oedema	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Malaise	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	17	8.9	5.7	13.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mucosal dryness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mucosal inflammation	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Non-cardiac chest pain	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oedema peripheral	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	22	11.6	7.8	16.9
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Peripheral swelling	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyrexia	0	84	29.9	19	22.6	15.0	32.6
		1	190	67.6	27	14.2	10.0	19.9
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Swelling	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Temperature intolerance	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Xerosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Hepatobiliary disorders	-Total	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cholecystitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic function abnormal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic steatosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatocellular injury	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperbilirubinaemia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Liver disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumobilia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Portal vein thrombosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Immune system disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Drug hypersensitivity	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Food allergy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypersensitivity	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Seasonal allergy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Infections and infestations	-Total	0	84	29.9	25	29.8	21.0	40.2
		1	190	67.6	37	19.5	14.5	25.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute sinusitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacterial disease carrier	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bronchitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Candida infection	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Chronic sinusitis	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Cystitis	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Ear infection	0	84	29.9	1	1.2		0.2	6.4
		1	190	67.6	0	0.0		0.0	2.0
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Epstein-Barr virus infection	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Escherichia bacteraemia	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Eye infection	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Folliculitis	0	84	29.9	1	1.2		0.2	6.4
		1	190	67.6	2	1.1		0.3	3.8
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Fungal infection	0	84	29.9	1	1.2		0.2	6.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Gastroenteritis	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Genital candidiasis	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Herpes simplex	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Herpes virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Herpes zoster	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Influenza	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lower respiratory tract infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymph node tuberculosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasal herpes	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasopharyngitis	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral candidiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Otitis externa	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Otitis media	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paronychia	0	84	29.9	3	3.6	1.2	10.0

		1	190	67.6	3	1.6		0.5	4.5
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Pharyngitis	0	84	29.9	1	1.2		0.2	6.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Pneumonia	0	84	29.9	3	3.6		1.2	10.0
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Pyelonephritis	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Respiratory tract infection	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Rhinitis	0	84	29.9	1	1.2		0.2	6.4
		1	190	67.6	0	0.0		0.0	2.0
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Sinusitis	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	4	2.1		0.8	5.3
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Skin infection	0	84	29.9	1	1.2		0.2	6.4
		1	190	67.6	0	0.0		0.0	2.0
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Tinea infection	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Tinea pedis	0	84	29.9	1	1.2		0.2	6.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Tooth infection	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Tracheitis	0	84	29.9	1	1.2		0.2	6.4
		1	190	67.6	0	0.0		0.0	2.0
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3

	Tuberculosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Upper respiratory tract infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary tract infection	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Viral infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Injury, poisoning and procedural complications	-Total	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Contusion	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epicondylitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fall	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Incision site pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint dislocation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Laceration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ligament sprain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Limb injury	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle strain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Procedural pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rib fracture	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Scar	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin abrasion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tendon rupture	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wound	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Investigations	-Total	0	84	29.9	48	57.1	46.5	67.2
		1	190	67.6	135	71.1	64.2	77.0
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	1	100.0	20.7	100.0

	Alanine aminotransferase increased	0	84	29.9	16	19.0	12.1	28.7
		1	190	67.6	53	27.9	22.0	34.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	1	100.0	20.7	100.0
	Albumin urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alpha hydroxybutyrate dehydrogenase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aspartate aminotransferase increased	0	84	29.9	23	27.4	19.0	37.7
		1	190	67.6	73	38.4	31.8	45.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	1	100.0	20.7	100.0
	Bacterial test	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bilirubin conjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood albumin decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase increased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	20	10.5	6.9	15.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin increased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin unconjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Blood calcium decreased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood calcium increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood chloride increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood cholesterol increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine increased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase MB increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatinine	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatinine increased	0	84	29.9	14	16.7	10.2	26.1
		1	190	67.6	37	19.5	14.5	25.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood fibrinogen increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood glucose increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood ketone body increased	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood lactate dehydrogenase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood magnesium decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood phosphorus increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood potassium increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood pressure increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood sodium decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood thyroid stimulating hormone increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood triglycerides increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood urea increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood uric acid decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood uric acid increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Blood urine	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	C-reactive protein increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Carbon dioxide decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Complement factor C1 decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Computerised tomogram thorax abnormal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Crystal urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystatin C increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrocardiogram QT prolonged	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrocardiogram ST-T change	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fibrin D dimer increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fibrin degradation products increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Free fatty acids increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gamma-glutamyltransferase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glomerular filtration rate decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glutamate dehydrogenase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematocrit decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemoglobin decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Heart rate increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic enzyme increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	International normalised ratio increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intraocular pressure increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Laboratory test abnormal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Lipase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Liver function test increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphocyte count decreased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mean cell volume increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myoglobin blood increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil count decreased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil count increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Occult blood positive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count decreased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Protein total decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Protein total increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Protein urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Prothrombin time prolonged	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Red blood cell count decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombin time prolonged	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Total bile acids increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Transaminases increased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Transferrin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Troponin T increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Troponin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary sediment present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urine ketone body present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urine leukocyte esterase positive	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urobilinogen urine increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Weight decreased	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Weight increased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	White blood cell count decreased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	White blood cells urine positive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Metabolism and nutrition disorders	-Total	0	84	29.9	29	34.5	25.2	45.2
		1	190	67.6	82	43.2	36.3	50.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alkalosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cell death	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Decreased appetite	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dehydration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fluid retention	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Hypercalcaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercholesterolaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperglycaemia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperkalaemia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperlipidaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypermagnesaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypernatraemia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperphosphataemia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	21	11.1	7.3	16.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertriglyceridaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperuricaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoalbuminaemia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypocalcaemia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	16	8.4	5.2	13.2

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypochloraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoglycaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypokalaemia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypomagnesaemia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	18	9.5	6.1	14.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyponatraemia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypophosphataemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoproteinaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Increased appetite	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vitamin D deficiency	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Musculoskeletal and connective tissue disorders	-Total	0	84	29.9	34	40.5	30.6	51.2
		1	190	67.6	57	30.0	23.9	36.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Arthralgia	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Arthropathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Back pain	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Bone pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Coccydynia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Costochondritis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Flank pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Groin pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercreatinaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intervertebral disc protrusion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint stiffness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint swelling	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle fatigue	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle spasms	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscular weakness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal chest pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal pain	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal stiffness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myalgia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neck pain	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Osteopenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain in extremity	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain in jaw	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rotator cuff syndrome	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Spinal column stenosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tendon pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anogenital warts	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Basal cell carcinoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bowen's disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal cell carcinoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Squamous cell carcinoma	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Squamous cell carcinoma of skin	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tumour pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Nervous system disorders	-Total	0	84	29.9	32	38.1	28.4	48.8
		1	190	67.6	86	45.3	38.3	52.4
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	1	100.0	20.7	100.0

	Ageusia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aphasia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ataxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Brain oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebellar haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disturbance in attention	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dizziness	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	21	11.1	7.3	16.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dizziness postural	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysarthria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysgeusia	0	84	29.9	12	14.3	8.4	23.3
		1	190	67.6	24	12.6	8.6	18.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyskinesia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Headache	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	18	9.5	6.1	14.5

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Hyperaesthesia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypersomnia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoaesthesia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypotonia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lethargy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Memory impairment	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Neuralgia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neuropathy peripheral	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paraesthesia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paralysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Parosmia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Peripheral sensory neuropathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Post herpetic neuralgia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Presyncope	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Psychomotor skills impaired	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sciatica	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Seizure	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sensory disturbance	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Slow speech	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Somnolence	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Syncope	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tension headache	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tremor	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Visual field defect	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Product issues	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Device dislocation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Psychiatric disorders	-Total	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	32	16.8	12.2	22.8
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal dreams	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anxiety	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bradyphrenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Confusional state	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Depression	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fear of falling	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Insomnia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	17	8.9	5.7	13.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Irritability	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Libido decreased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mood altered	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Psychomotor retardation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Restlessness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sleep disorder	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Renal and urinary disorders	-Total	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	17	8.9	5.7	13.9
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute kidney injury	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Azotaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis haemorrhagic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysuria	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Micturition urgency	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Nocturia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pollakiuria	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Proteinuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal colic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal disorder	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal failure	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal impairment	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary incontinence	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary retention	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary tract pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urine flow decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Reproductive system and breast disorders	-Total	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Benign prostatic hyperplasia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Breast discharge	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Erectile dysfunction	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Galactorrhoea	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Genital ulceration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Metrorrhagia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pelvic discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pelvic fluid collection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Perineal pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Postmenopausal haemorrhage	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Uterine polyp	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vaginal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vulvovaginal dryness	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vulvovaginal erythema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Respiratory, thoracic and mediastinal disorders	-Total	0	84	29.9	37	44.0	33.9	54.7
		1	190	67.6	76	40.0	33.3	47.1
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Aspiration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Choking	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cough	0	84	29.9	15	17.9	11.1	27.4
		1	190	67.6	27	14.2	10.0	19.9
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry throat	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysphonia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	16	8.4	5.2	13.2
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea exertional	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Epistaxis	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemoptysis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hiccups	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Interstitial lung disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Laryngeal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasal congestion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasal dryness	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasal polyps	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oropharyngeal discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oropharyngeal pain	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paranasal sinus discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pharyngeal disorder	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural thickening	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleuritic pain	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonitis	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumothorax	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Productive cough	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary embolism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary mass	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiration abnormal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinitis allergic	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinorrhoea	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Sinus congestion	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sleep apnoea syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Throat irritation	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Upper-airway cough syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wheezing	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Skin and subcutaneous tissue disorders	-Total	0	84	29.9	36	42.9	32.8	53.5
		1	190	67.6	50	26.3	20.6	33.0
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Acne	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alopecia	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chloasma	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermal cyst	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis acneiform	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5

		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Dermatitis bullous	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Dry skin	0	84	29.9	5	6.0		2.6	13.2
		1	190	67.6	6	3.2		1.5	6.7
		2	6	2.1	1	16.7		3.0	56.4
		Missing	1	0.4	0	0.0		0.0	79.3
	Ecchymosis	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Eczema	0	84	29.9	1	1.2		0.2	6.4
		1	190	67.6	0	0.0		0.0	2.0
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Erythema	0	84	29.9	1	1.2		0.2	6.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Hair growth abnormal	0	84	29.9	4	4.8		1.9	11.6
		1	190	67.6	2	1.1		0.3	3.8
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Hair texture abnormal	0	84	29.9	1	1.2		0.2	6.4
		1	190	67.6	0	0.0		0.0	2.0
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Hirsutism	0	84	29.9	4	4.8		1.9	11.6
		1	190	67.6	2	1.1		0.3	3.8
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Hyperhidrosis	0	84	29.9	0	0.0		0.0	4.4
		1	190	67.6	1	0.5		0.1	2.9
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Hyperkeratosis	0	84	29.9	1	1.2		0.2	6.4
		1	190	67.6	0	0.0		0.0	2.0
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3
	Hypertrichosis	0	84	29.9	1	1.2		0.2	6.4
		1	190	67.6	5	2.6		1.1	6.0
		2	6	2.1	0	0.0		0.0	39.0
		Missing	1	0.4	0	0.0		0.0	79.3

	Madarosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nail discolouration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nail disorder	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Night sweats	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Onychalgia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Onycholysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Onychomadesis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain of skin	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Palmar-plantar erythrodysaesthesia syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Photosensitivity reaction	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pruritus	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pruritus generalised	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Purpura	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash erythematous	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash macular	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash maculo-papular	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash papular	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Scab	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Scar pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin discolouration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin hyperpigmentation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin lesion	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Swelling face	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urticaria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Surgical and medical procedures	-Total	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Astringent therapy	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Vascular disorders	-Total	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	18	9.5	6.1	14.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Circulatory collapse	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Flushing	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hot flush	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertension	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypotension	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Phlebitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Raynaud's phenomenon	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR1_SG.xls
26MAR2021 14:11

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	21	22.1	14.9	31.4
		Asia (AS)	122	43.4	23	18.9	12.9	26.7
	Anaemia	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Cytopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Febrile neutropenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyperfibrinogenaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Leukocytosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Leukopenia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Lymph node pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lymphadenopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lymphopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neutropenia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Neutrophilia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pancytopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thrombocytopenia	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Thrombocytosis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Cardiac disorders	-Total	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Aortic valve calcification	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Atrial flutter	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Bradycardia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bundle branch block right	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Extrasystoles	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Myocardial ischaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nodal arrhythmia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Palpitations	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pericardial effusion	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinus bradycardia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Sinus tachycardia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Tachycardia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Ventricular extrasystoles	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Ventricular pre-excitation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Congenital, familial and genetic disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hydrocele	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Ear and labyrinth disorders	-Total	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Ear congestion	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ear discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ear pain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tinnitus	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Vertigo	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
Endocrine disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperthyroidism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypothyroidism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Eye disorders	-Total	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Abnormal sensation in eye	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blepharitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Conjunctival haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Diplopia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dry eye	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eye swelling	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eyelid oedema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Eyelid ptosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Periorbital oedema	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Photophobia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Photopsia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vision blurred	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Visual acuity reduced	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

Gastrointestinal disorders	-Total	USA	64	22.8	47	73.4	61.5	82.7
		Europe (EU)	95	33.8	63	66.3	56.3	75.0
		Asia (AS)	122	43.4	63	51.6	42.9	60.3
	Abdominal discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Abdominal distension	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Abdominal pain	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Abdominal pain lower	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Abdominal pain upper	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Abdominal symptom	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Anal incontinence	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Aphthous ulcer	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ascites	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Constipation	USA	64	22.8	22	34.4	23.9	46.6
		Europe (EU)	95	33.8	30	31.6	23.1	41.5
		Asia (AS)	122	43.4	41	33.6	25.8	42.4
	Dental dysaesthesia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Diarrhoea	USA	64	22.8	16	25.0	16.0	36.8
		Europe (EU)	95	33.8	23	24.2	16.7	33.7
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Dry mouth	USA	64	22.8	18	28.1	18.6	40.1
		Europe (EU)	95	33.8	17	17.9	11.5	26.8
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Dyspepsia	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dysphagia	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Epigastric discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eructation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Faeces soft	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Flatulence	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Frequent bowel movements	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastrointestinal haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastrointestinal inflammation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal wall thickening	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrooesophageal reflux disease	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gingival bleeding	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Gingival swelling	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Glossitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Glossodynia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haematochezia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haemorrhoids	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypoaesthesia oral	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Impaired gastric emptying	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Melaena	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Mouth ulceration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Nausea	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	10	10.5	5.8	18.3
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Odynophagia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oesophageal irritation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oesophagitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oral disorder	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oral dysaesthesia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oral mucosal erythema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oral pain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Paraesthesia oral	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Regurgitation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sensitivity of teeth	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Stomatitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Swollen tongue	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tongue coated	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tongue discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tongue ulceration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tooth discolouration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Toothache	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Vomiting	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
General disorders and administration site conditions	-Total	USA	64	22.8	40	62.5	50.3	73.3
		Europe (EU)	95	33.8	54	56.8	46.8	66.3
		Asia (AS)	122	43.4	65	53.3	44.5	61.9
	Asthenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	6	4.9	2.3	10.3

	Axillary pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Catheter site pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Chest discomfort	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Chest pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Chills	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Face oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Fatigue	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Feeling abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Feeling cold	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Feeling hot	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gait disturbance	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	General physical health deterioration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Generalised oedema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Impaired healing	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Influenza like illness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Injection site bruising	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Localised oedema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Malaise	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	16	13.1	8.2	20.2
	Mucosal dryness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Mucosal inflammation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	10	10.5	5.8	18.3
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Non-cardiac chest pain	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Oedema	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oedema peripheral	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Pain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Peripheral swelling	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pyrexia	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	19	20.0	13.2	29.1
		Asia (AS)	122	43.4	21	17.2	11.5	24.9
	Swelling	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Temperature intolerance	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Xerosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

Hepatobiliary disorders	-Total	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Cholecystitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hepatic function abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Hepatic steatosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hepatocellular injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperbilirubinaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Liver disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumobilia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Portal vein thrombosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Immune system disorders	-Total	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Drug hypersensitivity	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Food allergy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypersensitivity	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Seasonal allergy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Infections and infestations	-Total	USA	64	22.8	17	26.6	17.3	38.5
		Europe (EU)	95	33.8	27	28.4	20.3	38.2

		Asia (AS)	122	43.4	19	15.6	10.2	23.0
	Acute sinusitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacterial disease carrier	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bronchitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Candida infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Chronic sinusitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cystitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ear infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epstein-Barr virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Escherichia bacteraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eye infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Folliculitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fungal infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastroenteritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Genital candidiasis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Herpes simplex	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Herpes virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Herpes zoster	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Influenza	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lower respiratory tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lymph node tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasal herpes	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasopharyngitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oral candidiasis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Otitis externa	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Otitis media	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Paronychia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Pharyngitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4

		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Pyelonephritis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhinitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sinusitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Skin infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tinea infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tinea pedis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tooth infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tracheitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Upper respiratory tract infection	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Urinary tract infection	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Viral infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Injury, poisoning and procedural complications	-Total	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	4	3.3	1.3	8.1

	Contusion	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epicondylitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fall	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Incision site pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Joint dislocation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Laceration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ligament sprain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Limb injury	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle strain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Procedural pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rib fracture	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Scar	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin abrasion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tendon rupture	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Wound	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Investigations	-Total	USA	64	22.8	44	68.8	56.6	78.8
		Europe (EU)	95	33.8	54	56.8	46.8	66.3
		Asia (AS)	122	43.4	88	72.1	63.6	79.3
	Alanine aminotransferase increased	USA	64	22.8	16	25.0	16.0	36.8
		Europe (EU)	95	33.8	15	15.8	9.8	24.4
		Asia (AS)	122	43.4	40	32.8	25.1	41.5
	Albumin urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Alpha hydroxybutyrate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Aspartate aminotransferase increased	USA	64	22.8	24	37.5	26.7	49.7
		Europe (EU)	95	33.8	21	22.1	14.9	31.4
		Asia (AS)	122	43.4	53	43.4	35.0	52.3
	Bacterial test	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bilirubin conjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
	Blood albumin decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood alkaline phosphatase	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood alkaline phosphatase decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood alkaline phosphatase increased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Blood bilirubin increased	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	14	11.5	7.0	18.3

	Blood bilirubin unconjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Blood calcium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood calcium increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood chloride increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood cholesterol increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Blood creatine increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood creatine phosphokinase MB increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Blood creatine phosphokinase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Blood creatinine	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood creatinine increased	USA	64	22.8	12	18.8	11.1	30.0
		Europe (EU)	95	33.8	18	18.9	12.3	28.0
		Asia (AS)	122	43.4	21	17.2	11.5	24.9
	Blood fibrinogen increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood glucose increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood ketone body increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood lactate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Blood magnesium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood phosphorus increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Blood potassium increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood pressure increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood sodium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood thyroid stimulating hormone increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood triglycerides increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Blood urea increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Blood uric acid decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood uric acid increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Blood urine	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Blood urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	C-reactive protein increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Carbon dioxide decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Complement factor C1 decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Computerised tomogram thorax abnormal	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Crystal urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cystatin C increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Electrocardiogram QT prolonged	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Electrocardiogram ST-T change	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Fibrin D dimer increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Fibrin degradation products increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Free fatty acids increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gamma-glutamyltransferase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
	Glomerular filtration rate decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Glutamate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Haematocrit decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haemoglobin decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Heart rate increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Hepatic enzyme increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	International normalised ratio increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Intraocular pressure increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Laboratory test abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lipase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Liver function test increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymphocyte count decreased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Mean cell volume increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Myoglobin blood increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Neutrophil count decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
	Neutrophil count increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Occult blood positive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Platelet count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Platelet count increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Protein total decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

	Protein total increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Protein urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Prothrombin time prolonged	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Red blood cell count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Thrombin time prolonged	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Total bile acids increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Transaminases increased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Transferrin increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Troponin T increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Troponin increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary sediment present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urine ketone body present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Urine leukocyte esterase positive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urobilinogen urine increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Weight decreased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4

		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Weight increased	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	White blood cell count decreased	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	White blood cells urine positive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
Metabolism and nutrition disorders	-Total	USA	64	22.8	21	32.8	22.6	45.0
		Europe (EU)	95	33.8	35	36.8	27.8	46.9
		Asia (AS)	122	43.4	55	45.1	36.5	53.9
	Alkalosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cell death	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Decreased appetite	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	16	13.1	8.2	20.2
	Dehydration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fluid retention	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypercalcaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Hypercholesterolaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hyperglycaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Hyperkalaemia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hyperlipidaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3

	Hypermagnesaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hypernatraemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hyperphosphataemia	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
	Hypertriglyceridaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hyperuricaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Hypoalbuminaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Hypocalcaemia	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Hypochloraemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hypoglycaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypokalaemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Hypomagnesaemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Hyponatraemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	12	9.8	5.7	16.4
	Hypophosphataemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hypoproteinaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Increased appetite	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vitamin D deficiency	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Musculoskeletal and connective tissue disorders	-Total	USA	64	22.8	34	53.1	41.1	64.8
		Europe (EU)	95	33.8	27	28.4	20.3	38.2
		Asia (AS)	122	43.4	31	25.4	18.5	33.8
	Arthralgia	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Arthropathy	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Back pain	USA	64	22.8	10	15.6	8.7	26.4
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Bone pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Coccydynia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Costochondritis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Flank pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Groin pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypercreatinaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Intervertebral disc protrusion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Joint stiffness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Joint swelling	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Muscle fatigue	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Muscle spasms	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Muscular weakness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Musculoskeletal chest pain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Musculoskeletal pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Musculoskeletal stiffness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Myalgia	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Myopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neck pain	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Osteopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pain in extremity	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Pain in jaw	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rotator cuff syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Spinal column stenosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tendon pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Anogenital warts	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Basal cell carcinoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bowen's disease	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal cell carcinoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Squamous cell carcinoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Squamous cell carcinoma of skin	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tumour pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Nervous system disorders	-Total	USA	64	22.8	37	57.8	45.6	69.1
		Europe (EU)	95	33.8	40	42.1	32.7	52.2
		Asia (AS)	122	43.4	44	36.1	28.1	44.9
	Ageusia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aphasia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ataxia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Brain oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebellar haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Disturbance in attention	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dizziness	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Dizziness postural	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dysarthria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dysgeusia	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	19	20.0	13.2	29.1
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Dyskinesia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Headache	USA	64	22.8	12	18.8	11.1	30.0
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Hyperaesthesia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypersomnia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypoaesthesia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Hypotonia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lethargy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Memory impairment	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neuralgia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neuropathy peripheral	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Paraesthesia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Paralysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Parosmia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Peripheral sensory neuropathy	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Post herpetic neuralgia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Presyncope	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Psychomotor skills impaired	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sciatica	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Seizure	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sensory disturbance	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Slow speech	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Somnolence	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Syncope	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tension headache	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Tremor	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Visual field defect	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Product issues	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Device dislocation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Psychiatric disorders	-Total	USA	64	22.8	12	18.8	11.1	30.0
		Europe (EU)	95	33.8	13	13.7	8.2	22.0
		Asia (AS)	122	43.4	20	16.4	10.9	24.0
	Abnormal dreams	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Anxiety	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Bradyphrenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Confusional state	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Depression	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fear of falling	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Insomnia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Irritability	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Libido decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Mood altered	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Psychomotor retardation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Restlessness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Sleep disorder	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Renal and urinary disorders	-Total	USA	64	22.8	16	25.0	16.0	36.8
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Acute kidney injury	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Azotaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cystitis haemorrhagic	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dysuria	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Haematuria	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Micturition urgency	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nocturia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pollakiuria	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Proteinuria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Renal colic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Renal disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal failure	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal impairment	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urinary incontinence	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary retention	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urinary tract pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urine flow decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Reproductive system and breast disorders	-Total	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Benign prostatic hyperplasia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Breast discharge	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Erectile dysfunction	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Galactorrhoea	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Genital ulceration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Metrorrhagia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pelvic discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pelvic fluid collection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Perineal pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Postmenopausal haemorrhage	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Uterine polyp	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vaginal haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vulvovaginal dryness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vulvovaginal erythema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Respiratory, thoracic and mediastinal disorders	-Total	USA	64	22.8	31	48.4	36.6	60.4
		Europe (EU)	95	33.8	40	42.1	32.7	52.2
		Asia (AS)	122	43.4	45	36.9	28.8	45.7
	Aspiration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Choking	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cough	USA	64	22.8	12	18.8	11.1	30.0
		Europe (EU)	95	33.8	18	18.9	12.3	28.0
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Dry throat	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dysphonia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Dyspnoea	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	11	9.0	5.1	15.4

	Dyspnoea exertional	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Epistaxis	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Haemoptysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Hiccups	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Interstitial lung disease	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Laryngeal haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nasal congestion	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasal dryness	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasal polyps	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oropharyngeal discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oropharyngeal pain	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Paranasal sinus discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pharyngeal disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pleural thickening	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pleuritic pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Pneumothorax	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Productive cough	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Pulmonary embolism	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pulmonary mass	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pulmonary pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiration abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rhinitis allergic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rhinorrhoea	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinus congestion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sleep apnoea syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Throat irritation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Upper-airway cough syndrome	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Wheezing	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

Skin and subcutaneous tissue disorders	-Total	USA	64	22.8	31	48.4	36.6	60.4
		Europe (EU)	95	33.8	23	24.2	16.7	33.7
		Asia (AS)	122	43.4	34	27.9	20.7	36.4
	Acne	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Alopecia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Chloasma	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dermal cyst	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dermatitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dermatitis acneiform	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Dermatitis bullous	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dry skin	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Ecchymosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Eczema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Erythema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hair growth abnormal	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hair texture abnormal	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hirsutism	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperhidrosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperkeratosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypertrichosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Madarosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nail discolouration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nail disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Night sweats	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Onychalgia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Onycholysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Onychomadesis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Pain of skin	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Palmar-plantar erythrodysaesthesia syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Photosensitivity reaction	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pruritus	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

	Pruritus generalised	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Purpura	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rash	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Rash erythematous	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rash macular	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rash maculo-papular	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rash papular	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Scab	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Scar pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Skin discolouration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin hyperpigmentation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin lesion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Swelling face	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Urticaria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Surgical and medical procedures	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Astringent therapy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Vascular disorders	-Total	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Circulatory collapse	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Embolism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Flushing	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haematoma	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hot flush	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypertension	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hypotension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Phlebitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Raynaud's phenomenon	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR1_SG.xls
26MAR2021 14:11

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	116	41.3	24	20.7	14.3	28.9
		1	77	27.4	15	19.5	12.2	29.7
		>= 2	88	31.3	20	22.7	15.2	32.5
	Anaemia	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	9	10.2	5.5	18.3
	Cytopenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Febrile neutropenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperfibrinogenaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Leukocytosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Leukopenia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lymph node pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymphadenopathy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymphopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Neutropenia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Neutrophilia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	0	0.0	0.0	4.2
	Pancytopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Thrombocytopenia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	5	5.7	2.5	12.6
	Thrombocytosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
Cardiac disorders	-Total	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	11	12.5	7.1	21.0
	Aortic valve calcification	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Atrial flutter	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bradycardia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bundle branch block right	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Extrasystoles	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Myocardial ischaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nodal arrhythmia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Palpitations	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pericardial effusion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sinus bradycardia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9

	Sinus tachycardia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Tachycardia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Ventricular extrasystoles	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ventricular pre-excitation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Congenital, familial and genetic disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hydrocele	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Ear and labyrinth disorders	-Total	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	8	9.1	4.7	16.9
	Ear congestion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ear discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ear pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Tinnitus	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vertigo	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
Endocrine disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hyperthyroidism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypothyroidism	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	2	2.3	0.6	7.9
Eye disorders	-Total	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	12	13.6	8.0	22.3
	Abnormal sensation in eye	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blepharitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Conjunctival haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Diplopia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dry eye	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Eye swelling	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eyelid oedema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Eyelid ptosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Periorbital oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	0	0.0	0.0	4.2
	Photophobia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Photopsia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vision blurred	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	5	5.7	2.5	12.6
	Visual acuity reduced	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

Gastrointestinal disorders	-Total	0	116	41.3	70	60.3	51.2	68.8
		1	77	27.4	49	63.6	52.5	73.5
		>= 2	88	31.3	54	61.4	50.9	70.9
	Abdominal discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Abdominal distension	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Abdominal pain	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	2	2.3	0.6	7.9
	Abdominal pain lower	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Abdominal pain upper	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Abdominal symptom	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Anal incontinence	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Aphthous ulcer	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ascites	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Constipation	0	116	41.3	44	37.9	29.6	47.0
		1	77	27.4	25	32.5	23.1	43.5
		>= 2	88	31.3	24	27.3	19.1	37.4
	Dental dysaesthesia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Diarrhoea	0	116	41.3	21	18.1	12.2	26.1
		1	77	27.4	16	20.8	13.2	31.1
		>= 2	88	31.3	16	18.2	11.5	27.5
	Dry mouth	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	20	22.7	15.2	32.5
	Dyspepsia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0

		>= 2	88	31.3	3	3.4	1.2	9.5
	Dysphagia	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	7	8.0	3.9	15.5
	Epigastric discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Eructation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Faeces soft	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Flatulence	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Frequent bowel movements	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Gastrointestinal haemorrhage	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrointestinal inflammation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrointestinal oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastrointestinal wall thickening	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrooesophageal reflux disease	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Gingival bleeding	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Gingival swelling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Glossitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Glossodynia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haematochezia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemorrhoids	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypoaesthesia oral	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Impaired gastric emptying	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Melaena	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Mouth ulceration	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Nausea	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	7	8.0	3.9	15.5
	Odynophagia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oesophageal irritation	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oesophagitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oral disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Oral dysaesthesia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oral mucosal erythema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1	0.2	6.2
	Oral pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Paraesthesia oral	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Regurgitation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sensitivity of teeth	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Stomatitis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Swollen tongue	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tongue coated	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tongue discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tongue ulceration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tooth discolouration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Toothache	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vomiting	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	4	4.5	1.8	11.1
General disorders and administration site conditions	-Total	0	116	41.3	61	52.6	43.6	61.4
		1	77	27.4	42	54.5	43.5	65.2
		>= 2	88	31.3	56	63.6	53.2	72.9
	Asthenia	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	4	4.5	1.8	11.1

	Axillary pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Catheter site pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Chest discomfort	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Chest pain	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Chills	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Face oedema	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	6	6.8	3.2	14.1
	Fatigue	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	13	14.8	8.8	23.7
	Feeling abnormal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Feeling cold	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Feeling hot	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gait disturbance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	General physical health deterioration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Generalised oedema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Impaired healing	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Influenza like illness	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	0	0.0		0.0	4.2
	Injection site bruising	0	116	41.3	1	0.9		0.2	4.7
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	0	0.0		0.0	4.2
	Localised oedema	0	116	41.3	0	0.0		0.0	3.2
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	2	2.3		0.6	7.9
	Malaise	0	116	41.3	7	6.0		3.0	11.9
		1	77	27.4	4	5.2		2.0	12.6
		>= 2	88	31.3	6	6.8		3.2	14.1
	Mucosal dryness	0	116	41.3	0	0.0		0.0	3.2
		1	77	27.4	1	1.3		0.2	7.0
		>= 2	88	31.3	0	0.0		0.0	4.2
	Mucosal inflammation	0	116	41.3	7	6.0		3.0	11.9
		1	77	27.4	1	1.3		0.2	7.0
		>= 2	88	31.3	4	4.5		1.8	11.1
	Non-cardiac chest pain	0	116	41.3	5	4.3		1.9	9.7
		1	77	27.4	3	3.9		1.3	10.8
		>= 2	88	31.3	2	2.3		0.6	7.9
	Oedema	0	116	41.3	2	1.7		0.5	6.1
		1	77	27.4	2	2.6		0.7	9.0
		>= 2	88	31.3	0	0.0		0.0	4.2
	Oedema peripheral	0	116	41.3	8	6.9		3.5	13.0
		1	77	27.4	9	11.7		6.3	20.7
		>= 2	88	31.3	16	18.2		11.5	27.5
	Pain	0	116	41.3	1	0.9		0.2	4.7
		1	77	27.4	2	2.6		0.7	9.0
		>= 2	88	31.3	1	1.1		0.2	6.2
	Peripheral swelling	0	116	41.3	1	0.9		0.2	4.7
		1	77	27.4	3	3.9		1.3	10.8
		>= 2	88	31.3	2	2.3		0.6	7.9
	Pyrexia	0	116	41.3	14	12.1		7.3	19.2
		1	77	27.4	14	18.2		11.2	28.2
		>= 2	88	31.3	20	22.7		15.2	32.5
	Swelling	0	116	41.3	1	0.9		0.2	4.7
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	0	0.0		0.0	4.2
	Temperature intolerance	0	116	41.3	0	0.0		0.0	3.2
		1	77	27.4	1	1.3		0.2	7.0
		>= 2	88	31.3	2	2.3		0.6	7.9
	Xerosis	0	116	41.3	1	0.9		0.2	4.7
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	0	0.0		0.0	4.2

Hepatobiliary disorders	-Total	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Cholecystitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hepatic function abnormal	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hepatic steatosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hepatocellular injury	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hyperbilirubinaemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Liver disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumobilia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Portal vein thrombosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Immune system disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Drug hypersensitivity	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Food allergy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypersensitivity	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Seasonal allergy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Infections and infestations	-Total	0	116	41.3	22	19.0	12.9	27.0
		1	77	27.4	19	24.7	16.4	35.4

		>= 2	88	31.3	22	25.0	17.1	35.0
	Acute sinusitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bacterial disease carrier	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bronchitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	0	0.0	0.0	4.2
	Candida infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Chronic sinusitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cystitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ear infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Epstein-Barr virus infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Escherichia bacteraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eye infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Folliculitis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fungal infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastroenteritis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Genital candidiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Herpes simplex	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Herpes virus infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Herpes zoster	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Influenza	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lower respiratory tract infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymph node tuberculosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasal herpes	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasopharyngitis	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Oral candidiasis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Otitis externa	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Otitis media	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Paronychia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pharyngitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	1	1.1	0.2	6.2
	Pyelonephritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Respiratory tract infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sinusitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Skin infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tinea infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tinea pedis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Tooth infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tracheitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tuberculosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Upper respiratory tract infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Urinary tract infection	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Viral infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Injury, poisoning and procedural complications	-Total	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	8	9.1	4.7	16.9

	Contusion	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Epicondylitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Fall	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Incision site pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Joint dislocation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Laceration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ligament sprain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Limb injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Muscle strain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Procedural pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rib fracture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Scar	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Skin abrasion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Skin injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Tendon rupture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Wound	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Investigations	-Total	0	116	41.3	77	66.4	57.4	74.3
		1	77	27.4	52	67.5	56.5	76.9
		>= 2	88	31.3	57	64.8	54.4	73.9
	Alanine aminotransferase increased	0	116	41.3	32	27.6	20.3	36.3
		1	77	27.4	15	19.5	12.2	29.7
		>= 2	88	31.3	24	27.3	19.1	37.4
	Albumin urine present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Alpha hydroxybutyrate dehydrogenase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Aspartate aminotransferase increased	0	116	41.3	42	36.2	28.0	45.3
		1	77	27.4	28	36.4	26.5	47.5
		>= 2	88	31.3	28	31.8	23.0	42.1
	Bacterial test	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bilirubin conjugated increased	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood albumin decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood alkaline phosphatase	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood alkaline phosphatase decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood alkaline phosphatase increased	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	7	8.0	3.9	15.5
	Blood bilirubin increased	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	5	5.7	2.5	12.6

	Blood bilirubin unconjugated increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood calcium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood calcium increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood chloride increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood cholesterol increased	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Blood creatine increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood creatine phosphokinase MB increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood creatine phosphokinase increased	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	7	8.0	3.9	15.5
	Blood creatinine	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood creatinine increased	0	116	41.3	15	12.9	8.0	20.2
		1	77	27.4	16	20.8	13.2	31.1
		>= 2	88	31.3	20	22.7	15.2	32.5
	Blood fibrinogen increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood glucose increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Blood ketone body increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood lactate dehydrogenase increased	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood magnesium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood phosphorus increased	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood potassium increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood pressure increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood sodium decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood thyroid stimulating hormone increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood triglycerides increased	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood urea increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood uric acid decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood uric acid increased	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Blood urine	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood urine present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	C-reactive protein increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Carbon dioxide decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Complement factor C1 decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Computerised tomogram thorax abnormal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Crystal urine present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cystatin C increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Electrocardiogram QT prolonged	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	6	6.8	3.2	14.1
	Electrocardiogram ST-T change	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Fibrin D dimer increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Fibrin degradation products increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Free fatty acids increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gamma-glutamyltransferase increased	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	6	6.8	3.2	14.1
	Glomerular filtration rate decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Glutamate dehydrogenase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haematocrit decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemoglobin decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Heart rate increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hepatic enzyme increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	0	0.0	0.0	4.2
	International normalised ratio increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intraocular pressure increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Laboratory test abnormal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lipase increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Liver function test increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymphocyte count decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	1	1.1	0.2	6.2
	Mean cell volume increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Myoglobin blood increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neutrophil count decreased	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	6	6.8	3.2	14.1
	Neutrophil count increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Occult blood positive	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Platelet count decreased	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Platelet count increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Protein total decreased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Protein total increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Protein urine present	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Prothrombin time prolonged	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Red blood cell count decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Thrombin time prolonged	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Total bile acids increased	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Transaminases increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Transferrin increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Troponin T increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Troponin increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Urinary sediment present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urine ketone body present	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Urine leukocyte esterase positive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urobilinogen urine increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Weight decreased	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	3	3.9	1.3	10.8

		>= 2	88	31.3	6	6.8	3.2	14.1
	Weight increased	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	White blood cell count decreased	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	White blood cells urine positive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
Metabolism and nutrition disorders	-Total	0	116	41.3	47	40.5	32.0	49.6
		1	77	27.4	28	36.4	26.5	47.5
		>= 2	88	31.3	36	40.9	31.2	51.4
	Alkalosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cell death	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Decreased appetite	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	6	6.8	3.2	14.1
	Dehydration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fluid retention	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypercalcaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hypercholesterolaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperglycaemia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	7	8.0	3.9	15.5
	Hyperkalaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hyperlipidaemia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Hypermagnesaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypernatraemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperphosphataemia	0	116	41.3	14	12.1	7.3	19.2
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	8	9.1	4.7	16.9
	Hypertriglyceridaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hyperuricaemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hypoalbuminaemia	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	8	9.1	4.7	16.9
	Hypocalcaemia	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	8	9.1	4.7	16.9
	Hypochloraemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypoglycaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypokalaemia	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	7	8.0	3.9	15.5
	Hypomagnesaemia	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	10	11.4	6.3	19.7
	Hyponatraemia	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	5	5.7	2.5	12.6
	Hypophosphataemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hypoproteinaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Increased appetite	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1	0.2	6.2
	Vitamin D deficiency	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Musculoskeletal and connective tissue disorders	-Total	0	116	41.3	38	32.8	24.9	41.7
		1	77	27.4	26	33.8	24.2	44.9
		>= 2	88	31.3	28	31.8	23.0	42.1
	Arthralgia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Arthropathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Back pain	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	9	10.2	5.5	18.3
	Bone pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Coccydynia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Costochondritis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Flank pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Groin pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypercreatinaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intervertebral disc protrusion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Joint stiffness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Joint swelling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Muscle fatigue	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Muscle spasms	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	9	10.2	5.5	18.3
	Muscular weakness	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Musculoskeletal chest pain	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Musculoskeletal pain	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	5	5.7	2.5	12.6
	Musculoskeletal stiffness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Myalgia	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	3	3.4	1.2	9.5
	Myopathy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neck pain	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Osteopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pain in extremity	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	8	9.1	4.7	16.9
	Pain in jaw	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rotator cuff syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Spinal column stenosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tendon pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Anogenital warts	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Basal cell carcinoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bowen's disease	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal cell carcinoma	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Squamous cell carcinoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Squamous cell carcinoma of skin	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tumour pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Nervous system disorders	-Total	0	116	41.3	46	39.7	31.2	48.8
		1	77	27.4	36	46.8	36.0	57.8
		>= 2	88	31.3	39	44.3	34.4	54.7
	Ageusia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Aphasia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ataxia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Brain oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Cerebellar haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Disturbance in attention	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dizziness	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	7	8.0	3.9	15.5
	Dizziness postural	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dysarthria	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dysgeusia	0	116	41.3	16	13.8	8.7	21.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	8	9.1	4.7	16.9
	Dyskinesia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Headache	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	7	8.0	3.9	15.5
	Hyperaesthesia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypersomnia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypoaesthesia	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	6	6.8	3.2	14.1
	Hypotonia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lethargy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Memory impairment	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Neuralgia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neuropathy peripheral	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	5	6.5	2.8	14.3

		>= 2	88	31.3	3	3.4	1.2	9.5
	Paraesthesia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	2	2.3	0.6	7.9
	Paralysis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Parosmia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Peripheral sensory neuropathy	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Post herpetic neuralgia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Presyncope	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Psychomotor skills impaired	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sciatica	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Seizure	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sensory disturbance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Slow speech	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Somnolence	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Syncope	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tension headache	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Tremor	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Visual field defect	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Product issues	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Device dislocation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Psychiatric disorders	-Total	0	116	41.3	16	13.8	8.7	21.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	16	18.2	11.5	27.5
	Abnormal dreams	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Anxiety	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	2	2.3	0.6	7.9
	Bradyphrenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Confusional state	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Depression	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fear of falling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Insomnia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	7	8.0	3.9	15.5
	Irritability	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Libido decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Mood altered	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1	0.2	6.2
	Psychomotor retardation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Restlessness	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sleep disorder	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Renal and urinary disorders	-Total	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	9	10.2	5.5	18.3
	Acute kidney injury	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Azotaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cystitis haemorrhagic	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dysuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Haematuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Micturition urgency	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Nocturia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pollakiuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Proteinuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal colic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Renal disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal failure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal impairment	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urinary incontinence	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urinary retention	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Urinary tract pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urine flow decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Reproductive system and breast disorders	-Total	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	6	6.8	3.2	14.1
	Benign prostatic hyperplasia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Breast discharge	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Erectile dysfunction	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Galactorrhoea	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Genital ulceration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Metrorrhagia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pelvic discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	0	0.0	0.0	4.2
	Pelvic fluid collection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Perineal pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Postmenopausal haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Uterine polyp	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vaginal haemorrhage	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vulvovaginal dryness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vulvovaginal erythema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Respiratory, thoracic and mediastinal disorders	-Total	0	116	41.3	43	37.1	28.8	46.1
		1	77	27.4	32	41.6	31.2	52.7
		>= 2	88	31.3	41	46.6	36.5	56.9
	Aspiration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Choking	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cough	0	116	41.3	14	12.1	7.3	19.2
		1	77	27.4	15	19.5	12.2	29.7
		>= 2	88	31.3	15	17.0	10.6	26.2
	Dry throat	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dysphonia	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Dyspnoea	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	10	11.4	6.3	19.7

	Dyspnoea exertional	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	1	1.1	0.2	6.2
	Epistaxis	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	3	3.4	1.2	9.5
	Haemoptysis	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hiccups	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Interstitial lung disease	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Laryngeal haemorrhage	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasal congestion	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Nasal dryness	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasal polyps	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oropharyngeal discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oropharyngeal pain	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Paranasal sinus discomfort	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pharyngeal disorder	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pleural thickening	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pleuritic pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Pneumothorax	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Productive cough	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Pulmonary embolism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pulmonary mass	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pulmonary pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiration abnormal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinitis allergic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinorrhoea	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sinus congestion	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sleep apnoea syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Throat irritation	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Upper-airway cough syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Wheezing	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

Skin and subcutaneous tissue disorders	-Total	0	116	41.3	28	24.1	17.3	32.7
		1	77	27.4	30	39.0	28.8	50.1
		>= 2	88	31.3	30	34.1	25.0	44.5
	Acne	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Alopecia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	4	4.5	1.8	11.1
	Chloasma	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dermal cyst	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dermatitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dermatitis acneiform	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Dermatitis bullous	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dry skin	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Ecchymosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eczema	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Erythema	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hair growth abnormal	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Hair texture abnormal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hirsutism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8

		>= 2	88	31.3	2	2.3	0.6	7.9
	Hyperhidrosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperkeratosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypertrichosis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	0	0.0	0.0	4.2
	Madarosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Nail discolouration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nail disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Night sweats	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Onychalgia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Onycholysis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Onychomadesis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pain of skin	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Palmar-plantar erythrodysaesthesia syndrome	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Photosensitivity reaction	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pruritus	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2

	Pruritus generalised	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Purpura	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rash	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	9	10.2	5.5	18.3
	Rash erythematous	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Rash macular	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Rash maculo-papular	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rash papular	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Scab	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Scar pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Skin discolouration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Skin hyperpigmentation	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Skin lesion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Swelling face	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urticaria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Surgical and medical procedures	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0

		>= 2	88	31.3	0	0.0		0.0	4.2
	Astringent therapy	0	116	41.3	2	1.7		0.5	6.1
		1	77	27.4	2	2.6		0.7	9.0
		>= 2	88	31.3	0	0.0		0.0	4.2
Vascular disorders	-Total	0	116	41.3	7	6.0		3.0	11.9
		1	77	27.4	4	5.2		2.0	12.6
		>= 2	88	31.3	11	12.5		7.1	21.0
	Circulatory collapse	0	116	41.3	0	0.0		0.0	3.2
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	1	1.1		0.2	6.2
	Embolism	0	116	41.3	0	0.0		0.0	3.2
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	1	1.1		0.2	6.2
	Flushing	0	116	41.3	0	0.0		0.0	3.2
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	1	1.1		0.2	6.2
	Haematoma	0	116	41.3	2	1.7		0.5	6.1
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	0	0.0		0.0	4.2
	Hot flush	0	116	41.3	0	0.0		0.0	3.2
		1	77	27.4	3	3.9		1.3	10.8
		>= 2	88	31.3	0	0.0		0.0	4.2
	Hypertension	0	116	41.3	3	2.6		0.9	7.3
		1	77	27.4	1	1.3		0.2	7.0
		>= 2	88	31.3	6	6.8		3.2	14.1
	Hypotension	0	116	41.3	2	1.7		0.5	6.1
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	2	2.3		0.6	7.9
	Phlebitis	0	116	41.3	1	0.9		0.2	4.7
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	0	0.0		0.0	4.2
	Raynaud's phenomenon	0	116	41.3	0	0.0		0.0	3.2
		1	77	27.4	0	0.0		0.0	4.8
		>= 2	88	31.3	1	1.1		0.2	6.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR1_SG.xls
26MAR2021 14:11

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Asian	128	45.6	23	18.0	12.3	25.5
		Non-Asian	135	48.0	33	24.4	18.0	32.3
		Unknown	18	6.4	3	16.7	5.8	39.2
	Anaemia	Asian	128	45.6	15	11.7	7.2	18.4
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	3	16.7	5.8	39.2
	Cytopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Febrile neutropenia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperfibrinogenaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Leukocytosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Leukopenia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymph node pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphadenopathy	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutropenia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutrophilia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancytopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytopenia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
Cardiac disorders	-Total	Asian	128	45.6	15	11.7	7.2	18.4
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Aortic valve calcification	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Atrial flutter	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bradycardia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bundle branch block right	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Extrasystoles	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Myocardial ischaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nodal arrhythmia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Palpitations	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pericardial effusion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinus bradycardia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8

	Sinus tachycardia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tachycardia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ventricular extrasystoles	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ventricular pre-excitation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Congenital, familial and genetic disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hydrocele	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Ear and labyrinth disorders	-Total	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	Ear congestion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ear discomfort	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ear pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinnitus	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vertigo	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	2	11.1	3.1	32.8
Endocrine disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyperthyroidism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypothyroidism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2

		Unknown	18	6.4	0	0.0	0.0	17.6
Eye disorders	-Total	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	20	14.8	9.8	21.8
		Unknown	18	6.4	3	16.7	5.8	39.2
	Abnormal sensation in eye	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blepharitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Conjunctival haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diplopia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dry eye	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Eye swelling	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eyelid oedema	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eyelid ptosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Periorbital oedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Photophobia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Photopsia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vision blurred	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Visual acuity reduced	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8

Gastrointestinal disorders	-Total	Asian	128	45.6	68	53.1	44.5	61.6
		Non-Asian	135	48.0	92	68.1	59.9	75.4
		Unknown	18	6.4	13	72.2	49.1	87.5
	Abdominal discomfort	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal distension	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Abdominal pain lower	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal pain upper	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal symptom	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anal incontinence	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aphthous ulcer	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ascites	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Constipation	Asian	128	45.6	43	33.6	26.0	42.1
		Non-Asian	135	48.0	44	32.6	25.3	40.9
		Unknown	18	6.4	6	33.3	16.3	56.3
	Dental dysaesthesia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diarrhoea	Asian	128	45.6	15	11.7	7.2	18.4
		Non-Asian	135	48.0	34	25.2	18.6	33.1
		Unknown	18	6.4	4	22.2	9.0	45.2
	Dry mouth	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	30	22.2	16.0	29.9
		Unknown	18	6.4	4	22.2	9.0	45.2
	Dyspepsia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2

		Unknown	18	6.4	3	16.7	5.8	39.2
	Dysphagia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	12	8.9	5.2	14.9
		Unknown	18	6.4	1	5.6	1.0	25.8
	Epigastric discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eructation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Faeces soft	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Flatulence	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Frequent bowel movements	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal haemorrhage	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal inflammation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal oedema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal wall thickening	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrooesophageal reflux disease	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Gingival bleeding	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gingival swelling	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Glossitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Glossodynia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematochezia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhoids	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoaesthesia oral	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Impaired gastric emptying	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Melaena	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mouth ulceration	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nausea	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	16	11.9	7.4	18.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Odynophagia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oesophageal irritation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oesophagitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral dysaesthesia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral mucosal erythema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Paraesthesia oral	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Regurgitation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sensitivity of teeth	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Stomatitis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Swollen tongue	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tongue coated	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tongue discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tongue ulceration	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tooth discolouration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Toothache	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vomiting	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	1	5.6	1.0	25.8
General disorders and administration site conditions	-Total	Asian	128	45.6	69	53.9	45.3	62.3
		Non-Asian	135	48.0	81	60.0	51.6	67.9
		Unknown	18	6.4	9	50.0	29.0	71.0
	Asthenia	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	2	11.1	3.1	32.8

	Axillary pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Catheter site pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chest discomfort	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chest pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chills	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Face oedema	Asian	128	45.6	14	10.9	6.6	17.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fatigue	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	20	14.8	9.8	21.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Feeling abnormal	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Feeling cold	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Feeling hot	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gait disturbance	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	General physical health deterioration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Generalised oedema	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Impaired healing	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Influenza like illness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Injection site bruising	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Localised oedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Malaise	Asian	128	45.6	17	13.3	8.5	20.2
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mucosal dryness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mucosal inflammation	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Non-cardiac chest pain	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Oedema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oedema peripheral	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	19	14.1	9.2	20.9
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Peripheral swelling	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pyrexia	Asian	128	45.6	22	17.2	11.6	24.7
		Non-Asian	135	48.0	23	17.0	11.6	24.3
		Unknown	18	6.4	3	16.7	5.8	39.2
	Swelling	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Temperature intolerance	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Xerosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

Hepatobiliary disorders	-Total	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	3	16.7	5.8	39.2
	Cholecystitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatic function abnormal	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatic steatosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatocellular injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	3	16.7	5.8	39.2
	Hyperbilirubinaemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Liver disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumobilia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Portal vein thrombosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Immune system disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Drug hypersensitivity	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Food allergy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypersensitivity	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Seasonal allergy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Infections and infestations	-Total	Asian	128	45.6	22	17.2	11.6	24.7
		Non-Asian	135	48.0	38	28.1	21.2	36.3

		Unknown	18	6.4	3	16.7	5.8	39.2
	Acute sinusitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bacterial disease carrier	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bronchitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Candida infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chronic sinusitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ear infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Epstein-Barr virus infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Escherichia bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eye infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Folliculitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fungal infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastroenteritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Genital candidiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Herpes simplex	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Herpes virus infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Herpes zoster	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Influenza	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lower respiratory tract infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymph node tuberculosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal herpes	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasopharyngitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral candidiasis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Otitis externa	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Otitis media	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Paronychia	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pharyngitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2

		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyelonephritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory tract infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinusitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Skin infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinea infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinea pedis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tooth infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tracheitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tuberculosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Upper respiratory tract infection	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary tract infection	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Viral infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Injury, poisoning and procedural complications	-Total	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	12	8.9	5.2	14.9
		Unknown	18	6.4	0	0.0	0.0	17.6

	Contusion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epicondylitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fall	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Incision site pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint dislocation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Laceration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ligament sprain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Limb injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle strain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Procedural pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rib fracture	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Scar	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin abrasion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Tendon rupture	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wound	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Investigations	-Total	Asian	128	45.6	91	71.1	62.7	78.2
		Non-Asian	135	48.0	85	63.0	54.6	70.6
		Unknown	18	6.4	10	55.6	33.7	75.4
	Alanine aminotransferase increased	Asian	128	45.6	40	31.3	23.9	39.7
		Non-Asian	135	48.0	29	21.5	15.4	29.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Albumin urine present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alpha hydroxybutyrate dehydrogenase increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aspartate aminotransferase increased	Asian	128	45.6	55	43.0	34.7	51.6
		Non-Asian	135	48.0	40	29.6	22.6	37.8
		Unknown	18	6.4	3	16.7	5.8	39.2
	Bacterial test	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bilirubin conjugated increased	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood albumin decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood alkaline phosphatase	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood alkaline phosphatase decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood alkaline phosphatase increased	Asian	128	45.6	15	11.7	7.2	18.4
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood bilirubin increased	Asian	128	45.6	14	10.9	6.6	17.5
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8

	Blood bilirubin unconjugated increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood calcium decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood calcium increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood chloride increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood cholesterol increased	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine phosphokinase MB increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine phosphokinase increased	Asian	128	45.6	14	10.9	6.6	17.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Blood creatinine	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatinine increased	Asian	128	45.6	21	16.4	11.0	23.8
		Non-Asian	135	48.0	28	20.7	14.8	28.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Blood fibrinogen increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood glucose increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood ketone body increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood lactate dehydrogenase increased	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood magnesium decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood phosphorus increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood potassium increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood pressure increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood sodium decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood thyroid stimulating hormone increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood triglycerides increased	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood urea increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood uric acid decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood uric acid increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood urine	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood urine present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	C-reactive protein increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Carbon dioxide decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Complement factor C1 decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Computerised tomogram thorax abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Crystal urine present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystatin C increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrocardiogram QT prolonged	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrocardiogram ST-T change	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fibrin D dimer increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fibrin degradation products increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Free fatty acids increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gamma-glutamyltransferase increased	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Glomerular filtration rate decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Glutamate dehydrogenase increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematocrit decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemoglobin decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Heart rate increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatic enzyme increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2

		Unknown	18	6.4	0	0.0	0.0	17.6
	International normalised ratio increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intraocular pressure increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Laboratory test abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Lipase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Liver function test increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphocyte count decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mean cell volume increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Myoglobin blood increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutrophil count decreased	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutrophil count increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Occult blood positive	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Platelet count decreased	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Platelet count increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Protein total decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Protein total increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Protein urine present	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Prothrombin time prolonged	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Red blood cell count decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombin time prolonged	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Total bile acids increased	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Transaminases increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Transferrin increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Troponin T increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Troponin increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary sediment present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urine ketone body present	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urine leukocyte esterase positive	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urobilinogen urine increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Weight decreased	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	5	3.7	1.6	8.4

		Unknown	18	6.4	0	0.0	0.0	17.6
	Weight increased	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	White blood cell count decreased	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	White blood cells urine positive	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Metabolism and nutrition disorders	-Total	Asian	128	45.6	58	45.3	37.0	53.9
		Non-Asian	135	48.0	48	35.6	28.0	43.9
		Unknown	18	6.4	5	27.8	12.5	50.9
	Alkalosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cell death	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Decreased appetite	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dehydration	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fluid retention	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercalcaemia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercholesterolaemia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperglycaemia	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperkalaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyperlipidaemia	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Hypermagnesaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypernatraemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperphosphataemia	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	15	11.1	6.9	17.5
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypertriglyceridaemia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperuricaemia	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoalbuminaemia	Asian	128	45.6	15	11.7	7.2	18.4
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypocalcaemia	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypochloraemia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoglycaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypokalaemia	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	13	9.6	5.7	15.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypomagnesaemia	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyponatraemia	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypophosphataemia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypoproteinaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Increased appetite	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Vitamin D deficiency	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Musculoskeletal and connective tissue disorders	-Total	Asian	128	45.6	34	26.6	19.7	34.8
		Non-Asian	135	48.0	51	37.8	30.0	46.2
		Unknown	18	6.4	7	38.9	20.3	61.4
	Arthralgia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Arthropathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Back pain	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	12	8.9	5.2	14.9
		Unknown	18	6.4	2	11.1	3.1	32.8
	Bone pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Coccydynia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Costochondritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Flank pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Groin pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercreatinaemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intervertebral disc protrusion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint stiffness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint swelling	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8

	Muscle fatigue	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle spasms	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	12	8.9	5.2	14.9
		Unknown	18	6.4	3	16.7	5.8	39.2
	Muscular weakness	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Musculoskeletal chest pain	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Musculoskeletal pain	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Musculoskeletal stiffness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Myalgia	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	12	8.9	5.2	14.9
		Unknown	18	6.4	2	11.1	3.1	32.8
	Myopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neck pain	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Osteopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain in extremity	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	12	8.9	5.2	14.9
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain in jaw	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Rotator cuff syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Spinal column stenosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tendon pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	1	5.6	1.0	25.8
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anogenital warts	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Basal cell carcinoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bowen's disease	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal cell carcinoma	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Squamous cell carcinoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Squamous cell carcinoma of skin	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tumour pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Nervous system disorders	-Total	Asian	128	45.6	48	37.5	29.6	46.1
		Non-Asian	135	48.0	65	48.1	39.9	56.5
		Unknown	18	6.4	8	44.4	24.6	66.3
	Ageusia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aphasia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ataxia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Brain oedema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebellar haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Disturbance in attention	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dizziness	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	2	11.1	3.1	32.8
	Dizziness postural	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysarthria	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysgeusia	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	26	19.3	13.5	26.7
		Unknown	18	6.4	3	16.7	5.8	39.2
	Dyskinesia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Headache	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	Hyperaesthesia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Hypersomnia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoaesthesia	Asian	128	45.6	15	11.7	7.2	18.4
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypotonia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lethargy	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Memory impairment	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neuralgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neuropathy peripheral	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	8	5.9	3.0	11.3

		Unknown	18	6.4	1	5.6	1.0	25.8
	Paraesthesia	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	Paralysis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Parosmia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Peripheral sensory neuropathy	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Post herpetic neuralgia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Presyncope	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Psychomotor skills impaired	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sciatica	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Seizure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sensory disturbance	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Slow speech	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Somnolence	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Syncope	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tension headache	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Tremor	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Visual field defect	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Product issues	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Device dislocation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Psychiatric disorders	-Total	Asian	128	45.6	23	18.0	12.3	25.5
		Non-Asian	135	48.0	19	14.1	9.2	20.9
		Unknown	18	6.4	3	16.7	5.8	39.2
	Abnormal dreams	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Anxiety	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bradyphrenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Confusional state	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Depression	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Fear of falling	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Insomnia	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Irritability	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Libido decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mood altered	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0		0.0	17.6
	Psychomotor retardation	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	2	1.5		0.4	5.2
		Unknown	18	6.4	0	0.0		0.0	17.6
	Restlessness	Asian	128	45.6	2	1.6		0.4	5.5
		Non-Asian	135	48.0	3	2.2		0.8	6.3
		Unknown	18	6.4	0	0.0		0.0	17.6
	Sleep disorder	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
Renal and urinary disorders	-Total	Asian	128	45.6	8	6.3		3.2	11.8
		Non-Asian	135	48.0	22	16.3		11.0	23.4
		Unknown	18	6.4	0	0.0		0.0	17.6
	Acute kidney injury	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	3	2.2		0.8	6.3
		Unknown	18	6.4	0	0.0		0.0	17.6
	Azotaemia	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6
	Cystitis haemorrhagic	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Dysuria	Asian	128	45.6	2	1.6		0.4	5.5
		Non-Asian	135	48.0	4	3.0		1.2	7.4
		Unknown	18	6.4	0	0.0		0.0	17.6
	Haematuria	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Micturition urgency	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Nocturia	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	2	1.5		0.4	5.2
		Unknown	18	6.4	0	0.0		0.0	17.6
	Pollakiuria	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	2	1.5		0.4	5.2
		Unknown	18	6.4	0	0.0		0.0	17.6
	Proteinuria	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6
	Renal colic	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6

	Renal disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal impairment	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary incontinence	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary retention	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary tract pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urine flow decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Reproductive system and breast disorders	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	0	0.0	0.0	17.6
	Benign prostatic hyperplasia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Breast discharge	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Erectile dysfunction	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Galactorrhoea	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Genital ulceration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Metrorrhagia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pelvic discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Pelvic fluid collection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Perineal pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Postmenopausal haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Uterine polyp	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vaginal haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vulvovaginal dryness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vulvovaginal erythema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Respiratory, thoracic and mediastinal disorders	-Total	Asian	128	45.6	47	36.7	28.9	45.3
		Non-Asian	135	48.0	61	45.2	37.0	53.6
		Unknown	18	6.4	8	44.4	24.6	66.3
	Aspiration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Choking	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cough	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	24	17.8	12.2	25.1
		Unknown	18	6.4	4	22.2	9.0	45.2
	Dry throat	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysphonia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dyspnoea	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	1	5.6	1.0	25.8

	Dyspnoea exertional	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epistaxis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Haemoptysis	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hiccups	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Interstitial lung disease	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Laryngeal haemorrhage	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal congestion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal dryness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal polyps	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oropharyngeal discomfort	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oropharyngeal pain	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Paranasal sinus discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pharyngeal disorder	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleural thickening	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleuritic pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2

		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonitis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumothorax	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Productive cough	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary embolism	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary mass	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiration abnormal	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinitis allergic	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinorrhoea	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinus congestion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sleep apnoea syndrome	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Throat irritation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Upper-airway cough syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Wheezing	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

Skin and subcutaneous tissue disorders	-Total	Asian	128	45.6	37	28.9	21.8	37.3
		Non-Asian	135	48.0	44	32.6	25.3	40.9
		Unknown	18	6.4	7	38.9	20.3	61.4
	Acne	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alopecia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chloasma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermal cyst	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermatitis acneiform	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dermatitis bullous	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dry skin	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Ecchymosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eczema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Erythema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hair growth abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hair texture abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hirsutism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	5	3.7	1.6	8.4

		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyperhidrosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperkeratosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypertrichosis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Madarosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nail discolouration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nail disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Night sweats	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Onychalgia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Onycholysis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Onychomadesis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain of skin	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Palmar-plantar erythrodysaesthesia syndrome	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Photosensitivity reaction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pruritus	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Pruritus generalised	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Purpura	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rash	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Rash erythematous	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rash macular	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Rash maculo-papular	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rash papular	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Scab	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Scar pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin discolouration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin hyperpigmentation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin lesion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Swelling face	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Urticaria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Surgical and medical procedures	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4

		Unknown	18	6.4	0	0.0	0.0	17.6
	Astringent therapy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
Vascular disorders	-Total	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	12	8.9	5.2	14.9
		Unknown	18	6.4	3	16.7	5.8	39.2
	Circulatory collapse	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Embolism	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Flushing	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hot flush	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypertension	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypotension	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Phlebitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Raynaud's phenomenon	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR1_SG.xls
26MAR2021 14:11

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Female	152	54.1	40	26.3	20.0	33.8
		Male	129	45.9	19	14.7	9.6	21.9
	Anaemia	Female	152	54.1	17	11.2	7.1	17.2
		Male	129	45.9	11	8.5	4.8	14.6
	Cytopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Febrile neutropenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hyperfibrinogenaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Leukocytosis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Leukopenia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	5	3.9	1.7	8.8
	Lymph node pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lymphadenopathy	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Lymphopenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neutropenia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Neutrophilia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pancytopenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Thrombocytopenia	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	3	2.3	0.8	6.6
	Thrombocytosis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	0	0.0	0.0	2.9
Cardiac disorders	-Total	Female	152	54.1	13	8.6	5.1	14.1

		Male	129	45.9	12	9.3	5.4	15.6
	Aortic valve calcification	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Atrial flutter	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Bradycardia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Bundle branch block right	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Extrasystoles	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Myocardial ischaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Nodal arrhythmia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Palpitations	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Pericardial effusion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Sinus bradycardia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Sinus tachycardia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Tachycardia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ventricular extrasystoles	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Ventricular pre-excitation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Congenital, familial and genetic disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hydrocele	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Ear and labyrinth disorders	-Total	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	9	7.0	3.7	12.7
	Ear congestion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Ear discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Ear pain	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Tinnitus	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Vertigo	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	3	2.3	0.8	6.6
Endocrine disorders	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperthyroidism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypothyroidism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Eye disorders	-Total	Female	152	54.1	25	16.4	11.4	23.2
		Male	129	45.9	7	5.4	2.7	10.8
	Abnormal sensation in eye	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blepharitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Conjunctival haemorrhage	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Diplopia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dry eye	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Eye swelling	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Eyelid oedema	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	0	0.0	0.0	2.9
	Eyelid ptosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Periorbital oedema	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Photophobia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Photopsia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vision blurred	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	1	0.8	0.1	4.3

	Visual acuity reduced	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Gastrointestinal disorders	-Total	Female	152	54.1	101	66.4	58.6	73.5
		Male	129	45.9	72	55.8	47.2	64.1
	Abdominal discomfort	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Abdominal distension	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Abdominal pain	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	3	2.3	0.8	6.6
	Abdominal pain lower	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Abdominal pain upper	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	7	5.4	2.7	10.8
	Abdominal symptom	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Anal incontinence	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Aphthous ulcer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ascites	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Constipation	Female	152	54.1	58	38.2	30.8	46.1
		Male	129	45.9	35	27.1	20.2	35.4
	Dental dysaesthesia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Diarrhoea	Female	152	54.1	33	21.7	15.9	28.9
		Male	129	45.9	20	15.5	10.3	22.7
	Dry mouth	Female	152	54.1	25	16.4	11.4	23.2
		Male	129	45.9	18	14.0	9.0	21.0
	Dyspepsia	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Dysphagia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	4	3.1	1.2	7.7
	Epigastric discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Eructation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Faeces soft	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
	Flatulence	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Frequent bowel movements	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastritis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrointestinal haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrointestinal inflammation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrointestinal oedema	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gastrointestinal wall thickening	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrooesophageal reflux disease	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Gingival bleeding	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Gingival swelling	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Glossitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Glossodynia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haematochezia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haemorrhoids	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hypoaesthesia oral	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Impaired gastric emptying	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Melaena	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Mouth ulceration	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Nausea	Female	152	54.1	22	14.5	9.8	20.9
		Male	129	45.9	5	3.9	1.7	8.8

	Odynophagia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	0	0.0	0.0	2.9
	Oesophageal irritation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oesophagitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Oral disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Oral dysaesthesia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oral mucosal erythema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Oral pain	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Paraesthesia oral	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Regurgitation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Sensitivity of teeth	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Stomatitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Swollen tongue	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tongue coated	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tongue discomfort	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tongue ulceration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tooth discolouration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Toothache	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Vomiting	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	6	4.7	2.1	9.8
General disorders and administration site conditions	-Total	Female	152	54.1	98	64.5	56.6	71.6
		Male	129	45.9	61	47.3	38.9	55.9

	Asthenia	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	4	3.1	1.2	7.7
	Axillary pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Catheter site pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Chest discomfort	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	2	1.6	0.4	5.5
	Chest pain	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Chills	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Face oedema	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	4	3.1	1.2	7.7
	Fatigue	Female	152	54.1	17	11.2	7.1	17.2
		Male	129	45.9	16	12.4	7.8	19.2
	Feeling abnormal	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Feeling cold	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Feeling hot	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gait disturbance	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	General physical health deterioration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Generalised oedema	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Impaired healing	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Influenza like illness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Injection site bruising	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Localised oedema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Malaise	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	8	6.2	3.2	11.8
	Mucosal dryness	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Mucosal inflammation	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	2	1.6	0.4	5.5
	Non-cardiac chest pain	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	4	3.1	1.2	7.7
	Oedema	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Oedema peripheral	Female	152	54.1	18	11.8	7.6	17.9
		Male	129	45.9	15	11.6	7.2	18.3
	Pain	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Peripheral swelling	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pyrexia	Female	152	54.1	32	21.1	15.3	28.2
		Male	129	45.9	16	12.4	7.8	19.2
	Swelling	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Temperature intolerance	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Xerosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Hepatobiliary disorders	-Total	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	11	8.5	4.8	14.6
	Cholecystitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Hepatic function abnormal	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hepatic steatosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hepatocellular injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Hyperbilirubinaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Liver disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumobilia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Portal vein thrombosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

Immune system disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Drug hypersensitivity	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Food allergy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypersensitivity	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Seasonal allergy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Infections and infestations	-Total	Female	152	54.1	40	26.3	20.0	33.8
		Male	129	45.9	23	17.8	12.2	25.3
	Acute sinusitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bacterial disease carrier	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Bronchitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	4	3.1	1.2	7.7
	Candida infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Chronic sinusitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cystitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ear infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Epstein-Barr virus infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Escherichia bacteraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Eye infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Folliculitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Fungal infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Gastroenteritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Genital candidiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Herpes simplex	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Herpes virus infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Herpes zoster	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Influenza	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Lower respiratory tract infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lymph node tuberculosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nasal herpes	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nasopharyngitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	Oral candidiasis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Otitis externa	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Otitis media	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Paronychia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Pharyngitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Pyelonephritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Respiratory tract infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rhinitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Sinusitis	Female	152	54.1	3	2.0	0.7	5.6

		Male	129	45.9	1	0.8	0.1	4.3
	Skin infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tinea infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tinea pedis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Tooth infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tracheitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tuberculosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Upper respiratory tract infection	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Urinary tract infection	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	1	0.8	0.1	4.3
	Viral infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Injury, poisoning and procedural complications	-Total	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	10	7.8	4.3	13.7
	Contusion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	4	3.1	1.2	7.7
	Epicondylitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Fall	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Incision site pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Joint dislocation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Laceration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ligament sprain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Limb injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5

	Muscle strain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Procedural pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Rib fracture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Scar	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin abrasion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tendon rupture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Wound	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Investigations	-Total	Female	152	54.1	105	69.1	61.3	75.9
		Male	129	45.9	81	62.8	54.2	70.6
	Alanine aminotransferase increased	Female	152	54.1	44	28.9	22.3	36.6
		Male	129	45.9	27	20.9	14.8	28.7
	Albumin urine present	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Alpha hydroxybutyrate dehydrogenase increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Aspartate aminotransferase increased	Female	152	54.1	56	36.8	29.6	44.7
		Male	129	45.9	42	32.6	25.1	41.0
	Bacterial test	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bilirubin conjugated increased	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	3	2.3	0.8	6.6
	Blood albumin decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood alkaline phosphatase	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood alkaline phosphatase decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood alkaline phosphatase increased	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	7	5.4	2.7	10.8

	Blood bilirubin increased	Female	152	54.1	15	9.9	6.1	15.6
		Male	129	45.9	4	3.1	1.2	7.7
	Blood bilirubin unconjugated increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Blood calcium decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Blood calcium increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood chloride increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood cholesterol increased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	Blood creatine increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Blood creatine phosphokinase MB increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Blood creatine phosphokinase increased	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	3	2.3	0.8	6.6
	Blood creatinine	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood creatinine increased	Female	152	54.1	24	15.8	10.8	22.4
		Male	129	45.9	27	20.9	14.8	28.7
	Blood fibrinogen increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood glucose increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Blood ketone body increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood lactate dehydrogenase increased	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	2	1.6	0.4	5.5
	Blood magnesium decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood phosphorus increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Blood potassium increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood pressure increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood sodium decreased	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Blood thyroid stimulating hormone increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood triglycerides increased	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Blood urea increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Blood uric acid decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood uric acid increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Blood urine	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Blood urine present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	C-reactive protein increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Carbon dioxide decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Complement factor C1 decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Computerised tomogram thorax abnormal	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Crystal urine present	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cystatin C increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Electrocardiogram QT prolonged	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	2	1.6	0.4	5.5
	Electrocardiogram ST-T change	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Fibrin D dimer increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Fibrin degradation products increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Free fatty acids increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gamma-glutamyltransferase increased	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	2	1.6	0.4	5.5

	Glomerular filtration rate decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Glutamate dehydrogenase increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Haematocrit decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haemoglobin decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Heart rate increased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hepatic enzyme increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	International normalised ratio increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Intraocular pressure increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Laboratory test abnormal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lipase increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Liver function test increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lymphocyte count decreased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Mean cell volume increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Myoglobin blood increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Neutrophil count decreased	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	8	6.2	3.2	11.8
	Neutrophil count increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Occult blood positive	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Platelet count decreased	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	4	3.1	1.2	7.7
	Platelet count increased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3

	Protein total decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Protein total increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Protein urine present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Prothrombin time prolonged	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Red blood cell count decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombin time prolonged	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Total bile acids increased	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Transaminases increased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	Transferrin increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Troponin T increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Troponin increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urinary sediment present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urine ketone body present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Urine leukocyte esterase positive	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urobilinogen urine increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Weight decreased	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	3	2.3	0.8	6.6
	Weight increased	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	5	3.9	1.7	8.8
	White blood cell count decreased	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	10	7.8	4.3	13.7
	White blood cells urine positive	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
Metabolism and nutrition disorders	-Total	Female	152	54.1	67	44.1	36.4	52.0

		Male	129	45.9	44	34.1	26.5	42.6
	Alkalosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cell death	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Decreased appetite	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	10	7.8	4.3	13.7
	Dehydration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Fluid retention	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypercalcaemia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hypercholesterolaemia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Hyperglycaemia	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	6	4.7	2.1	9.8
	Hyperkalaemia	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Hyperlipidaemia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Hypermagnesaemia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hypernatraemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Hyperphosphataemia	Female	152	54.1	20	13.2	8.7	19.5
		Male	129	45.9	8	6.2	3.2	11.8
	Hypertriglyceridaemia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperuricaemia	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	4	3.1	1.2	7.7
	Hypoalbuminaemia	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	3	2.3	0.8	6.6
	Hypocalcaemia	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	6	4.7	2.1	9.8
	Hypochloraemia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hypoglycaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Hypokalaemia	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	7	5.4	2.7	10.8
	Hypomagnesaemia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	8	6.2	3.2	11.8
	Hyponatraemia	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	7	5.4	2.7	10.8
	Hypophosphataemia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	5	3.9	1.7	8.8
	Hypoproteinaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Increased appetite	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Vitamin D deficiency	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Musculoskeletal and connective tissue disorders	-Total	Female	152	54.1	54	35.5	28.4	43.4
		Male	129	45.9	38	29.5	22.3	37.8
	Arthralgia	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	4	3.1	1.2	7.7
	Arthropathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Back pain	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	9	7.0	3.7	12.7
	Bone pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Coccydynia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Costochondritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Flank pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Groin pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypercreatinaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Intervertebral disc protrusion	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Joint stiffness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Joint swelling	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Muscle fatigue	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Muscle spasms	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	7	5.4	2.7	10.8
	Muscular weakness	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	1	0.8	0.1	4.3
	Musculoskeletal chest pain	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Musculoskeletal pain	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	5	3.9	1.7	8.8
	Musculoskeletal stiffness	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Myalgia	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	7	5.4	2.7	10.8
	Myopathy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Neck pain	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	3	2.3	0.8	6.6
	Osteopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pain in extremity	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	4	3.1	1.2	7.7
	Pain in jaw	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Rotator cuff syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Spinal column stenosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tendon pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	Anogenital warts	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Basal cell carcinoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Bowen's disease	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Renal cell carcinoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Squamous cell carcinoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Squamous cell carcinoma of skin	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tumour pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Nervous system disorders	-Total	Female	152	54.1	64	42.1	34.5	50.1
		Male	129	45.9	57	44.2	35.9	52.8
	Ageusia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Aphasia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Ataxia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Brain oedema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cerebellar haemorrhage	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Disturbance in attention	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Dizziness	Female	152	54.1	15	9.9	6.1	15.6
		Male	129	45.9	13	10.1	6.0	16.5
	Dizziness postural	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dysarthria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dysgeusia	Female	152	54.1	21	13.8	9.2	20.2
		Male	129	45.9	16	12.4	7.8	19.2
	Dyskinesia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Headache	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	13	10.1	6.0	16.5
	Hyperaesthesia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypersomnia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Hypoaesthesia	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	6	4.7	2.1	9.8
	Hypotonia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lethargy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Memory impairment	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neuralgia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neuropathy peripheral	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	5	3.9	1.7	8.8
	Paraesthesia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	5	3.9	1.7	8.8
	Paralysis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Parosmia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Peripheral sensory neuropathy	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	3	2.3	0.8	6.6
	Post herpetic neuralgia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Presyncope	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Psychomotor skills impaired	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sciatica	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Seizure	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sensory disturbance	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Slow speech	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Somnolence	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Syncope	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Tension headache	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tremor	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Visual field defect	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
Product issues	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Device dislocation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Psychiatric disorders	-Total	Female	152	54.1	24	15.8	10.8	22.4
		Male	129	45.9	21	16.3	10.9	23.6
	Abnormal dreams	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Anxiety	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	2	1.6	0.4	5.5
	Bradyphrenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Confusional state	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	4	3.1	1.2	7.7
	Depression	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Fear of falling	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Insomnia	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	7	5.4	2.7	10.8
	Irritability	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Libido decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Mood altered	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Psychomotor retardation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Restlessness	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Sleep disorder	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Renal and urinary disorders	-Total	Female	152	54.1	13	8.6	5.1	14.1

		Male	129	45.9	17	13.2	8.4	20.1
	Acute kidney injury	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Azotaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cystitis haemorrhagic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dysuria	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Haematuria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Micturition urgency	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Nocturia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Pollakiuria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Proteinuria	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Renal colic	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Renal disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Renal failure	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Renal impairment	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urinary incontinence	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Urinary retention	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Urinary tract pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urine flow decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Reproductive system and breast disorders	-Total	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	8	6.2	3.2	11.8
	Benign prostatic hyperplasia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5

	Breast discharge	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Erectile dysfunction	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	5	3.9	1.7	8.8
	Galactorrhoea	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Genital ulceration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Metrorrhagia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pelvic discomfort	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pelvic fluid collection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Perineal pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Postmenopausal haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Uterine polyp	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vaginal haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vulvovaginal dryness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vulvovaginal erythema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Respiratory, thoracic and mediastinal disorders	-Total	Female	152	54.1	65	42.8	35.2	50.7
		Male	129	45.9	51	39.5	31.5	48.2
	Aspiration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Choking	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cough	Female	152	54.1	21	13.8	9.2	20.2
		Male	129	45.9	23	17.8	12.2	25.3
	Dry throat	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Dysphonia	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	5	3.9	1.7	8.8

	Dyspnoea	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	10	7.8	4.3	13.7
	Dyspnoea exertional	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Epistaxis	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	4	3.1	1.2	7.7
	Haemoptysis	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	4	3.1	1.2	7.7
	Hiccups	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Interstitial lung disease	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Laryngeal haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nasal congestion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Nasal dryness	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Nasal polyps	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oropharyngeal discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oropharyngeal pain	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	5	3.9	1.7	8.8
	Paranasal sinus discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pharyngeal disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pleural thickening	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pleuritic pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonitis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Pneumothorax	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Productive cough	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	5	3.9	1.7	8.8
	Pulmonary embolism	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	1	0.8	0.1	4.3
	Pulmonary mass	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pulmonary pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Respiration abnormal	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rhinitis allergic	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Rhinorrhoea	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Sinus congestion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sleep apnoea syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Throat irritation	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Upper-airway cough syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Wheezing	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
Skin and subcutaneous tissue disorders	-Total	Female	152	54.1	55	36.2	29.0	44.1
		Male	129	45.9	33	25.6	18.8	33.7
	Acne	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Alopecia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	2	1.6	0.4	5.5
	Chloasma	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dermal cyst	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dermatitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dermatitis acneiform	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Dermatitis bullous	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dry skin	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	6	4.7	2.1	9.8

	Ecchymosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Eczema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Erythema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hair growth abnormal	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hair texture abnormal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hirsutism	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Hyperhidrosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperkeratosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypertrichosis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Madarosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nail discolouration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nail disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Night sweats	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Onychalgia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Onycholysis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Onychomadesis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Pain of skin	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Palmar-plantar erythrodysaesthesia syndrome	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	0	0.0	0.0	2.9
	Photosensitivity reaction	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Pruritus	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Pruritus generalised	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Purpura	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rash	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	7	5.4	2.7	10.8
	Rash erythematous	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Rash macular	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Rash maculo-papular	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Rash papular	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Scab	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Scar pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin discolouration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin hyperpigmentation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Skin lesion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Swelling face	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urticaria	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Surgical and medical procedures	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Astringent therapy	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
Vascular disorders	-Total	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	10	7.8	4.3	13.7
	Circulatory collapse	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Embolism	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
	Flushing	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Haematoma	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hot flush	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hypertension	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	7	5.4	2.7	10.8
	Hypotension	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	0	0.0	0.0	2.9
	Phlebitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Raynaud's phenomenon	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR1_SG.xls
26MAR2021 14:11

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	n/a	281	100.0	59	21.0	16.6	26.1
	Anaemia	n/a	281	100.0	28	10.0	7.0	14.0
	Cytopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Febrile neutropenia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperfibrinogenaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Leukocytosis	n/a	281	100.0	3	1.1	0.4	3.1
	Leukopenia	n/a	281	100.0	8	2.8	1.4	5.5
	Lymph node pain	n/a	281	100.0	1	0.4	0.1	2.0
	Lymphadenopathy	n/a	281	100.0	2	0.7	0.2	2.6
	Lymphopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Neutropenia	n/a	281	100.0	7	2.5	1.2	5.1
	Neutrophilia	n/a	281	100.0	1	0.4	0.1	2.0
	Pancytopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombocytopenia	n/a	281	100.0	12	4.3	2.5	7.3
	Thrombocytosis	n/a	281	100.0	4	1.4	0.6	3.6
Cardiac disorders	-Total	n/a	281	100.0	25	8.9	6.1	12.8
	Aortic valve calcification	n/a	281	100.0	1	0.4	0.1	2.0
	Atrial flutter	n/a	281	100.0	2	0.7	0.2	2.6
	Bradycardia	n/a	281	100.0	1	0.4	0.1	2.0
	Bundle branch block right	n/a	281	100.0	1	0.4	0.1	2.0
	Extrasystoles	n/a	281	100.0	1	0.4	0.1	2.0
	Myocardial ischaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Nodal arrhythmia	n/a	281	100.0	2	0.7	0.2	2.6

	Palpitations	n/a	281	100.0	4	1.4	0.6	3.6
	Pericardial effusion	n/a	281	100.0	2	0.7	0.2	2.6
	Sinus bradycardia	n/a	281	100.0	4	1.4	0.6	3.6
	Sinus tachycardia	n/a	281	100.0	2	0.7	0.2	2.6
	Tachycardia	n/a	281	100.0	4	1.4	0.6	3.6
	Ventricular extrasystoles	n/a	281	100.0	1	0.4	0.1	2.0
	Ventricular pre-excitation	n/a	281	100.0	1	0.4	0.1	2.0
Congenital, familial and genetic disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Hydrocele	n/a	281	100.0	1	0.4	0.1	2.0
Ear and labyrinth disorders	-Total	n/a	281	100.0	17	6.0	3.8	9.5
	Ear congestion	n/a	281	100.0	2	0.7	0.2	2.6
	Ear discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Ear pain	n/a	281	100.0	3	1.1	0.4	3.1
	Tinnitus	n/a	281	100.0	3	1.1	0.4	3.1
	Vertigo	n/a	281	100.0	9	3.2	1.7	6.0
Endocrine disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Hyperthyroidism	n/a	281	100.0	1	0.4	0.1	2.0
	Hypothyroidism	n/a	281	100.0	2	0.7	0.2	2.6
Eye disorders	-Total	n/a	281	100.0	32	11.4	8.2	15.6
	Abnormal sensation in eye	n/a	281	100.0	1	0.4	0.1	2.0
	Blepharitis	n/a	281	100.0	1	0.4	0.1	2.0
	Conjunctival haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Diplopia	n/a	281	100.0	1	0.4	0.1	2.0
	Dry eye	n/a	281	100.0	7	2.5	1.2	5.1
	Eye swelling	n/a	281	100.0	2	0.7	0.2	2.6
	Eyelid oedema	n/a	281	100.0	5	1.8	0.8	4.1
	Eyelid ptosis	n/a	281	100.0	1	0.4	0.1	2.0
	Periorbital oedema	n/a	281	100.0	5	1.8	0.8	4.1
	Photophobia	n/a	281	100.0	1	0.4	0.1	2.0

	Photopsia	n/a	281	100.0	1	0.4	0.1	2.0
	Vision blurred	n/a	281	100.0	12	4.3	2.5	7.3
	Visual acuity reduced	n/a	281	100.0	1	0.4	0.1	2.0
Gastrointestinal disorders	-Total	n/a	281	100.0	173	61.6	55.8	67.1
	Abdominal discomfort	n/a	281	100.0	4	1.4	0.6	3.6
	Abdominal distension	n/a	281	100.0	7	2.5	1.2	5.1
	Abdominal pain	n/a	281	100.0	10	3.6	1.9	6.4
	Abdominal pain lower	n/a	281	100.0	2	0.7	0.2	2.6
	Abdominal pain upper	n/a	281	100.0	9	3.2	1.7	6.0
	Abdominal symptom	n/a	281	100.0	1	0.4	0.1	2.0
	Anal incontinence	n/a	281	100.0	2	0.7	0.2	2.6
	Aphthous ulcer	n/a	281	100.0	1	0.4	0.1	2.0
	Ascites	n/a	281	100.0	2	0.7	0.2	2.6
	Constipation	n/a	281	100.0	93	33.1	27.9	38.8
	Dental dysaesthesia	n/a	281	100.0	1	0.4	0.1	2.0
	Diarrhoea	n/a	281	100.0	53	18.9	14.7	23.8
	Dry mouth	n/a	281	100.0	43	15.3	11.6	20.0
	Dyspepsia	n/a	281	100.0	7	2.5	1.2	5.1
	Dysphagia	n/a	281	100.0	16	5.7	3.5	9.0
	Epigastric discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Eructation	n/a	281	100.0	1	0.4	0.1	2.0
	Faeces soft	n/a	281	100.0	1	0.4	0.1	2.0
	Flatulence	n/a	281	100.0	2	0.7	0.2	2.6
	Frequent bowel movements	n/a	281	100.0	1	0.4	0.1	2.0
	Gastritis	n/a	281	100.0	2	0.7	0.2	2.6
	Gastrointestinal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal inflammation	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal oedema	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal wall thickening	n/a	281	100.0	1	0.4	0.1	2.0

	Gastrooesophageal reflux disease	n/a	281	100.0	4	1.4	0.6	3.6
	Gingival bleeding	n/a	281	100.0	3	1.1	0.4	3.1
	Gingival swelling	n/a	281	100.0	1	0.4	0.1	2.0
	Glossitis	n/a	281	100.0	1	0.4	0.1	2.0
	Glossodynia	n/a	281	100.0	1	0.4	0.1	2.0
	Haematochezia	n/a	281	100.0	1	0.4	0.1	2.0
	Haemorrhoids	n/a	281	100.0	3	1.1	0.4	3.1
	Hypoaesthesia oral	n/a	281	100.0	5	1.8	0.8	4.1
	Impaired gastric emptying	n/a	281	100.0	1	0.4	0.1	2.0
	Melaena	n/a	281	100.0	1	0.4	0.1	2.0
	Mouth ulceration	n/a	281	100.0	8	2.8	1.4	5.5
	Nausea	n/a	281	100.0	27	9.6	6.7	13.6
	Odynophagia	n/a	281	100.0	4	1.4	0.6	3.6
	Oesophageal irritation	n/a	281	100.0	1	0.4	0.1	2.0
	Oesophagitis	n/a	281	100.0	2	0.7	0.2	2.6
	Oral disorder	n/a	281	100.0	2	0.7	0.2	2.6
	Oral dysaesthesia	n/a	281	100.0	1	0.4	0.1	2.0
	Oral mucosal erythema	n/a	281	100.0	1	0.4	0.1	2.0
	Oral pain	n/a	281	100.0	5	1.8	0.8	4.1
	Paraesthesia oral	n/a	281	100.0	1	0.4	0.1	2.0
	Regurgitation	n/a	281	100.0	1	0.4	0.1	2.0
	Sensitivity of teeth	n/a	281	100.0	1	0.4	0.1	2.0
	Stomatitis	n/a	281	100.0	4	1.4	0.6	3.6
	Swollen tongue	n/a	281	100.0	1	0.4	0.1	2.0
	Tongue coated	n/a	281	100.0	1	0.4	0.1	2.0
	Tongue discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Tongue ulceration	n/a	281	100.0	1	0.4	0.1	2.0
	Tooth discolouration	n/a	281	100.0	1	0.4	0.1	2.0
	Toothache	n/a	281	100.0	5	1.8	0.8	4.1

	Vomiting	n/a	281	100.0	18	6.4	4.1	9.9
General disorders and administration site conditions	-Total	n/a	281	100.0	160	56.9	51.1	62.6
	Asthenia	n/a	281	100.0	18	6.4	4.1	9.9
	Axillary pain	n/a	281	100.0	1	0.4	0.1	2.0
	Catheter site pain	n/a	281	100.0	1	0.4	0.1	2.0
	Chest discomfort	n/a	281	100.0	9	3.2	1.7	6.0
	Chest pain	n/a	281	100.0	6	2.1	1.0	4.6
	Chills	n/a	281	100.0	4	1.4	0.6	3.6
	Disease progression	n/a	281	100.0	1	0.4	0.1	2.0
	Face oedema	n/a	281	100.0	14	5.0	3.0	8.2
	Fatigue	n/a	281	100.0	33	11.7	8.5	16.0
	Feeling abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Feeling cold	n/a	281	100.0	1	0.4	0.1	2.0
	Feeling hot	n/a	281	100.0	1	0.4	0.1	2.0
	Gait disturbance	n/a	281	100.0	4	1.4	0.6	3.6
	General physical health deterioration	n/a	281	100.0	1	0.4	0.1	2.0
	Generalised oedema	n/a	281	100.0	3	1.1	0.4	3.1
	Impaired healing	n/a	281	100.0	4	1.4	0.6	3.6
	Influenza like illness	n/a	281	100.0	1	0.4	0.1	2.0
	Injection site bruising	n/a	281	100.0	1	0.4	0.1	2.0
	Localised oedema	n/a	281	100.0	2	0.7	0.2	2.6
	Malaise	n/a	281	100.0	17	6.0	3.8	9.5
	Mucosal dryness	n/a	281	100.0	1	0.4	0.1	2.0
	Mucosal inflammation	n/a	281	100.0	12	4.3	2.5	7.3
	Non-cardiac chest pain	n/a	281	100.0	10	3.6	1.9	6.4
	Oedema	n/a	281	100.0	4	1.4	0.6	3.6
	Oedema peripheral	n/a	281	100.0	33	11.7	8.5	16.0
	Pain	n/a	281	100.0	4	1.4	0.6	3.6
	Peripheral swelling	n/a	281	100.0	6	2.1	1.0	4.6

	Pyrexia	n/a	281	100.0	48	17.1	13.1	21.9
	Swelling	n/a	281	100.0	1	0.4	0.1	2.0
	Temperature intolerance	n/a	281	100.0	3	1.1	0.4	3.1
	Xerosis	n/a	281	100.0	1	0.4	0.1	2.0
Hepatobiliary disorders	-Total	n/a	281	100.0	15	5.3	3.3	8.6
	Cholecystitis	n/a	281	100.0	2	0.7	0.2	2.6
	Hepatic function abnormal	n/a	281	100.0	3	1.1	0.4	3.1
	Hepatic steatosis	n/a	281	100.0	1	0.4	0.1	2.0
	Hepatocellular injury	n/a	281	100.0	3	1.1	0.4	3.1
	Hyperbilirubinaemia	n/a	281	100.0	3	1.1	0.4	3.1
	Liver disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumobilia	n/a	281	100.0	1	0.4	0.1	2.0
	Portal vein thrombosis	n/a	281	100.0	1	0.4	0.1	2.0
Immune system disorders	-Total	n/a	281	100.0	4	1.4	0.6	3.6
	Drug hypersensitivity	n/a	281	100.0	1	0.4	0.1	2.0
	Food allergy	n/a	281	100.0	1	0.4	0.1	2.0
	Hypersensitivity	n/a	281	100.0	1	0.4	0.1	2.0
	Seasonal allergy	n/a	281	100.0	1	0.4	0.1	2.0
Infections and infestations	-Total	n/a	281	100.0	63	22.4	17.9	27.6
	Acute sinusitis	n/a	281	100.0	1	0.4	0.1	2.0
	Bacterial disease carrier	n/a	281	100.0	1	0.4	0.1	2.0
	Bronchitis	n/a	281	100.0	5	1.8	0.8	4.1
	Candida infection	n/a	281	100.0	1	0.4	0.1	2.0
	Chronic sinusitis	n/a	281	100.0	1	0.4	0.1	2.0
	Cystitis	n/a	281	100.0	1	0.4	0.1	2.0
	Ear infection	n/a	281	100.0	1	0.4	0.1	2.0
	Epstein-Barr virus infection	n/a	281	100.0	1	0.4	0.1	2.0
	Escherichia bacteraemia	n/a	281	100.0	1	0.4	0.1	2.0
	Eye infection	n/a	281	100.0	1	0.4	0.1	2.0

	Folliculitis	n/a	281	100.0	3	1.1	0.4	3.1
	Fungal infection	n/a	281	100.0	2	0.7	0.2	2.6
	Gastroenteritis	n/a	281	100.0	1	0.4	0.1	2.0
	Genital candidiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Herpes simplex	n/a	281	100.0	1	0.4	0.1	2.0
	Herpes virus infection	n/a	281	100.0	1	0.4	0.1	2.0
	Herpes zoster	n/a	281	100.0	2	0.7	0.2	2.6
	Infection	n/a	281	100.0	1	0.4	0.1	2.0
	Influenza	n/a	281	100.0	2	0.7	0.2	2.6
	Lower respiratory tract infection	n/a	281	100.0	1	0.4	0.1	2.0
	Lymph node tuberculosis	n/a	281	100.0	1	0.4	0.1	2.0
	Nasal herpes	n/a	281	100.0	1	0.4	0.1	2.0
	Nasopharyngitis	n/a	281	100.0	7	2.5	1.2	5.1
	Oral candidiasis	n/a	281	100.0	3	1.1	0.4	3.1
	Otitis externa	n/a	281	100.0	1	0.4	0.1	2.0
	Otitis media	n/a	281	100.0	1	0.4	0.1	2.0
	Paronychia	n/a	281	100.0	6	2.1	1.0	4.6
	Pharyngitis	n/a	281	100.0	2	0.7	0.2	2.6
	Pneumonia	n/a	281	100.0	4	1.4	0.6	3.6
	Pyelonephritis	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory tract infection	n/a	281	100.0	1	0.4	0.1	2.0
	Rhinitis	n/a	281	100.0	1	0.4	0.1	2.0
	Sinusitis	n/a	281	100.0	4	1.4	0.6	3.6
	Skin infection	n/a	281	100.0	1	0.4	0.1	2.0
	Tinea infection	n/a	281	100.0	1	0.4	0.1	2.0
	Tinea pedis	n/a	281	100.0	2	0.7	0.2	2.6
	Tooth infection	n/a	281	100.0	1	0.4	0.1	2.0
	Tracheitis	n/a	281	100.0	1	0.4	0.1	2.0
	Tuberculosis	n/a	281	100.0	1	0.4	0.1	2.0

	Upper respiratory tract infection	n/a	281	100.0	5	1.8	0.8	4.1
	Urinary tract infection	n/a	281	100.0	6	2.1	1.0	4.6
	Viral infection	n/a	281	100.0	1	0.4	0.1	2.0
Injury, poisoning and procedural complications	-Total	n/a	281	100.0	17	6.0	3.8	9.5
	Contusion	n/a	281	100.0	5	1.8	0.8	4.1
	Epicondylitis	n/a	281	100.0	1	0.4	0.1	2.0
	Fall	n/a	281	100.0	3	1.1	0.4	3.1
	Incision site pain	n/a	281	100.0	1	0.4	0.1	2.0
	Injury	n/a	281	100.0	1	0.4	0.1	2.0
	Joint dislocation	n/a	281	100.0	1	0.4	0.1	2.0
	Laceration	n/a	281	100.0	1	0.4	0.1	2.0
	Ligament sprain	n/a	281	100.0	2	0.7	0.2	2.6
	Limb injury	n/a	281	100.0	2	0.7	0.2	2.6
	Muscle strain	n/a	281	100.0	2	0.7	0.2	2.6
	Procedural pain	n/a	281	100.0	2	0.7	0.2	2.6
	Rib fracture	n/a	281	100.0	1	0.4	0.1	2.0
	Scar	n/a	281	100.0	1	0.4	0.1	2.0
	Skin abrasion	n/a	281	100.0	1	0.4	0.1	2.0
	Skin injury	n/a	281	100.0	1	0.4	0.1	2.0
	Tendon rupture	n/a	281	100.0	1	0.4	0.1	2.0
	Wound	n/a	281	100.0	1	0.4	0.1	2.0
Investigations	-Total	n/a	281	100.0	186	66.2	60.5	71.5
	Alanine aminotransferase increased	n/a	281	100.0	71	25.3	20.5	30.7
	Albumin urine present	n/a	281	100.0	1	0.4	0.1	2.0
	Alpha hydroxybutyrate dehydrogenase increased	n/a	281	100.0	2	0.7	0.2	2.6
	Aspartate aminotransferase increased	n/a	281	100.0	98	34.9	29.5	40.6
	Bacterial test	n/a	281	100.0	1	0.4	0.1	2.0
	Bilirubin conjugated increased	n/a	281	100.0	13	4.6	2.7	7.8
	Blood albumin decreased	n/a	281	100.0	1	0.4	0.1	2.0

	Blood alkaline phosphatase	n/a	281	100.0	1	0.4	0.1	2.0
	Blood alkaline phosphatase decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood alkaline phosphatase increased	n/a	281	100.0	23	8.2	5.5	12.0
	Blood bilirubin increased	n/a	281	100.0	19	6.8	4.4	10.3
	Blood bilirubin unconjugated increased	n/a	281	100.0	6	2.1	1.0	4.6
	Blood calcium decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood calcium increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood chloride increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood cholesterol increased	n/a	281	100.0	7	2.5	1.2	5.1
	Blood creatine increased	n/a	281	100.0	3	1.1	0.4	3.1
	Blood creatine phosphokinase MB increased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood creatine phosphokinase increased	n/a	281	100.0	16	5.7	3.5	9.0
	Blood creatinine	n/a	281	100.0	1	0.4	0.1	2.0
	Blood creatinine increased	n/a	281	100.0	51	18.1	14.1	23.1
	Blood fibrinogen increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood glucose increased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood ketone body increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood lactate dehydrogenase increased	n/a	281	100.0	10	3.6	1.9	6.4
	Blood magnesium decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood phosphorus increased	n/a	281	100.0	7	2.5	1.2	5.1
	Blood potassium increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood pressure increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood sodium decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood thyroid stimulating hormone increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood triglycerides increased	n/a	281	100.0	8	2.8	1.4	5.5
	Blood urea increased	n/a	281	100.0	6	2.1	1.0	4.6
	Blood uric acid decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood uric acid increased	n/a	281	100.0	7	2.5	1.2	5.1
	Blood urine	n/a	281	100.0	3	1.1	0.4	3.1

	Blood urine present	n/a	281	100.0	1	0.4	0.1	2.0
	C-reactive protein increased	n/a	281	100.0	2	0.7	0.2	2.6
	Carbon dioxide decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Complement factor C1 decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Computerised tomogram thorax abnormal	n/a	281	100.0	2	0.7	0.2	2.6
	Crystal urine present	n/a	281	100.0	1	0.4	0.1	2.0
	Cystatin C increased	n/a	281	100.0	1	0.4	0.1	2.0
	Electrocardiogram QT prolonged	n/a	281	100.0	13	4.6	2.7	7.8
	Electrocardiogram ST-T change	n/a	281	100.0	2	0.7	0.2	2.6
	Fibrin D dimer increased	n/a	281	100.0	2	0.7	0.2	2.6
	Fibrin degradation products increased	n/a	281	100.0	1	0.4	0.1	2.0
	Free fatty acids increased	n/a	281	100.0	1	0.4	0.1	2.0
	Gamma-glutamyltransferase increased	n/a	281	100.0	13	4.6	2.7	7.8
	Glomerular filtration rate decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Glutamate dehydrogenase increased	n/a	281	100.0	2	0.7	0.2	2.6
	Haematocrit decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Haemoglobin decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Heart rate increased	n/a	281	100.0	6	2.1	1.0	4.6
	Hepatic enzyme increased	n/a	281	100.0	2	0.7	0.2	2.6
	International normalised ratio increased	n/a	281	100.0	2	0.7	0.2	2.6
	Intraocular pressure increased	n/a	281	100.0	1	0.4	0.1	2.0
	Laboratory test abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Lipase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Liver function test increased	n/a	281	100.0	1	0.4	0.1	2.0
	Lymphocyte count decreased	n/a	281	100.0	6	2.1	1.0	4.6
	Mean cell volume increased	n/a	281	100.0	1	0.4	0.1	2.0
	Myoglobin blood increased	n/a	281	100.0	1	0.4	0.1	2.0
	Neutrophil count decreased	n/a	281	100.0	16	5.7	3.5	9.0
	Neutrophil count increased	n/a	281	100.0	2	0.7	0.2	2.6

	Occult blood positive	n/a	281	100.0	3	1.1	0.4	3.1
	Platelet count decreased	n/a	281	100.0	17	6.0	3.8	9.5
	Platelet count increased	n/a	281	100.0	4	1.4	0.6	3.6
	Protein total decreased	n/a	281	100.0	3	1.1	0.4	3.1
	Protein total increased	n/a	281	100.0	1	0.4	0.1	2.0
	Protein urine present	n/a	281	100.0	2	0.7	0.2	2.6
	Prothrombin time prolonged	n/a	281	100.0	1	0.4	0.1	2.0
	Red blood cell count decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombin time prolonged	n/a	281	100.0	1	0.4	0.1	2.0
	Total bile acids increased	n/a	281	100.0	8	2.8	1.4	5.5
	Transaminases increased	n/a	281	100.0	7	2.5	1.2	5.1
	Transferrin increased	n/a	281	100.0	1	0.4	0.1	2.0
	Troponin T increased	n/a	281	100.0	1	0.4	0.1	2.0
	Troponin increased	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary sediment present	n/a	281	100.0	1	0.4	0.1	2.0
	Urine ketone body present	n/a	281	100.0	3	1.1	0.4	3.1
	Urine leukocyte esterase positive	n/a	281	100.0	1	0.4	0.1	2.0
	Urobilinogen urine increased	n/a	281	100.0	2	0.7	0.2	2.6
	Weight decreased	n/a	281	100.0	14	5.0	3.0	8.2
	Weight increased	n/a	281	100.0	14	5.0	3.0	8.2
	White blood cell count decreased	n/a	281	100.0	23	8.2	5.5	12.0
	White blood cells urine positive	n/a	281	100.0	3	1.1	0.4	3.1
Metabolism and nutrition disorders	-Total	n/a	281	100.0	111	39.5	34.0	45.3
	Alkalosis	n/a	281	100.0	1	0.4	0.1	2.0
	Cell death	n/a	281	100.0	1	0.4	0.1	2.0
	Decreased appetite	n/a	281	100.0	24	8.5	5.8	12.4
	Dehydration	n/a	281	100.0	1	0.4	0.1	2.0
	Fluid retention	n/a	281	100.0	1	0.4	0.1	2.0
	Hypercalcaemia	n/a	281	100.0	5	1.8	0.8	4.1

	Hypercholesterolaemia	n/a	281	100.0	5	1.8	0.8	4.1
	Hyperglycaemia	n/a	281	100.0	16	5.7	3.5	9.0
	Hyperkalaemia	n/a	281	100.0	8	2.8	1.4	5.5
	Hyperlipidaemia	n/a	281	100.0	6	2.1	1.0	4.6
	Hypermagnesaemia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypernatraemia	n/a	281	100.0	2	0.7	0.2	2.6
	Hyperphosphataemia	n/a	281	100.0	28	10.0	7.0	14.0
	Hypertriglyceridaemia	n/a	281	100.0	5	1.8	0.8	4.1
	Hyperuricaemia	n/a	281	100.0	10	3.6	1.9	6.4
	Hypoalbuminaemia	n/a	281	100.0	17	6.0	3.8	9.5
	Hypocalcaemia	n/a	281	100.0	19	6.8	4.4	10.3
	Hypochloraemia	n/a	281	100.0	4	1.4	0.6	3.6
	Hypoglycaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypokalaemia	n/a	281	100.0	21	7.5	4.9	11.2
	Hypomagnesaemia	n/a	281	100.0	20	7.1	4.7	10.7
	Hyponatraemia	n/a	281	100.0	17	6.0	3.8	9.5
	Hypophosphataemia	n/a	281	100.0	8	2.8	1.4	5.5
	Hypoproteinaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Increased appetite	n/a	281	100.0	1	0.4	0.1	2.0
	Vitamin D deficiency	n/a	281	100.0	1	0.4	0.1	2.0
Musculoskeletal and connective tissue disorders	-Total	n/a	281	100.0	92	32.7	27.5	38.4
	Arthralgia	n/a	281	100.0	11	3.9	2.2	6.9
	Arthropathy	n/a	281	100.0	1	0.4	0.1	2.0
	Back pain	n/a	281	100.0	22	7.8	5.2	11.6
	Bone pain	n/a	281	100.0	2	0.7	0.2	2.6
	Coccydynia	n/a	281	100.0	1	0.4	0.1	2.0
	Costochondritis	n/a	281	100.0	2	0.7	0.2	2.6
	Flank pain	n/a	281	100.0	2	0.7	0.2	2.6
	Groin pain	n/a	281	100.0	1	0.4	0.1	2.0

	Hypercreatinaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Intervertebral disc protrusion	n/a	281	100.0	2	0.7	0.2	2.6
	Joint stiffness	n/a	281	100.0	1	0.4	0.1	2.0
	Joint swelling	n/a	281	100.0	2	0.7	0.2	2.6
	Muscle fatigue	n/a	281	100.0	1	0.4	0.1	2.0
	Muscle spasms	n/a	281	100.0	20	7.1	4.7	10.7
	Muscular weakness	n/a	281	100.0	6	2.1	1.0	4.6
	Musculoskeletal chest pain	n/a	281	100.0	5	1.8	0.8	4.1
	Musculoskeletal pain	n/a	281	100.0	15	5.3	3.3	8.6
	Musculoskeletal stiffness	n/a	281	100.0	1	0.4	0.1	2.0
	Myalgia	n/a	281	100.0	21	7.5	4.9	11.2
	Myopathy	n/a	281	100.0	2	0.7	0.2	2.6
	Neck pain	n/a	281	100.0	9	3.2	1.7	6.0
	Osteopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Pain in extremity	n/a	281	100.0	17	6.0	3.8	9.5
	Pain in jaw	n/a	281	100.0	2	0.7	0.2	2.6
	Rotator cuff syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Spinal column stenosis	n/a	281	100.0	1	0.4	0.1	2.0
	Tendon pain	n/a	281	100.0	1	0.4	0.1	2.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	281	100.0	7	2.5	1.2	5.1
	Anogenital warts	n/a	281	100.0	1	0.4	0.1	2.0
	Basal cell carcinoma	n/a	281	100.0	1	0.4	0.1	2.0
	Bowen's disease	n/a	281	100.0	1	0.4	0.1	2.0
	Renal cell carcinoma	n/a	281	100.0	1	0.4	0.1	2.0
	Squamous cell carcinoma	n/a	281	100.0	1	0.4	0.1	2.0
	Squamous cell carcinoma of skin	n/a	281	100.0	1	0.4	0.1	2.0
	Tumour pain	n/a	281	100.0	1	0.4	0.1	2.0
Nervous system disorders	-Total	n/a	281	100.0	121	43.1	37.4	48.9
	Ageusia	n/a	281	100.0	2	0.7	0.2	2.6

	Aphasia	n/a	281	100.0	1	0.4	0.1	2.0
	Ataxia	n/a	281	100.0	1	0.4	0.1	2.0
	Brain oedema	n/a	281	100.0	2	0.7	0.2	2.6
	Cerebellar haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Disturbance in attention	n/a	281	100.0	2	0.7	0.2	2.6
	Dizziness	n/a	281	100.0	28	10.0	7.0	14.0
	Dizziness postural	n/a	281	100.0	1	0.4	0.1	2.0
	Dysarthria	n/a	281	100.0	1	0.4	0.1	2.0
	Dysgeusia	n/a	281	100.0	37	13.2	9.7	17.6
	Dyskinesia	n/a	281	100.0	1	0.4	0.1	2.0
	Headache	n/a	281	100.0	25	8.9	6.1	12.8
	Hyperaesthesia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypersomnia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypoaesthesia	n/a	281	100.0	16	5.7	3.5	9.0
	Hypotonia	n/a	281	100.0	1	0.4	0.1	2.0
	Lethargy	n/a	281	100.0	1	0.4	0.1	2.0
	Memory impairment	n/a	281	100.0	1	0.4	0.1	2.0
	Neuralgia	n/a	281	100.0	1	0.4	0.1	2.0
	Neuropathy peripheral	n/a	281	100.0	11	3.9	2.2	6.9
	Paraesthesia	n/a	281	100.0	9	3.2	1.7	6.0
	Paralysis	n/a	281	100.0	1	0.4	0.1	2.0
	Parosmia	n/a	281	100.0	1	0.4	0.1	2.0
	Peripheral sensory neuropathy	n/a	281	100.0	9	3.2	1.7	6.0
	Post herpetic neuralgia	n/a	281	100.0	1	0.4	0.1	2.0
	Presyncope	n/a	281	100.0	1	0.4	0.1	2.0
	Psychomotor skills impaired	n/a	281	100.0	1	0.4	0.1	2.0
	Sciatica	n/a	281	100.0	4	1.4	0.6	3.6
	Seizure	n/a	281	100.0	1	0.4	0.1	2.0
	Sensory disturbance	n/a	281	100.0	1	0.4	0.1	2.0

	Slow speech	n/a	281	100.0	1	0.4	0.1	2.0
	Somnolence	n/a	281	100.0	1	0.4	0.1	2.0
	Syncope	n/a	281	100.0	1	0.4	0.1	2.0
	Tension headache	n/a	281	100.0	1	0.4	0.1	2.0
	Tremor	n/a	281	100.0	1	0.4	0.1	2.0
	Visual field defect	n/a	281	100.0	2	0.7	0.2	2.6
Product issues	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Device dislocation	n/a	281	100.0	1	0.4	0.1	2.0
Psychiatric disorders	-Total	n/a	281	100.0	45	16.0	12.2	20.8
	Abnormal dreams	n/a	281	100.0	1	0.4	0.1	2.0
	Anxiety	n/a	281	100.0	8	2.8	1.4	5.5
	Bradyphrenia	n/a	281	100.0	1	0.4	0.1	2.0
	Confusional state	n/a	281	100.0	5	1.8	0.8	4.1
	Depression	n/a	281	100.0	5	1.8	0.8	4.1
	Fear of falling	n/a	281	100.0	1	0.4	0.1	2.0
	Insomnia	n/a	281	100.0	18	6.4	4.1	9.9
	Irritability	n/a	281	100.0	1	0.4	0.1	2.0
	Libido decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Mood altered	n/a	281	100.0	1	0.4	0.1	2.0
	Psychomotor retardation	n/a	281	100.0	2	0.7	0.2	2.6
	Restlessness	n/a	281	100.0	5	1.8	0.8	4.1
	Sleep disorder	n/a	281	100.0	2	0.7	0.2	2.6
Renal and urinary disorders	-Total	n/a	281	100.0	30	10.7	7.6	14.8
	Acute kidney injury	n/a	281	100.0	3	1.1	0.4	3.1
	Azotaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Cystitis haemorrhagic	n/a	281	100.0	1	0.4	0.1	2.0
	Dysuria	n/a	281	100.0	6	2.1	1.0	4.6
	Haematuria	n/a	281	100.0	2	0.7	0.2	2.6
	Micturition urgency	n/a	281	100.0	1	0.4	0.1	2.0

	Nocturia	n/a	281	100.0	3	1.1	0.4	3.1
	Pollakiuria	n/a	281	100.0	2	0.7	0.2	2.6
	Proteinuria	n/a	281	100.0	1	0.4	0.1	2.0
	Renal colic	n/a	281	100.0	1	0.4	0.1	2.0
	Renal disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Renal failure	n/a	281	100.0	2	0.7	0.2	2.6
	Renal impairment	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary incontinence	n/a	281	100.0	2	0.7	0.2	2.6
	Urinary retention	n/a	281	100.0	5	1.8	0.8	4.1
	Urinary tract pain	n/a	281	100.0	1	0.4	0.1	2.0
	Urine flow decreased	n/a	281	100.0	1	0.4	0.1	2.0
Reproductive system and breast disorders	-Total	n/a	281	100.0	16	5.7	3.5	9.0
	Benign prostatic hyperplasia	n/a	281	100.0	2	0.7	0.2	2.6
	Breast discharge	n/a	281	100.0	1	0.4	0.1	2.0
	Erectile dysfunction	n/a	281	100.0	5	1.8	0.8	4.1
	Galactorrhoea	n/a	281	100.0	1	0.4	0.1	2.0
	Genital ulceration	n/a	281	100.0	1	0.4	0.1	2.0
	Metrorrhagia	n/a	281	100.0	1	0.4	0.1	2.0
	Pelvic discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Pelvic fluid collection	n/a	281	100.0	1	0.4	0.1	2.0
	Perineal pain	n/a	281	100.0	1	0.4	0.1	2.0
	Postmenopausal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Uterine polyp	n/a	281	100.0	1	0.4	0.1	2.0
	Vaginal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Vulvovaginal dryness	n/a	281	100.0	1	0.4	0.1	2.0
	Vulvovaginal erythema	n/a	281	100.0	1	0.4	0.1	2.0
Respiratory, thoracic and mediastinal disorders	-Total	n/a	281	100.0	116	41.3	35.7	47.1
	Aspiration	n/a	281	100.0	1	0.4	0.1	2.0
	Choking	n/a	281	100.0	1	0.4	0.1	2.0

	Cough	n/a	281	100.0	44	15.7	11.9	20.4
	Dry throat	n/a	281	100.0	2	0.7	0.2	2.6
	Dysphonia	n/a	281	100.0	12	4.3	2.5	7.3
	Dyspnoea	n/a	281	100.0	22	7.8	5.2	11.6
	Dyspnoea exertional	n/a	281	100.0	7	2.5	1.2	5.1
	Epistaxis	n/a	281	100.0	11	3.9	2.2	6.9
	Haemoptysis	n/a	281	100.0	10	3.6	1.9	6.4
	Hiccups	n/a	281	100.0	2	0.7	0.2	2.6
	Interstitial lung disease	n/a	281	100.0	1	0.4	0.1	2.0
	Laryngeal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Nasal congestion	n/a	281	100.0	4	1.4	0.6	3.6
	Nasal dryness	n/a	281	100.0	4	1.4	0.6	3.6
	Nasal polyps	n/a	281	100.0	1	0.4	0.1	2.0
	Oropharyngeal discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Oropharyngeal pain	n/a	281	100.0	16	5.7	3.5	9.0
	Paranasal sinus discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Pharyngeal disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Pleural thickening	n/a	281	100.0	2	0.7	0.2	2.6
	Pleuritic pain	n/a	281	100.0	2	0.7	0.2	2.6
	Pneumonitis	n/a	281	100.0	7	2.5	1.2	5.1
	Pneumothorax	n/a	281	100.0	2	0.7	0.2	2.6
	Productive cough	n/a	281	100.0	10	3.6	1.9	6.4
	Pulmonary embolism	n/a	281	100.0	2	0.7	0.2	2.6
	Pulmonary mass	n/a	281	100.0	1	0.4	0.1	2.0
	Pulmonary pain	n/a	281	100.0	1	0.4	0.1	2.0
	Respiration abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Rhinitis allergic	n/a	281	100.0	2	0.7	0.2	2.6
	Rhinorrhoea	n/a	281	100.0	2	0.7	0.2	2.6
	Sinus congestion	n/a	281	100.0	1	0.4	0.1	2.0

	Sleep apnoea syndrome	n/a	281	100.0	3	1.1	0.4	3.1
	Throat irritation	n/a	281	100.0	2	0.7	0.2	2.6
	Upper-airway cough syndrome	n/a	281	100.0	2	0.7	0.2	2.6
	Wheezing	n/a	281	100.0	2	0.7	0.2	2.6
Skin and subcutaneous tissue disorders	-Total	n/a	281	100.0	88	31.3	26.2	37.0
	Acne	n/a	281	100.0	1	0.4	0.1	2.0
	Alopecia	n/a	281	100.0	14	5.0	3.0	8.2
	Chloasma	n/a	281	100.0	1	0.4	0.1	2.0
	Dermal cyst	n/a	281	100.0	1	0.4	0.1	2.0
	Dermatitis	n/a	281	100.0	1	0.4	0.1	2.0
	Dermatitis acneiform	n/a	281	100.0	7	2.5	1.2	5.1
	Dermatitis bullous	n/a	281	100.0	1	0.4	0.1	2.0
	Dry skin	n/a	281	100.0	12	4.3	2.5	7.3
	Ecchymosis	n/a	281	100.0	1	0.4	0.1	2.0
	Eczema	n/a	281	100.0	1	0.4	0.1	2.0
	Erythema	n/a	281	100.0	2	0.7	0.2	2.6
	Hair growth abnormal	n/a	281	100.0	6	2.1	1.0	4.6
	Hair texture abnormal	n/a	281	100.0	1	0.4	0.1	2.0
	Hirsutism	n/a	281	100.0	6	2.1	1.0	4.6
	Hyperhidrosis	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperkeratosis	n/a	281	100.0	1	0.4	0.1	2.0
	Hypertrichosis	n/a	281	100.0	6	2.1	1.0	4.6
	Madarosis	n/a	281	100.0	1	0.4	0.1	2.0
	Nail discolouration	n/a	281	100.0	1	0.4	0.1	2.0
	Nail disorder	n/a	281	100.0	1	0.4	0.1	2.0
	Night sweats	n/a	281	100.0	2	0.7	0.2	2.6
	Onychalgia	n/a	281	100.0	1	0.4	0.1	2.0
	Onycholysis	n/a	281	100.0	1	0.4	0.1	2.0
	Onychomadesis	n/a	281	100.0	3	1.1	0.4	3.1

	Pain of skin	n/a	281	100.0	1	0.4	0.1	2.0
	Palmar-plantar erythrodysaesthesia syndrome	n/a	281	100.0	5	1.8	0.8	4.1
	Photosensitivity reaction	n/a	281	100.0	1	0.4	0.1	2.0
	Pruritus	n/a	281	100.0	4	1.4	0.6	3.6
	Pruritus generalised	n/a	281	100.0	1	0.4	0.1	2.0
	Purpura	n/a	281	100.0	1	0.4	0.1	2.0
	Rash	n/a	281	100.0	19	6.8	4.4	10.3
	Rash erythematous	n/a	281	100.0	2	0.7	0.2	2.6
	Rash macular	n/a	281	100.0	3	1.1	0.4	3.1
	Rash maculo-papular	n/a	281	100.0	2	0.7	0.2	2.6
	Rash papular	n/a	281	100.0	1	0.4	0.1	2.0
	Scab	n/a	281	100.0	1	0.4	0.1	2.0
	Scar pain	n/a	281	100.0	1	0.4	0.1	2.0
	Skin discolouration	n/a	281	100.0	1	0.4	0.1	2.0
	Skin hyperpigmentation	n/a	281	100.0	1	0.4	0.1	2.0
	Skin lesion	n/a	281	100.0	1	0.4	0.1	2.0
	Swelling face	n/a	281	100.0	3	1.1	0.4	3.1
	Urticaria	n/a	281	100.0	2	0.7	0.2	2.6
Surgical and medical procedures	-Total	n/a	281	100.0	4	1.4	0.6	3.6
	Astringent therapy	n/a	281	100.0	4	1.4	0.6	3.6
Vascular disorders	-Total	n/a	281	100.0	22	7.8	5.2	11.6
	Circulatory collapse	n/a	281	100.0	1	0.4	0.1	2.0
	Embolism	n/a	281	100.0	1	0.4	0.1	2.0
	Flushing	n/a	281	100.0	1	0.4	0.1	2.0
	Haematoma	n/a	281	100.0	2	0.7	0.2	2.6
	Hot flush	n/a	281	100.0	3	1.1	0.4	3.1
	Hypertension	n/a	281	100.0	10	3.6	1.9	6.4
	Hypotension	n/a	281	100.0	4	1.4	0.6	3.6
	Phlebitis	n/a	281	100.0	1	0.4	0.1	2.0

	Raynaud's phenomenon	n/a	281	100.0	1	0.4	0.1	2.0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR1_SG.xls
26MAR2021 13:34

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	< 65	176	62.6	38	21.6	16.2	28.2
		>= 65	105	37.4	21	20.0	13.5	28.6
	Anaemia	< 65	176	62.6	23	13.1	8.9	18.8
		>= 65	105	37.4	5	4.8	2.1	10.7
	Cytopenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Febrile neutropenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperfibrinogenaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Leukocytosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Leukopenia	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
	Lymph node pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lymphadenopathy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymphopenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neutropenia	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Neutrophilia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pancytopenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Thrombocytopenia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	6	5.7	2.6	11.9
	Thrombocytosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
Cardiac disorders	-Total	< 65	176	62.6	15	8.5	5.2	13.6

		>= 65	105	37.4	10	9.5	5.3	16.6
	Aortic valve calcification	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Atrial flutter	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bradycardia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bundle branch block right	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Extrasystoles	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Myocardial ischaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nodal arrhythmia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Palpitations	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pericardial effusion	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sinus bradycardia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sinus tachycardia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tachycardia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Ventricular extrasystoles	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ventricular pre-excitation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Congenital, familial and genetic disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hydrocele	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Ear and labyrinth disorders	-Total	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	5	4.8	2.1	10.7
	Ear congestion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ear discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Ear pain	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tinnitus	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Vertigo	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	2	1.9	0.5	6.7
Endocrine disorders	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperthyroidism	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypothyroidism	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
Eye disorders	-Total	< 65	176	62.6	24	13.6	9.3	19.5
		>= 65	105	37.4	8	7.6	3.9	14.3
	Abnormal sensation in eye	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blepharitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Conjunctival haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diplopia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dry eye	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eye swelling	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Eyelid oedema	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Eyelid ptosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Periorbital oedema	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Photophobia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Photopsia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vision blurred	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	2	1.9	0.5	6.7

	Visual acuity reduced	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Gastrointestinal disorders	-Total	< 65	176	62.6	105	59.7	52.3	66.6
		>= 65	105	37.4	68	64.8	55.3	73.2
	Abdominal discomfort	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Abdominal distension	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Abdominal pain	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Abdominal pain lower	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Abdominal pain upper	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	3	2.9	1.0	8.1
	Abdominal symptom	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Anal incontinence	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Aphthous ulcer	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ascites	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Constipation	< 65	176	62.6	57	32.4	25.9	39.6
		>= 65	105	37.4	36	34.3	25.9	43.8
	Dental dysaesthesia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diarrhoea	< 65	176	62.6	33	18.8	13.7	25.2
		>= 65	105	37.4	20	19.0	12.7	27.6
	Dry mouth	< 65	176	62.6	22	12.5	8.4	18.2
		>= 65	105	37.4	21	20.0	13.5	28.6
	Dyspepsia	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Dysphagia	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	11	10.5	6.0	17.8
	Epigastric discomfort	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eructation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Faeces soft	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Flatulence	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Frequent bowel movements	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastritis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrointestinal haemorrhage	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastrointestinal inflammation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrointestinal oedema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrointestinal wall thickening	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrooesophageal reflux disease	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Gingival bleeding	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gingival swelling	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Glossitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Glossodynia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haematochezia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haemorrhoids	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypoaesthesia oral	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	0	0.0	0.0	3.5
	Impaired gastric emptying	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Melaena	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mouth ulceration	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	5	4.8	2.1	10.7
	Nausea	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	12	11.4	6.7	18.9

	Odynophagia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oesophageal irritation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oesophagitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oral disorder	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oral dysaesthesia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oral mucosal erythema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oral pain	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Paraesthesia oral	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Regurgitation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sensitivity of teeth	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Stomatitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Swollen tongue	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tongue coated	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tongue discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tongue ulceration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tooth discolouration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Toothache	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Vomiting	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	11	10.5	6.0	17.8
General disorders and administration site conditions	-Total	< 65	176	62.6	101	57.4	50.0	64.5
		>= 65	105	37.4	59	56.2	46.6	65.3

	Asthenia	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	5	4.8	2.1	10.7
	Axillary pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Catheter site pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Chest discomfort	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	4	3.8	1.5	9.4
	Chest pain	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Chills	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Disease progression	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Face oedema	< 65	176	62.6	11	6.3	3.5	10.8
		>= 65	105	37.4	3	2.9	1.0	8.1
	Fatigue	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	16	15.2	9.6	23.3
	Feeling abnormal	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Feeling cold	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Feeling hot	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gait disturbance	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	General physical health deterioration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Generalised oedema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Impaired healing	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Influenza like illness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Injection site bruising	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Localised oedema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Malaise	< 65	176	62.6	16	9.1	5.7	14.3

		>= 65	105	37.4	1	1.0	0.2	5.2
	Mucosal dryness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mucosal inflammation	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Non-cardiac chest pain	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Oedema	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oedema peripheral	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	18	17.1	11.1	25.5
	Pain	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Peripheral swelling	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pyrexia	< 65	176	62.6	31	17.6	12.7	23.9
		>= 65	105	37.4	17	16.2	10.4	24.4
	Swelling	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Temperature intolerance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Xerosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Hepatobiliary disorders	-Total	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	9	8.6	4.6	15.5
	Cholecystitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hepatic function abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hepatic steatosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hepatocellular injury	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperbilirubinaemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Liver disorder	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pneumobilia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Portal vein thrombosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Immune system disorders	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Drug hypersensitivity	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Food allergy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypersensitivity	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Seasonal allergy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Infections and infestations	-Total	< 65	176	62.6	41	23.3	17.7	30.1
		>= 65	105	37.4	22	21.0	14.3	29.7
	Acute sinusitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bacterial disease carrier	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bronchitis	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Candida infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Chronic sinusitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cystitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ear infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Epstein-Barr virus infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Escherichia bacteraemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eye infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Folliculitis	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fungal infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Gastroenteritis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Genital candidiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Herpes simplex	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Herpes virus infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Herpes zoster	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Influenza	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lower respiratory tract infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymph node tuberculosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nasal herpes	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nasopharyngitis	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Oral candidiasis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Otitis externa	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Otitis media	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Paronychia	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pharyngitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pyelonephritis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory tract infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rhinitis	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Sinusitis	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Skin infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tinea infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tinea pedis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tooth infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tracheitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tuberculosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Upper respiratory tract infection	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary tract infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	4	3.8	1.5	9.4
	Viral infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Injury, poisoning and procedural complications	-Total	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	9	8.6	4.6	15.5
	Contusion	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Epicondylitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fall	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Incision site pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Joint dislocation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Laceration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ligament sprain	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

	Limb injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Muscle strain	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Procedural pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Rib fracture	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Scar	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Skin abrasion	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Skin injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tendon rupture	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Wound	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Investigations	-Total	< 65	176	62.6	120	68.2	61.0	74.6
		>= 65	105	37.4	66	62.9	53.3	71.5
	Alanine aminotransferase increased	< 65	176	62.6	48	27.3	21.2	34.3
		>= 65	105	37.4	23	21.9	15.1	30.7
	Albumin urine present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Alpha hydroxybutyrate dehydrogenase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Aspartate aminotransferase increased	< 65	176	62.6	66	37.5	30.7	44.8
		>= 65	105	37.4	32	30.5	22.5	39.8
	Bacterial test	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bilirubin conjugated increased	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	4	3.8	1.5	9.4
	Blood albumin decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood alkaline phosphatase	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood alkaline phosphatase decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Blood alkaline phosphatase increased	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	8	7.6	3.9	14.3
	Blood bilirubin increased	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	9	8.6	4.6	15.5
	Blood bilirubin unconjugated increased	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood calcium decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood calcium increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood chloride increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood cholesterol increased	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood creatine increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood creatine phosphokinase MB increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood creatine phosphokinase increased	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	4	3.8	1.5	9.4
	Blood creatinine	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood creatinine increased	< 65	176	62.6	32	18.2	13.2	24.5
		>= 65	105	37.4	19	18.1	11.9	26.5
	Blood fibrinogen increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood glucose increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood ketone body increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood lactate dehydrogenase increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	4	3.8	1.5	9.4
	Blood magnesium decreased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood phosphorus increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood potassium increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood pressure increased	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood sodium decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood thyroid stimulating hormone increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood triglycerides increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood urea increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood uric acid decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood uric acid increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood urine	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood urine present	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	C-reactive protein increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Carbon dioxide decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Complement factor C1 decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Computerised tomogram thorax abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Crystal urine present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cystatin C increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Electrocardiogram QT prolonged	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	5	4.8	2.1	10.7
	Electrocardiogram ST-T change	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Fibrin D dimer increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Fibrin degradation products increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Free fatty acids increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Gamma-glutamyltransferase increased	< 65	176	62.6	11	6.3	3.5	10.8
		>= 65	105	37.4	2	1.9	0.5	6.7
	Glomerular filtration rate decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Glutamate dehydrogenase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haematocrit decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haemoglobin decreased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Heart rate increased	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hepatic enzyme increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	International normalised ratio increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Intraocular pressure increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Laboratory test abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lipase increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Liver function test increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lymphocyte count decreased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Mean cell volume increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Myoglobin blood increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neutrophil count decreased	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	3	2.9	1.0	8.1
	Neutrophil count increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Occult blood positive	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Platelet count decreased	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	7	6.7	3.3	13.1

	Platelet count increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Protein total decreased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Protein total increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Protein urine present	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Prothrombin time prolonged	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Red blood cell count decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Thrombin time prolonged	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Total bile acids increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	2	1.9	0.5	6.7
	Transaminases increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Transferrin increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Troponin T increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Troponin increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary sediment present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urine ketone body present	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Urine leukocyte esterase positive	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urobilinogen urine increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Weight decreased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	8	7.6	3.9	14.3
	Weight increased	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	White blood cell count decreased	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	7	6.7	3.3	13.1
	White blood cells urine positive	< 65	176	62.6	3	1.7	0.6	4.9

		>= 65	105	37.4	0	0.0	0.0	3.5
Metabolism and nutrition disorders	-Total	< 65	176	62.6	66	37.5	30.7	44.8
		>= 65	105	37.4	45	42.9	33.8	52.4
	Alkalosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cell death	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Decreased appetite	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	11	10.5	6.0	17.8
	Dehydration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Fluid retention	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypercalcaemia	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypercholesterolaemia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperglycaemia	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	7	6.7	3.3	13.1
	Hyperkalaemia	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hyperlipidaemia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypermagnesaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hypernatraemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperphosphataemia	< 65	176	62.6	21	11.9	7.9	17.6
		>= 65	105	37.4	7	6.7	3.3	13.1
	Hypertriglyceridaemia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hyperuricaemia	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypoalbuminaemia	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	4	3.8	1.5	9.4
	Hypocalcaemia	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	6	5.7	2.6	11.9
	Hypochloraemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7

	Hypoglycaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypokalaemia	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	14	13.3	8.1	21.1
	Hypomagnesaemia	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	5	4.8	2.1	10.7
	Hyponatraemia	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	4	3.8	1.5	9.4
	Hypophosphataemia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Hypoproteinaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Increased appetite	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vitamin D deficiency	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Musculoskeletal and connective tissue disorders	-Total	< 65	176	62.6	60	34.1	27.5	41.4
		>= 65	105	37.4	32	30.5	22.5	39.8
	Arthralgia	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	3	2.9	1.0	8.1
	Arthropathy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Back pain	< 65	176	62.6	14	8.0	4.8	12.9
		>= 65	105	37.4	8	7.6	3.9	14.3
	Bone pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Coccydynia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Costochondritis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Flank pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Groin pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypercreatinaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Intervertebral disc protrusion	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

	Joint stiffness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Joint swelling	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Muscle fatigue	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscle spasms	< 65	176	62.6	11	6.3	3.5	10.8
		>= 65	105	37.4	9	8.6	4.6	15.5
	Muscular weakness	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Musculoskeletal chest pain	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Musculoskeletal pain	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	6	5.7	2.6	11.9
	Musculoskeletal stiffness	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Myalgia	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	5	4.8	2.1	10.7
	Myopathy	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neck pain	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Osteopenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pain in extremity	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	7	6.7	3.3	13.1
	Pain in jaw	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rotator cuff syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Spinal column stenosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tendon pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Anogenital warts	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Basal cell carcinoma	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Bowen's disease	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Renal cell carcinoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Squamous cell carcinoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Squamous cell carcinoma of skin	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tumour pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Nervous system disorders	-Total	< 65	176	62.6	70	39.8	32.8	47.1
		>= 65	105	37.4	51	48.6	39.2	58.0
	Ageusia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Aphasia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ataxia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Brain oedema	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cerebellar haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Disturbance in attention	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dizziness	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	12	11.4	6.7	18.9
	Dizziness postural	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dysarthria	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dysgeusia	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	22	21.0	14.3	29.7
	Dyskinesia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Headache	< 65	176	62.6	20	11.4	7.5	16.9
		>= 65	105	37.4	5	4.8	2.1	10.7
	Hyperaesthesia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2

	Hypersomnia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypoaesthesia	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	7	6.7	3.3	13.1
	Hypotonia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lethargy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Memory impairment	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neuralgia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neuropathy peripheral	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	4	3.8	1.5	9.4
	Paraesthesia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	3	2.9	1.0	8.1
	Paralysis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Parosmia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Peripheral sensory neuropathy	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Post herpetic neuralgia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Presyncope	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Psychomotor skills impaired	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sciatica	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Seizure	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sensory disturbance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Slow speech	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Somnolence	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Syncope	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tension headache	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tremor	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Visual field defect	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
Product issues	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Device dislocation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Psychiatric disorders	-Total	< 65	176	62.6	29	16.5	11.7	22.7
		>= 65	105	37.4	16	15.2	9.6	23.3
	Abnormal dreams	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Anxiety	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	2	1.9	0.5	6.7
	Bradyphrenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Confusional state	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Depression	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Fear of falling	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Insomnia	< 65	176	62.6	14	8.0	4.8	12.9
		>= 65	105	37.4	4	3.8	1.5	9.4
	Irritability	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Libido decreased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mood altered	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Psychomotor retardation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Restlessness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Sleep disorder	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	1	1.0	0.2	5.2
Renal and urinary disorders	-Total	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	17	16.2	10.4	24.4
	Acute kidney injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Azotaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cystitis haemorrhagic	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dysuria	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Haematuria	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Micturition urgency	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nocturia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pollakiuria	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Proteinuria	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Renal colic	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Renal disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Renal failure	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Renal impairment	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Urinary incontinence	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Urinary retention	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Urinary tract pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urine flow decreased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Reproductive system and breast disorders	-Total	< 65	176	62.6	11	6.3	3.5	10.8
		>= 65	105	37.4	5	4.8	2.1	10.7

	Benign prostatic hyperplasia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Breast discharge	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Erectile dysfunction	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Galactorrhoea	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Genital ulceration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Metrorrhagia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pelvic discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pelvic fluid collection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Perineal pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Postmenopausal haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Uterine polyp	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vaginal haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vulvovaginal dryness	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Vulvovaginal erythema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Respiratory, thoracic and mediastinal disorders	-Total	< 65	176	62.6	76	43.2	36.1	50.6
		>= 65	105	37.4	40	38.1	29.4	47.6
	Aspiration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Choking	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cough	< 65	176	62.6	28	15.9	11.2	22.0
		>= 65	105	37.4	16	15.2	9.6	23.3
	Dry throat	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

	Dysphonia	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Dyspnoea	< 65	176	62.6	14	8.0	4.8	12.9
		>= 65	105	37.4	8	7.6	3.9	14.3
	Dyspnoea exertional	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Epistaxis	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	5	4.8	2.1	10.7
	Haemoptysis	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hiccups	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Interstitial lung disease	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Laryngeal haemorrhage	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nasal congestion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Nasal dryness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Nasal polyps	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oropharyngeal discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oropharyngeal pain	< 65	176	62.6	11	6.3	3.5	10.8
		>= 65	105	37.4	5	4.8	2.1	10.7
	Paranasal sinus discomfort	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pharyngeal disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pleural thickening	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pleuritic pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pneumonitis	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pneumothorax	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Productive cough	< 65	176	62.6	7	4.0	1.9	8.0

		>= 65	105	37.4	3	2.9	1.0	8.1
	Pulmonary embolism	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pulmonary mass	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pulmonary pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiration abnormal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rhinitis allergic	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rhinorrhoea	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sinus congestion	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sleep apnoea syndrome	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Throat irritation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Upper-airway cough syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Wheezing	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
Skin and subcutaneous tissue disorders	-Total	< 65	176	62.6	62	35.2	28.6	42.5
		>= 65	105	37.4	26	24.8	17.5	33.8
	Acne	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Alopecia	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Chloasma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermal cyst	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermatitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermatitis acneiform	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermatitis bullous	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Dry skin	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Ecchymosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eczema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Erythema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hair growth abnormal	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hair texture abnormal	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hirsutism	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperhidrosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperkeratosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypertrichosis	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	0	0.0	0.0	3.5
	Madarosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nail discolouration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nail disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Night sweats	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Onychalgia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Onycholysis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Onychomadesis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pain of skin	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Palmar-plantar erythrodysaesthesia syndrome	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2

	Photosensitivity reaction	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pruritus	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pruritus generalised	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Purpura	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rash	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	4	3.8	1.5	9.4
	Rash erythematous	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rash macular	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Rash maculo-papular	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rash papular	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Scab	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Scar pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Skin discolouration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Skin hyperpigmentation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Skin lesion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Swelling face	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urticaria	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Surgical and medical procedures	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Astringent therapy	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
Vascular disorders	-Total	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	12	11.4	6.7	18.9
	Circulatory collapse	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Embolism	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Flushing	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haematoma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hot flush	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hypertension	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	5	4.8	2.1	10.7
	Hypotension	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Phlebitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Raynaud's phenomenon	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR1_SG.xls
26MAR2021 13:34

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	84	29.9	16	19.0	12.1	28.7
		1	190	67.6	43	22.6	17.3	29.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	24	12.6	8.6	18.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Febrile neutropenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperfibrinogenaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Leukocytosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Leukopenia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymph node pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphadenopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphopenia	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutropenia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophilia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytopenia	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytosis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Cardiac disorders	-Total	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	20	10.5	6.9	15.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aortic valve calcification	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Atrial flutter	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bradycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bundle branch block right	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Extrasystoles	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Myocardial ischaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nodal arrhythmia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Palpitations	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pericardial effusion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinus bradycardia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinus tachycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tachycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ventricular extrasystoles	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ventricular pre-excitation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Congenital, familial and genetic disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hydrocele	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Ear and labyrinth disorders	-Total	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	9	4.7	2.5	8.8

		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear congestion	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear pain	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tinnitus	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Vertigo	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Endocrine disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperthyroidism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypothyroidism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Eye disorders	-Total	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	21	11.1	7.3	16.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal sensation in eye	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blepharitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Conjunctival haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diplopia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry eye	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eye swelling	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eyelid oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eyelid ptosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Periorbital oedema	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Photophobia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Photopsia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vision blurred	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Visual acuity reduced	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Gastrointestinal disorders	-Total	0	84	29.9	57	67.9	57.3	76.9
		1	190	67.6	111	58.4	51.3	65.2
		2	6	2.1	4	66.7	30.0	90.3

		Missing	1	0.4	1	100.0	20.7	100.0
	Abdominal discomfort	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal distension	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain lower	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain upper	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal symptom	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anal incontinence	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aphthous ulcer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ascites	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Constipation	0	84	29.9	35	41.7	31.7	52.3
		1	190	67.6	57	30.0	23.9	36.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Dental dysaesthesia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diarrhoea	0	84	29.9	19	22.6	15.0	32.6

		1	190	67.6	32	16.8	12.2	22.8
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry mouth	0	84	29.9	18	21.4	14.0	31.3
		1	190	67.6	24	12.6	8.6	18.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspepsia	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysphagia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Epigastric discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eructation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Faeces soft	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Flatulence	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Frequent bowel movements	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal inflammation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Gastrointestinal oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal wall thickening	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrooesophageal reflux disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gingival bleeding	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gingival swelling	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glossitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glossodynia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematochezia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhoids	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoaesthesia oral	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Impaired gastric emptying	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Melaena	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Mouth ulceration	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nausea	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	18	9.5	6.1	14.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	1	100.0	20.7	100.0
	Odynophagia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oesophageal irritation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oesophagitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral dysaesthesia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral mucosal erythema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paraesthesia oral	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Regurgitation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Sensitivity of teeth	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Stomatitis	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Swollen tongue	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tongue coated	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tongue discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tongue ulceration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tooth discolouration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Toothache	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vomiting	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
General disorders and administration site conditions	-Total	0	84	29.9	49	58.3	47.7	68.3
		1	190	67.6	106	55.8	48.7	62.7
		2	6	2.1	4	66.7	30.0	90.3
		Missing	1	0.4	1	100.0	20.7	100.0
	Asthenia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Axillary pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Catheter site pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest pain	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chills	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disease progression	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Face oedema	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fatigue	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	21	11.1	7.3	16.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Feeling abnormal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Feeling cold	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Feeling hot	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gait disturbance	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	General physical health deterioration	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Generalised oedema	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Impaired healing	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Influenza like illness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Injection site bruising	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Localised oedema	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Malaise	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	17	8.9	5.7	13.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mucosal dryness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mucosal inflammation	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Non-cardiac chest pain	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oedema peripheral	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	22	11.6	7.8	16.9
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Pain	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Peripheral swelling	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyrexia	0	84	29.9	19	22.6	15.0	32.6
		1	190	67.6	27	14.2	10.0	19.9
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Swelling	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Temperature intolerance	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Xerosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Hepatobiliary disorders	-Total	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cholecystitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic function abnormal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic steatosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatocellular injury	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperbilirubinaemia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Liver disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumobilia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Portal vein thrombosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Immune system disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Drug hypersensitivity	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Food allergy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypersensitivity	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Seasonal allergy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Infections and infestations	-Total	0	84	29.9	25	29.8	21.0	40.2
		1	190	67.6	37	19.5	14.5	25.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute sinusitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacterial disease carrier	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Bronchitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Candida infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chronic sinusitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epstein-Barr virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Escherichia bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eye infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Folliculitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fungal infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastroenteritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Genital candidiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Herpes simplex	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Herpes virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Herpes zoster	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Influenza	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lower respiratory tract infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymph node tuberculosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasal herpes	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasopharyngitis	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral candidiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Otitis externa	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Otitis media	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paronychia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pharyngitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyelonephritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory tract infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinusitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tinea infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tinea pedis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tooth infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Tracheitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tuberculosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Upper respiratory tract infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary tract infection	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Viral infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Injury, poisoning and procedural complications	-Total	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Contusion	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epicondylitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fall	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Incision site pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint dislocation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Laceration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ligament sprain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Limb injury	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle strain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Procedural pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rib fracture	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Scar	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin abrasion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tendon rupture	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wound	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

Investigations	-Total	0	84	29.9	48	57.1	46.5	67.2
		1	190	67.6	135	71.1	64.2	77.0
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Alanine aminotransferase increased	0	84	29.9	16	19.0	12.1	28.7
		1	190	67.6	53	27.9	22.0	34.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	1	100.0	20.7	100.0
	Albumin urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alpha hydroxybutyrate dehydrogenase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aspartate aminotransferase increased	0	84	29.9	23	27.4	19.0	37.7
		1	190	67.6	73	38.4	31.8	45.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	1	100.0	20.7	100.0
	Bacterial test	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bilirubin conjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood albumin decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase increased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	20	10.5	6.9	15.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin increased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin unconjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood calcium decreased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood calcium increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood chloride increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood cholesterol increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine increased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase MB increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatinine	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatinine increased	0	84	29.9	14	16.7	10.2	26.1
		1	190	67.6	37	19.5	14.5	25.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood fibrinogen increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood glucose increased	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood ketone body increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood lactate dehydrogenase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood magnesium decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood phosphorus increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood potassium increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood pressure increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood sodium decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood thyroid stimulating hormone increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood triglycerides increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood urea increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood uric acid decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Blood uric acid increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood urine	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	C-reactive protein increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Carbon dioxide decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Complement factor C1 decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Computerised tomogram thorax abnormal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Crystal urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystatin C increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrocardiogram QT prolonged	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrocardiogram ST-T change	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fibrin D dimer increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fibrin degradation products increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Free fatty acids increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gamma-glutamyltransferase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glomerular filtration rate decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Glutamate dehydrogenase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematocrit decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemoglobin decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Heart rate increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic enzyme increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	International normalised ratio increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intraocular pressure increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Laboratory test abnormal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lipase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Liver function test increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphocyte count decreased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mean cell volume increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myoglobin blood increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil count decreased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil count increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Occult blood positive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count decreased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Protein total decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Protein total increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Protein urine present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Prothrombin time prolonged	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Red blood cell count decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombin time prolonged	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Total bile acids increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Transaminases increased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Transferrin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Troponin T increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Troponin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary sediment present	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urine ketone body present	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urine leukocyte esterase positive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urobilinogen urine increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Weight decreased	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Weight increased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	White blood cell count decreased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	White blood cells urine positive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Metabolism and nutrition disorders	-Total	0	84	29.9	29	34.5	25.2	45.2
		1	190	67.6	82	43.2	36.3	50.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alkalosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cell death	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Decreased appetite	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dehydration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Fluid retention	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercalcaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercholesterolaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperglycaemia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperkalaemia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperlipidaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypermagnesaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypernatraemia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperphosphataemia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	21	11.1	7.3	16.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertriglyceridaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperuricaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoalbuminaemia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	15	7.9	4.8	12.6

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypocalcaemia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	16	8.4	5.2	13.2
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypochloraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoglycaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypokalaemia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypomagnesaemia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	18	9.5	6.1	14.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyponatraemia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypophosphataemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoproteinaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Increased appetite	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vitamin D deficiency	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Musculoskeletal and connective tissue disorders	-Total	0	84	29.9	34	40.5	30.6	51.2
		1	190	67.6	57	30.0	23.9	36.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Arthralgia	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Arthropathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Back pain	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Bone pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Coccydynia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Costochondritis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Flank pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Groin pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercreatinaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intervertebral disc protrusion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint stiffness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint swelling	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle fatigue	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle spasms	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscular weakness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal chest pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal pain	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal stiffness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myalgia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neck pain	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Osteopenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain in extremity	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain in jaw	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rotator cuff syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Spinal column stenosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tendon pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anogenital warts	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Basal cell carcinoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bowen's disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal cell carcinoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Squamous cell carcinoma	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Squamous cell carcinoma of skin	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tumour pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

Nervous system disorders	-Total	0	84	29.9	32	38.1	28.4	48.8
		1	190	67.6	86	45.3	38.3	52.4
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Ageusia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aphasia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ataxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Brain oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebellar haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disturbance in attention	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dizziness	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	21	11.1	7.3	16.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dizziness postural	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysarthria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysgeusia	0	84	29.9	12	14.3	8.4	23.3
		1	190	67.6	24	12.6	8.6	18.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyskinesia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Headache	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	18	9.5	6.1	14.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Hyperaesthesia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypersomnia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoaesthesia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypotonia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lethargy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Memory impairment	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Neuralgia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neuropathy peripheral	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paraesthesia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paralysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Parosmia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Peripheral sensory neuropathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Post herpetic neuralgia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Presyncope	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Psychomotor skills impaired	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sciatica	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Seizure	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sensory disturbance	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Slow speech	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Somnolence	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Syncope	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tension headache	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Tremor	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Visual field defect	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Product issues	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Device dislocation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Psychiatric disorders	-Total	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	32	16.8	12.2	22.8
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal dreams	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anxiety	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bradyphrenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Confusional state	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Depression	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fear of falling	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Insomnia	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	17	8.9	5.7	13.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Irritability	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Libido decreased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mood altered	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Psychomotor retardation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Restlessness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sleep disorder	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Renal and urinary disorders	-Total	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	17	8.9	5.7	13.9
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute kidney injury	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Azotaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis haemorrhagic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysuria	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Haematuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Micturition urgency	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Nocturia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pollakiuria	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Proteinuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal colic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal disorder	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal failure	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal impairment	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary incontinence	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary retention	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary tract pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urine flow decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Reproductive system and breast disorders	-Total	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Benign prostatic hyperplasia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Breast discharge	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Erectile dysfunction	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Galactorrhoea	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Genital ulceration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Metrorrhagia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pelvic discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pelvic fluid collection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Perineal pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Postmenopausal haemorrhage	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Uterine polyp	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vaginal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vulvovaginal dryness	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vulvovaginal erythema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Respiratory, thoracic and mediastinal disorders	-Total	0	84	29.9	37	44.0	33.9	54.7
		1	190	67.6	76	40.0	33.3	47.1
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Aspiration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Choking	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cough	0	84	29.9	15	17.9	11.1	27.4
		1	190	67.6	27	14.2	10.0	19.9
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry throat	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysphonia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	16	8.4	5.2	13.2
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea exertional	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epistaxis	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemoptysis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hiccups	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Interstitial lung disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Laryngeal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasal congestion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasal dryness	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasal polyps	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oropharyngeal discomfort	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oropharyngeal pain	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paranasal sinus discomfort	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pharyngeal disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural thickening	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleuritic pain	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonitis	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumothorax	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Productive cough	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary embolism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary mass	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiration abnormal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinitis allergic	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Rhinorrhoea	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinus congestion	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sleep apnoea syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Throat irritation	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Upper-airway cough syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wheezing	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Skin and subcutaneous tissue disorders	-Total	0	84	29.9	36	42.9	32.8	53.5
		1	190	67.6	50	26.3	20.6	33.0
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Acne	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alopecia	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chloasma	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermal cyst	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis acneiform	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis bullous	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry skin	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Ecchymosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eczema	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Erythema	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hair growth abnormal	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hair texture abnormal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hirsutism	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperhidrosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperkeratosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Hypertrichosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Madarosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nail discolouration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nail disorder	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Night sweats	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Onychalgia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Onycholysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Onychomadesis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain of skin	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Palmar-plantar erythrodysaesthesia syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Photosensitivity reaction	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pruritus	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Pruritus generalised	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Purpura	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash erythematous	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash macular	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash maculo-papular	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash papular	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Scab	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Scar pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin discolouration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin hyperpigmentation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin lesion	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Swelling face	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urticaria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Surgical and medical procedures	-Total	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Astringent therapy	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Vascular disorders	-Total	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	18	9.5	6.1	14.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Circulatory collapse	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Flushing	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hot flush	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertension	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Hypotension	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Phlebitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Raynaud's phenomenon	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR1_SG.xls
26MAR2021 13:34

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	21	22.1	14.9	31.4
		Asia (AS)	122	43.4	23	18.9	12.9	26.7
	Anaemia	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Cytopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Febrile neutropenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyperfibrinogenaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Leukocytosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Leukopenia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Lymph node pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lymphadenopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lymphopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neutropenia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Neutrophilia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pancytopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thrombocytopenia	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Thrombocytosis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Cardiac disorders	-Total	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Aortic valve calcification	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Atrial flutter	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Bradycardia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bundle branch block right	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Extrasystoles	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Myocardial ischaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nodal arrhythmia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Palpitations	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pericardial effusion	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinus bradycardia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Sinus tachycardia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Tachycardia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Ventricular extrasystoles	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Ventricular pre-excitation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Congenital, familial and genetic disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hydrocele	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Ear and labyrinth disorders	-Total	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Ear congestion	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ear discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ear pain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tinnitus	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Vertigo	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
Endocrine disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperthyroidism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypothyroidism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Eye disorders	-Total	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Abnormal sensation in eye	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blepharitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Conjunctival haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Diplopia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dry eye	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eye swelling	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eyelid oedema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Eyelid ptosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Periorbital oedema	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Photophobia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Photopsia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vision blurred	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Visual acuity reduced	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

Gastrointestinal disorders	-Total	USA	64	22.8	47	73.4	61.5	82.7
		Europe (EU)	95	33.8	63	66.3	56.3	75.0
		Asia (AS)	122	43.4	63	51.6	42.9	60.3
	Abdominal discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Abdominal distension	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Abdominal pain	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Abdominal pain lower	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Abdominal pain upper	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Abdominal symptom	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Anal incontinence	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Aphthous ulcer	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ascites	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Constipation	USA	64	22.8	22	34.4	23.9	46.6
		Europe (EU)	95	33.8	30	31.6	23.1	41.5
		Asia (AS)	122	43.4	41	33.6	25.8	42.4
	Dental dysaesthesia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Diarrhoea	USA	64	22.8	16	25.0	16.0	36.8
		Europe (EU)	95	33.8	23	24.2	16.7	33.7
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Dry mouth	USA	64	22.8	18	28.1	18.6	40.1
		Europe (EU)	95	33.8	17	17.9	11.5	26.8
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Dyspepsia	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dysphagia	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Epigastric discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eructation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Faeces soft	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Flatulence	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Frequent bowel movements	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastrointestinal haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastrointestinal inflammation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal wall thickening	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrooesophageal reflux disease	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gingival bleeding	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Gingival swelling	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Glossitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Glossodynia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haematochezia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haemorrhoids	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypoaesthesia oral	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Impaired gastric emptying	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Melaena	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Mouth ulceration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Nausea	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	10	10.5	5.8	18.3
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Odynophagia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oesophageal irritation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oesophagitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oral disorder	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oral dysaesthesia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oral mucosal erythema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oral pain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Paraesthesia oral	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Regurgitation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sensitivity of teeth	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Stomatitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Swollen tongue	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tongue coated	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tongue discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tongue ulceration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tooth discolouration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Toothache	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Vomiting	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
General disorders and administration site conditions	-Total	USA	64	22.8	40	62.5	50.3	73.3
		Europe (EU)	95	33.8	54	56.8	46.8	66.3
		Asia (AS)	122	43.4	66	54.1	45.3	62.7
	Asthenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	6	4.9	2.3	10.3

	Axillary pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Catheter site pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Chest discomfort	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Chest pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Chills	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Disease progression	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Face oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Fatigue	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Feeling abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Feeling cold	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Feeling hot	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gait disturbance	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	General physical health deterioration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Generalised oedema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Impaired healing	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Influenza like illness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Injection site bruising	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Localised oedema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Malaise	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	16	13.1	8.2	20.2
	Mucosal dryness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Mucosal inflammation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	10	10.5	5.8	18.3
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Non-cardiac chest pain	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Oedema	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oedema peripheral	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Pain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Peripheral swelling	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pyrexia	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	19	20.0	13.2	29.1
		Asia (AS)	122	43.4	21	17.2	11.5	24.9
	Swelling	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Temperature intolerance	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Xerosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Hepatobiliary disorders	-Total	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Cholecystitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hepatic function abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Hepatic steatosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hepatocellular injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperbilirubinaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Liver disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumobilia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Portal vein thrombosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Immune system disorders	-Total	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Drug hypersensitivity	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Food allergy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypersensitivity	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Seasonal allergy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Infections and infestations	-Total	USA	64	22.8	17	26.6	17.3	38.5
		Europe (EU)	95	33.8	27	28.4	20.3	38.2
		Asia (AS)	122	43.4	19	15.6	10.2	23.0
	Acute sinusitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacterial disease carrier	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bronchitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Candida infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Chronic sinusitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cystitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ear infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epstein-Barr virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Escherichia bacteraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eye infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Folliculitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fungal infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastroenteritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Genital candidiasis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Herpes simplex	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Herpes virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Herpes zoster	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Influenza	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lower respiratory tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lymph node tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasal herpes	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasopharyngitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oral candidiasis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Otitis externa	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Otitis media	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Paronychia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Pharyngitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Pyelonephritis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhinitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sinusitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Skin infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tinea infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tinea pedis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tooth infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tracheitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Upper respiratory tract infection	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Urinary tract infection	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Viral infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

Injury, poisoning and procedural complications	-Total	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Contusion	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epicondylitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fall	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Incision site pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Joint dislocation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Laceration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ligament sprain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Limb injury	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle strain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Procedural pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rib fracture	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Scar	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin abrasion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tendon rupture	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Wound	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Investigations	-Total	USA	64	22.8	44	68.8	56.6	78.8
		Europe (EU)	95	33.8	54	56.8	46.8	66.3
		Asia (AS)	122	43.4	88	72.1	63.6	79.3
	Alanine aminotransferase increased	USA	64	22.8	16	25.0	16.0	36.8
		Europe (EU)	95	33.8	15	15.8	9.8	24.4
		Asia (AS)	122	43.4	40	32.8	25.1	41.5
	Albumin urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Alpha hydroxybutyrate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Aspartate aminotransferase increased	USA	64	22.8	24	37.5	26.7	49.7
		Europe (EU)	95	33.8	21	22.1	14.9	31.4
		Asia (AS)	122	43.4	53	43.4	35.0	52.3
	Bacterial test	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bilirubin conjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
	Blood albumin decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood alkaline phosphatase	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood alkaline phosphatase decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood alkaline phosphatase increased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	15	12.3	7.6	19.3

	Blood bilirubin increased	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Blood bilirubin unconjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Blood calcium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood calcium increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood chloride increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood cholesterol increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Blood creatine increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood creatine phosphokinase MB increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Blood creatine phosphokinase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Blood creatinine	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood creatinine increased	USA	64	22.8	12	18.8	11.1	30.0
		Europe (EU)	95	33.8	18	18.9	12.3	28.0
		Asia (AS)	122	43.4	21	17.2	11.5	24.9
	Blood fibrinogen increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood glucose increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood ketone body increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood lactate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Blood magnesium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood phosphorus increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Blood potassium increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood pressure increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood sodium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood thyroid stimulating hormone increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood triglycerides increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Blood urea increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Blood uric acid decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood uric acid increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Blood urine	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Blood urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	C-reactive protein increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Carbon dioxide decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Complement factor C1 decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Computerised tomogram thorax abnormal	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Crystal urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cystatin C increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Electrocardiogram QT prolonged	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Electrocardiogram ST-T change	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Fibrin D dimer increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Fibrin degradation products increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Free fatty acids increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gamma-glutamyltransferase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
	Glomerular filtration rate decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Glutamate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Haematocrit decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haemoglobin decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Heart rate increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Hepatic enzyme increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	International normalised ratio increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Intraocular pressure increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Laboratory test abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lipase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Liver function test increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymphocyte count decreased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Mean cell volume increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Myoglobin blood increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Neutrophil count decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
	Neutrophil count increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Occult blood positive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Platelet count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Platelet count increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

	Protein total decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Protein total increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Protein urine present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Prothrombin time prolonged	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Red blood cell count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Thrombin time prolonged	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Total bile acids increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Transaminases increased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Transferrin increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Troponin T increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Troponin increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary sediment present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urine ketone body present	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Urine leukocyte esterase positive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urobilinogen urine increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	2	1.6		0.5	5.8
	Weight decreased	USA	64	22.8	3	4.7		1.6	12.9
		Europe (EU)	95	33.8	2	2.1		0.6	7.4
		Asia (AS)	122	43.4	9	7.4		3.9	13.4
	Weight increased	USA	64	22.8	4	6.3		2.5	15.0
		Europe (EU)	95	33.8	2	2.1		0.6	7.4
		Asia (AS)	122	43.4	8	6.6		3.4	12.4
	White blood cell count decreased	USA	64	22.8	7	10.9		5.4	20.9
		Europe (EU)	95	33.8	6	6.3		2.9	13.1
		Asia (AS)	122	43.4	10	8.2		4.5	14.4
	White blood cells urine positive	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	3	2.5		0.8	7.0
Metabolism and nutrition disorders	-Total	USA	64	22.8	21	32.8		22.6	45.0
		Europe (EU)	95	33.8	35	36.8		27.8	46.9
		Asia (AS)	122	43.4	55	45.1		36.5	53.9
	Alkalosis	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	1	0.8		0.1	4.5
	Cell death	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	1	1.1		0.2	5.7
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
	Decreased appetite	USA	64	22.8	2	3.1		0.9	10.7
		Europe (EU)	95	33.8	6	6.3		2.9	13.1
		Asia (AS)	122	43.4	16	13.1		8.2	20.2
	Dehydration	USA	64	22.8	1	1.6		0.3	8.3
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
	Fluid retention	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	1	0.8		0.1	4.5
	Hypercalcaemia	USA	64	22.8	1	1.6		0.3	8.3
		Europe (EU)	95	33.8	1	1.1		0.2	5.7
		Asia (AS)	122	43.4	3	2.5		0.8	7.0
	Hypercholesterolaemia	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	1	1.1		0.2	5.7
		Asia (AS)	122	43.4	4	3.3		1.3	8.1
	Hyperglycaemia	USA	64	22.8	1	1.6		0.3	8.3
		Europe (EU)	95	33.8	4	4.2		1.6	10.3
		Asia (AS)	122	43.4	11	9.0		5.1	15.4
	Hyperkalaemia	USA	64	22.8	3	4.7		1.6	12.9
		Europe (EU)	95	33.8	3	3.2		1.1	8.9
		Asia (AS)	122	43.4	2	1.6		0.5	5.8

	Hyperlipidaemia	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	6	4.9		2.3	10.3
	Hypermagnesaemia	USA	64	22.8	1	1.6		0.3	8.3
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	2	1.6		0.5	5.8
	Hypernatraemia	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	2	1.6		0.5	5.8
	Hyperphosphataemia	USA	64	22.8	4	6.3		2.5	15.0
		Europe (EU)	95	33.8	11	11.6		6.6	19.6
		Asia (AS)	122	43.4	13	10.7		6.3	17.4
	Hypertriglyceridaemia	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	1	1.1		0.2	5.7
		Asia (AS)	122	43.4	4	3.3		1.3	8.1
	Hyperuricaemia	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	10	8.2		4.5	14.4
	Hypoalbuminaemia	USA	64	22.8	1	1.6		0.3	8.3
		Europe (EU)	95	33.8	1	1.1		0.2	5.7
		Asia (AS)	122	43.4	15	12.3		7.6	19.3
	Hypocalcaemia	USA	64	22.8	7	10.9		5.4	20.9
		Europe (EU)	95	33.8	3	3.2		1.1	8.9
		Asia (AS)	122	43.4	9	7.4		3.9	13.4
	Hypochloraemia	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	4	3.3		1.3	8.1
	Hypoglycaemia	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	1	0.8		0.1	4.5
	Hypokalaemia	USA	64	22.8	2	3.1		0.9	10.7
		Europe (EU)	95	33.8	11	11.6		6.6	19.6
		Asia (AS)	122	43.4	8	6.6		3.4	12.4
	Hypomagnesaemia	USA	64	22.8	2	3.1		0.9	10.7
		Europe (EU)	95	33.8	8	8.4		4.3	15.7
		Asia (AS)	122	43.4	10	8.2		4.5	14.4
	Hyponatraemia	USA	64	22.8	2	3.1		0.9	10.7
		Europe (EU)	95	33.8	3	3.2		1.1	8.9
		Asia (AS)	122	43.4	12	9.8		5.7	16.4
	Hypophosphataemia	USA	64	22.8	2	3.1		0.9	10.7
		Europe (EU)	95	33.8	4	4.2		1.6	10.3
		Asia (AS)	122	43.4	2	1.6		0.5	5.8
	Hypoproteinaemia	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	0	0.0		0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Increased appetite	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vitamin D deficiency	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Musculoskeletal and connective tissue disorders	-Total	USA	64	22.8	34	53.1	41.1	64.8
		Europe (EU)	95	33.8	27	28.4	20.3	38.2
		Asia (AS)	122	43.4	31	25.4	18.5	33.8
	Arthralgia	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Arthropathy	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Back pain	USA	64	22.8	10	15.6	8.7	26.4
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Bone pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Coccydynia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Costochondritis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Flank pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Groin pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypercreatinaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Intervertebral disc protrusion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Joint stiffness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Joint swelling	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle fatigue	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Muscle spasms	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Muscular weakness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Musculoskeletal chest pain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Musculoskeletal pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Musculoskeletal stiffness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Myalgia	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Myopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neck pain	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Osteopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pain in extremity	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Pain in jaw	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rotator cuff syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Spinal column stenosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tendon pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Anogenital warts	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Basal cell carcinoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bowen's disease	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal cell carcinoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Squamous cell carcinoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Squamous cell carcinoma of skin	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tumour pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Nervous system disorders	-Total	USA	64	22.8	37	57.8	45.6	69.1
		Europe (EU)	95	33.8	40	42.1	32.7	52.2
		Asia (AS)	122	43.4	44	36.1	28.1	44.9
	Ageusia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aphasia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ataxia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Brain oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Cerebellar haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Disturbance in attention	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dizziness	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Dizziness postural	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dysarthria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dysgeusia	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	19	20.0	13.2	29.1
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Dyskinesia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Headache	USA	64	22.8	12	18.8	11.1	30.0
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Hyperaesthesia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypersomnia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypoaesthesia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Hypotonia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lethargy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Memory impairment	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neuralgia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neuropathy peripheral	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Paraesthesia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Paralysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Parosmia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Peripheral sensory neuropathy	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Post herpetic neuralgia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Presyncope	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Psychomotor skills impaired	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sciatica	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Seizure	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sensory disturbance	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Slow speech	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Somnolence	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Syncope	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Tension headache	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tremor	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Visual field defect	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Product issues	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Device dislocation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Psychiatric disorders	-Total	USA	64	22.8	12	18.8	11.1	30.0
		Europe (EU)	95	33.8	13	13.7	8.2	22.0
		Asia (AS)	122	43.4	20	16.4	10.9	24.0
	Abnormal dreams	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Anxiety	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Bradyphrenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Confusional state	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Depression	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fear of falling	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Insomnia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Irritability	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Libido decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Mood altered	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Psychomotor retardation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Restlessness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Sleep disorder	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Renal and urinary disorders	-Total	USA	64	22.8	16	25.0	16.0	36.8
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Acute kidney injury	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Azotaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cystitis haemorrhagic	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dysuria	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Haematuria	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Micturition urgency	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nocturia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pollakiuria	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Proteinuria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Renal colic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal failure	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal impairment	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urinary incontinence	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary retention	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urinary tract pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urine flow decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Reproductive system and breast disorders	-Total	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Benign prostatic hyperplasia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Breast discharge	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Erectile dysfunction	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Galactorrhoea	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Genital ulceration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Metrorrhagia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pelvic discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pelvic fluid collection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Perineal pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Postmenopausal haemorrhage	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Uterine polyp	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vaginal haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vulvovaginal dryness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vulvovaginal erythema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Respiratory, thoracic and mediastinal disorders	-Total	USA	64	22.8	31	48.4	36.6	60.4
		Europe (EU)	95	33.8	40	42.1	32.7	52.2
		Asia (AS)	122	43.4	45	36.9	28.8	45.7
	Aspiration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Choking	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cough	USA	64	22.8	12	18.8	11.1	30.0
		Europe (EU)	95	33.8	18	18.9	12.3	28.0
		Asia (AS)	122	43.4	14	11.5	7.0	18.3
	Dry throat	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dysphonia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

	Dyspnoea	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Dyspnoea exertional	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Epistaxis	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Haemoptysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Hiccups	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Interstitial lung disease	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Laryngeal haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nasal congestion	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasal dryness	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nasal polyps	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oropharyngeal discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oropharyngeal pain	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Paranasal sinus discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pharyngeal disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pleural thickening	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pleuritic pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Pneumothorax	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Productive cough	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Pulmonary embolism	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pulmonary mass	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pulmonary pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiration abnormal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rhinitis allergic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rhinorrhoea	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinus congestion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sleep apnoea syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Throat irritation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Upper-airway cough syndrome	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Wheezing	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Skin and subcutaneous tissue disorders	-Total	USA	64	22.8	31	48.4	36.6	60.4
		Europe (EU)	95	33.8	23	24.2	16.7	33.7
		Asia (AS)	122	43.4	34	27.9	20.7	36.4
	Acne	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Alopecia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Chloasma	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dermal cyst	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dermatitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dermatitis acneiform	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Dermatitis bullous	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dry skin	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Ecchymosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Eczema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Erythema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hair growth abnormal	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hair texture abnormal	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hirsutism	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperhidrosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperkeratosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypertrichosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Madarosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nail discolouration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nail disorder	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Night sweats	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Onychalgia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Onycholysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Onychomadesis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Pain of skin	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Palmar-plantar erythrodysaesthesia syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Photosensitivity reaction	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Pruritus	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Pruritus generalised	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Purpura	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rash	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Rash erythematous	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rash macular	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rash maculo-papular	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rash papular	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Scab	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Scar pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Skin discolouration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin hyperpigmentation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Skin lesion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Swelling face	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Urticaria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Surgical and medical procedures	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Astringent therapy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Vascular disorders	-Total	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Circulatory collapse	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Embolism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Flushing	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haematoma	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hot flush	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypertension	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hypotension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Phlebitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Raynaud's phenomenon	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR1_SG.xls
26MAR2021 13:34

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	116	41.3	24	20.7	14.3	28.9
		1	77	27.4	15	19.5	12.2	29.7
		>= 2	88	31.3	20	22.7	15.2	32.5
	Anaemia	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	9	10.2	5.5	18.3
	Cytopenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Febrile neutropenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperfibrinogenaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Leukocytosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Leukopenia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lymph node pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymphadenopathy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymphopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Neutropenia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Neutrophilia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	0	0.0	0.0	4.2
	Pancytopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Thrombocytopenia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	5	5.7	2.5	12.6
	Thrombocytosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
Cardiac disorders	-Total	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	11	12.5	7.1	21.0
	Aortic valve calcification	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Atrial flutter	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bradycardia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bundle branch block right	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Extrasystoles	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Myocardial ischaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nodal arrhythmia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Palpitations	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pericardial effusion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sinus bradycardia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9

	Sinus tachycardia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Tachycardia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Ventricular extrasystoles	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ventricular pre-excitation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Congenital, familial and genetic disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hydrocele	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Ear and labyrinth disorders	-Total	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	8	9.1	4.7	16.9
	Ear congestion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ear discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ear pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Tinnitus	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vertigo	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
Endocrine disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hyperthyroidism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypothyroidism	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	2	2.3	0.6	7.9
Eye disorders	-Total	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	12	13.6	8.0	22.3
	Abnormal sensation in eye	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blepharitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Conjunctival haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Diplopia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dry eye	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Eye swelling	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eyelid oedema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Eyelid ptosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Periorbital oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	0	0.0	0.0	4.2
	Photophobia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Photopsia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vision blurred	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	5	5.7	2.5	12.6
	Visual acuity reduced	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

Gastrointestinal disorders	-Total	0	116	41.3	70	60.3	51.2	68.8
		1	77	27.4	49	63.6	52.5	73.5
		>= 2	88	31.3	54	61.4	50.9	70.9
	Abdominal discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Abdominal distension	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Abdominal pain	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	2	2.3	0.6	7.9
	Abdominal pain lower	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Abdominal pain upper	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Abdominal symptom	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Anal incontinence	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Aphthous ulcer	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ascites	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Constipation	0	116	41.3	44	37.9	29.6	47.0
		1	77	27.4	25	32.5	23.1	43.5
		>= 2	88	31.3	24	27.3	19.1	37.4
	Dental dysaesthesia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Diarrhoea	0	116	41.3	21	18.1	12.2	26.1
		1	77	27.4	16	20.8	13.2	31.1
		>= 2	88	31.3	16	18.2	11.5	27.5
	Dry mouth	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	20	22.7	15.2	32.5
	Dyspepsia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0

		>= 2	88	31.3	3	3.4	1.2	9.5
	Dysphagia	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	7	8.0	3.9	15.5
	Epigastric discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Eructation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Faeces soft	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Flatulence	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Frequent bowel movements	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Gastrointestinal haemorrhage	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrointestinal inflammation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrointestinal oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastrointestinal wall thickening	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrooesophageal reflux disease	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Gingival bleeding	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Gingival swelling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Glossitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Glossodynia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haematochezia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemorrhoids	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypoaesthesia oral	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Impaired gastric emptying	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Melaena	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Mouth ulceration	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Nausea	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	7	8.0	3.9	15.5
	Odynophagia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oesophageal irritation	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oesophagitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oral disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Oral dysaesthesia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oral mucosal erythema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1	0.2	6.2
	Oral pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Paraesthesia oral	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Regurgitation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sensitivity of teeth	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Stomatitis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Swollen tongue	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tongue coated	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tongue discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tongue ulceration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tooth discolouration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Toothache	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vomiting	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	4	4.5	1.8	11.1
General disorders and administration site conditions	-Total	0	116	41.3	61	52.6	43.6	61.4
		1	77	27.4	43	55.8	44.7	66.4
		>= 2	88	31.3	56	63.6	53.2	72.9
	Asthenia	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	4	4.5	1.8	11.1

	Axillary pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Catheter site pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Chest discomfort	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Chest pain	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Chills	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Disease progression	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Face oedema	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	6	6.8	3.2	14.1
	Fatigue	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	13	14.8	8.8	23.7
	Feeling abnormal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Feeling cold	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Feeling hot	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gait disturbance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	General physical health deterioration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Generalised oedema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Impaired healing	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	1	1.1	0.2	6.2
	Influenza like illness	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Injection site bruising	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Localised oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Malaise	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	6	6.8	3.2	14.1
	Mucosal dryness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Mucosal inflammation	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Non-cardiac chest pain	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oedema	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oedema peripheral	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	16	18.2	11.5	27.5
	Pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Peripheral swelling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pyrexia	0	116	41.3	14	12.1	7.3	19.2
		1	77	27.4	14	18.2	11.2	28.2
		>= 2	88	31.3	20	22.7	15.2	32.5
	Swelling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Temperature intolerance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9

	Xerosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Hepatobiliary disorders	-Total	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Cholecystitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hepatic function abnormal	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hepatic steatosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hepatocellular injury	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hyperbilirubinaemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Liver disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumobilia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Portal vein thrombosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Immune system disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Drug hypersensitivity	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Food allergy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypersensitivity	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Seasonal allergy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
Infections and infestations	-Total	0	116	41.3	22	19.0	12.9	27.0
		1	77	27.4	19	24.7	16.4	35.4
		>= 2	88	31.3	22	25.0	17.1	35.0
	Acute sinusitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bacterial disease carrier	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bronchitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	0	0.0	0.0	4.2
	Candida infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Chronic sinusitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cystitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ear infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Epstein-Barr virus infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Escherichia bacteraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eye infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Folliculitis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fungal infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastroenteritis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Genital candidiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Herpes simplex	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Herpes virus infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Herpes zoster	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Influenza	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lower respiratory tract infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymph node tuberculosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasal herpes	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasopharyngitis	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Oral candidiasis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Otitis externa	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Otitis media	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Paronychia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pharyngitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pyelonephritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Respiratory tract infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sinusitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Skin infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tinea infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tinea pedis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Tooth infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tracheitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tuberculosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Upper respiratory tract infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Urinary tract infection	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Viral infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

Injury, poisoning and procedural complications	-Total	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	8	9.1	4.7	16.9
	Contusion	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Epicondylitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Fall	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Incision site pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Joint dislocation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Laceration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ligament sprain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Limb injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Muscle strain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Procedural pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rib fracture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Scar	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Skin abrasion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1	0.2	6.2
	Skin injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tendon rupture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Wound	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Investigations	-Total	0	116	41.3	77	66.4	57.4	74.3
		1	77	27.4	52	67.5	56.5	76.9
		>= 2	88	31.3	57	64.8	54.4	73.9
	Alanine aminotransferase increased	0	116	41.3	32	27.6	20.3	36.3
		1	77	27.4	15	19.5	12.2	29.7
		>= 2	88	31.3	24	27.3	19.1	37.4
	Albumin urine present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Alpha hydroxybutyrate dehydrogenase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Aspartate aminotransferase increased	0	116	41.3	42	36.2	28.0	45.3
		1	77	27.4	28	36.4	26.5	47.5
		>= 2	88	31.3	28	31.8	23.0	42.1
	Bacterial test	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bilirubin conjugated increased	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood albumin decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood alkaline phosphatase	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood alkaline phosphatase decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood alkaline phosphatase increased	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	7	8.0	3.9	15.5

	Blood bilirubin increased	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	5	5.7	2.5	12.6
	Blood bilirubin unconjugated increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood calcium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood calcium increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood chloride increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood cholesterol increased	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Blood creatine increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood creatine phosphokinase MB increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood creatine phosphokinase increased	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	7	8.0	3.9	15.5
	Blood creatinine	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood creatinine increased	0	116	41.3	15	12.9	8.0	20.2
		1	77	27.4	16	20.8	13.2	31.1
		>= 2	88	31.3	20	22.7	15.2	32.5
	Blood fibrinogen increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood glucose increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Blood ketone body increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood lactate dehydrogenase increased	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	2	2.6	0.7	9.0

		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood magnesium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood phosphorus increased	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood potassium increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood pressure increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood sodium decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood thyroid stimulating hormone increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood triglycerides increased	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood urea increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood uric acid decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood uric acid increased	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Blood urine	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Blood urine present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	C-reactive protein increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Carbon dioxide decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Complement factor C1 decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Computerised tomogram thorax abnormal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Crystal urine present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cystatin C increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Electrocardiogram QT prolonged	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	6	6.8	3.2	14.1
	Electrocardiogram ST-T change	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Fibrin D dimer increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Fibrin degradation products increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Free fatty acids increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gamma-glutamyltransferase increased	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	6	6.8	3.2	14.1
	Glomerular filtration rate decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Glutamate dehydrogenase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haematocrit decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemoglobin decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Heart rate increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	4	4.5	1.8	11.1
	Hepatic enzyme increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	International normalised ratio increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intraocular pressure increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Laboratory test abnormal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lipase increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Liver function test increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymphocyte count decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	1	1.1	0.2	6.2
	Mean cell volume increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Myoglobin blood increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neutrophil count decreased	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	6	6.8	3.2	14.1
	Neutrophil count increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Occult blood positive	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Platelet count decreased	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Platelet count increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Protein total decreased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Protein total increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Protein urine present	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Prothrombin time prolonged	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Red blood cell count decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Thrombin time prolonged	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Total bile acids increased	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Transaminases increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Transferrin increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Troponin T increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Troponin increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Urinary sediment present	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urine ketone body present	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Urine leukocyte esterase positive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urobilinogen urine increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	2	2.3	0.6	7.9
	Weight decreased	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	6	6.8	3.2	14.1
	Weight increased	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	White blood cell count decreased	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	White blood cells urine positive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
Metabolism and nutrition disorders	-Total	0	116	41.3	47	40.5	32.0	49.6
		1	77	27.4	28	36.4	26.5	47.5
		>= 2	88	31.3	36	40.9	31.2	51.4
	Alkalosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cell death	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Decreased appetite	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	6	6.8	3.2	14.1
	Dehydration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fluid retention	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypercalcaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hypercholesterolaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperglycaemia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	7	8.0	3.9	15.5
	Hyperkalaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1

	Hyperlipidaemia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypermagnesaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypernatraemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperphosphataemia	0	116	41.3	14	12.1	7.3	19.2
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	8	9.1	4.7	16.9
	Hypertriglyceridaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hyperuricaemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hypoalbuminaemia	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	8	9.1	4.7	16.9
	Hypocalcaemia	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	8	9.1	4.7	16.9
	Hypochloraemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypoglycaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypokalaemia	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	7	8.0	3.9	15.5
	Hypomagnesaemia	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	10	11.4	6.3	19.7
	Hyponatraemia	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	5	5.7	2.5	12.6
	Hypophosphataemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hypoproteinaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1	0.2	6.2
	Increased appetite	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vitamin D deficiency	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Musculoskeletal and connective tissue disorders	-Total	0	116	41.3	38	32.8	24.9	41.7
		1	77	27.4	26	33.8	24.2	44.9
		>= 2	88	31.3	28	31.8	23.0	42.1
	Arthralgia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Arthropathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Back pain	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	9	10.2	5.5	18.3
	Bone pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Coccydynia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Costochondritis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Flank pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Groin pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypercreatinaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intervertebral disc protrusion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Joint stiffness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Joint swelling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Muscle fatigue	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Muscle spasms	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	9	10.2	5.5	18.3
	Muscular weakness	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Musculoskeletal chest pain	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Musculoskeletal pain	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	5	5.7	2.5	12.6
	Musculoskeletal stiffness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Myalgia	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	3	3.4	1.2	9.5
	Myopathy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neck pain	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Osteopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pain in extremity	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	8	9.1	4.7	16.9
	Pain in jaw	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rotator cuff syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Spinal column stenosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	0	0.0	0.0	4.2
	Tendon pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Anogenital warts	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Basal cell carcinoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bowen's disease	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal cell carcinoma	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Squamous cell carcinoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Squamous cell carcinoma of skin	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tumour pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Nervous system disorders	-Total	0	116	41.3	46	39.7	31.2	48.8
		1	77	27.4	36	46.8	36.0	57.8
		>= 2	88	31.3	39	44.3	34.4	54.7
	Ageusia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Aphasia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ataxia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Brain oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9

	Cerebellar haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Disturbance in attention	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dizziness	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	7	8.0	3.9	15.5
	Dizziness postural	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dysarthria	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dysgeusia	0	116	41.3	16	13.8	8.7	21.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	8	9.1	4.7	16.9
	Dyskinesia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Headache	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	7	8.0	3.9	15.5
	Hyperaesthesia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypersomnia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypoaesthesia	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	6	6.8	3.2	14.1
	Hypotonia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lethargy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Memory impairment	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Neuralgia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Neuropathy peripheral	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	3	3.4	1.2	9.5
	Paraesthesia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	2	2.3	0.6	7.9
	Paralysis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Parosmia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Peripheral sensory neuropathy	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Post herpetic neuralgia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Presyncope	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Psychomotor skills impaired	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sciatica	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Seizure	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sensory disturbance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Slow speech	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Somnolence	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Syncope	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Tension headache	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tremor	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Visual field defect	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Product issues	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Device dislocation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Psychiatric disorders	-Total	0	116	41.3	16	13.8	8.7	21.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	16	18.2	11.5	27.5
	Abnormal dreams	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Anxiety	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	2	2.3	0.6	7.9
	Bradyphrenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Confusional state	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Depression	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fear of falling	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Insomnia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	7	8.0	3.9	15.5
	Irritability	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Libido decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	2	2.3	0.6	7.9
	Mood altered	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Psychomotor retardation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Restlessness	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sleep disorder	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Renal and urinary disorders	-Total	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	9	10.2	5.5	18.3
	Acute kidney injury	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Azotaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cystitis haemorrhagic	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dysuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Haematuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Micturition urgency	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Nocturia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pollakiuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Proteinuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Renal colic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal failure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Renal impairment	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urinary incontinence	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urinary retention	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Urinary tract pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urine flow decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Reproductive system and breast disorders	-Total	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	6	6.8	3.2	14.1
	Benign prostatic hyperplasia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Breast discharge	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Erectile dysfunction	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Galactorrhoea	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Genital ulceration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Metrorrhagia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	0	0.0	0.0	4.2
	Pelvic discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pelvic fluid collection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Perineal pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Postmenopausal haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Uterine polyp	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vaginal haemorrhage	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vulvovaginal dryness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vulvovaginal erythema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Respiratory, thoracic and mediastinal disorders	-Total	0	116	41.3	43	37.1	28.8	46.1
		1	77	27.4	32	41.6	31.2	52.7
		>= 2	88	31.3	41	46.6	36.5	56.9
	Aspiration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Choking	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cough	0	116	41.3	14	12.1	7.3	19.2
		1	77	27.4	15	19.5	12.2	29.7
		>= 2	88	31.3	15	17.0	10.6	26.2
	Dry throat	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dysphonia	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9

	Dyspnoea	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	10	11.4	6.3	19.7
	Dyspnoea exertional	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	1	1.1	0.2	6.2
	Epistaxis	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	3	3.4	1.2	9.5
	Haemoptysis	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hiccups	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Interstitial lung disease	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Laryngeal haemorrhage	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasal congestion	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Nasal dryness	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasal polyps	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oropharyngeal discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oropharyngeal pain	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Paranasal sinus discomfort	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pharyngeal disorder	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pleural thickening	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1	0.2	6.2
	Pleuritic pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Pneumothorax	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Productive cough	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Pulmonary embolism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pulmonary mass	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pulmonary pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiration abnormal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinitis allergic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinorrhoea	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sinus congestion	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sleep apnoea syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Throat irritation	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Upper-airway cough syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9

	Wheezing	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Skin and subcutaneous tissue disorders	-Total	0	116	41.3	28	24.1	17.3	32.7
		1	77	27.4	30	39.0	28.8	50.1
		>= 2	88	31.3	30	34.1	25.0	44.5
	Acne	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Alopecia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	4	4.5	1.8	11.1
	Chloasma	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dermal cyst	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dermatitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dermatitis acneiform	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Dermatitis bullous	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dry skin	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Ecchymosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eczema	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Erythema	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hair growth abnormal	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Hair texture abnormal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	0	0.0	0.0	4.2
	Hirsutism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hyperhidrosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperkeratosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypertrichosis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	0	0.0	0.0	4.2
	Madarosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Nail discolouration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nail disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Night sweats	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Onychalgia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Onycholysis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Onychomadesis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pain of skin	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Palmar-plantar erythrodysaesthesia syndrome	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Photosensitivity reaction	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Pruritus	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pruritus generalised	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Purpura	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rash	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	9	10.2	5.5	18.3
	Rash erythematous	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Rash macular	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Rash maculo-papular	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rash papular	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Scab	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Scar pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Skin discolouration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Skin hyperpigmentation	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Skin lesion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Swelling face	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urticaria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1	0.2	6.2
Surgical and medical procedures	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Astringent therapy	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Vascular disorders	-Total	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	11	12.5	7.1	21.0
	Circulatory collapse	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Embolism	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Flushing	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haematoma	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hot flush	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypertension	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	6	6.8	3.2	14.1
	Hypotension	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Phlebitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Raynaud's phenomenon	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR1_SG.xls
26MAR2021 13:34

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Asian	128	45.6	23	18.0	12.3	25.5
		Non-Asian	135	48.0	33	24.4	18.0	32.3
		Unknown	18	6.4	3	16.7	5.8	39.2
	Anaemia	Asian	128	45.6	15	11.7	7.2	18.4
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	3	16.7	5.8	39.2
	Cytopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Febrile neutropenia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperfibrinogenaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Leukocytosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Leukopenia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymph node pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphadenopathy	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutropenia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutrophilia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancytopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytopenia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
Cardiac disorders	-Total	Asian	128	45.6	15	11.7	7.2	18.4
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Aortic valve calcification	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Atrial flutter	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bradycardia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bundle branch block right	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Extrasystoles	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Myocardial ischaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nodal arrhythmia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Palpitations	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pericardial effusion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinus bradycardia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8

	Sinus tachycardia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tachycardia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ventricular extrasystoles	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ventricular pre-excitation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Congenital, familial and genetic disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hydrocele	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Ear and labyrinth disorders	-Total	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	Ear congestion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ear discomfort	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ear pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinnitus	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vertigo	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	2	11.1	3.1	32.8
Endocrine disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyperthyroidism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypothyroidism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2

		Unknown	18	6.4	0	0.0	0.0	17.6
Eye disorders	-Total	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	20	14.8	9.8	21.8
		Unknown	18	6.4	3	16.7	5.8	39.2
	Abnormal sensation in eye	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blepharitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Conjunctival haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diplopia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dry eye	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Eye swelling	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eyelid oedema	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eyelid ptosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Periorbital oedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Photophobia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Photopsia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vision blurred	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Visual acuity reduced	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8

Gastrointestinal disorders	-Total	Asian	128	45.6	68	53.1	44.5	61.6
		Non-Asian	135	48.0	92	68.1	59.9	75.4
		Unknown	18	6.4	13	72.2	49.1	87.5
	Abdominal discomfort	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal distension	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Abdominal pain lower	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal pain upper	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal symptom	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anal incontinence	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aphthous ulcer	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ascites	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Constipation	Asian	128	45.6	43	33.6	26.0	42.1
		Non-Asian	135	48.0	44	32.6	25.3	40.9
		Unknown	18	6.4	6	33.3	16.3	56.3
	Dental dysaesthesia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diarrhoea	Asian	128	45.6	15	11.7	7.2	18.4
		Non-Asian	135	48.0	34	25.2	18.6	33.1
		Unknown	18	6.4	4	22.2	9.0	45.2
	Dry mouth	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	30	22.2	16.0	29.9
		Unknown	18	6.4	4	22.2	9.0	45.2
	Dyspepsia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2

		Unknown	18	6.4	3	16.7	5.8	39.2
	Dysphagia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	12	8.9	5.2	14.9
		Unknown	18	6.4	1	5.6	1.0	25.8
	Epigastric discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eructation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Faeces soft	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Flatulence	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Frequent bowel movements	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal haemorrhage	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal inflammation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal oedema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal wall thickening	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrooesophageal reflux disease	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Gingival bleeding	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gingival swelling	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Glossitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Glossodynia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematochezia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhoids	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoaesthesia oral	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Impaired gastric emptying	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Melaena	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mouth ulceration	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nausea	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	16	11.9	7.4	18.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Odynophagia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oesophageal irritation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oesophagitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral dysaesthesia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral mucosal erythema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Paraesthesia oral	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Regurgitation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sensitivity of teeth	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Stomatitis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Swollen tongue	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tongue coated	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tongue discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tongue ulceration	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tooth discolouration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Toothache	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vomiting	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	1	5.6	1.0	25.8
General disorders and administration site conditions	-Total	Asian	128	45.6	70	54.7	46.1	63.0
		Non-Asian	135	48.0	81	60.0	51.6	67.9
		Unknown	18	6.4	9	50.0	29.0	71.0
	Asthenia	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	2	11.1	3.1	32.8

	Axillary pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Catheter site pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chest discomfort	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chest pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chills	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Disease progression	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Face oedema	Asian	128	45.6	14	10.9	6.6	17.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fatigue	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	20	14.8	9.8	21.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Feeling abnormal	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Feeling cold	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Feeling hot	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gait disturbance	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	General physical health deterioration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Generalised oedema	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Impaired healing	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3

		Unknown	18	6.4	0	0.0	0.0	17.6
	Influenza like illness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Injection site bruising	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Localised oedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Malaise	Asian	128	45.6	17	13.3	8.5	20.2
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mucosal dryness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mucosal inflammation	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Non-cardiac chest pain	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Oedema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oedema peripheral	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	19	14.1	9.2	20.9
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Peripheral swelling	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pyrexia	Asian	128	45.6	22	17.2	11.6	24.7
		Non-Asian	135	48.0	23	17.0	11.6	24.3
		Unknown	18	6.4	3	16.7	5.8	39.2
	Swelling	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Temperature intolerance	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8

	Xerosis	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
Hepatobiliary disorders	-Total	Asian	128	45.6	4	3.1		1.2	7.8
		Non-Asian	135	48.0	8	5.9		3.0	11.3
		Unknown	18	6.4	3	16.7		5.8	39.2
	Cholecystitis	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Hepatic function abnormal	Asian	128	45.6	3	2.3		0.8	6.7
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6
	Hepatic steatosis	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Hepatocellular injury	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	3	16.7		5.8	39.2
	Hyperbilirubinaemia	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	3	2.2		0.8	6.3
		Unknown	18	6.4	0	0.0		0.0	17.6
	Liver disorder	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Pneumobilia	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Portal vein thrombosis	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
Immune system disorders	-Total	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	3	2.2		0.8	6.3
		Unknown	18	6.4	1	5.6		1.0	25.8
	Drug hypersensitivity	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	1	5.6		1.0	25.8
	Food allergy	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Hypersensitivity	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Seasonal allergy	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
Infections and infestations	-Total	Asian	128	45.6	22	17.2	11.6	24.7
		Non-Asian	135	48.0	38	28.1	21.2	36.3
		Unknown	18	6.4	3	16.7	5.8	39.2
	Acute sinusitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bacterial disease carrier	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bronchitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Candida infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chronic sinusitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ear infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Epstein-Barr virus infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Escherichia bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eye infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Folliculitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fungal infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastroenteritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Genital candidiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Herpes simplex	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Herpes virus infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Herpes zoster	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Influenza	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lower respiratory tract infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymph node tuberculosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal herpes	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasopharyngitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral candidiasis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Otitis externa	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Otitis media	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Paronychia	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pharyngitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyelonephritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory tract infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinusitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Skin infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinea infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinea pedis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tooth infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tracheitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tuberculosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Upper respiratory tract infection	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary tract infection	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Viral infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

Injury, poisoning and procedural complications	-Total	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	12	8.9	5.2	14.9
		Unknown	18	6.4	0	0.0	0.0	17.6
	Contusion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epicondylitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fall	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Incision site pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint dislocation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Laceration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ligament sprain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Limb injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle strain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Procedural pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rib fracture	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Scar	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin abrasion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tendon rupture	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wound	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Investigations	-Total	Asian	128	45.6	91	71.1	62.7	78.2
		Non-Asian	135	48.0	85	63.0	54.6	70.6
		Unknown	18	6.4	10	55.6	33.7	75.4
	Alanine aminotransferase increased	Asian	128	45.6	40	31.3	23.9	39.7
		Non-Asian	135	48.0	29	21.5	15.4	29.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Albumin urine present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alpha hydroxybutyrate dehydrogenase increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aspartate aminotransferase increased	Asian	128	45.6	55	43.0	34.7	51.6
		Non-Asian	135	48.0	40	29.6	22.6	37.8
		Unknown	18	6.4	3	16.7	5.8	39.2
	Bacterial test	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bilirubin conjugated increased	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood albumin decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood alkaline phosphatase	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood alkaline phosphatase decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood alkaline phosphatase increased	Asian	128	45.6	15	11.7	7.2	18.4
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	0	0.0	0.0	17.6

	Blood bilirubin increased	Asian	128	45.6	14	10.9	6.6	17.5
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Blood bilirubin unconjugated increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood calcium decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood calcium increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood chloride increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood cholesterol increased	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine phosphokinase MB increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine phosphokinase increased	Asian	128	45.6	14	10.9	6.6	17.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Blood creatinine	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatinine increased	Asian	128	45.6	21	16.4	11.0	23.8
		Non-Asian	135	48.0	28	20.7	14.8	28.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Blood fibrinogen increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood glucose increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood ketone body increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood lactate dehydrogenase increased	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood magnesium decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood phosphorus increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood potassium increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood pressure increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood sodium decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood thyroid stimulating hormone increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood triglycerides increased	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood urea increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood uric acid decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood uric acid increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood urine	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood urine present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	C-reactive protein increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Carbon dioxide decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Complement factor C1 decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Computerised tomogram thorax abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Crystal urine present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystatin C increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrocardiogram QT prolonged	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrocardiogram ST-T change	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fibrin D dimer increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fibrin degradation products increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Free fatty acids increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gamma-glutamyltransferase increased	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Glomerular filtration rate decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Glutamate dehydrogenase increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematocrit decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemoglobin decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Heart rate increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatic enzyme increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	International normalised ratio increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intraocular pressure increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Laboratory test abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Lipase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Liver function test increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphocyte count decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mean cell volume increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Myoglobin blood increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutrophil count decreased	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutrophil count increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Occult blood positive	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Platelet count decreased	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Platelet count increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8

	Protein total decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Protein total increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Protein urine present	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Prothrombin time prolonged	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Red blood cell count decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombin time prolonged	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Total bile acids increased	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Transaminases increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Transferrin increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Troponin T increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Troponin increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary sediment present	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urine ketone body present	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urine leukocyte esterase positive	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urobilinogen urine increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Weight decreased	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Weight increased	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	White blood cell count decreased	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	White blood cells urine positive	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Metabolism and nutrition disorders	-Total	Asian	128	45.6	58	45.3	37.0	53.9
		Non-Asian	135	48.0	48	35.6	28.0	43.9
		Unknown	18	6.4	5	27.8	12.5	50.9
	Alkalosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cell death	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Decreased appetite	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dehydration	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fluid retention	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercalcaemia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercholesterolaemia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperglycaemia	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperkalaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8

	Hyperlipidaemia	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypermagnesaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypernatraemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperphosphataemia	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	15	11.1	6.9	17.5
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypertriglyceridaemia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperuricaemia	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoalbuminaemia	Asian	128	45.6	15	11.7	7.2	18.4
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypocalcaemia	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypochloraemia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoglycaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypokalaemia	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	13	9.6	5.7	15.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypomagnesaemia	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyponatraemia	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypophosphataemia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypoproteinaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Increased appetite	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vitamin D deficiency	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Musculoskeletal and connective tissue disorders	-Total	Asian	128	45.6	34	26.6	19.7	34.8
		Non-Asian	135	48.0	51	37.8	30.0	46.2
		Unknown	18	6.4	7	38.9	20.3	61.4
	Arthralgia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Arthropathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Back pain	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	12	8.9	5.2	14.9
		Unknown	18	6.4	2	11.1	3.1	32.8
	Bone pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Coccydynia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Costochondritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Flank pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Groin pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercreatinaemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intervertebral disc protrusion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint stiffness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Joint swelling	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	1	5.6		1.0	25.8
	Muscle fatigue	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6
	Muscle spasms	Asian	128	45.6	5	3.9		1.7	8.8
		Non-Asian	135	48.0	12	8.9		5.2	14.9
		Unknown	18	6.4	3	16.7		5.8	39.2
	Muscular weakness	Asian	128	45.6	4	3.1		1.2	7.8
		Non-Asian	135	48.0	2	1.5		0.4	5.2
		Unknown	18	6.4	0	0.0		0.0	17.6
	Musculoskeletal chest pain	Asian	128	45.6	3	2.3		0.8	6.7
		Non-Asian	135	48.0	2	1.5		0.4	5.2
		Unknown	18	6.4	0	0.0		0.0	17.6
	Musculoskeletal pain	Asian	128	45.6	7	5.5		2.7	10.9
		Non-Asian	135	48.0	6	4.4		2.1	9.4
		Unknown	18	6.4	2	11.1		3.1	32.8
	Musculoskeletal stiffness	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Myalgia	Asian	128	45.6	7	5.5		2.7	10.9
		Non-Asian	135	48.0	12	8.9		5.2	14.9
		Unknown	18	6.4	2	11.1		3.1	32.8
	Myopathy	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	2	1.5		0.4	5.2
		Unknown	18	6.4	0	0.0		0.0	17.6
	Neck pain	Asian	128	45.6	4	3.1		1.2	7.8
		Non-Asian	135	48.0	4	3.0		1.2	7.4
		Unknown	18	6.4	1	5.6		1.0	25.8
	Osteopenia	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Pain in extremity	Asian	128	45.6	5	3.9		1.7	8.8
		Non-Asian	135	48.0	12	8.9		5.2	14.9
		Unknown	18	6.4	0	0.0		0.0	17.6
	Pain in jaw	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	1	5.6		1.0	25.8
	Rotator cuff syndrome	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Spinal column stenosis	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	0	0.0		0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Tendon pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anogenital warts	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Basal cell carcinoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bowen's disease	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal cell carcinoma	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Squamous cell carcinoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Squamous cell carcinoma of skin	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tumour pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Nervous system disorders	-Total	Asian	128	45.6	48	37.5	29.6	46.1
		Non-Asian	135	48.0	65	48.1	39.9	56.5
		Unknown	18	6.4	8	44.4	24.6	66.3
	Ageusia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aphasia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ataxia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Brain oedema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

	Cerebellar haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Disturbance in attention	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dizziness	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	2	11.1	3.1	32.8
	Dizziness postural	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysarthria	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysgeusia	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	26	19.3	13.5	26.7
		Unknown	18	6.4	3	16.7	5.8	39.2
	Dyskinesia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Headache	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	Hyperaesthesia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Hypersomnia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoaesthesia	Asian	128	45.6	15	11.7	7.2	18.4
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypotonia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lethargy	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Memory impairment	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neuralgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Neuropathy peripheral	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Paraesthesia	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	Paralysis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Parosmia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Peripheral sensory neuropathy	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Post herpetic neuralgia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Presyncope	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Psychomotor skills impaired	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sciatica	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Seizure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sensory disturbance	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Slow speech	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Somnolence	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Syncope	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Tension headache	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tremor	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Visual field defect	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Product issues	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Device dislocation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Psychiatric disorders	-Total	Asian	128	45.6	23	18.0	12.3	25.5
		Non-Asian	135	48.0	19	14.1	9.2	20.9
		Unknown	18	6.4	3	16.7	5.8	39.2
	Abnormal dreams	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Anxiety	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bradyphrenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Confusional state	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Depression	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Fear of falling	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Insomnia	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Irritability	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Libido decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Mood altered	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Psychomotor retardation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Restlessness	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sleep disorder	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Renal and urinary disorders	-Total	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	22	16.3	11.0	23.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Acute kidney injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Azotaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis haemorrhagic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysuria	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematuria	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Micturition urgency	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nocturia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pollakiuria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Proteinuria	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Renal colic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal impairment	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary incontinence	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary retention	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary tract pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urine flow decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Reproductive system and breast disorders	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	0	0.0	0.0	17.6
	Benign prostatic hyperplasia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Breast discharge	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Erectile dysfunction	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Galactorrhoea	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Genital ulceration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Metrorrhagia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Pelvic discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pelvic fluid collection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Perineal pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Postmenopausal haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Uterine polyp	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vaginal haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vulvovaginal dryness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vulvovaginal erythema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Respiratory, thoracic and mediastinal disorders	-Total	Asian	128	45.6	47	36.7	28.9	45.3
		Non-Asian	135	48.0	61	45.2	37.0	53.6
		Unknown	18	6.4	8	44.4	24.6	66.3
	Aspiration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Choking	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cough	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	24	17.8	12.2	25.1
		Unknown	18	6.4	4	22.2	9.0	45.2
	Dry throat	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysphonia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8

	Dyspnoea	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dyspnoea exertional	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epistaxis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Haemoptysis	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hiccups	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Interstitial lung disease	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Laryngeal haemorrhage	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal congestion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal dryness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasal polyps	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oropharyngeal discomfort	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oropharyngeal pain	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Paranasal sinus discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pharyngeal disorder	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleural thickening	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2

		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleuritic pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonitis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumothorax	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Productive cough	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary embolism	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary mass	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiration abnormal	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinitis allergic	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinorrhoea	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinus congestion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sleep apnoea syndrome	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Throat irritation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Upper-airway cough syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8

	Wheezing	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Skin and subcutaneous tissue disorders	-Total	Asian	128	45.6	37	28.9	21.8	37.3
		Non-Asian	135	48.0	44	32.6	25.3	40.9
		Unknown	18	6.4	7	38.9	20.3	61.4
	Acne	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alopecia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chloasma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermal cyst	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermatitis acneiform	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dermatitis bullous	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dry skin	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Ecchymosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eczema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Erythema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hair growth abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hair texture abnormal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Hirsutism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hyperhidrosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperkeratosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypertrichosis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Madarosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nail discolouration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nail disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Night sweats	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Onychalgia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Onycholysis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Onychomadesis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain of skin	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Palmar-plantar erythrodysaesthesia syndrome	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Photosensitivity reaction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Pruritus	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pruritus generalised	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Purpura	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rash	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Rash erythematous	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rash macular	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Rash maculo-papular	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rash papular	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Scab	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Scar pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin discolouration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin hyperpigmentation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin lesion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Swelling face	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Urticaria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2

		Unknown	18	6.4	0	0.0	0.0	17.6
Surgical and medical procedures	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Astringent therapy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
Vascular disorders	-Total	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	12	8.9	5.2	14.9
		Unknown	18	6.4	3	16.7	5.8	39.2
	Circulatory collapse	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Embolism	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Flushing	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hot flush	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypertension	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypotension	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Phlebitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Raynaud's phenomenon	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR1_SG.xls
26MAR2021 13:34

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 1
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Female	152	54.1	40	26.3	20.0	33.8
		Male	129	45.9	19	14.7	9.6	21.9
	Anaemia	Female	152	54.1	17	11.2	7.1	17.2
		Male	129	45.9	11	8.5	4.8	14.6
	Cytopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Febrile neutropenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hyperfibrinogenaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Leukocytosis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Leukopenia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	5	3.9	1.7	8.8
	Lymph node pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lymphadenopathy	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Lymphopenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neutropenia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Neutrophilia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pancytopenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Thrombocytopenia	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	3	2.3	0.8	6.6
	Thrombocytosis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	0	0.0	0.0	2.9
Cardiac disorders	-Total	Female	152	54.1	13	8.6	5.1	14.1

		Male	129	45.9	12	9.3	5.4	15.6
	Aortic valve calcification	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Atrial flutter	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Bradycardia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Bundle branch block right	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Extrasystoles	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Myocardial ischaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Nodal arrhythmia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Palpitations	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Pericardial effusion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Sinus bradycardia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Sinus tachycardia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Tachycardia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ventricular extrasystoles	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Ventricular pre-excitation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Congenital, familial and genetic disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hydrocele	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Ear and labyrinth disorders	-Total	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	9	7.0	3.7	12.7
	Ear congestion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Ear discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Ear pain	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Tinnitus	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Vertigo	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	3	2.3	0.8	6.6
Endocrine disorders	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperthyroidism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypothyroidism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Eye disorders	-Total	Female	152	54.1	25	16.4	11.4	23.2
		Male	129	45.9	7	5.4	2.7	10.8
	Abnormal sensation in eye	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blepharitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Conjunctival haemorrhage	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Diplopia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dry eye	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Eye swelling	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Eyelid oedema	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	0	0.0	0.0	2.9
	Eyelid ptosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Periorbital oedema	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Photophobia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Photopsia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vision blurred	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	1	0.8	0.1	4.3

	Visual acuity reduced	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Gastrointestinal disorders	-Total	Female	152	54.1	101	66.4	58.6	73.5
		Male	129	45.9	72	55.8	47.2	64.1
	Abdominal discomfort	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Abdominal distension	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Abdominal pain	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	3	2.3	0.8	6.6
	Abdominal pain lower	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Abdominal pain upper	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	7	5.4	2.7	10.8
	Abdominal symptom	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Anal incontinence	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Aphthous ulcer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ascites	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Constipation	Female	152	54.1	58	38.2	30.8	46.1
		Male	129	45.9	35	27.1	20.2	35.4
	Dental dysaesthesia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Diarrhoea	Female	152	54.1	33	21.7	15.9	28.9
		Male	129	45.9	20	15.5	10.3	22.7
	Dry mouth	Female	152	54.1	25	16.4	11.4	23.2
		Male	129	45.9	18	14.0	9.0	21.0
	Dyspepsia	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Dysphagia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	4	3.1	1.2	7.7
	Epigastric discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Eructation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Faeces soft	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
	Flatulence	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Frequent bowel movements	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastritis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrointestinal haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrointestinal inflammation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrointestinal oedema	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gastrointestinal wall thickening	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrooesophageal reflux disease	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Gingival bleeding	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Gingival swelling	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Glossitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Glossodynia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haematochezia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haemorrhoids	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hypoaesthesia oral	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Impaired gastric emptying	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Melaena	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Mouth ulceration	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Nausea	Female	152	54.1	22	14.5	9.8	20.9
		Male	129	45.9	5	3.9	1.7	8.8

	Odynophagia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	0	0.0	0.0	2.9
	Oesophageal irritation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oesophagitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Oral disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Oral dysaesthesia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oral mucosal erythema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Oral pain	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Paraesthesia oral	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Regurgitation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Sensitivity of teeth	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Stomatitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Swollen tongue	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tongue coated	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tongue discomfort	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tongue ulceration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tooth discolouration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Toothache	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Vomiting	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	6	4.7	2.1	9.8
General disorders and administration site conditions	-Total	Female	152	54.1	98	64.5	56.6	71.6
		Male	129	45.9	62	48.1	39.6	56.6

	Asthenia	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	4	3.1	1.2	7.7
	Axillary pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Catheter site pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Chest discomfort	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	2	1.6	0.4	5.5
	Chest pain	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Chills	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Disease progression	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Face oedema	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	4	3.1	1.2	7.7
	Fatigue	Female	152	54.1	17	11.2	7.1	17.2
		Male	129	45.9	16	12.4	7.8	19.2
	Feeling abnormal	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Feeling cold	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Feeling hot	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gait disturbance	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	General physical health deterioration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Generalised oedema	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Impaired healing	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Influenza like illness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Injection site bruising	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Localised oedema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Malaise	Female	152	54.1	9	5.9	3.1	10.9

		Male	129	45.9	8	6.2	3.2	11.8
	Mucosal dryness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Mucosal inflammation	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	2	1.6	0.4	5.5
	Non-cardiac chest pain	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	4	3.1	1.2	7.7
	Oedema	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Oedema peripheral	Female	152	54.1	18	11.8	7.6	17.9
		Male	129	45.9	15	11.6	7.2	18.3
	Pain	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Peripheral swelling	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pyrexia	Female	152	54.1	32	21.1	15.3	28.2
		Male	129	45.9	16	12.4	7.8	19.2
	Swelling	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Temperature intolerance	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Xerosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Hepatobiliary disorders	-Total	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	11	8.5	4.8	14.6
	Cholecystitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Hepatic function abnormal	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hepatic steatosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hepatocellular injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Hyperbilirubinaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Liver disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumobilia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Portal vein thrombosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Immune system disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Drug hypersensitivity	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Food allergy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypersensitivity	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Seasonal allergy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Infections and infestations	-Total	Female	152	54.1	40	26.3	20.0	33.8
		Male	129	45.9	23	17.8	12.2	25.3
	Acute sinusitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bacterial disease carrier	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Bronchitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	4	3.1	1.2	7.7
	Candida infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Chronic sinusitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cystitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ear infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Epstein-Barr virus infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Escherichia bacteraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Eye infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Folliculitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Fungal infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9

	Gastroenteritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Genital candidiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Herpes simplex	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Herpes virus infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Herpes zoster	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Influenza	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Lower respiratory tract infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lymph node tuberculosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nasal herpes	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nasopharyngitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	Oral candidiasis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Otitis externa	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Otitis media	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Paronychia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Pharyngitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Pyelonephritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Respiratory tract infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rhinitis	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Sinusitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Skin infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tinea infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tinea pedis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Tooth infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tracheitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tuberculosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Upper respiratory tract infection	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Urinary tract infection	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	1	0.8	0.1	4.3
	Viral infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Injury, poisoning and procedural complications	-Total	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	10	7.8	4.3	13.7
	Contusion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	4	3.1	1.2	7.7
	Epicondylitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Fall	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Incision site pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Joint dislocation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Laceration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ligament sprain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5

	Limb injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Muscle strain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Procedural pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Rib fracture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Scar	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin abrasion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tendon rupture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Wound	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Investigations	-Total	Female	152	54.1	105	69.1	61.3	75.9
		Male	129	45.9	81	62.8	54.2	70.6
	Alanine aminotransferase increased	Female	152	54.1	44	28.9	22.3	36.6
		Male	129	45.9	27	20.9	14.8	28.7
	Albumin urine present	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Alpha hydroxybutyrate dehydrogenase increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Aspartate aminotransferase increased	Female	152	54.1	56	36.8	29.6	44.7
		Male	129	45.9	42	32.6	25.1	41.0
	Bacterial test	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bilirubin conjugated increased	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	3	2.3	0.8	6.6
	Blood albumin decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood alkaline phosphatase	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood alkaline phosphatase decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Blood alkaline phosphatase increased	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	7	5.4	2.7	10.8
	Blood bilirubin increased	Female	152	54.1	15	9.9	6.1	15.6
		Male	129	45.9	4	3.1	1.2	7.7
	Blood bilirubin unconjugated increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Blood calcium decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Blood calcium increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood chloride increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood cholesterol increased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	Blood creatine increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Blood creatine phosphokinase MB increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Blood creatine phosphokinase increased	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	3	2.3	0.8	6.6
	Blood creatinine	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood creatinine increased	Female	152	54.1	24	15.8	10.8	22.4
		Male	129	45.9	27	20.9	14.8	28.7
	Blood fibrinogen increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood glucose increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Blood ketone body increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood lactate dehydrogenase increased	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	2	1.6	0.4	5.5
	Blood magnesium decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood phosphorus increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Blood potassium increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood pressure increased	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
	Blood sodium decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood thyroid stimulating hormone increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood triglycerides increased	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Blood urea increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Blood uric acid decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood uric acid increased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Blood urine	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Blood urine present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	C-reactive protein increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Carbon dioxide decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Complement factor C1 decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Computerised tomogram thorax abnormal	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Crystal urine present	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cystatin C increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Electrocardiogram QT prolonged	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	2	1.6	0.4	5.5
	Electrocardiogram ST-T change	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Fibrin D dimer increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Fibrin degradation products increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Free fatty acids increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Gamma-glutamyltransferase increased	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	2	1.6	0.4	5.5
	Glomerular filtration rate decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Glutamate dehydrogenase increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Haematocrit decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haemoglobin decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Heart rate increased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hepatic enzyme increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	International normalised ratio increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Intraocular pressure increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Laboratory test abnormal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lipase increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Liver function test increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lymphocyte count decreased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Mean cell volume increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Myoglobin blood increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Neutrophil count decreased	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	8	6.2	3.2	11.8
	Neutrophil count increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Occult blood positive	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Platelet count decreased	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	4	3.1	1.2	7.7

	Platelet count increased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Protein total decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Protein total increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Protein urine present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Prothrombin time prolonged	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Red blood cell count decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombin time prolonged	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Total bile acids increased	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Transaminases increased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	Transferrin increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Troponin T increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Troponin increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urinary sediment present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urine ketone body present	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Urine leukocyte esterase positive	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urobilinogen urine increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Weight decreased	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	3	2.3	0.8	6.6
	Weight increased	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	5	3.9	1.7	8.8
	White blood cell count decreased	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	10	7.8	4.3	13.7
	White blood cells urine positive	Female	152	54.1	2	1.3	0.4	4.7

		Male	129	45.9	1	0.8	0.1	4.3
Metabolism and nutrition disorders	-Total	Female	152	54.1	67	44.1	36.4	52.0
		Male	129	45.9	44	34.1	26.5	42.6
	Alkalosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cell death	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Decreased appetite	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	10	7.8	4.3	13.7
	Dehydration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Fluid retention	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypercalcaemia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hypercholesterolaemia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Hyperglycaemia	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	6	4.7	2.1	9.8
	Hyperkalaemia	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Hyperlipidaemia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Hypermagnesaemia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hypernatraemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Hyperphosphataemia	Female	152	54.1	20	13.2	8.7	19.5
		Male	129	45.9	8	6.2	3.2	11.8
	Hypertriglyceridaemia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperuricaemia	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	4	3.1	1.2	7.7
	Hypoalbuminaemia	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	3	2.3	0.8	6.6
	Hypocalcaemia	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	6	4.7	2.1	9.8
	Hypochloraemia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3

	Hypoglycaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypokalaemia	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	7	5.4	2.7	10.8
	Hypomagnesaemia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	8	6.2	3.2	11.8
	Hyponatraemia	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	7	5.4	2.7	10.8
	Hypophosphataemia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	5	3.9	1.7	8.8
	Hypoproteinaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Increased appetite	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Vitamin D deficiency	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Musculoskeletal and connective tissue disorders	-Total	Female	152	54.1	54	35.5	28.4	43.4
		Male	129	45.9	38	29.5	22.3	37.8
	Arthralgia	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	4	3.1	1.2	7.7
	Arthropathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Back pain	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	9	7.0	3.7	12.7
	Bone pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Coccydynia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Costochondritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Flank pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Groin pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypercreatinaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Intervertebral disc protrusion	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9

	Joint stiffness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Joint swelling	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Muscle fatigue	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Muscle spasms	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	7	5.4	2.7	10.8
	Muscular weakness	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	1	0.8	0.1	4.3
	Musculoskeletal chest pain	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Musculoskeletal pain	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	5	3.9	1.7	8.8
	Musculoskeletal stiffness	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Myalgia	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	7	5.4	2.7	10.8
	Myopathy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Neck pain	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	3	2.3	0.8	6.6
	Osteopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pain in extremity	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	4	3.1	1.2	7.7
	Pain in jaw	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Rotator cuff syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Spinal column stenosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tendon pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	Anogenital warts	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Basal cell carcinoma	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
	Bowen's disease	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Renal cell carcinoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Squamous cell carcinoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Squamous cell carcinoma of skin	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tumour pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Nervous system disorders	-Total	Female	152	54.1	64	42.1	34.5	50.1
		Male	129	45.9	57	44.2	35.9	52.8
	Ageusia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Aphasia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Ataxia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Brain oedema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cerebellar haemorrhage	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Disturbance in attention	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Dizziness	Female	152	54.1	15	9.9	6.1	15.6
		Male	129	45.9	13	10.1	6.0	16.5
	Dizziness postural	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dysarthria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dysgeusia	Female	152	54.1	21	13.8	9.2	20.2
		Male	129	45.9	16	12.4	7.8	19.2
	Dyskinesia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Headache	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	13	10.1	6.0	16.5
	Hyperaesthesia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9

	Hypersomnia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypoaesthesia	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	6	4.7	2.1	9.8
	Hypotonia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lethargy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Memory impairment	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neuralgia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neuropathy peripheral	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	5	3.9	1.7	8.8
	Paraesthesia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	5	3.9	1.7	8.8
	Paralysis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Parosmia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Peripheral sensory neuropathy	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	3	2.3	0.8	6.6
	Post herpetic neuralgia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Presyncope	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Psychomotor skills impaired	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sciatica	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Seizure	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sensory disturbance	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Slow speech	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Somnolence	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Syncope	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tension headache	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tremor	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Visual field defect	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
Product issues	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Device dislocation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Psychiatric disorders	-Total	Female	152	54.1	24	15.8	10.8	22.4
		Male	129	45.9	21	16.3	10.9	23.6
	Abnormal dreams	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Anxiety	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	2	1.6	0.4	5.5
	Bradyphrenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Confusional state	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	4	3.1	1.2	7.7
	Depression	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Fear of falling	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Insomnia	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	7	5.4	2.7	10.8
	Irritability	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Libido decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Mood altered	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Psychomotor retardation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Restlessness	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Sleep disorder	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	1	0.8	0.1	4.3
Renal and urinary disorders	-Total	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	17	13.2	8.4	20.1
	Acute kidney injury	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Azotaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cystitis haemorrhagic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dysuria	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Haematuria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Micturition urgency	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Nocturia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Pollakiuria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Proteinuria	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Renal colic	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Renal disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Renal failure	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Renal impairment	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urinary incontinence	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Urinary retention	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Urinary tract pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urine flow decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Reproductive system and breast disorders	-Total	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	8	6.2	3.2	11.8

	Benign prostatic hyperplasia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Breast discharge	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Erectile dysfunction	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	5	3.9	1.7	8.8
	Galactorrhoea	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Genital ulceration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Metrorrhagia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pelvic discomfort	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pelvic fluid collection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Perineal pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Postmenopausal haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Uterine polyp	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vaginal haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vulvovaginal dryness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vulvovaginal erythema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Respiratory, thoracic and mediastinal disorders	-Total	Female	152	54.1	65	42.8	35.2	50.7
		Male	129	45.9	51	39.5	31.5	48.2
	Aspiration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Choking	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cough	Female	152	54.1	21	13.8	9.2	20.2
		Male	129	45.9	23	17.8	12.2	25.3
	Dry throat	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3

	Dysphonia	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	5	3.9	1.7	8.8
	Dyspnoea	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	10	7.8	4.3	13.7
	Dyspnoea exertional	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Epistaxis	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	4	3.1	1.2	7.7
	Haemoptysis	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	4	3.1	1.2	7.7
	Hiccups	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Interstitial lung disease	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Laryngeal haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nasal congestion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Nasal dryness	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Nasal polyps	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oropharyngeal discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oropharyngeal pain	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	5	3.9	1.7	8.8
	Paranasal sinus discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pharyngeal disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pleural thickening	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pleuritic pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonitis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Pneumothorax	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Productive cough	Female	152	54.1	5	3.3	1.4	7.5

		Male	129	45.9	5	3.9	1.7	8.8
	Pulmonary embolism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pulmonary mass	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pulmonary pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Respiration abnormal	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rhinitis allergic	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Rhinorrhoea	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Sinus congestion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sleep apnoea syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Throat irritation	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Upper-airway cough syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Wheezing	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
Skin and subcutaneous tissue disorders	-Total	Female	152	54.1	55	36.2	29.0	44.1
		Male	129	45.9	33	25.6	18.8	33.7
	Acne	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Alopecia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	2	1.6	0.4	5.5
	Chloasma	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dermal cyst	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dermatitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dermatitis acneiform	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Dermatitis bullous	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Dry skin	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	6	4.7	2.1	9.8
	Ecchymosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Eczema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Erythema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hair growth abnormal	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hair texture abnormal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hirsutism	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Hyperhidrosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperkeratosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypertrichosis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Madarosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nail discolouration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nail disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Night sweats	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Onychalgia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Onycholysis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Onychomadesis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Pain of skin	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Palmar-plantar erythrodysaesthesia syndrome	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	0	0.0	0.0	2.9

	Photosensitivity reaction	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pruritus	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Pruritus generalised	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Purpura	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rash	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	7	5.4	2.7	10.8
	Rash erythematous	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Rash macular	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Rash maculo-papular	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Rash papular	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Scab	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Scar pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin discolouration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin hyperpigmentation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Skin lesion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Swelling face	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urticaria	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Surgical and medical procedures	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Astringent therapy	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
Vascular disorders	-Total	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	10	7.8	4.3	13.7
	Circulatory collapse	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Embolism	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Flushing	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Haematoma	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hot flush	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hypertension	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	7	5.4	2.7	10.8
	Hypotension	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	0	0.0	0.0	2.9
	Phlebitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Raynaud's phenomenon	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR1_SG.xls
26MAR2021 13:34

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	58	20.6	16.3	25.8
Sex	Female	152	54.1	30	19.7	14.2	26.8
	Male	129	45.9	28	21.7	15.5	29.6
Age	< 65	176	62.6	46	26.1	20.2	33.1
	>= 65	105	37.4	12	11.4	6.7	18.9
ECOG performance status	0	84	29.9	23	27.4	19.0	37.7
	1	190	67.6	34	17.9	13.1	24.0
	2	6	2.1	0	0.0	0.0	39.0
	Missing	1	0.4	1	100.0	20.7	100.0
Geographic region	USA	64	22.8	8	12.5	6.5	22.8
	Europe (EU)	95	33.8	28	29.5	21.2	39.3
	Asia (AS)	122	43.4	22	18.0	12.2	25.8
Race/ethnicity	Asian	128	45.6	22	17.2	11.6	24.7
	Non-Asian	135	48.0	33	24.4	18.0	32.3
	Unknown	18	6.4	3	16.7	5.8	39.2
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	28	24.1	17.3	32.7
	1	77	27.4	15	19.5	12.2	29.7
	>= 2	88	31.3	15	17.0	10.6	26.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AEGR2_SG.xls
26MAR2021 10:17

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	57	20.3	16.0	25.4
Sex	Female	152	54.1	30	19.7	14.2	26.8
	Male	129	45.9	27	20.9	14.8	28.7
Age	< 65	176	62.6	45	25.6	19.7	32.5
	>= 65	105	37.4	12	11.4	6.7	18.9
ECOG performance status	0	84	29.9	23	27.4	19.0	37.7
	1	190	67.6	33	17.4	12.6	23.4
	2	6	2.1	0	0.0	0.0	39.0
	Missing	1	0.4	1	100.0	20.7	100.0
Geographic region	USA	64	22.8	8	12.5	6.5	22.8
	Europe (EU)	95	33.8	28	29.5	21.2	39.3
	Asia (AS)	122	43.4	21	17.2	11.5	24.9
Race/ethnicity	Asian	128	45.6	21	16.4	11.0	23.8
	Non-Asian	135	48.0	33	24.4	18.0	32.3
	Unknown	18	6.4	3	16.7	5.8	39.2
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	27	23.3	16.5	31.7
	1	77	27.4	15	19.5	12.2	29.7
	>= 2	88	31.3	15	17.0	10.6	26.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw_B63_06NOV2020_SE_TO_AEGR2_SG.xls
26MAR2021 9:55

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	n/a	281	100.0	84	29.9	24.8	35.5
	Anaemia	n/a	281	100.0	55	19.6	15.4	24.6
	Aplastic anaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Bone marrow oedema	n/a	281	100.0	1	0.4	0.1	2.0
	Leukopenia	n/a	281	100.0	14	5.0	3.0	8.2
	Lymphopenia	n/a	281	100.0	5	1.8	0.8	4.1
	Neutropenia	n/a	281	100.0	24	8.5	5.8	12.4
	Pancytopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombocytopenia	n/a	281	100.0	4	1.4	0.6	3.6
	Thrombocytosis	n/a	281	100.0	1	0.4	0.1	2.0
Cardiac disorders	-Total	n/a	281	100.0	10	3.6	1.9	6.4
	Acute coronary syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Angina pectoris	n/a	281	100.0	1	0.4	0.1	2.0
	Atrial fibrillation	n/a	281	100.0	1	0.4	0.1	2.0
	Cardiac failure	n/a	281	100.0	2	0.7	0.2	2.6
	Nodal arrhythmia	n/a	281	100.0	1	0.4	0.1	2.0
	Pericardial effusion	n/a	281	100.0	1	0.4	0.1	2.0
	Tachycardia	n/a	281	100.0	3	1.1	0.4	3.1
Congenital, familial and genetic disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Gilbert's syndrome	n/a	281	100.0	1	0.4	0.1	2.0
Ear and labyrinth disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Ear pain	n/a	281	100.0	1	0.4	0.1	2.0
	Tinnitus	n/a	281	100.0	1	0.4	0.1	2.0
	Vertigo	n/a	281	100.0	1	0.4	0.1	2.0
Eye disorders	-Total	n/a	281	100.0	6	2.1	1.0	4.6

	Chalazion	n/a	281	100.0	1	0.4	0.1	2.0
	Conjunctival cyst	n/a	281	100.0	1	0.4	0.1	2.0
	Keratitis	n/a	281	100.0	1	0.4	0.1	2.0
	Ocular discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Periorbital oedema	n/a	281	100.0	1	0.4	0.1	2.0
	Photopsia	n/a	281	100.0	1	0.4	0.1	2.0
	Ulcerative keratitis	n/a	281	100.0	1	0.4	0.1	2.0
	Vision blurred	n/a	281	100.0	2	0.7	0.2	2.6
Gastrointestinal disorders	-Total	n/a	281	100.0	76	27.0	22.2	32.5
	Abdominal discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Abdominal distension	n/a	281	100.0	1	0.4	0.1	2.0
	Abdominal pain	n/a	281	100.0	8	2.8	1.4	5.5
	Abdominal pain upper	n/a	281	100.0	5	1.8	0.8	4.1
	Ascites	n/a	281	100.0	1	0.4	0.1	2.0
	Constipation	n/a	281	100.0	23	8.2	5.5	12.0
	Diarrhoea	n/a	281	100.0	12	4.3	2.5	7.3
	Dry mouth	n/a	281	100.0	4	1.4	0.6	3.6
	Dyspepsia	n/a	281	100.0	2	0.7	0.2	2.6
	Dysphagia	n/a	281	100.0	4	1.4	0.6	3.6
	Enteritis	n/a	281	100.0	1	0.4	0.1	2.0
	Gastric ulcer	n/a	281	100.0	1	0.4	0.1	2.0
	Gastritis	n/a	281	100.0	1	0.4	0.1	2.0
	Gastritis erosive	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrooesophageal reflux disease	n/a	281	100.0	5	1.8	0.8	4.1
	Haematochezia	n/a	281	100.0	1	0.4	0.1	2.0
	Haemorrhoids	n/a	281	100.0	4	1.4	0.6	3.6
	Irritable bowel syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Mouth ulceration	n/a	281	100.0	1	0.4	0.1	2.0
	Nausea	n/a	281	100.0	15	5.3	3.3	8.6
	Odynophagia	n/a	281	100.0	1	0.4	0.1	2.0

	Oesophagitis	n/a	281	100.0	1	0.4	0.1	2.0
	Oral pain	n/a	281	100.0	2	0.7	0.2	2.6
	Pancreatitis	n/a	281	100.0	1	0.4	0.1	2.0
	Rectal prolapse	n/a	281	100.0	1	0.4	0.1	2.0
	Stomatitis	n/a	281	100.0	4	1.4	0.6	3.6
	Toothache	n/a	281	100.0	3	1.1	0.4	3.1
	Vomiting	n/a	281	100.0	11	3.9	2.2	6.9
General disorders and administration site conditions	-Total	n/a	281	100.0	87	31.0	25.8	36.6
	Asthenia	n/a	281	100.0	19	6.8	4.4	10.3
	Chest pain	n/a	281	100.0	2	0.7	0.2	2.6
	Face oedema	n/a	281	100.0	4	1.4	0.6	3.6
	Facial pain	n/a	281	100.0	1	0.4	0.1	2.0
	Fatigue	n/a	281	100.0	28	10.0	7.0	14.0
	Gait disturbance	n/a	281	100.0	3	1.1	0.4	3.1
	General physical health deterioration	n/a	281	100.0	1	0.4	0.1	2.0
	Influenza like illness	n/a	281	100.0	2	0.7	0.2	2.6
	Malaise	n/a	281	100.0	3	1.1	0.4	3.1
	Mucosal inflammation	n/a	281	100.0	9	3.2	1.7	6.0
	Non-cardiac chest pain	n/a	281	100.0	1	0.4	0.1	2.0
	Oedema peripheral	n/a	281	100.0	9	3.2	1.7	6.0
	Pain	n/a	281	100.0	2	0.7	0.2	2.6
	Peripheral swelling	n/a	281	100.0	2	0.7	0.2	2.6
	Pyrexia	n/a	281	100.0	23	8.2	5.5	12.0
Hepatobiliary disorders	-Total	n/a	281	100.0	4	1.4	0.6	3.6
	Hyperbilirubinaemia	n/a	281	100.0	3	1.1	0.4	3.1
	Portal vein thrombosis	n/a	281	100.0	1	0.4	0.1	2.0
Immune system disorders	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Contrast media allergy	n/a	281	100.0	1	0.4	0.1	2.0
	Seasonal allergy	n/a	281	100.0	1	0.4	0.1	2.0
Infections and infestations	-Total	n/a	281	100.0	84	29.9	24.8	35.5
	Abdominal abscess	n/a	281	100.0	1	0.4	0.1	2.0

	Arthritis infective	n/a	281	100.0	1	0.4	0.1	2.0
	Atypical pneumonia	n/a	281	100.0	1	0.4	0.1	2.0
	Bacteraemia	n/a	281	100.0	2	0.7	0.2	2.6
	Bacterial vaginosis	n/a	281	100.0	1	0.4	0.1	2.0
	Bronchitis	n/a	281	100.0	2	0.7	0.2	2.6
	Cellulitis	n/a	281	100.0	1	0.4	0.1	2.0
	Chronic sinusitis	n/a	281	100.0	2	0.7	0.2	2.6
	Conjunctivitis	n/a	281	100.0	1	0.4	0.1	2.0
	Corona virus infection	n/a	281	100.0	1	0.4	0.1	2.0
	Cystitis	n/a	281	100.0	1	0.4	0.1	2.0
	Cystitis escherichia	n/a	281	100.0	1	0.4	0.1	2.0
	Epididymitis	n/a	281	100.0	1	0.4	0.1	2.0
	Escherichia infection	n/a	281	100.0	1	0.4	0.1	2.0
	Escherichia urinary tract infection	n/a	281	100.0	1	0.4	0.1	2.0
	Febrile infection	n/a	281	100.0	1	0.4	0.1	2.0
	Fungal infection	n/a	281	100.0	1	0.4	0.1	2.0
	Gastroenteritis	n/a	281	100.0	1	0.4	0.1	2.0
	Genital herpes	n/a	281	100.0	2	0.7	0.2	2.6
	Gingivitis	n/a	281	100.0	1	0.4	0.1	2.0
	Herpes virus infection	n/a	281	100.0	2	0.7	0.2	2.6
	Herpes zoster	n/a	281	100.0	9	3.2	1.7	6.0
	Influenza	n/a	281	100.0	1	0.4	0.1	2.0
	Lung infection	n/a	281	100.0	1	0.4	0.1	2.0
	Lyme disease	n/a	281	100.0	1	0.4	0.1	2.0
	Lymph node tuberculosis	n/a	281	100.0	1	0.4	0.1	2.0
	Nasopharyngitis	n/a	281	100.0	2	0.7	0.2	2.6
	Oral candidiasis	n/a	281	100.0	6	2.1	1.0	4.6
	Oral fungal infection	n/a	281	100.0	2	0.7	0.2	2.6
	Oropharyngeal candidiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Otitis externa	n/a	281	100.0	1	0.4	0.1	2.0

	Paronychia	n/a	281	100.0	1	0.4	0.1	2.0
	Pharyngitis	n/a	281	100.0	2	0.7	0.2	2.6
	Pneumonia	n/a	281	100.0	13	4.6	2.7	7.8
	Pneumonia influenzal	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia pseudomonal	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia streptococcal	n/a	281	100.0	1	0.4	0.1	2.0
	Pyuria	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory tract infection	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory tract infection bacterial	n/a	281	100.0	1	0.4	0.1	2.0
	Rhinitis	n/a	281	100.0	4	1.4	0.6	3.6
	Sepsis	n/a	281	100.0	1	0.4	0.1	2.0
	Sinusitis	n/a	281	100.0	3	1.1	0.4	3.1
	Skin infection	n/a	281	100.0	1	0.4	0.1	2.0
	Staphylococcal infection	n/a	281	100.0	1	0.4	0.1	2.0
	Systemic infection	n/a	281	100.0	1	0.4	0.1	2.0
	Tinea cruris	n/a	281	100.0	1	0.4	0.1	2.0
	Tonsillitis	n/a	281	100.0	1	0.4	0.1	2.0
	Upper respiratory tract infection	n/a	281	100.0	8	2.8	1.4	5.5
	Urethritis	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary tract infection	n/a	281	100.0	23	8.2	5.5	12.0
	Varicella	n/a	281	100.0	1	0.4	0.1	2.0
	Varicella zoster virus infection	n/a	281	100.0	1	0.4	0.1	2.0
	Viral hepatitis carrier	n/a	281	100.0	1	0.4	0.1	2.0
	Viral infection	n/a	281	100.0	1	0.4	0.1	2.0
	Vulvovaginal candidiasis	n/a	281	100.0	1	0.4	0.1	2.0
Injury, poisoning and procedural complications	-Total	n/a	281	100.0	12	4.3	2.5	7.3
	Fall	n/a	281	100.0	5	1.8	0.8	4.1
	Joint dislocation	n/a	281	100.0	1	0.4	0.1	2.0
	Muscle rupture	n/a	281	100.0	1	0.4	0.1	2.0
	Procedural pneumothorax	n/a	281	100.0	1	0.4	0.1	2.0
	Thermal burn	n/a	281	100.0	1	0.4	0.1	2.0

	Wound	n/a	281	100.0	1	0.4	0.1	2.0
	Wound complication	n/a	281	100.0	1	0.4	0.1	2.0
	Wrist fracture	n/a	281	100.0	1	0.4	0.1	2.0
Investigations	-Total	n/a	281	100.0	113	40.2	34.6	46.0
	Alanine aminotransferase increased	n/a	281	100.0	12	4.3	2.5	7.3
	Amylase increased	n/a	281	100.0	2	0.7	0.2	2.6
	Aspartate aminotransferase increased	n/a	281	100.0	13	4.6	2.7	7.8
	Bilirubin conjugated increased	n/a	281	100.0	6	2.1	1.0	4.6
	Blood alkaline phosphatase increased	n/a	281	100.0	8	2.8	1.4	5.5
	Blood bilirubin increased	n/a	281	100.0	6	2.1	1.0	4.6
	Blood bilirubin unconjugated increased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood cholesterol increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood creatine phosphokinase increased	n/a	281	100.0	18	6.4	4.1	9.9
	Blood creatinine increased	n/a	281	100.0	9	3.2	1.7	6.0
	Blood glucose increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood iron decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood potassium decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood pressure increased	n/a	281	100.0	2	0.7	0.2	2.6
	C-reactive protein increased	n/a	281	100.0	1	0.4	0.1	2.0
	Electrocardiogram QT prolonged	n/a	281	100.0	1	0.4	0.1	2.0
	Gamma-glutamyltransferase increased	n/a	281	100.0	4	1.4	0.6	3.6
	Granulocyte count decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Haemoglobin decreased	n/a	281	100.0	3	1.1	0.4	3.1
	Liver function test increased	n/a	281	100.0	1	0.4	0.1	2.0
	Lymphocyte count decreased	n/a	281	100.0	7	2.5	1.2	5.1
	Lymphocyte count increased	n/a	281	100.0	1	0.4	0.1	2.0
	Neutrophil count decreased	n/a	281	100.0	29	10.3	7.3	14.4
	Neutrophil percentage increased	n/a	281	100.0	1	0.4	0.1	2.0
	Platelet count decreased	n/a	281	100.0	8	2.8	1.4	5.5
	Platelet count increased	n/a	281	100.0	1	0.4	0.1	2.0

	Procalcitonin increased	n/a	281	100.0	1	0.4	0.1	2.0
	Serum amyloid A protein increased	n/a	281	100.0	1	0.4	0.1	2.0
	Total bile acids increased	n/a	281	100.0	1	0.4	0.1	2.0
	Weight decreased	n/a	281	100.0	4	1.4	0.6	3.6
	Weight increased	n/a	281	100.0	10	3.6	1.9	6.4
	White blood cell count decreased	n/a	281	100.0	34	12.1	8.8	16.4
Metabolism and nutrition disorders	-Total	n/a	281	100.0	56	19.9	15.7	25.0
	Abnormal loss of weight	n/a	281	100.0	1	0.4	0.1	2.0
	Decreased appetite	n/a	281	100.0	12	4.3	2.5	7.3
	Dehydration	n/a	281	100.0	3	1.1	0.4	3.1
	Electrolyte imbalance	n/a	281	100.0	1	0.4	0.1	2.0
	Hypercalcaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperglycaemia	n/a	281	100.0	2	0.7	0.2	2.6
	Hyperkalaemia	n/a	281	100.0	4	1.4	0.6	3.6
	Hyperlipidaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperphosphataemia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypertriglyceridaemia	n/a	281	100.0	2	0.7	0.2	2.6
	Hypoalbuminaemia	n/a	281	100.0	20	7.1	4.7	10.7
	Hypocalcaemia	n/a	281	100.0	12	4.3	2.5	7.3
	Hypochloraemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypokalaemia	n/a	281	100.0	8	2.8	1.4	5.5
	Hypomagnesaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyponatraemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypophosphataemia	n/a	281	100.0	7	2.5	1.2	5.1
	Hypoproteinaemia	n/a	281	100.0	5	1.8	0.8	4.1
Musculoskeletal and connective tissue disorders	-Total	n/a	281	100.0	40	14.2	10.6	18.8
	Arthralgia	n/a	281	100.0	1	0.4	0.1	2.0
	Back pain	n/a	281	100.0	13	4.6	2.7	7.8
	Bone pain	n/a	281	100.0	2	0.7	0.2	2.6
	Bursitis	n/a	281	100.0	1	0.4	0.1	2.0
	Flank pain	n/a	281	100.0	1	0.4	0.1	2.0

	Joint range of motion decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Muscle spasms	n/a	281	100.0	2	0.7	0.2	2.6
	Muscular weakness	n/a	281	100.0	2	0.7	0.2	2.6
	Musculoskeletal chest pain	n/a	281	100.0	1	0.4	0.1	2.0
	Musculoskeletal pain	n/a	281	100.0	9	3.2	1.7	6.0
	Myalgia	n/a	281	100.0	2	0.7	0.2	2.6
	Neck pain	n/a	281	100.0	5	1.8	0.8	4.1
	Pain in extremity	n/a	281	100.0	8	2.8	1.4	5.5
	Spinal column stenosis	n/a	281	100.0	1	0.4	0.1	2.0
	Spinal osteoarthritis	n/a	281	100.0	1	0.4	0.1	2.0
	Tendon disorder	n/a	281	100.0	1	0.4	0.1	2.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Metastases to central nervous system	n/a	281	100.0	1	0.4	0.1	2.0
Nervous system disorders	-Total	n/a	281	100.0	37	13.2	9.7	17.6
	Balance disorder	n/a	281	100.0	2	0.7	0.2	2.6
	Dizziness	n/a	281	100.0	9	3.2	1.7	6.0
	Dysgeusia	n/a	281	100.0	5	1.8	0.8	4.1
	Headache	n/a	281	100.0	7	2.5	1.2	5.1
	Hemiplegia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypoaesthesia	n/a	281	100.0	2	0.7	0.2	2.6
	Lumbar radiculopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Memory impairment	n/a	281	100.0	1	0.4	0.1	2.0
	Migraine with aura	n/a	281	100.0	1	0.4	0.1	2.0
	Neuropathy peripheral	n/a	281	100.0	1	0.4	0.1	2.0
	Paraesthesia	n/a	281	100.0	3	1.1	0.4	3.1
	Polyneuropathy chronic	n/a	281	100.0	1	0.4	0.1	2.0
	Presyncope	n/a	281	100.0	2	0.7	0.2	2.6
	Restless legs syndrome	n/a	281	100.0	2	0.7	0.2	2.6
	Seizure	n/a	281	100.0	4	1.4	0.6	3.6
	Somnolence	n/a	281	100.0	1	0.4	0.1	2.0

	Syncope	n/a	281	100.0	3	1.1	0.4	3.1
Psychiatric disorders	-Total	n/a	281	100.0	12	4.3	2.5	7.3
	Abnormal behaviour	n/a	281	100.0	1	0.4	0.1	2.0
	Adjustment disorder with mixed anxiety and depressed mood	n/a	281	100.0	1	0.4	0.1	2.0
	Anxiety	n/a	281	100.0	4	1.4	0.6	3.6
	Delirium	n/a	281	100.0	3	1.1	0.4	3.1
	Depressed mood	n/a	281	100.0	1	0.4	0.1	2.0
	Insomnia	n/a	281	100.0	2	0.7	0.2	2.6
	Mental status changes	n/a	281	100.0	1	0.4	0.1	2.0
Renal and urinary disorders	-Total	n/a	281	100.0	12	4.3	2.5	7.3
	Acute kidney injury	n/a	281	100.0	3	1.1	0.4	3.1
	Azotaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Dysuria	n/a	281	100.0	5	1.8	0.8	4.1
	Haematuria	n/a	281	100.0	1	0.4	0.1	2.0
	Haemorrhage urinary tract	n/a	281	100.0	1	0.4	0.1	2.0
	Nephritis	n/a	281	100.0	1	0.4	0.1	2.0
	Proteinuria	n/a	281	100.0	1	0.4	0.1	2.0
	Strangury	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary retention	n/a	281	100.0	1	0.4	0.1	2.0
Reproductive system and breast disorders	-Total	n/a	281	100.0	6	2.1	1.0	4.6
	Benign prostatic hyperplasia	n/a	281	100.0	1	0.4	0.1	2.0
	Erectile dysfunction	n/a	281	100.0	4	1.4	0.6	3.6
	Prostatitis	n/a	281	100.0	1	0.4	0.1	2.0
Respiratory, thoracic and mediastinal disorders	-Total	n/a	281	100.0	69	24.6	19.9	29.9
	Bronchospasm	n/a	281	100.0	1	0.4	0.1	2.0
	Cough	n/a	281	100.0	20	7.1	4.7	10.7
	Dyspnoea	n/a	281	100.0	17	6.0	3.8	9.5
	Dyspnoea exertional	n/a	281	100.0	5	1.8	0.8	4.1
	Epistaxis	n/a	281	100.0	3	1.1	0.4	3.1
	Haemoptysis	n/a	281	100.0	1	0.4	0.1	2.0
	Hypoxia	n/a	281	100.0	1	0.4	0.1	2.0

	Interstitial lung disease	n/a	281	100.0	3	1.1	0.4	3.1
	Oropharyngeal pain	n/a	281	100.0	5	1.8	0.8	4.1
	Pleural effusion	n/a	281	100.0	7	2.5	1.2	5.1
	Pneumonitis	n/a	281	100.0	19	6.8	4.4	10.3
	Productive cough	n/a	281	100.0	4	1.4	0.6	3.6
	Pulmonary embolism	n/a	281	100.0	2	0.7	0.2	2.6
	Rhinalgia	n/a	281	100.0	1	0.4	0.1	2.0
	Rhinorrhoea	n/a	281	100.0	1	0.4	0.1	2.0
	Sputum discoloured	n/a	281	100.0	1	0.4	0.1	2.0
	Vocal cord leukoplakia	n/a	281	100.0	1	0.4	0.1	2.0
Skin and subcutaneous tissue disorders	-Total	n/a	281	100.0	17	6.0	3.8	9.5
	Decubitus ulcer	n/a	281	100.0	1	0.4	0.1	2.0
	Dermatitis allergic	n/a	281	100.0	1	0.4	0.1	2.0
	Dermatitis bullous	n/a	281	100.0	1	0.4	0.1	2.0
	Eczema	n/a	281	100.0	1	0.4	0.1	2.0
	Erythema	n/a	281	100.0	2	0.7	0.2	2.6
	Hirsutism	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperhidrosis	n/a	281	100.0	1	0.4	0.1	2.0
	Pruritus	n/a	281	100.0	3	1.1	0.4	3.1
	Rash	n/a	281	100.0	4	1.4	0.6	3.6
	Rash macular	n/a	281	100.0	1	0.4	0.1	2.0
	Scab	n/a	281	100.0	1	0.4	0.1	2.0
	Swelling face	n/a	281	100.0	3	1.1	0.4	3.1
Surgical and medical procedures	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Astringent therapy	n/a	281	100.0	1	0.4	0.1	2.0
	Therapy cessation	n/a	281	100.0	1	0.4	0.1	2.0
Vascular disorders	-Total	n/a	281	100.0	52	18.5	14.4	23.5
	Aortic dissection	n/a	281	100.0	1	0.4	0.1	2.0
	Deep vein thrombosis	n/a	281	100.0	2	0.7	0.2	2.6
	Embolism	n/a	281	100.0	2	0.7	0.2	2.6

	Haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Hypertension	n/a	281	100.0	41	14.6	10.9	19.2
	Lymphoedema	n/a	281	100.0	2	0.7	0.2	2.6
	Orthostatic hypotension	n/a	281	100.0	2	0.7	0.2	2.6
	Pallor	n/a	281	100.0	1	0.4	0.1	2.0
	Superior vena cava syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombophlebitis superficial	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombosis	n/a	281	100.0	2	0.7	0.2	2.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR2_SG.xls
26MAR2021 14:16

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	< 65	176	62.6	46	26.1	20.2	33.1
		>= 65	105	37.4	38	36.2	27.6	45.7
	Anaemia	< 65	176	62.6	27	15.3	10.8	21.4
		>= 65	105	37.4	28	26.7	19.1	35.8
	Aplastic anaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bone marrow oedema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Leukopenia	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Lymphopenia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Neutropenia	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	9	8.6	4.6	15.5
	Pancytopenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Thrombocytopenia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Thrombocytosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Cardiac disorders	-Total	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	5	4.8	2.1	10.7
	Acute coronary syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Angina pectoris	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Atrial fibrillation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cardiac failure	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nodal arrhythmia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pericardial effusion	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Tachycardia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
Congenital, familial and genetic disorders	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gilbert's syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Ear and labyrinth disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ear pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tinnitus	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vertigo	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Eye disorders	-Total	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Chalazion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Conjunctival cyst	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Keratitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ocular discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Periorbital oedema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Photopsia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ulcerative keratitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vision blurred	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
Gastrointestinal disorders	-Total	< 65	176	62.6	43	24.4	18.7	31.3
		>= 65	105	37.4	33	31.4	23.3	40.8
	Abdominal discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Abdominal distension	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Abdominal pain	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1

	Abdominal pain upper	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Ascites	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Constipation	< 65	176	62.6	14	8.0	4.8	12.9
		>= 65	105	37.4	9	8.6	4.6	15.5
	Diarrhoea	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	7	6.7	3.3	13.1
	Dry mouth	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Dyspepsia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dysphagia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Enteritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastric ulcer	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastritis erosive	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastrooesophageal reflux disease	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Haematochezia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haemorrhoids	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Irritable bowel syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Mouth ulceration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nausea	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	6	5.7	2.6	11.9
	Odynophagia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oesophagitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oral pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Pancreatitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rectal prolapse	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Stomatitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Toothache	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vomiting	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	2	1.9	0.5	6.7
General disorders and administration site conditions	-Total	< 65	176	62.6	45	25.6	19.7	32.5
		>= 65	105	37.4	42	40.0	31.1	49.6
	Asthenia	< 65	176	62.6	11	6.3	3.5	10.8
		>= 65	105	37.4	8	7.6	3.9	14.3
	Chest pain	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Face oedema	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Facial pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fatigue	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	15	14.3	8.9	22.2
	Gait disturbance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	General physical health deterioration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Influenza like illness	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Malaise	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Mucosal inflammation	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	5	4.8	2.1	10.7
	Non-cardiac chest pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oedema peripheral	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	5	4.8	2.1	10.7
	Pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Peripheral swelling	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pyrexia	< 65	176	62.6	12	6.8	3.9	11.5

		>= 65	105	37.4	11	10.5	6.0	17.8
Hepatobiliary disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hyperbilirubinaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Portal vein thrombosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Immune system disorders	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Contrast media allergy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Seasonal allergy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Infections and infestations	-Total	< 65	176	62.6	59	33.5	27.0	40.8
		>= 65	105	37.4	25	23.8	16.7	32.8
	Abdominal abscess	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Arthritis infective	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Atypical pneumonia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bacteraemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bacterial vaginosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bronchitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cellulitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Chronic sinusitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Conjunctivitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Corona virus infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cystitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cystitis escherichia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Epididymitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Escherichia infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Escherichia urinary tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Febrile infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Fungal infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastroenteritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Genital herpes	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gingivitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Herpes virus infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Herpes zoster	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Influenza	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lung infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lyme disease	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymph node tuberculosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nasopharyngitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oral candidiasis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	5	4.8	2.1	10.7
	Oral fungal infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oropharyngeal candidiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Otitis externa	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Paronychia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pharyngitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

	Pneumonia	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	5	4.8	2.1	10.7
	Pneumonia influenzal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia pseudomonal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia streptococcal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyuria	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Respiratory tract infection bacterial	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rhinitis	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sepsis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sinusitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Skin infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Staphylococcal infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Systemic infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tinea cruris	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tonsillitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Upper respiratory tract infection	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
	Urethritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary tract infection	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	7	6.7	3.3	13.1
	Varicella	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Varicella zoster virus infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Viral hepatitis carrier	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Viral infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vulvovaginal candidiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Injury, poisoning and procedural complications	-Total	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	6	5.7	2.6	11.9
	Fall	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Joint dislocation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscle rupture	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Procedural pneumothorax	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Thermal burn	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Wound	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Wound complication	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Wrist fracture	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Investigations	-Total	< 65	176	62.6	81	46.0	38.8	53.4
		>= 65	105	37.4	32	30.5	22.5	39.8
	Alanine aminotransferase increased	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	3	2.9	1.0	8.1
	Amylase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Aspartate aminotransferase increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	7	6.7	3.3	13.1
	Bilirubin conjugated increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood alkaline phosphatase increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood bilirubin increased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Blood bilirubin unconjugated increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood cholesterol increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Blood creatine phosphokinase increased	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	3	2.9	1.0	8.1
	Blood creatinine increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	3	2.9	1.0	8.1
	Blood glucose increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood iron decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood potassium decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood pressure increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	C-reactive protein increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Electrocardiogram QT prolonged	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gamma-glutamyltransferase increased	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Granulocyte count decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haemoglobin decreased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Liver function test increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymphocyte count decreased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Lymphocyte count increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neutrophil count decreased	< 65	176	62.6	22	12.5	8.4	18.2
		>= 65	105	37.4	7	6.7	3.3	13.1
	Neutrophil percentage increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Platelet count decreased	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Platelet count increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Procalcitonin increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Serum amyloid A protein increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Total bile acids increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Weight decreased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Weight increased	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	White blood cell count decreased	< 65	176	62.6	27	15.3	10.8	21.4
		>= 65	105	37.4	7	6.7	3.3	13.1
Metabolism and nutrition disorders	-Total	< 65	176	62.6	35	19.9	14.7	26.4
		>= 65	105	37.4	21	20.0	13.5	28.6
	Abnormal loss of weight	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Decreased appetite	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	7	6.7	3.3	13.1
	Dehydration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Electrolyte imbalance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypercalcaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperglycaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperkalaemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hyperlipidaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperphosphataemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypertriglyceridaemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypoalbuminaemia	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	4	3.8	1.5	9.4
	Hypocalcaemia	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Hypochloraemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypokalaemia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hypomagnesaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyponatraemia	< 65	176	62.6	0	0.0	0.0	2.1

		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypophosphataemia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypoproteinaemia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
Musculoskeletal and connective tissue disorders	-Total	< 65	176	62.6	24	13.6	9.3	19.5
		>= 65	105	37.4	16	15.2	9.6	23.3
	Arthralgia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Back pain	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	5	4.8	2.1	10.7
	Bone pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bursitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Flank pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Joint range of motion decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscle spasms	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscular weakness	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Musculoskeletal chest pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Musculoskeletal pain	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Myalgia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neck pain	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pain in extremity	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
	Spinal column stenosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Spinal osteoarthritis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tendon disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Metastases to central nervous system	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Nervous system disorders	-Total	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	20	19.0	12.7	27.6
	Balance disorder	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dizziness	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	5	4.8	2.1	10.7
	Dysgeusia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Headache	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hemiplegia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypoaesthesia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Lumbar radiculopathy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Memory impairment	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Migraine with aura	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neuropathy peripheral	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Paraesthesia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Polyneuropathy chronic	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Presyncope	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Restless legs syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Seizure	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Somnolence	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Syncope	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
Psychiatric disorders	-Total	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	4	3.8	1.5	9.4

	Abnormal behaviour	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Adjustment disorder with mixed anxiety and depressed mood	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Anxiety	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Delirium	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Depressed mood	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Insomnia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mental status changes	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Renal and urinary disorders	-Total	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Acute kidney injury	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Azotaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dysuria	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haematuria	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haemorrhage urinary tract	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nephritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Proteinuria	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Strangury	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary retention	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Reproductive system and breast disorders	-Total	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Benign prostatic hyperplasia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Erectile dysfunction	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Prostatitis	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
Respiratory, thoracic and mediastinal disorders	-Total	< 65	176	62.6	42	23.9	18.2	30.7
		>= 65	105	37.4	27	25.7	18.3	34.8
	Bronchospasm	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cough	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	7	6.7	3.3	13.1
	Dyspnoea	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	7	6.7	3.3	13.1
	Dyspnoea exertional	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Epistaxis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haemoptysis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypoxia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Interstitial lung disease	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oropharyngeal pain	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pleural effusion	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pneumonitis	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	7	6.7	3.3	13.1
	Productive cough	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Pulmonary embolism	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rhinalgia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rhinorrhoea	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sputum discoloured	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Vocal cord leukoplakia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Skin and subcutaneous tissue disorders	-Total	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	12	11.4	6.7	18.9
	Decubitus ulcer	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Dermatitis allergic	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dermatitis bullous	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eczema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Erythema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hirsutism	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperhidrosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pruritus	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Rash	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Rash macular	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Scab	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Swelling face	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
Surgical and medical procedures	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Astringent therapy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Therapy cessation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Vascular disorders	-Total	< 65	176	62.6	33	18.8	13.7	25.2
		>= 65	105	37.4	19	18.1	11.9	26.5
	Aortic dissection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Deep vein thrombosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Embolism	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haematoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypertension	< 65	176	62.6	26	14.8	10.3	20.8
		>= 65	105	37.4	15	14.3	8.9	22.2

	Lymphoedema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Orthostatic hypotension	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pallor	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Superior vena cava syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Thrombophlebitis superficial	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Thrombosis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR2_SG.xls
26MAR2021 14:16

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	84	29.9	29	34.5	25.2	45.2
		1	190	67.6	53	27.9	22.0	34.7
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia	0	84	29.9	19	22.6	15.0	32.6
		1	190	67.6	35	18.4	13.6	24.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Aplastic anaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bone marrow oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Leukopenia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphopenia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutropenia	0	84	29.9	12	14.3	8.4	23.3
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

Cardiac disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute coronary syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Angina pectoris	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Atrial fibrillation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cardiac failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nodal arrhythmia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pericardial effusion	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tachycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
Congenital, familial and genetic disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gilbert's syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Ear and labyrinth disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Tinnitus	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vertigo	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Eye disorders	-Total	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Chalazion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Conjunctival cyst	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Keratitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ocular discomfort	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Periorbital oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Photopsia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ulcerative keratitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vision blurred	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Gastrointestinal disorders	-Total	0	84	29.9	28	33.3	24.2	43.9
		1	190	67.6	46	24.2	18.7	30.8
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal discomfort	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal distension	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain upper	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ascites	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Constipation	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diarrhoea	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry mouth	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspepsia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysphagia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Enteritis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastric ulcer	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastritis erosive	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrooesophageal reflux disease	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematochezia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhoids	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Irritable bowel syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mouth ulceration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nausea	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Odynophagia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oesophagitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancreatitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rectal prolapse	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Stomatitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Toothache	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vomiting	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
General disorders and administration site conditions	-Total	0	84	29.9	24	28.6	20.0	39.0
		1	190	67.6	58	30.5	24.4	37.4
		2	6	2.1	5	83.3	43.6	97.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Asthenia	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Face oedema	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Facial pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fatigue	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	20	10.5	6.9	15.7
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gait disturbance	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	General physical health deterioration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Influenza like illness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Malaise	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mucosal inflammation	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Non-cardiac chest pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oedema peripheral	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Peripheral swelling	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyrexia	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
Hepatobiliary disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperbilirubinaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Portal vein thrombosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
Immune system disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Contrast media allergy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Seasonal allergy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Infections and infestations	-Total	0	84	29.9	31	36.9	27.4	47.6
		1	190	67.6	52	27.4	21.5	34.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal abscess	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Arthritis infective	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Atypical pneumonia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacterial vaginosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bronchitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cellulitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chronic sinusitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Conjunctivitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Corona virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis escherichia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epididymitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Escherichia infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Escherichia urinary tract infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Febrile infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fungal infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastroenteritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Genital herpes	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gingivitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Herpes virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Herpes zoster	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Influenza	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lung infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lyme disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymph node tuberculosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasopharyngitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral candidiasis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral fungal infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oropharyngeal candidiasis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Otitis externa	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paronychia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pharyngitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia influenzal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia pseudomonal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia streptococcal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory tract infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory tract infection bacterial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sepsis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinusitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Staphylococcal infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Systemic infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tinea cruris	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Tonsillitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Upper respiratory tract infection	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urethritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary tract infection	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Varicella	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Varicella zoster virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Viral hepatitis carrier	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Viral infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vulvovaginal candidiasis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Injury, poisoning and procedural complications	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Fall	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint dislocation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Muscle rupture	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Procedural pneumothorax	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thermal burn	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wound	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wound complication	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wrist fracture	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Investigations	-Total	0	84	29.9	28	33.3	24.2	43.9
		1	190	67.6	84	44.2	37.3	51.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Alanine aminotransferase increased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Amylase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aspartate aminotransferase increased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bilirubin conjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin increased	0	84	29.9	2	2.4	0.7	8.3

		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin unconjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood cholesterol increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase increased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatinine increased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood glucose increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood iron decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood potassium decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood pressure increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	C-reactive protein increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrocardiogram QT prolonged	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gamma-glutamyltransferase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Granulocyte count decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemoglobin decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Liver function test increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphocyte count decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphocyte count increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil count decreased	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil percentage increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Procalcitonin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Serum amyloid A protein increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Total bile acids increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Weight decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Weight increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	White blood cell count decreased	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	28	14.7	10.4	20.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
Metabolism and nutrition disorders	-Total	0	84	29.9	16	19.0	12.1	28.7
		1	190	67.6	40	21.1	15.9	27.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal loss of weight	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Decreased appetite	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dehydration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrolyte imbalance	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercalcaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperglycaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperkalaemia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperlipidaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperphosphataemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Hypertriglyceridaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoalbuminaemia	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypocalcaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypochloraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypokalaemia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypomagnesaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyponatraemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypophosphataemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoproteinaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Musculoskeletal and connective tissue disorders	-Total	0	84	29.9	13	15.5	9.3	24.7
		1	190	67.6	24	12.6	8.6	18.1
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Arthralgia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Back pain	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Bone pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bursitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Flank pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint range of motion decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle spasms	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscular weakness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal chest pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal pain	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myalgia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neck pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain in extremity	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Spinal column stenosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Spinal osteoarthritis	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tendon disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Metastases to central nervous system	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Nervous system disorders	-Total	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	25	13.2	9.1	18.7
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Balance disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dizziness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysgeusia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Headache	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hemiplegia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoaesthesia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lumbar radiculopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Memory impairment	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Migraine with aura	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neuropathy peripheral	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paraesthesia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Polyneuropathy chronic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Presyncope	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Restless legs syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Seizure	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Somnolence	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Syncope	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Psychiatric disorders	-Total	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal behaviour	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Adjustment disorder with mixed anxiety and depressed mood	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Anxiety	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Delirium	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Depressed mood	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Insomnia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mental status changes	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Renal and urinary disorders	-Total	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute kidney injury	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Azotaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysuria	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhage urinary tract	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nephritis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Proteinuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Strangury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary retention	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Reproductive system and breast disorders	-Total	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Benign prostatic hyperplasia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Erectile dysfunction	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Prostatitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Respiratory, thoracic and mediastinal disorders	-Total	0	84	29.9	27	32.1	23.1	42.7
		1	190	67.6	42	22.1	16.8	28.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bronchospasm	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cough	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea exertional	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Epistaxis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemoptysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Interstitial lung disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oropharyngeal pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural effusion	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonitis	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Productive cough	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary embolism	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinalgia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinorrhoea	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sputum discoloured	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vocal cord leukoplakia	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Skin and subcutaneous tissue disorders	-Total	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Decubitus ulcer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis allergic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis bullous	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eczema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Erythema	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hirsutism	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperhidrosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pruritus	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash macular	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Scab	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Swelling face	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Surgical and medical procedures	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Astringent therapy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Therapy cessation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Vascular disorders	-Total	0	84	29.9	13	15.5	9.3	24.7
		1	190	67.6	38	20.0	14.9	26.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Aortic dissection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Deep vein thrombosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertension	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	30	15.8	11.3	21.6
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphoedema	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Orthostatic hypotension	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Pallor	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Superior vena cava syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombophlebitis superficial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR2_SG.xls
26MAR2021 14:16

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	USA	64	22.8	21	32.8	22.6	45.0
		Europe (EU)	95	33.8	28	29.5	21.2	39.3
		Asia (AS)	122	43.4	35	28.7	21.4	37.3
	Anaemia	USA	64	22.8	13	20.3	12.3	31.7
		Europe (EU)	95	33.8	19	20.0	13.2	29.1
		Asia (AS)	122	43.4	23	18.9	12.9	26.7
	Aplastic anaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bone marrow oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Leukopenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Lymphopenia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neutropenia	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Pancytopenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thrombocytopenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Thrombocytosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Cardiac disorders	-Total	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Acute coronary syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Angina pectoris	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Atrial fibrillation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cardiac failure	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Nodal arrhythmia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pericardial effusion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tachycardia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Congenital, familial and genetic disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gilbert's syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Ear and labyrinth disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Ear pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tinnitus	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Vertigo	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Eye disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Chalazion	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Conjunctival cyst	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Keratitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ocular discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Periorbital oedema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Photopsia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ulcerative keratitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vision blurred	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Gastrointestinal disorders	-Total	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	29	30.5	22.2	40.4
		Asia (AS)	122	43.4	32	26.2	19.2	34.7
	Abdominal discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Abdominal distension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Abdominal pain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Abdominal pain upper	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Ascites	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Constipation	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Diarrhoea	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Dry mouth	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Dyspepsia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Dysphagia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Enteritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastric ulcer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastritis erosive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrooesophageal reflux disease	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haematochezia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haemorrhoids	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Irritable bowel syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Mouth ulceration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nausea	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Odynophagia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oesophagitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oral pain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pancreatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Rectal prolapse	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Stomatitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Toothache	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Vomiting	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
General disorders and administration site conditions	-Total	USA	64	22.8	23	35.9	25.3	48.2
		Europe (EU)	95	33.8	37	38.9	29.8	49.0
		Asia (AS)	122	43.4	27	22.1	15.7	30.3
	Asthenia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	14	14.7	9.0	23.2
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Chest pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Face oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Facial pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fatigue	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Gait disturbance	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	General physical health deterioration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Influenza like illness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Malaise	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Mucosal inflammation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Non-cardiac chest pain	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oedema peripheral	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Peripheral swelling	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pyrexia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
Hepatobiliary disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hyperbilirubinaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Portal vein thrombosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Immune system disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Contrast media allergy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Seasonal allergy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Infections and infestations	-Total	USA	64	22.8	20	31.3	21.2	43.4
		Europe (EU)	95	33.8	34	35.8	26.9	45.8
		Asia (AS)	122	43.4	30	24.6	17.8	32.9
	Abdominal abscess	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Arthritis infective	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Atypical pneumonia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacteraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacterial vaginosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bronchitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cellulitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Chronic sinusitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Conjunctivitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Corona virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cystitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cystitis escherichia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epididymitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Escherichia infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Escherichia urinary tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Febrile infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fungal infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastroenteritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Genital herpes	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Gingivitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Herpes virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Herpes zoster	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Influenza	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lung infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lyme disease	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymph node tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nasopharyngitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Oral candidiasis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oral fungal infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oropharyngeal candidiasis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Otitis externa	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Paronychia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pharyngitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	7	5.7	2.8	11.4

	Pneumonia influenzal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonia pseudomonal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonia streptococcal	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pyuria	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory tract infection bacterial	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhinitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Sepsis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinusitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Skin infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Staphylococcal infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Systemic infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tinea cruris	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tonsillitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Upper respiratory tract infection	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urethritis	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary tract infection	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Varicella	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Varicella zoster virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Viral hepatitis carrier	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Viral infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vulvovaginal candidiasis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Injury, poisoning and procedural complications	-Total	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Fall	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Joint dislocation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle rupture	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Procedural pneumothorax	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thermal burn	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Wound	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Wound complication	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Wrist fracture	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Investigations	-Total	USA	64	22.8	22	34.4	23.9	46.6
		Europe (EU)	95	33.8	24	25.3	17.6	34.8
		Asia (AS)	122	43.4	67	54.9	46.1	63.5
	Alanine aminotransferase increased	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Amylase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Aspartate aminotransferase increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Bilirubin conjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Blood alkaline phosphatase increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Blood bilirubin increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Blood bilirubin unconjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Blood cholesterol increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood creatine phosphokinase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Blood creatinine increased	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Blood glucose increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood iron decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood potassium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood pressure increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	C-reactive protein increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Electrocardiogram QT prolonged	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gamma-glutamyltransferase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Granulocyte count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haemoglobin decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Liver function test increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymphocyte count decreased	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Lymphocyte count increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neutrophil count decreased	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	23	18.9	12.9	26.7
	Neutrophil percentage increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Platelet count decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Platelet count increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Procalcitonin increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Serum amyloid A protein increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Total bile acids increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Weight decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Weight increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	White blood cell count decreased	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	22	18.0	12.2	25.8
Metabolism and nutrition disorders	-Total	USA	64	22.8	10	15.6	8.7	26.4
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	35	28.7	21.4	37.3
	Abnormal loss of weight	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Decreased appetite	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Dehydration	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Electrolyte imbalance	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypercalcaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyperglycaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hyperkalaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hyperlipidaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyperphosphataemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hypertriglyceridaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hypoalbuminaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	17	13.9	8.9	21.2
	Hypocalcaemia	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Hypochloraemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypokalaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Hypomagnesaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyponatraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypophosphataemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Hypoproteinaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
Musculoskeletal and connective tissue disorders	-Total	USA	64	22.8	10	15.6	8.7	26.4
		Europe (EU)	95	33.8	15	15.8	9.8	24.4
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Arthralgia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Back pain	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Bone pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Bursitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Flank pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Joint range of motion decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Muscle spasms	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscular weakness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Musculoskeletal chest pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Musculoskeletal pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Myalgia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neck pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pain in extremity	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Spinal column stenosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Spinal osteoarthritis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tendon disorder	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Metastases to central nervous system	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Nervous system disorders	-Total	USA	64	22.8	12	18.8	11.1	30.0
		Europe (EU)	95	33.8	12	12.6	7.4	20.8
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
	Balance disorder	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dizziness	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Dysgeusia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Headache	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Hemiplegia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypoaesthesia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Lumbar radiculopathy	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Memory impairment	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Migraine with aura	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neuropathy peripheral	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Paraesthesia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Polyneuropathy chronic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Presyncope	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Restless legs syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Seizure	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Somnolence	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Syncope	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Psychiatric disorders	-Total	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Abnormal behaviour	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Adjustment disorder with mixed anxiety and depressed mood	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Anxiety	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Delirium	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Depressed mood	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Insomnia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Mental status changes	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Renal and urinary disorders	-Total	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Acute kidney injury	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Azotaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dysuria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Haematuria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haemorrhage urinary tract	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nephritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Proteinuria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Strangury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urinary retention	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Reproductive system and breast disorders	-Total	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Benign prostatic hyperplasia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Erectile dysfunction	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Prostatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Respiratory, thoracic and mediastinal disorders	-Total	USA	64	22.8	16	25.0	16.0	36.8
		Europe (EU)	95	33.8	22	23.2	15.8	32.6
		Asia (AS)	122	43.4	31	25.4	18.5	33.8
	Bronchospasm	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cough	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	12	9.8	5.7	16.4
	Dyspnoea	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Dyspnoea exertional	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Epistaxis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haemoptysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypoxia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Interstitial lung disease	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Oropharyngeal pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pleural effusion	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonitis	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Productive cough	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Pulmonary embolism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhinalgia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhinorrhoea	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sputum discoloured	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Vocal cord leukoplakia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Skin and subcutaneous tissue disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Decubitus ulcer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dermatitis allergic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dermatitis bullous	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Eczema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Erythema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hirsutism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperhidrosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Pruritus	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Rash	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rash macular	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Scab	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Swelling face	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
Surgical and medical procedures	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Astringent therapy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Therapy cessation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Vascular disorders	-Total	USA	64	22.8	10	15.6	8.7	26.4
		Europe (EU)	95	33.8	16	16.8	10.6	25.6
		Asia (AS)	122	43.4	26	21.3	15.0	29.4
	Aortic dissection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Deep vein thrombosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Embolism	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haematoma	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypertension	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	24	19.7	13.6	27.6
	Lymphoedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Orthostatic hypotension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pallor	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Superior vena cava syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Thrombophlebitis superficial	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thrombosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR2_SG.xls
26MAR2021 14:16

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	116	41.3	32	27.6	20.3	36.3
		1	77	27.4	25	32.5	23.1	43.5
		>= 2	88	31.3	27	30.7	22.0	41.0
	Anaemia	0	116	41.3	19	16.4	10.7	24.2
		1	77	27.4	17	22.1	14.3	32.5
		>= 2	88	31.3	19	21.6	14.3	31.3
	Aplastic anaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bone marrow oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Leukopenia	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Lymphopenia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Neutropenia	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	5	5.7	2.5	12.6
	Pancytopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Thrombocytopenia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Thrombocytosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Cardiac disorders	-Total	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Acute coronary syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Angina pectoris	0	116	41.3	1	0.9	0.2	4.7

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Atrial fibrillation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cardiac failure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Nodal arrhythmia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pericardial effusion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tachycardia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Congenital, familial and genetic disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gilbert's syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Ear and labyrinth disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ear pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tinnitus	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vertigo	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Eye disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	1	1.1	0.2	6.2
	Chalazion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Conjunctival cyst	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Keratitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Ocular discomfort	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Periorbital oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Photopsia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ulcerative keratitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vision blurred	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Gastrointestinal disorders	-Total	0	116	41.3	26	22.4	15.8	30.8
		1	77	27.4	21	27.3	18.6	38.1
		>= 2	88	31.3	29	33.0	24.0	43.3
	Abdominal discomfort	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Abdominal distension	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Abdominal pain	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Abdominal pain upper	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Ascites	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Constipation	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	9	10.2	5.5	18.3
	Diarrhoea	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	4	4.5	1.8	11.1
	Dry mouth	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dyspepsia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Dysphagia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Enteritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastric ulcer	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastritis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastritis erosive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrooesophageal reflux disease	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haematochezia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haemorrhoids	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Irritable bowel syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Mouth ulceration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nausea	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Odynophagia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oesophagitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oral pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pancreatitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Rectal prolapse	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Stomatitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Toothache	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Vomiting	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
General disorders and administration site conditions	-Total	0	116	41.3	34	29.3	21.8	38.2
		1	77	27.4	24	31.2	21.9	42.2
		>= 2	88	31.3	29	33.0	24.0	43.3
	Asthenia	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	4	4.5	1.8	11.1
	Chest pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Face oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Facial pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fatigue	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	11	12.5	7.1	21.0
	Gait disturbance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	General physical health deterioration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Influenza like illness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Malaise	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Mucosal inflammation	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	1	1.1	0.2	6.2
	Non-cardiac chest pain	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oedema peripheral	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Peripheral swelling	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pyrexia	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	6	6.8	3.2	14.1
Hepatobiliary disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperbilirubinaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Portal vein thrombosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Immune system disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Contrast media allergy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Seasonal allergy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Infections and infestations	-Total	0	116	41.3	25	21.6	15.0	29.9
		1	77	27.4	23	29.9	20.8	40.8
		>= 2	88	31.3	36	40.9	31.2	51.4
	Abdominal abscess	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Arthritis infective	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Atypical pneumonia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bacteraemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1	0.2	6.2
	Bacterial vaginosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bronchitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Cellulitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Chronic sinusitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Conjunctivitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Corona virus infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cystitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cystitis escherichia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Epididymitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Escherichia infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Escherichia urinary tract infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Febrile infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Fungal infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastroenteritis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Genital herpes	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Gingivitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Herpes virus infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Herpes zoster	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Influenza	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lung infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lyme disease	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lymph node tuberculosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasopharyngitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oral candidiasis	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oral fungal infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oropharyngeal candidiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Otitis externa	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Paronychia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pharyngitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	7	8.0	3.9	15.5

	Pneumonia influenzal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonia pseudomonal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia streptococcal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pyuria	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Respiratory tract infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiratory tract infection bacterial	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Sepsis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sinusitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Skin infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Staphylococcal infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Systemic infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tinea cruris	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tonsillitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Upper respiratory tract infection	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Urethritis	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urinary tract infection	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	11	12.5	7.1	21.0
	Varicella	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Varicella zoster virus infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Viral hepatitis carrier	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Viral infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vulvovaginal candidiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Injury, poisoning and procedural complications	-Total	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	7	8.0	3.9	15.5
	Fall	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Joint dislocation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Muscle rupture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Procedural pneumothorax	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Thermal burn	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Wound	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Wound complication	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Wrist fracture	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	0	0.0	0.0	4.2
Investigations	-Total	0	116	41.3	46	39.7	31.2	48.8
		1	77	27.4	27	35.1	25.3	46.2
		>= 2	88	31.3	40	45.5	35.5	55.8
	Alanine aminotransferase increased	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Amylase increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Aspartate aminotransferase increased	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	8	9.1	4.7	16.9
	Bilirubin conjugated increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Blood alkaline phosphatase increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	6	6.8	3.2	14.1
	Blood bilirubin increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Blood bilirubin unconjugated increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood cholesterol increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood creatine phosphokinase increased	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Blood creatinine increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Blood glucose increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood iron decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood potassium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood pressure increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2

	C-reactive protein increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Electrocardiogram QT prolonged	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gamma-glutamyltransferase increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Granulocyte count decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haemoglobin decreased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Liver function test increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lymphocyte count decreased	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Lymphocyte count increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neutrophil count decreased	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	11	12.5	7.1	21.0
	Neutrophil percentage increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Platelet count decreased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Platelet count increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Procalcitonin increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Serum amyloid A protein increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Total bile acids increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Weight decreased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Weight increased	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	White blood cell count decreased	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	15	17.0	10.6	26.2
Metabolism and nutrition disorders	-Total	0	116	41.3	19	16.4	10.7	24.2
		1	77	27.4	15	19.5	12.2	29.7
		>= 2	88	31.3	22	25.0	17.1	35.0
	Abnormal loss of weight	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Decreased appetite	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	5	5.7	2.5	12.6
	Dehydration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Electrolyte imbalance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypercalcaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperglycaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperkalaemia	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperlipidaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperphosphataemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hypertriglyceridaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypoalbuminaemia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	9	10.2	5.5	18.3
	Hypocalcaemia	0	116	41.3	5	4.3	1.9	9.7

		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hypochloraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypokalaemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hypomagnesaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyponatraemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypophosphataemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hypoproteinaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
Musculoskeletal and connective tissue disorders	-Total	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	14	18.2	11.2	28.2
		>= 2	88	31.3	13	14.8	8.8	23.7
	Arthralgia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Back pain	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	6	6.8	3.2	14.1
	Bone pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bursitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Flank pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Joint range of motion decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Muscle spasms	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Muscular weakness	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	0	0.0	0.0	4.2
	Musculoskeletal chest pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Musculoskeletal pain	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Myalgia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neck pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Pain in extremity	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Spinal column stenosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Spinal osteoarthritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tendon disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Metastases to central nervous system	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Nervous system disorders	-Total	0	116	41.3	12	10.3	6.0	17.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	12	13.6	8.0	22.3
	Balance disorder	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Dizziness	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Dysgeusia	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Headache	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9

	Hemiplegia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypoaesthesia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lumbar radiculopathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Memory impairment	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Migraine with aura	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Neuropathy peripheral	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Paraesthesia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Polyneuropathy chronic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Presyncope	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Restless legs syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Seizure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Somnolence	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Syncope	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
Psychiatric disorders	-Total	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	6	6.8	3.2	14.1
	Abnormal behaviour	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Adjustment disorder with mixed anxiety and depressed mood	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Anxiety	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Delirium	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Depressed mood	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Insomnia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Mental status changes	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Renal and urinary disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	9	10.2	5.5	18.3
	Acute kidney injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Azotaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dysuria	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Haematuria	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemorrhage urinary tract	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Nephritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Proteinuria	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Strangury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Urinary retention	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Reproductive system and breast disorders	-Total	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Benign prostatic hyperplasia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Erectile dysfunction	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Prostatitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Respiratory, thoracic and mediastinal disorders	-Total	0	116	41.3	26	22.4	15.8	30.8
		1	77	27.4	23	29.9	20.8	40.8
		>= 2	88	31.3	20	22.7	15.2	32.5
	Bronchospasm	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cough	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	11	14.3	8.2	23.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Dyspnoea	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	7	8.0	3.9	15.5
	Dyspnoea exertional	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Epistaxis	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haemoptysis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypoxia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Interstitial lung disease	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oropharyngeal pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pleural effusion	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0

		>= 2	88	31.3	2	2.3	0.6	7.9
	Pneumonitis	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	7	8.0	3.9	15.5
	Productive cough	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pulmonary embolism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinalgia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinorrhoea	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sputum discoloured	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vocal cord leukoplakia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Skin and subcutaneous tissue disorders	-Total	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	4	4.5	1.8	11.1
	Decubitus ulcer	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dermatitis allergic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dermatitis bullous	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Eczema	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Erythema	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hirsutism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperhidrosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Pruritus	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Rash	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rash macular	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Scab	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Swelling face	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Surgical and medical procedures	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Astringent therapy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Therapy cessation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Vascular disorders	-Total	0	116	41.3	15	12.9	8.0	20.2
		1	77	27.4	15	19.5	12.2	29.7
		>= 2	88	31.3	22	25.0	17.1	35.0
	Aortic dissection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Deep vein thrombosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Embolism	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haematoma	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypertension	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	12	15.6	9.1	25.3
		>= 2	88	31.3	16	18.2	11.5	27.5
	Lymphoedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9

	Orthostatic hypotension	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pallor	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Superior vena cava syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Thrombophlebitis superficial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Thrombosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR2_SG.xls
26MAR2021 14:16

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Asian	128	45.6	38	29.7	22.5	38.1
		Non-Asian	135	48.0	41	30.4	23.2	38.6
		Unknown	18	6.4	5	27.8	12.5	50.9
	Anaemia	Asian	128	45.6	25	19.5	13.6	27.2
		Non-Asian	135	48.0	28	20.7	14.8	28.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Aplastic anaemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bone marrow oedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Leukopenia	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutropenia	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	16	11.9	7.4	18.4
		Unknown	18	6.4	3	16.7	5.8	39.2
	Pancytopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytopenia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Cardiac disorders	-Total	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Acute coronary syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Angina pectoris	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Atrial fibrillation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cardiac failure	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nodal arrhythmia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pericardial effusion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tachycardia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Congenital, familial and genetic disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gilbert's syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Ear and labyrinth disorders	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ear pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinnitus	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vertigo	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Eye disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chalazion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Conjunctival cyst	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Keratitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Ocular discomfort	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Periorbital oedema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Photopsia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ulcerative keratitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vision blurred	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Gastrointestinal disorders	-Total	Asian	128	45.6	35	27.3	20.4	35.6
		Non-Asian	135	48.0	37	27.4	20.6	35.5
		Unknown	18	6.4	4	22.2	9.0	45.2
	Abdominal discomfort	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal distension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal pain	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal pain upper	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Ascites	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Constipation	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Diarrhoea	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dry mouth	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dyspepsia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Dysphagia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Enteritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastric ulcer	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastritis erosive	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrooesophageal reflux disease	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematochezia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhoids	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Irritable bowel syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mouth ulceration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nausea	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Odynophagia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oesophagitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancreatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Rectal prolapse	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Stomatitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Toothache	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vomiting	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	1	5.6	1.0	25.8
General disorders and administration site conditions	-Total	Asian	128	45.6	30	23.4	16.9	31.5
		Non-Asian	135	48.0	51	37.8	30.0	46.2
		Unknown	18	6.4	6	33.3	16.3	56.3
	Asthenia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	12	8.9	5.2	14.9
		Unknown	18	6.4	3	16.7	5.8	39.2
	Chest pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Face oedema	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Facial pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fatigue	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	20	14.8	9.8	21.8
		Unknown	18	6.4	2	11.1	3.1	32.8
	Gait disturbance	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	General physical health deterioration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Influenza like illness	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Malaise	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Mucosal inflammation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Non-cardiac chest pain	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oedema peripheral	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Peripheral swelling	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyrexia	Asian	128	45.6	14	10.9	6.6	17.5
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
Hepatobiliary disorders	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperbilirubinaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Portal vein thrombosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Immune system disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Contrast media allergy	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Seasonal allergy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Infections and infestations	-Total	Asian	128	45.6	30	23.4	16.9	31.5
		Non-Asian	135	48.0	50	37.0	29.4	45.4
		Unknown	18	6.4	4	22.2	9.0	45.2
	Abdominal abscess	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Arthritis infective	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Atypical pneumonia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	1	5.6	1.0	25.8
	Bacterial vaginosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bronchitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cellulitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chronic sinusitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Conjunctivitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Corona virus infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis escherichia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epididymitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Escherichia infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Escherichia urinary tract infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Febrile infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fungal infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastroenteritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Genital herpes	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

	Gingivitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Herpes virus infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Herpes zoster	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Influenza	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lung infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Lyme disease	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymph node tuberculosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasopharyngitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral candidiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral fungal infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oropharyngeal candidiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Otitis externa	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Paronychia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pharyngitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6

	Pneumonia influenzal	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia pseudomonal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumonia streptococcal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyuria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory tract infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory tract infection bacterial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sepsis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinusitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Staphylococcal infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Systemic infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinea cruris	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tonsillitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Upper respiratory tract infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urethritis	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary tract infection	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Varicella	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Varicella zoster virus infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Viral hepatitis carrier	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Viral infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vulvovaginal candidiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Injury, poisoning and procedural complications	-Total	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fall	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint dislocation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle rupture	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Procedural pneumothorax	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thermal burn	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wound	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wound complication	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wrist fracture	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
Investigations	-Total	Asian	128	45.6	67	52.3	43.7	60.8
		Non-Asian	135	48.0	40	29.6	22.6	37.8
		Unknown	18	6.4	6	33.3	16.3	56.3
	Alanine aminotransferase increased	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Amylase increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aspartate aminotransferase increased	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Bilirubin conjugated increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood alkaline phosphatase increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood bilirubin increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood bilirubin unconjugated increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood cholesterol increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine phosphokinase increased	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Blood creatinine increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Blood glucose increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood iron decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood potassium decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood pressure increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	C-reactive protein increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrocardiogram QT prolonged	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gamma-glutamyltransferase increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Granulocyte count decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemoglobin decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Liver function test increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphocyte count decreased	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphocyte count increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutrophil count decreased	Asian	128	45.6	23	18.0	12.3	25.5
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Neutrophil percentage increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Platelet count decreased	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Platelet count increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Procalcitonin increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Serum amyloid A protein increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Total bile acids increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Weight decreased	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Weight increased	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	White blood cell count decreased	Asian	128	45.6	22	17.2	11.6	24.7
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	1	5.6	1.0	25.8
Metabolism and nutrition disorders	-Total	Asian	128	45.6	37	28.9	21.8	37.3
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	Abnormal loss of weight	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Decreased appetite	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dehydration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Electrolyte imbalance	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercalcaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperglycaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperkalaemia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperlipidaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperphosphataemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypertriglyceridaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoalbuminaemia	Asian	128	45.6	17	13.3	8.5	20.2
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypocalcaemia	Asian	128	45.6	8	6.3	3.2	11.8

		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypochloraemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypokalaemia	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypomagnesaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyponatraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypophosphataemia	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoproteinaemia	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Musculoskeletal and connective tissue disorders	-Total	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	22	16.3	11.0	23.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Arthralgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Back pain	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bone pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bursitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Flank pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint range of motion decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle spasms	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscular weakness	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	1	5.6	1.0	25.8
	Musculoskeletal chest pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Musculoskeletal pain	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Myalgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neck pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pain in extremity	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Spinal column stenosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Spinal osteoarthritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tendon disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Metastases to central nervous system	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Nervous system disorders	-Total	Asian	128	45.6	15	11.7	7.2	18.4
		Non-Asian	135	48.0	19	14.1	9.2	20.9
		Unknown	18	6.4	3	16.7	5.8	39.2
	Balance disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dizziness	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysgeusia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Headache	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	2	11.1	3.1	32.8

	Hemiplegia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoaesthesia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lumbar radiculopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Memory impairment	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Migraine with aura	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Neuropathy peripheral	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Paraesthesia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Polyneuropathy chronic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Presyncope	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Restless legs syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Seizure	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Somnolence	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Syncope	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
Psychiatric disorders	-Total	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Abnormal behaviour	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Adjustment disorder with mixed anxiety and depressed mood	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anxiety	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Delirium	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Depressed mood	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Insomnia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Mental status changes	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Renal and urinary disorders	-Total	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Acute kidney injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Azotaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysuria	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematuria	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhage urinary tract	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nephritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Proteinuria	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Strangury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary retention	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Reproductive system and breast disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Benign prostatic hyperplasia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Erectile dysfunction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Prostatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Respiratory, thoracic and mediastinal disorders	-Total	Asian	128	45.6	33	25.8	19.0	34.0
		Non-Asian	135	48.0	32	23.7	17.3	31.5
		Unknown	18	6.4	4	22.2	9.0	45.2
	Bronchospasm	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cough	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dyspnoea	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dyspnoea exertional	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epistaxis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Haemoptysis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoxia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Interstitial lung disease	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oropharyngeal pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleural effusion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	5	3.7	1.6	8.4

		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumonitis	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Productive cough	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary embolism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinalgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinorrhoea	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sputum discoloured	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vocal cord leukoplakia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Skin and subcutaneous tissue disorders	-Total	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Decubitus ulcer	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermatitis allergic	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermatitis bullous	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eczema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Erythema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hirsutism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperhidrosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8

	Pruritus	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rash	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rash macular	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Scab	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Swelling face	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Surgical and medical procedures	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Astringent therapy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Therapy cessation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Vascular disorders	-Total	Asian	128	45.6	27	21.1	14.9	29.0
		Non-Asian	135	48.0	23	17.0	11.6	24.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Aortic dissection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Deep vein thrombosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Embolism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypertension	Asian	128	45.6	25	19.5	13.6	27.2
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	2	11.1	3.1	32.8
	Lymphoedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Orthostatic hypotension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pallor	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Superior vena cava syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombophlebitis superficial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR2_SG.xls
26MAR2021 14:16

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Female	152	54.1	52	34.2	27.1	42.1
		Male	129	45.9	32	24.8	18.2	32.9
	Anaemia	Female	152	54.1	34	22.4	16.5	29.6
		Male	129	45.9	21	16.3	10.9	23.6
	Aplastic anaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bone marrow oedema	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Leukopenia	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	5	3.9	1.7	8.8
	Lymphopenia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Neutropenia	Female	152	54.1	17	11.2	7.1	17.2
		Male	129	45.9	7	5.4	2.7	10.8
	Pancytopenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Thrombocytopenia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Thrombocytosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Cardiac disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	7	5.4	2.7	10.8
	Acute coronary syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Angina pectoris	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Atrial fibrillation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cardiac failure	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Nodal arrhythmia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pericardial effusion	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
	Tachycardia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
Congenital, familial and genetic disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gilbert's syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Ear and labyrinth disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ear pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tinnitus	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vertigo	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Eye disorders	-Total	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Chalazion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Conjunctival cyst	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Keratitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ocular discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Periorbital oedema	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Photopsia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ulcerative keratitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vision blurred	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
Gastrointestinal disorders	-Total	Female	152	54.1	42	27.6	21.1	35.2
		Male	129	45.9	34	26.4	19.5	34.6
	Abdominal discomfort	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Abdominal distension	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Abdominal pain	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	2	1.6	0.4	5.5

	Abdominal pain upper	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Ascites	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Constipation	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	11	8.5	4.8	14.6
	Diarrhoea	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	7	5.4	2.7	10.8
	Dry mouth	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Dyspepsia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Dysphagia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Enteritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastric ulcer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastritis erosive	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrooesophageal reflux disease	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Haematochezia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Haemorrhoids	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Irritable bowel syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Mouth ulceration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nausea	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	6	4.7	2.1	9.8
	Odynophagia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Oesophagitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oral pain	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9

	Pancreatitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rectal prolapse	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Stomatitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Toothache	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Vomiting	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	4	3.1	1.2	7.7
General disorders and administration site conditions	-Total	Female	152	54.1	44	28.9	22.3	36.6
		Male	129	45.9	43	33.3	25.8	41.8
	Asthenia	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	8	6.2	3.2	11.8
	Chest pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Face oedema	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Facial pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Fatigue	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	16	12.4	7.8	19.2
	Gait disturbance	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	General physical health deterioration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Influenza like illness	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Malaise	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Mucosal inflammation	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	1	0.8	0.1	4.3
	Non-cardiac chest pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Oedema peripheral	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	1	0.8	0.1	4.3
	Pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Peripheral swelling	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Pyrexia	Female	152	54.1	9	5.9	3.1	10.9

		Male	129	45.9	14	10.9	6.6	17.4
Hepatobiliary disorders	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Hyperbilirubinaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Portal vein thrombosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Immune system disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Contrast media allergy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Seasonal allergy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Infections and infestations	-Total	Female	152	54.1	49	32.2	25.3	40.0
		Male	129	45.9	35	27.1	20.2	35.4
	Abdominal abscess	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Arthritis infective	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Atypical pneumonia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bacteraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Bacterial vaginosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bronchitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Cellulitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Chronic sinusitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Conjunctivitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Corona virus infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cystitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cystitis escherichia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Epididymitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Escherichia infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Escherichia urinary tract infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Febrile infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Fungal infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gastroenteritis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Genital herpes	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Gingivitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Herpes virus infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Herpes zoster	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	3	2.3	0.8	6.6
	Influenza	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lung infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lyme disease	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lymph node tuberculosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nasopharyngitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Oral candidiasis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	4	3.1	1.2	7.7
	Oral fungal infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Oropharyngeal candidiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Otitis externa	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Paronychia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pharyngitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3

	Pneumonia	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	7	5.4	2.7	10.8
	Pneumonia influenzal	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonia pseudomonal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pneumonia streptococcal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pyuria	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Respiratory tract infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Respiratory tract infection bacterial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rhinitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Sepsis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sinusitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Staphylococcal infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Systemic infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tinea cruris	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tonsillitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Upper respiratory tract infection	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	2	1.6	0.4	5.5
	Urethritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urinary tract infection	Female	152	54.1	18	11.8	7.6	17.9
		Male	129	45.9	5	3.9	1.7	8.8
	Varicella	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Varicella zoster virus infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Viral hepatitis carrier	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Viral infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Vulvovaginal candidiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Injury, poisoning and procedural complications	-Total	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	8	6.2	3.2	11.8
	Fall	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	5	3.9	1.7	8.8
	Joint dislocation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Muscle rupture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Procedural pneumothorax	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thermal burn	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Wound	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Wound complication	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Wrist fracture	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Investigations	-Total	Female	152	54.1	70	46.1	38.3	54.0
		Male	129	45.9	43	33.3	25.8	41.8
	Alanine aminotransferase increased	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	6	4.7	2.1	9.8
	Amylase increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Aspartate aminotransferase increased	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	4	3.1	1.2	7.7
	Bilirubin conjugated increased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Blood alkaline phosphatase increased	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Blood bilirubin increased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Blood bilirubin unconjugated increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Blood cholesterol increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Blood creatine phosphokinase increased	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	5	3.9	1.7	8.8
	Blood creatinine increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	7	5.4	2.7	10.8
	Blood glucose increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood iron decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood potassium decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood pressure increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	C-reactive protein increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Electrocardiogram QT prolonged	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gamma-glutamyltransferase increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Granulocyte count decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haemoglobin decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Liver function test increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lymphocyte count decreased	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Lymphocyte count increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Neutrophil count decreased	Female	152	54.1	19	12.5	8.2	18.7
		Male	129	45.9	10	7.8	4.3	13.7
	Neutrophil percentage increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Platelet count decreased	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	2	1.6	0.4	5.5
	Platelet count increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Procalcitonin increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Serum amyloid A protein increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Total bile acids increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Weight decreased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Weight increased	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	4	3.1	1.2	7.7
	White blood cell count decreased	Female	152	54.1	21	13.8	9.2	20.2
		Male	129	45.9	13	10.1	6.0	16.5
Metabolism and nutrition disorders	-Total	Female	152	54.1	33	21.7	15.9	28.9
		Male	129	45.9	23	17.8	12.2	25.3
	Abnormal loss of weight	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Decreased appetite	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	6	4.7	2.1	9.8
	Dehydration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Electrolyte imbalance	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypercalcaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperglycaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperkalaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	4	3.1	1.2	7.7
	Hyperlipidaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperphosphataemia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypertriglyceridaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hypoalbuminaemia	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	9	7.0	3.7	12.7
	Hypocalcaemia	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	4	3.1	1.2	7.7
	Hypochloraemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypokalaemia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	4	3.1	1.2	7.7
	Hypomagnesaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hyponatraemia	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Hypophosphataemia	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Hypoproteinaemia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
Musculoskeletal and connective tissue disorders	-Total	Female	152	54.1	20	13.2	8.7	19.5
		Male	129	45.9	20	15.5	10.3	22.7
	Arthralgia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Back pain	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	7	5.4	2.7	10.8
	Bone pain	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Bursitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Flank pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Joint range of motion decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Muscle spasms	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Muscular weakness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Musculoskeletal chest pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Musculoskeletal pain	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	6	4.7	2.1	9.8
	Myalgia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Neck pain	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Pain in extremity	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	4	3.1	1.2	7.7
	Spinal column stenosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Spinal osteoarthritis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tendon disorder	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Metastases to central nervous system	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Nervous system disorders	-Total	Female	152	54.1	22	14.5	9.8	20.9
		Male	129	45.9	15	11.6	7.2	18.3
	Balance disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Dizziness	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	4	3.1	1.2	7.7
	Dysgeusia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Headache	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hemiplegia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypoaesthesia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Lumbar radiculopathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Memory impairment	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Migraine with aura	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neuropathy peripheral	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Paraesthesia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Polyneuropathy chronic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Presyncope	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Restless legs syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Seizure	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Somnolence	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Syncope	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
Psychiatric disorders	-Total	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	7	5.4	2.7	10.8

	Abnormal behaviour	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Adjustment disorder with mixed anxiety and depressed mood	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Anxiety	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Delirium	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Depressed mood	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Insomnia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Mental status changes	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Renal and urinary disorders	-Total	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	8	6.2	3.2	11.8
	Acute kidney injury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Azotaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dysuria	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	4	3.1	1.2	7.7
	Haematuria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Haemorrhage urinary tract	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Nephritis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Proteinuria	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Strangury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urinary retention	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Reproductive system and breast disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	6	4.7	2.1	9.8
	Benign prostatic hyperplasia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Erectile dysfunction	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	4	3.1	1.2	7.7
	Prostatitis	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
Respiratory, thoracic and mediastinal disorders	-Total	Female	152	54.1	42	27.6	21.1	35.2
		Male	129	45.9	27	20.9	14.8	28.7
	Bronchospasm	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cough	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	7	5.4	2.7	10.8
	Dyspnoea	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	8	6.2	3.2	11.8
	Dyspnoea exertional	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	5	3.9	1.7	8.8
	Epistaxis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Haemoptysis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypoxia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Interstitial lung disease	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Oropharyngeal pain	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	0	0.0	0.0	2.9
	Pleural effusion	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Pneumonitis	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	5	3.9	1.7	8.8
	Productive cough	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Pulmonary embolism	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Rhinalgia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rhinorrhoea	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Sputum discoloured	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Vocal cord leukoplakia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Skin and subcutaneous tissue disorders	-Total	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	6	4.7	2.1	9.8
	Decubitus ulcer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Dermatitis allergic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dermatitis bullous	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Eczema	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Erythema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hirsutism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hyperhidrosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pruritus	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Rash	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rash macular	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Scab	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Swelling face	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
Surgical and medical procedures	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Astringent therapy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Therapy cessation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Vascular disorders	-Total	Female	152	54.1	28	18.4	13.1	25.3
		Male	129	45.9	24	18.6	12.8	26.2
	Aortic dissection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Deep vein thrombosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Embolism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Haematoma	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypertension	Female	152	54.1	21	13.8	9.2	20.2
		Male	129	45.9	20	15.5	10.3	22.7

	Lymphoedema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Orthostatic hypotension	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pallor	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Superior vena cava syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombophlebitis superficial	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR2_SG.xls
26MAR2021 14:16

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	n/a	281	100.0	84	29.9	24.8	35.5
	Anaemia	n/a	281	100.0	55	19.6	15.4	24.6
	Aplastic anaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Bone marrow oedema	n/a	281	100.0	1	0.4	0.1	2.0
	Leukopenia	n/a	281	100.0	14	5.0	3.0	8.2
	Lymphopenia	n/a	281	100.0	5	1.8	0.8	4.1
	Neutropenia	n/a	281	100.0	24	8.5	5.8	12.4
	Pancytopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombocytopenia	n/a	281	100.0	4	1.4	0.6	3.6
	Thrombocytosis	n/a	281	100.0	1	0.4	0.1	2.0
Cardiac disorders	-Total	n/a	281	100.0	10	3.6	1.9	6.4
	Acute coronary syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Angina pectoris	n/a	281	100.0	1	0.4	0.1	2.0
	Atrial fibrillation	n/a	281	100.0	1	0.4	0.1	2.0
	Cardiac failure	n/a	281	100.0	2	0.7	0.2	2.6
	Nodal arrhythmia	n/a	281	100.0	1	0.4	0.1	2.0
	Pericardial effusion	n/a	281	100.0	1	0.4	0.1	2.0
	Tachycardia	n/a	281	100.0	3	1.1	0.4	3.1
Congenital, familial and genetic disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Gilbert's syndrome	n/a	281	100.0	1	0.4	0.1	2.0
Ear and labyrinth disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Ear pain	n/a	281	100.0	1	0.4	0.1	2.0
	Tinnitus	n/a	281	100.0	1	0.4	0.1	2.0
	Vertigo	n/a	281	100.0	1	0.4	0.1	2.0
Eye disorders	-Total	n/a	281	100.0	6	2.1	1.0	4.6

	Chalazion	n/a	281	100.0	1	0.4	0.1	2.0
	Conjunctival cyst	n/a	281	100.0	1	0.4	0.1	2.0
	Keratitis	n/a	281	100.0	1	0.4	0.1	2.0
	Ocular discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Periorbital oedema	n/a	281	100.0	1	0.4	0.1	2.0
	Photopsia	n/a	281	100.0	1	0.4	0.1	2.0
	Ulcerative keratitis	n/a	281	100.0	1	0.4	0.1	2.0
	Vision blurred	n/a	281	100.0	2	0.7	0.2	2.6
Gastrointestinal disorders	-Total	n/a	281	100.0	76	27.0	22.2	32.5
	Abdominal discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Abdominal distension	n/a	281	100.0	1	0.4	0.1	2.0
	Abdominal pain	n/a	281	100.0	8	2.8	1.4	5.5
	Abdominal pain upper	n/a	281	100.0	5	1.8	0.8	4.1
	Ascites	n/a	281	100.0	1	0.4	0.1	2.0
	Constipation	n/a	281	100.0	23	8.2	5.5	12.0
	Diarrhoea	n/a	281	100.0	12	4.3	2.5	7.3
	Dry mouth	n/a	281	100.0	4	1.4	0.6	3.6
	Dyspepsia	n/a	281	100.0	2	0.7	0.2	2.6
	Dysphagia	n/a	281	100.0	4	1.4	0.6	3.6
	Enteritis	n/a	281	100.0	1	0.4	0.1	2.0
	Gastric ulcer	n/a	281	100.0	1	0.4	0.1	2.0
	Gastritis	n/a	281	100.0	1	0.4	0.1	2.0
	Gastritis erosive	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrooesophageal reflux disease	n/a	281	100.0	5	1.8	0.8	4.1
	Haematochezia	n/a	281	100.0	1	0.4	0.1	2.0
	Haemorrhoids	n/a	281	100.0	4	1.4	0.6	3.6
	Irritable bowel syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Mouth ulceration	n/a	281	100.0	1	0.4	0.1	2.0
	Nausea	n/a	281	100.0	15	5.3	3.3	8.6
	Odynophagia	n/a	281	100.0	1	0.4	0.1	2.0

	Oesophagitis	n/a	281	100.0	1	0.4	0.1	2.0
	Oral pain	n/a	281	100.0	2	0.7	0.2	2.6
	Pancreatitis	n/a	281	100.0	1	0.4	0.1	2.0
	Rectal prolapse	n/a	281	100.0	1	0.4	0.1	2.0
	Stomatitis	n/a	281	100.0	4	1.4	0.6	3.6
	Toothache	n/a	281	100.0	3	1.1	0.4	3.1
	Vomiting	n/a	281	100.0	11	3.9	2.2	6.9
General disorders and administration site conditions	-Total	n/a	281	100.0	87	31.0	25.8	36.6
	Asthenia	n/a	281	100.0	19	6.8	4.4	10.3
	Chest pain	n/a	281	100.0	2	0.7	0.2	2.6
	Disease progression	n/a	281	100.0	1	0.4	0.1	2.0
	Face oedema	n/a	281	100.0	4	1.4	0.6	3.6
	Facial pain	n/a	281	100.0	1	0.4	0.1	2.0
	Fatigue	n/a	281	100.0	28	10.0	7.0	14.0
	Gait disturbance	n/a	281	100.0	3	1.1	0.4	3.1
	General physical health deterioration	n/a	281	100.0	1	0.4	0.1	2.0
	Influenza like illness	n/a	281	100.0	2	0.7	0.2	2.6
	Malaise	n/a	281	100.0	3	1.1	0.4	3.1
	Mucosal inflammation	n/a	281	100.0	9	3.2	1.7	6.0
	Non-cardiac chest pain	n/a	281	100.0	1	0.4	0.1	2.0
	Oedema peripheral	n/a	281	100.0	9	3.2	1.7	6.0
	Pain	n/a	281	100.0	2	0.7	0.2	2.6
	Peripheral swelling	n/a	281	100.0	2	0.7	0.2	2.6
	Pyrexia	n/a	281	100.0	23	8.2	5.5	12.0
Hepatobiliary disorders	-Total	n/a	281	100.0	4	1.4	0.6	3.6
	Hyperbilirubinaemia	n/a	281	100.0	3	1.1	0.4	3.1
	Portal vein thrombosis	n/a	281	100.0	1	0.4	0.1	2.0
Immune system disorders	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Contrast media allergy	n/a	281	100.0	1	0.4	0.1	2.0
	Seasonal allergy	n/a	281	100.0	1	0.4	0.1	2.0
Infections and infestations	-Total	n/a	281	100.0	84	29.9	24.8	35.5

	Abdominal abscess	n/a	281	100.0	1	0.4	0.1	2.0
	Arthritis infective	n/a	281	100.0	1	0.4	0.1	2.0
	Atypical pneumonia	n/a	281	100.0	1	0.4	0.1	2.0
	Bacteraemia	n/a	281	100.0	2	0.7	0.2	2.6
	Bacterial vaginosis	n/a	281	100.0	1	0.4	0.1	2.0
	Bronchitis	n/a	281	100.0	2	0.7	0.2	2.6
	Cellulitis	n/a	281	100.0	1	0.4	0.1	2.0
	Chronic sinusitis	n/a	281	100.0	2	0.7	0.2	2.6
	Conjunctivitis	n/a	281	100.0	1	0.4	0.1	2.0
	Corona virus infection	n/a	281	100.0	1	0.4	0.1	2.0
	Cystitis	n/a	281	100.0	1	0.4	0.1	2.0
	Cystitis escherichia	n/a	281	100.0	1	0.4	0.1	2.0
	Epididymitis	n/a	281	100.0	1	0.4	0.1	2.0
	Escherichia infection	n/a	281	100.0	1	0.4	0.1	2.0
	Escherichia urinary tract infection	n/a	281	100.0	1	0.4	0.1	2.0
	Febrile infection	n/a	281	100.0	1	0.4	0.1	2.0
	Fungal infection	n/a	281	100.0	1	0.4	0.1	2.0
	Gastroenteritis	n/a	281	100.0	1	0.4	0.1	2.0
	Genital herpes	n/a	281	100.0	2	0.7	0.2	2.6
	Gingivitis	n/a	281	100.0	1	0.4	0.1	2.0
	Herpes virus infection	n/a	281	100.0	2	0.7	0.2	2.6
	Herpes zoster	n/a	281	100.0	9	3.2	1.7	6.0
	Influenza	n/a	281	100.0	1	0.4	0.1	2.0
	Lung infection	n/a	281	100.0	1	0.4	0.1	2.0
	Lyme disease	n/a	281	100.0	1	0.4	0.1	2.0
	Lymph node tuberculosis	n/a	281	100.0	1	0.4	0.1	2.0
	Nasopharyngitis	n/a	281	100.0	2	0.7	0.2	2.6
	Oral candidiasis	n/a	281	100.0	6	2.1	1.0	4.6
	Oral fungal infection	n/a	281	100.0	2	0.7	0.2	2.6
	Oropharyngeal candidiasis	n/a	281	100.0	1	0.4	0.1	2.0

	Otitis externa	n/a	281	100.0	1	0.4	0.1	2.0
	Paronychia	n/a	281	100.0	1	0.4	0.1	2.0
	Pharyngitis	n/a	281	100.0	2	0.7	0.2	2.6
	Pneumonia	n/a	281	100.0	13	4.6	2.7	7.8
	Pneumonia influenzal	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia pseudomonal	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia streptococcal	n/a	281	100.0	1	0.4	0.1	2.0
	Pyuria	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory tract infection	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory tract infection bacterial	n/a	281	100.0	1	0.4	0.1	2.0
	Rhinitis	n/a	281	100.0	4	1.4	0.6	3.6
	Sepsis	n/a	281	100.0	1	0.4	0.1	2.0
	Sinusitis	n/a	281	100.0	3	1.1	0.4	3.1
	Skin infection	n/a	281	100.0	1	0.4	0.1	2.0
	Staphylococcal infection	n/a	281	100.0	1	0.4	0.1	2.0
	Systemic infection	n/a	281	100.0	1	0.4	0.1	2.0
	Tinea cruris	n/a	281	100.0	1	0.4	0.1	2.0
	Tonsillitis	n/a	281	100.0	1	0.4	0.1	2.0
	Upper respiratory tract infection	n/a	281	100.0	8	2.8	1.4	5.5
	Urethritis	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary tract infection	n/a	281	100.0	23	8.2	5.5	12.0
	Varicella	n/a	281	100.0	1	0.4	0.1	2.0
	Varicella zoster virus infection	n/a	281	100.0	1	0.4	0.1	2.0
	Viral hepatitis carrier	n/a	281	100.0	1	0.4	0.1	2.0
	Viral infection	n/a	281	100.0	1	0.4	0.1	2.0
	Vulvovaginal candidiasis	n/a	281	100.0	1	0.4	0.1	2.0
Injury, poisoning and procedural complications	-Total	n/a	281	100.0	12	4.3	2.5	7.3
	Fall	n/a	281	100.0	5	1.8	0.8	4.1
	Joint dislocation	n/a	281	100.0	1	0.4	0.1	2.0
	Muscle rupture	n/a	281	100.0	1	0.4	0.1	2.0
	Procedural pneumothorax	n/a	281	100.0	1	0.4	0.1	2.0

	Thermal burn	n/a	281	100.0	1	0.4	0.1	2.0
	Wound	n/a	281	100.0	1	0.4	0.1	2.0
	Wound complication	n/a	281	100.0	1	0.4	0.1	2.0
	Wrist fracture	n/a	281	100.0	1	0.4	0.1	2.0
Investigations	-Total	n/a	281	100.0	113	40.2	34.6	46.0
	Alanine aminotransferase increased	n/a	281	100.0	12	4.3	2.5	7.3
	Amylase increased	n/a	281	100.0	2	0.7	0.2	2.6
	Aspartate aminotransferase increased	n/a	281	100.0	13	4.6	2.7	7.8
	Bilirubin conjugated increased	n/a	281	100.0	6	2.1	1.0	4.6
	Blood alkaline phosphatase increased	n/a	281	100.0	8	2.8	1.4	5.5
	Blood bilirubin increased	n/a	281	100.0	6	2.1	1.0	4.6
	Blood bilirubin unconjugated increased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood cholesterol increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood creatine phosphokinase increased	n/a	281	100.0	18	6.4	4.1	9.9
	Blood creatinine increased	n/a	281	100.0	9	3.2	1.7	6.0
	Blood glucose increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood iron decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood potassium decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood pressure increased	n/a	281	100.0	2	0.7	0.2	2.6
	C-reactive protein increased	n/a	281	100.0	1	0.4	0.1	2.0
	Electrocardiogram QT prolonged	n/a	281	100.0	1	0.4	0.1	2.0
	Gamma-glutamyltransferase increased	n/a	281	100.0	4	1.4	0.6	3.6
	Granulocyte count decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Haemoglobin decreased	n/a	281	100.0	3	1.1	0.4	3.1
	Liver function test increased	n/a	281	100.0	1	0.4	0.1	2.0
	Lymphocyte count decreased	n/a	281	100.0	7	2.5	1.2	5.1
	Lymphocyte count increased	n/a	281	100.0	1	0.4	0.1	2.0
	Neutrophil count decreased	n/a	281	100.0	29	10.3	7.3	14.4
	Neutrophil percentage increased	n/a	281	100.0	1	0.4	0.1	2.0
	Platelet count decreased	n/a	281	100.0	8	2.8	1.4	5.5

	Platelet count increased	n/a	281	100.0	1	0.4	0.1	2.0
	Procalcitonin increased	n/a	281	100.0	1	0.4	0.1	2.0
	Serum amyloid A protein increased	n/a	281	100.0	1	0.4	0.1	2.0
	Total bile acids increased	n/a	281	100.0	1	0.4	0.1	2.0
	Weight decreased	n/a	281	100.0	4	1.4	0.6	3.6
	Weight increased	n/a	281	100.0	10	3.6	1.9	6.4
	White blood cell count decreased	n/a	281	100.0	34	12.1	8.8	16.4
Metabolism and nutrition disorders	-Total	n/a	281	100.0	56	19.9	15.7	25.0
	Abnormal loss of weight	n/a	281	100.0	1	0.4	0.1	2.0
	Decreased appetite	n/a	281	100.0	12	4.3	2.5	7.3
	Dehydration	n/a	281	100.0	3	1.1	0.4	3.1
	Electrolyte imbalance	n/a	281	100.0	1	0.4	0.1	2.0
	Hypercalcaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperglycaemia	n/a	281	100.0	2	0.7	0.2	2.6
	Hyperkalaemia	n/a	281	100.0	4	1.4	0.6	3.6
	Hyperlipidaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperphosphataemia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypertriglyceridaemia	n/a	281	100.0	2	0.7	0.2	2.6
	Hypoalbuminaemia	n/a	281	100.0	20	7.1	4.7	10.7
	Hypocalcaemia	n/a	281	100.0	12	4.3	2.5	7.3
	Hypochloraemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypokalaemia	n/a	281	100.0	8	2.8	1.4	5.5
	Hypomagnesaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyponatraemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypophosphataemia	n/a	281	100.0	7	2.5	1.2	5.1
	Hypoproteinaemia	n/a	281	100.0	5	1.8	0.8	4.1
Musculoskeletal and connective tissue disorders	-Total	n/a	281	100.0	40	14.2	10.6	18.8
	Arthralgia	n/a	281	100.0	1	0.4	0.1	2.0
	Back pain	n/a	281	100.0	13	4.6	2.7	7.8
	Bone pain	n/a	281	100.0	2	0.7	0.2	2.6
	Bursitis	n/a	281	100.0	1	0.4	0.1	2.0

	Flank pain	n/a	281	100.0	1	0.4	0.1	2.0
	Joint range of motion decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Muscle spasms	n/a	281	100.0	2	0.7	0.2	2.6
	Muscular weakness	n/a	281	100.0	2	0.7	0.2	2.6
	Musculoskeletal chest pain	n/a	281	100.0	1	0.4	0.1	2.0
	Musculoskeletal pain	n/a	281	100.0	9	3.2	1.7	6.0
	Myalgia	n/a	281	100.0	2	0.7	0.2	2.6
	Neck pain	n/a	281	100.0	5	1.8	0.8	4.1
	Pain in extremity	n/a	281	100.0	8	2.8	1.4	5.5
	Spinal column stenosis	n/a	281	100.0	1	0.4	0.1	2.0
	Spinal osteoarthritis	n/a	281	100.0	1	0.4	0.1	2.0
	Tendon disorder	n/a	281	100.0	1	0.4	0.1	2.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Metastases to central nervous system	n/a	281	100.0	1	0.4	0.1	2.0
Nervous system disorders	-Total	n/a	281	100.0	37	13.2	9.7	17.6
	Balance disorder	n/a	281	100.0	2	0.7	0.2	2.6
	Dizziness	n/a	281	100.0	9	3.2	1.7	6.0
	Dysgeusia	n/a	281	100.0	5	1.8	0.8	4.1
	Headache	n/a	281	100.0	7	2.5	1.2	5.1
	Hemiplegia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypoaesthesia	n/a	281	100.0	2	0.7	0.2	2.6
	Lumbar radiculopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Memory impairment	n/a	281	100.0	1	0.4	0.1	2.0
	Migraine with aura	n/a	281	100.0	1	0.4	0.1	2.0
	Neuropathy peripheral	n/a	281	100.0	1	0.4	0.1	2.0
	Paraesthesia	n/a	281	100.0	3	1.1	0.4	3.1
	Polyneuropathy chronic	n/a	281	100.0	1	0.4	0.1	2.0
	Presyncope	n/a	281	100.0	2	0.7	0.2	2.6
	Restless legs syndrome	n/a	281	100.0	2	0.7	0.2	2.6
	Seizure	n/a	281	100.0	4	1.4	0.6	3.6

	Somnolence	n/a	281	100.0	1	0.4	0.1	2.0
	Syncope	n/a	281	100.0	3	1.1	0.4	3.1
Psychiatric disorders	-Total	n/a	281	100.0	12	4.3	2.5	7.3
	Abnormal behaviour	n/a	281	100.0	1	0.4	0.1	2.0
	Adjustment disorder with mixed anxiety and depressed mood	n/a	281	100.0	1	0.4	0.1	2.0
	Anxiety	n/a	281	100.0	4	1.4	0.6	3.6
	Delirium	n/a	281	100.0	3	1.1	0.4	3.1
	Depressed mood	n/a	281	100.0	1	0.4	0.1	2.0
	Insomnia	n/a	281	100.0	2	0.7	0.2	2.6
	Mental status changes	n/a	281	100.0	1	0.4	0.1	2.0
Renal and urinary disorders	-Total	n/a	281	100.0	12	4.3	2.5	7.3
	Acute kidney injury	n/a	281	100.0	3	1.1	0.4	3.1
	Azotaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Dysuria	n/a	281	100.0	5	1.8	0.8	4.1
	Haematuria	n/a	281	100.0	1	0.4	0.1	2.0
	Haemorrhage urinary tract	n/a	281	100.0	1	0.4	0.1	2.0
	Nephritis	n/a	281	100.0	1	0.4	0.1	2.0
	Proteinuria	n/a	281	100.0	1	0.4	0.1	2.0
	Strangury	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary retention	n/a	281	100.0	1	0.4	0.1	2.0
Reproductive system and breast disorders	-Total	n/a	281	100.0	6	2.1	1.0	4.6
	Benign prostatic hyperplasia	n/a	281	100.0	1	0.4	0.1	2.0
	Erectile dysfunction	n/a	281	100.0	4	1.4	0.6	3.6
	Prostatitis	n/a	281	100.0	1	0.4	0.1	2.0
Respiratory, thoracic and mediastinal disorders	-Total	n/a	281	100.0	69	24.6	19.9	29.9
	Bronchospasm	n/a	281	100.0	1	0.4	0.1	2.0
	Cough	n/a	281	100.0	20	7.1	4.7	10.7
	Dyspnoea	n/a	281	100.0	17	6.0	3.8	9.5
	Dyspnoea exertional	n/a	281	100.0	5	1.8	0.8	4.1
	Epistaxis	n/a	281	100.0	3	1.1	0.4	3.1
	Haemoptysis	n/a	281	100.0	1	0.4	0.1	2.0

	Hypoxia	n/a	281	100.0	1	0.4	0.1	2.0
	Interstitial lung disease	n/a	281	100.0	3	1.1	0.4	3.1
	Oropharyngeal pain	n/a	281	100.0	5	1.8	0.8	4.1
	Pleural effusion	n/a	281	100.0	7	2.5	1.2	5.1
	Pneumonitis	n/a	281	100.0	19	6.8	4.4	10.3
	Productive cough	n/a	281	100.0	4	1.4	0.6	3.6
	Pulmonary embolism	n/a	281	100.0	2	0.7	0.2	2.6
	Rhinalgia	n/a	281	100.0	1	0.4	0.1	2.0
	Rhinorrhoea	n/a	281	100.0	1	0.4	0.1	2.0
	Sputum discoloured	n/a	281	100.0	1	0.4	0.1	2.0
	Vocal cord leukoplakia	n/a	281	100.0	1	0.4	0.1	2.0
Skin and subcutaneous tissue disorders	-Total	n/a	281	100.0	17	6.0	3.8	9.5
	Decubitus ulcer	n/a	281	100.0	1	0.4	0.1	2.0
	Dermatitis allergic	n/a	281	100.0	1	0.4	0.1	2.0
	Dermatitis bullous	n/a	281	100.0	1	0.4	0.1	2.0
	Eczema	n/a	281	100.0	1	0.4	0.1	2.0
	Erythema	n/a	281	100.0	2	0.7	0.2	2.6
	Hirsutism	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperhidrosis	n/a	281	100.0	1	0.4	0.1	2.0
	Pruritus	n/a	281	100.0	3	1.1	0.4	3.1
	Rash	n/a	281	100.0	4	1.4	0.6	3.6
	Rash macular	n/a	281	100.0	1	0.4	0.1	2.0
	Scab	n/a	281	100.0	1	0.4	0.1	2.0
	Swelling face	n/a	281	100.0	3	1.1	0.4	3.1
Surgical and medical procedures	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Astringent therapy	n/a	281	100.0	1	0.4	0.1	2.0
	Therapy cessation	n/a	281	100.0	1	0.4	0.1	2.0
Vascular disorders	-Total	n/a	281	100.0	52	18.5	14.4	23.5
	Aortic dissection	n/a	281	100.0	1	0.4	0.1	2.0
	Deep vein thrombosis	n/a	281	100.0	2	0.7	0.2	2.6

	Embolism	n/a	281	100.0	2	0.7	0.2	2.6
	Haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Hypertension	n/a	281	100.0	41	14.6	10.9	19.2
	Lymphoedema	n/a	281	100.0	2	0.7	0.2	2.6
	Orthostatic hypotension	n/a	281	100.0	2	0.7	0.2	2.6
	Pallor	n/a	281	100.0	1	0.4	0.1	2.0
	Superior vena cava syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombophlebitis superficial	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombosis	n/a	281	100.0	2	0.7	0.2	2.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR2_SG.xls
26MAR2021 13:39

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	< 65	176	62.6	46	26.1	20.2	33.1
		>= 65	105	37.4	38	36.2	27.6	45.7
	Anaemia	< 65	176	62.6	27	15.3	10.8	21.4
		>= 65	105	37.4	28	26.7	19.1	35.8
	Aplastic anaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bone marrow oedema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Leukopenia	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Lymphopenia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Neutropenia	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	9	8.6	4.6	15.5
	Pancytopenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Thrombocytopenia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Thrombocytosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Cardiac disorders	-Total	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	5	4.8	2.1	10.7
	Acute coronary syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Angina pectoris	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Atrial fibrillation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cardiac failure	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nodal arrhythmia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pericardial effusion	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Tachycardia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
Congenital, familial and genetic disorders	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gilbert's syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Ear and labyrinth disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ear pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tinnitus	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vertigo	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Eye disorders	-Total	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Chalazion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Conjunctival cyst	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Keratitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ocular discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Periorbital oedema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Photopsia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ulcerative keratitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vision blurred	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
Gastrointestinal disorders	-Total	< 65	176	62.6	43	24.4	18.7	31.3
		>= 65	105	37.4	33	31.4	23.3	40.8
	Abdominal discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Abdominal distension	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Abdominal pain	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1

	Abdominal pain upper	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Ascites	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Constipation	< 65	176	62.6	14	8.0	4.8	12.9
		>= 65	105	37.4	9	8.6	4.6	15.5
	Diarrhoea	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	7	6.7	3.3	13.1
	Dry mouth	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Dyspepsia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dysphagia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Enteritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastric ulcer	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastritis erosive	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastrooesophageal reflux disease	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Haematochezia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haemorrhoids	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Irritable bowel syndrome	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Mouth ulceration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nausea	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	6	5.7	2.6	11.9
	Odynophagia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oesophagitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oral pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Pancreatitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rectal prolapse	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Stomatitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Toothache	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vomiting	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	2	1.9	0.5	6.7
General disorders and administration site conditions	-Total	< 65	176	62.6	45	25.6	19.7	32.5
		>= 65	105	37.4	42	40.0	31.1	49.6
	Asthenia	< 65	176	62.6	11	6.3	3.5	10.8
		>= 65	105	37.4	8	7.6	3.9	14.3
	Chest pain	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Disease progression	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Face oedema	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Facial pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fatigue	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	15	14.3	8.9	22.2
	Gait disturbance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	General physical health deterioration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Influenza like illness	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Malaise	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Mucosal inflammation	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	5	4.8	2.1	10.7
	Non-cardiac chest pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oedema peripheral	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	5	4.8	2.1	10.7
	Pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Peripheral swelling	< 65	176	62.6	0	0.0	0.0	2.1

		>= 65	105	37.4	2	1.9	0.5	6.7
	Pyrexia	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	11	10.5	6.0	17.8
Hepatobiliary disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hyperbilirubinaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Portal vein thrombosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Immune system disorders	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Contrast media allergy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Seasonal allergy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Infections and infestations	-Total	< 65	176	62.6	59	33.5	27.0	40.8
		>= 65	105	37.4	25	23.8	16.7	32.8
	Abdominal abscess	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Arthritis infective	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Atypical pneumonia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bacteraemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bacterial vaginosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bronchitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cellulitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Chronic sinusitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Conjunctivitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Corona virus infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cystitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cystitis escherichia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Epididymitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Escherichia infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Escherichia urinary tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Febrile infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Fungal infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastroenteritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Genital herpes	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gingivitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Herpes virus infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Herpes zoster	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Influenza	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lung infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lyme disease	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymph node tuberculosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nasopharyngitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oral candidiasis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	5	4.8	2.1	10.7
	Oral fungal infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oropharyngeal candidiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Otitis externa	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Paronychia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Pharyngitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	5	4.8	2.1	10.7
	Pneumonia influenzal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia pseudomonal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia streptococcal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyuria	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Respiratory tract infection bacterial	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rhinitis	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sepsis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sinusitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Skin infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Staphylococcal infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Systemic infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tinea cruris	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tonsillitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Upper respiratory tract infection	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
	Urethritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary tract infection	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	7	6.7	3.3	13.1
	Varicella	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Varicella zoster virus infection	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Viral hepatitis carrier	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Viral infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vulvovaginal candidiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Injury, poisoning and procedural complications	-Total	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	6	5.7	2.6	11.9
	Fall	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Joint dislocation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscle rupture	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Procedural pneumothorax	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Thermal burn	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Wound	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Wound complication	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Wrist fracture	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Investigations	-Total	< 65	176	62.6	81	46.0	38.8	53.4
		>= 65	105	37.4	32	30.5	22.5	39.8
	Alanine aminotransferase increased	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	3	2.9	1.0	8.1
	Amylase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Aspartate aminotransferase increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	7	6.7	3.3	13.1
	Bilirubin conjugated increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood alkaline phosphatase increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood bilirubin increased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Blood bilirubin unconjugated increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

	Blood cholesterol increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood creatine phosphokinase increased	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	3	2.9	1.0	8.1
	Blood creatinine increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	3	2.9	1.0	8.1
	Blood glucose increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood iron decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood potassium decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood pressure increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	C-reactive protein increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Electrocardiogram QT prolonged	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gamma-glutamyltransferase increased	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Granulocyte count decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haemoglobin decreased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Liver function test increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymphocyte count decreased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Lymphocyte count increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neutrophil count decreased	< 65	176	62.6	22	12.5	8.4	18.2
		>= 65	105	37.4	7	6.7	3.3	13.1
	Neutrophil percentage increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Platelet count decreased	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Platelet count increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Procalcitonin increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Serum amyloid A protein increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Total bile acids increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Weight decreased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Weight increased	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	White blood cell count decreased	< 65	176	62.6	27	15.3	10.8	21.4
		>= 65	105	37.4	7	6.7	3.3	13.1
Metabolism and nutrition disorders	-Total	< 65	176	62.6	35	19.9	14.7	26.4
		>= 65	105	37.4	21	20.0	13.5	28.6
	Abnormal loss of weight	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Decreased appetite	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	7	6.7	3.3	13.1
	Dehydration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Electrolyte imbalance	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypercalcaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperglycaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperkalaemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hyperlipidaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperphosphataemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypertriglyceridaemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypoalbuminaemia	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	4	3.8	1.5	9.4
	Hypocalcaemia	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Hypochloraemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypokalaemia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hypomagnesaemia	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyponatraemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypophosphataemia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypoproteinaemia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
Musculoskeletal and connective tissue disorders	-Total	< 65	176	62.6	24	13.6	9.3	19.5
		>= 65	105	37.4	16	15.2	9.6	23.3
	Arthralgia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Back pain	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	5	4.8	2.1	10.7
	Bone pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bursitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Flank pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Joint range of motion decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscle spasms	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscular weakness	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Musculoskeletal chest pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Musculoskeletal pain	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Myalgia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neck pain	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pain in extremity	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
	Spinal column stenosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Spinal osteoarthritis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Tendon disorder	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Metastases to central nervous system	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Nervous system disorders	-Total	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	20	19.0	12.7	27.6
	Balance disorder	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dizziness	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	5	4.8	2.1	10.7
	Dysgeusia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Headache	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hemiplegia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypoaesthesia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Lumbar radiculopathy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Memory impairment	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Migraine with aura	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neuropathy peripheral	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Paraesthesia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Polyneuropathy chronic	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Presyncope	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Restless legs syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Seizure	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Somnolence	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Syncope	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1

Psychiatric disorders	-Total	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Abnormal behaviour	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Adjustment disorder with mixed anxiety and depressed mood	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Anxiety	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Delirium	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Depressed mood	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Insomnia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mental status changes	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Renal and urinary disorders	-Total	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Acute kidney injury	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Azotaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dysuria	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haematuria	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haemorrhage urinary tract	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Nephritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Proteinuria	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Strangury	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary retention	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Reproductive system and breast disorders	-Total	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Benign prostatic hyperplasia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Erectile dysfunction	< 65	176	62.6	4	2.3	0.9	5.7

		>= 65	105	37.4	0	0.0	0.0	3.5
	Prostatitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Respiratory, thoracic and mediastinal disorders	-Total	< 65	176	62.6	42	23.9	18.2	30.7
		>= 65	105	37.4	27	25.7	18.3	34.8
	Bronchospasm	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cough	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	7	6.7	3.3	13.1
	Dyspnoea	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	7	6.7	3.3	13.1
	Dyspnoea exertional	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Epistaxis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haemoptysis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypoxia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Interstitial lung disease	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oropharyngeal pain	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pleural effusion	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pneumonitis	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	7	6.7	3.3	13.1
	Productive cough	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Pulmonary embolism	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rhinalgia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rhinorrhoea	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sputum discoloured	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Vocal cord leukoplakia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Skin and subcutaneous tissue disorders	-Total	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	12	11.4	6.7	18.9

	Decubitus ulcer	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dermatitis allergic	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dermatitis bullous	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eczema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Erythema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hirsutism	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperhidrosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pruritus	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Rash	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Rash macular	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Scab	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Swelling face	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
Surgical and medical procedures	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Astringent therapy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Therapy cessation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Vascular disorders	-Total	< 65	176	62.6	33	18.8	13.7	25.2
		>= 65	105	37.4	19	18.1	11.9	26.5
	Aortic dissection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Deep vein thrombosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Embolism	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haematoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Hypertension	< 65	176	62.6	26	14.8	10.3	20.8
		>= 65	105	37.4	15	14.3	8.9	22.2
	Lymphoedema	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Orthostatic hypotension	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pallor	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Superior vena cava syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Thrombophlebitis superficial	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Thrombosis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR2_SG.xls
26MAR2021 13:39

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	84	29.9	29	34.5	25.2	45.2
		1	190	67.6	53	27.9	22.0	34.7
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia	0	84	29.9	19	22.6	15.0	32.6
		1	190	67.6	35	18.4	13.6	24.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Aplastic anaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bone marrow oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Leukopenia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphopenia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutropenia	0	84	29.9	12	14.3	8.4	23.3
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

Cardiac disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute coronary syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Angina pectoris	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Atrial fibrillation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cardiac failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nodal arrhythmia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pericardial effusion	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tachycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
Congenital, familial and genetic disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gilbert's syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Ear and labyrinth disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ear pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Tinnitus	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vertigo	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Eye disorders	-Total	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Chalazion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Conjunctival cyst	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Keratitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ocular discomfort	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Periorbital oedema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Photopsia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ulcerative keratitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vision blurred	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Gastrointestinal disorders	-Total	0	84	29.9	28	33.3	24.2	43.9
		1	190	67.6	46	24.2	18.7	30.8
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal discomfort	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal distension	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain upper	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ascites	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Constipation	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diarrhoea	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dry mouth	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspepsia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysphagia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Enteritis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastric ulcer	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastritis erosive	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrooesophageal reflux disease	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematochezia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhoids	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Irritable bowel syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mouth ulceration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nausea	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Odynophagia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oesophagitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancreatitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rectal prolapse	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Stomatitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Toothache	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vomiting	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
General disorders and administration site conditions	-Total	0	84	29.9	24	28.6	20.0	39.0
		1	190	67.6	58	30.5	24.4	37.4
		2	6	2.1	5	83.3	43.6	97.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Asthenia	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disease progression	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Face oedema	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Facial pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fatigue	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	20	10.5	6.9	15.7
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gait disturbance	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	General physical health deterioration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Influenza like illness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Malaise	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mucosal inflammation	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Non-cardiac chest pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oedema peripheral	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Peripheral swelling	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyrexia	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
Hepatobiliary disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperbilirubinaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Portal vein thrombosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
Immune system disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Contrast media allergy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Seasonal allergy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Infections and infestations	-Total	0	84	29.9	31	36.9	27.4	47.6
		1	190	67.6	52	27.4	21.5	34.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal abscess	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Arthritis infective	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Atypical pneumonia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacterial vaginosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bronchitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cellulitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chronic sinusitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Conjunctivitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Corona virus infection	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis escherichia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epididymitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Escherichia infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Escherichia urinary tract infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Febrile infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fungal infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastroenteritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Genital herpes	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gingivitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Herpes virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Herpes zoster	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	5	2.6	1.1	6.0

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Influenza	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lung infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lyme disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymph node tuberculosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nasopharyngitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral candidiasis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oral fungal infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oropharyngeal candidiasis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Otitis externa	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paronychia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pharyngitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia influenzal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia pseudomonal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia streptococcal	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory tract infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory tract infection bacterial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sepsis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinusitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Skin infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Staphylococcal infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Systemic infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Tinea cruris	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tonsillitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Upper respiratory tract infection	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urethritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary tract infection	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Varicella	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Varicella zoster virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Viral hepatitis carrier	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Viral infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vulvovaginal candidiasis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Injury, poisoning and procedural complications	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Fall	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Joint dislocation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle rupture	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Procedural pneumothorax	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thermal burn	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wound	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wound complication	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Wrist fracture	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Investigations	-Total	0	84	29.9	28	33.3	24.2	43.9
		1	190	67.6	84	44.2	37.3	51.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Alanine aminotransferase increased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Amylase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aspartate aminotransferase increased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bilirubin conjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase increased	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin increased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin unconjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood cholesterol increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase increased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatinine increased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood glucose increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood iron decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood potassium decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood pressure increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	C-reactive protein increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrocardiogram QT prolonged	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gamma-glutamyltransferase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Granulocyte count decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemoglobin decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Liver function test increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphocyte count decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphocyte count increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil count decreased	0	84	29.9	9	10.7	5.7	19.1
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil percentage increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Procalcitonin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Serum amyloid A protein increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Total bile acids increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Weight decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Weight increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	White blood cell count decreased	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	28	14.7	10.4	20.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
Metabolism and nutrition disorders	-Total	0	84	29.9	16	19.0	12.1	28.7
		1	190	67.6	40	21.1	15.9	27.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal loss of weight	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Decreased appetite	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dehydration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrolyte imbalance	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercalcaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperglycaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperkalaemia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperlipidaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Hyperphosphataemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertriglyceridaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoalbuminaemia	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypocalcaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypochloraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypokalaemia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypomagnesaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyponatraemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypophosphataemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoproteinaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Musculoskeletal and connective tissue disorders	-Total	0	84	29.9	13	15.5	9.3	24.7
		1	190	67.6	24	12.6	8.6	18.1
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Arthralgia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Back pain	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Bone pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bursitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	1	100.0	20.7	100.0
	Flank pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Joint range of motion decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle spasms	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscular weakness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal chest pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal pain	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Myalgia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neck pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain in extremity	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Spinal column stenosis	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Spinal osteoarthritis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tendon disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Metastases to central nervous system	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Nervous system disorders	-Total	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	25	13.2	9.1	18.7
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Balance disorder	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dizziness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysgeusia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Headache	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hemiplegia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoaesthesia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lumbar radiculopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Memory impairment	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Migraine with aura	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neuropathy peripheral	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Paraesthesia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Polyneuropathy chronic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Presyncope	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Restless legs syndrome	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Seizure	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Somnolence	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Syncope	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Psychiatric disorders	-Total	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Abnormal behaviour	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Adjustment disorder with mixed anxiety and depressed mood	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anxiety	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Delirium	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Depressed mood	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Insomnia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mental status changes	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Renal and urinary disorders	-Total	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute kidney injury	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Azotaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dysuria	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhage urinary tract	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Nephritis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Proteinuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Strangury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary retention	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Reproductive system and breast disorders	-Total	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Benign prostatic hyperplasia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Erectile dysfunction	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Prostatitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Respiratory, thoracic and mediastinal disorders	-Total	0	84	29.9	27	32.1	23.1	42.7
		1	190	67.6	42	22.1	16.8	28.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bronchospasm	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cough	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Dyspnoea exertional	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epistaxis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemoptysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Interstitial lung disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oropharyngeal pain	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural effusion	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonitis	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Productive cough	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary embolism	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinalgia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhinorrhoea	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sputum discoloured	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vocal cord leukoplakia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Skin and subcutaneous tissue disorders	-Total	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Decubitus ulcer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis allergic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dermatitis bullous	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eczema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Erythema	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hirsutism	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperhidrosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pruritus	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rash macular	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Scab	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Swelling face	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Surgical and medical procedures	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Astringent therapy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Therapy cessation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Vascular disorders	-Total	0	84	29.9	13	15.5	9.3	24.7
		1	190	67.6	38	20.0	14.9	26.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Aortic dissection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Deep vein thrombosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertension	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	30	15.8	11.3	21.6
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphoedema	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Orthostatic hypotension	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pallor	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Superior vena cava syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombophlebitis superficial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR2_SG.xls
26MAR2021 13:39

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	USA	64	22.8	21	32.8	22.6	45.0
		Europe (EU)	95	33.8	28	29.5	21.2	39.3
		Asia (AS)	122	43.4	35	28.7	21.4	37.3
	Anaemia	USA	64	22.8	13	20.3	12.3	31.7
		Europe (EU)	95	33.8	19	20.0	13.2	29.1
		Asia (AS)	122	43.4	23	18.9	12.9	26.7
	Aplastic anaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bone marrow oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Leukopenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Lymphopenia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neutropenia	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Pancytopenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thrombocytopenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Thrombocytosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Cardiac disorders	-Total	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Acute coronary syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Angina pectoris	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Atrial fibrillation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cardiac failure	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Nodal arrhythmia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pericardial effusion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tachycardia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Congenital, familial and genetic disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gilbert's syndrome	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Ear and labyrinth disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Ear pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tinnitus	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Vertigo	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Eye disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Chalazion	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Conjunctival cyst	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Keratitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ocular discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Periorbital oedema	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Photopsia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ulcerative keratitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vision blurred	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Gastrointestinal disorders	-Total	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	29	30.5	22.2	40.4
		Asia (AS)	122	43.4	32	26.2	19.2	34.7
	Abdominal discomfort	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Abdominal distension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Abdominal pain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Abdominal pain upper	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Ascites	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Constipation	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Diarrhoea	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Dry mouth	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Dyspepsia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Dysphagia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Enteritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastric ulcer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastritis erosive	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrooesophageal reflux disease	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haematochezia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haemorrhoids	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Irritable bowel syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Mouth ulceration	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nausea	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Odynophagia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oesophagitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oral pain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pancreatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Rectal prolapse	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Stomatitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Toothache	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Vomiting	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
General disorders and administration site conditions	-Total	USA	64	22.8	23	35.9	25.3	48.2
		Europe (EU)	95	33.8	37	38.9	29.8	49.0
		Asia (AS)	122	43.4	27	22.1	15.7	30.3
	Asthenia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	14	14.7	9.0	23.2
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Chest pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Disease progression	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Face oedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Facial pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fatigue	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Gait disturbance	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	General physical health deterioration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Influenza like illness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Malaise	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Mucosal inflammation	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Non-cardiac chest pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Oedema peripheral	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Peripheral swelling	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pyrexia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
Hepatobiliary disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hyperbilirubinaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Portal vein thrombosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Immune system disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Contrast media allergy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Seasonal allergy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Infections and infestations	-Total	USA	64	22.8	20	31.3	21.2	43.4
		Europe (EU)	95	33.8	34	35.8	26.9	45.8
		Asia (AS)	122	43.4	30	24.6	17.8	32.9
	Abdominal abscess	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Arthritis infective	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Atypical pneumonia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacteraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacterial vaginosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bronchitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cellulitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Chronic sinusitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Conjunctivitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Corona virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cystitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cystitis escherichia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epididymitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Escherichia infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Escherichia urinary tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Febrile infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fungal infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gastroenteritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Genital herpes	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gingivitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Herpes virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Herpes zoster	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Influenza	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lung infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lyme disease	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymph node tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nasopharyngitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Oral candidiasis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oral fungal infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oropharyngeal candidiasis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Otitis externa	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Paronychia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pharyngitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Pneumonia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Pneumonia influenzal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonia pseudomonal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonia streptococcal	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pyuria	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory tract infection bacterial	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhinitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Sepsis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinusitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Skin infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Staphylococcal infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Systemic infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tinea cruris	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tonsillitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Upper respiratory tract infection	USA	64	22.8	5	7.8	3.4	17.0

		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urethritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary tract infection	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Varicella	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Varicella zoster virus infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Viral hepatitis carrier	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Viral infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vulvovaginal candidiasis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Injury, poisoning and procedural complications	-Total	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Fall	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Joint dislocation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle rupture	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Procedural pneumothorax	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thermal burn	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Wound	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Wound complication	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Wrist fracture	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Investigations	-Total	USA	64	22.8	22	34.4	23.9	46.6
		Europe (EU)	95	33.8	24	25.3	17.6	34.8
		Asia (AS)	122	43.4	67	54.9	46.1	63.5
	Alanine aminotransferase increased	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Amylase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Aspartate aminotransferase increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Bilirubin conjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Blood alkaline phosphatase increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Blood bilirubin increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Blood bilirubin unconjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Blood cholesterol increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood creatine phosphokinase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Blood creatinine increased	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Blood glucose increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood iron decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood potassium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Blood pressure increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	C-reactive protein increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Electrocardiogram QT prolonged	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Gamma-glutamyltransferase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Granulocyte count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haemoglobin decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Liver function test increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymphocyte count decreased	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Lymphocyte count increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neutrophil count decreased	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	23	18.9	12.9	26.7
	Neutrophil percentage increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Platelet count decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Platelet count increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Procalcitonin increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Serum amyloid A protein increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Total bile acids increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Weight decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Weight increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	White blood cell count decreased	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	22	18.0	12.2	25.8
Metabolism and nutrition disorders	-Total	USA	64	22.8	10	15.6	8.7	26.4
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	35	28.7	21.4	37.3
	Abnormal loss of weight	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Decreased appetite	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Dehydration	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Electrolyte imbalance	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypercalcaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyperglycaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hyperkalaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hyperlipidaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyperphosphataemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hypertriglyceridaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hypoalbuminaemia	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	17	13.9	8.9	21.2
	Hypocalcaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Hypochloraemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypokalaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Hypomagnesaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyponatraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypophosphataemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Hypoproteinaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
Musculoskeletal and connective tissue disorders	-Total	USA	64	22.8	10	15.6	8.7	26.4
		Europe (EU)	95	33.8	15	15.8	9.8	24.4
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Arthralgia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Back pain	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Bone pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Bursitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Flank pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Joint range of motion decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Muscle spasms	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscular weakness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Musculoskeletal chest pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Musculoskeletal pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Myalgia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neck pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pain in extremity	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Spinal column stenosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Spinal osteoarthritis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tendon disorder	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Metastases to central nervous system	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Nervous system disorders	-Total	USA	64	22.8	12	18.8	11.1	30.0
		Europe (EU)	95	33.8	12	12.6	7.4	20.8
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
	Balance disorder	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dizziness	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Dysgeusia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Headache	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hemiplegia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypoaesthesia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Lumbar radiculopathy	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Memory impairment	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Migraine with aura	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neuropathy peripheral	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Paraesthesia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Polyneuropathy chronic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Presyncope	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Restless legs syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Seizure	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Somnolence	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Syncope	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Psychiatric disorders	-Total	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0

	Abnormal behaviour	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Adjustment disorder with mixed anxiety and depressed mood	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Anxiety	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Delirium	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Depressed mood	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Insomnia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Mental status changes	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Renal and urinary disorders	-Total	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Acute kidney injury	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Azotaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dysuria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Haematuria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haemorrhage urinary tract	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Nephritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Proteinuria	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Strangury	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urinary retention	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Reproductive system and breast disorders	-Total	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Benign prostatic hyperplasia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Erectile dysfunction	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Prostatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Respiratory, thoracic and mediastinal disorders	-Total	USA	64	22.8	16	25.0	16.0	36.8
		Europe (EU)	95	33.8	22	23.2	15.8	32.6
		Asia (AS)	122	43.4	31	25.4	18.5	33.8
	Bronchospasm	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cough	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	12	9.8	5.7	16.4
	Dyspnoea	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Dyspnoea exertional	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Epistaxis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haemoptysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypoxia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Interstitial lung disease	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Oropharyngeal pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pleural effusion	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonitis	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Productive cough	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Pulmonary embolism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhinalgia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhinorrhoea	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sputum discoloured	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Vocal cord leukoplakia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Skin and subcutaneous tissue disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Decubitus ulcer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dermatitis allergic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dermatitis bullous	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Eczema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Erythema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hirsutism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Hyperhidrosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pruritus	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Rash	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rash macular	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Scab	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Swelling face	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
Surgical and medical procedures	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Astringent therapy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Therapy cessation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Vascular disorders	-Total	USA	64	22.8	10	15.6	8.7	26.4
		Europe (EU)	95	33.8	16	16.8	10.6	25.6
		Asia (AS)	122	43.4	26	21.3	15.0	29.4
	Aortic dissection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Deep vein thrombosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Embolism	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haematoma	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypertension	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	24	19.7	13.6	27.6

	Lymphoedema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Orthostatic hypotension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pallor	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Superior vena cava syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Thrombophlebitis superficial	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thrombosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR2_SG.xls
26MAR2021 13:39

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	116	41.3	32	27.6	20.3	36.3
		1	77	27.4	25	32.5	23.1	43.5
		>= 2	88	31.3	27	30.7	22.0	41.0
	Anaemia	0	116	41.3	19	16.4	10.7	24.2
		1	77	27.4	17	22.1	14.3	32.5
		>= 2	88	31.3	19	21.6	14.3	31.3
	Aplastic anaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bone marrow oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Leukopenia	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Lymphopenia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Neutropenia	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	5	5.7	2.5	12.6
	Pancytopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Thrombocytopenia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Thrombocytosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Cardiac disorders	-Total	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Acute coronary syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Angina pectoris	0	116	41.3	1	0.9	0.2	4.7

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Atrial fibrillation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cardiac failure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Nodal arrhythmia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pericardial effusion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tachycardia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Congenital, familial and genetic disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gilbert's syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Ear and labyrinth disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ear pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tinnitus	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vertigo	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Eye disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	1	1.1	0.2	6.2
	Chalazion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Conjunctival cyst	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Keratitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Ocular discomfort	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Periorbital oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Photopsia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ulcerative keratitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vision blurred	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Gastrointestinal disorders	-Total	0	116	41.3	26	22.4	15.8	30.8
		1	77	27.4	21	27.3	18.6	38.1
		>= 2	88	31.3	29	33.0	24.0	43.3
	Abdominal discomfort	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Abdominal distension	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Abdominal pain	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Abdominal pain upper	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Ascites	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Constipation	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	9	10.2	5.5	18.3
	Diarrhoea	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	4	4.5	1.8	11.1
	Dry mouth	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dyspepsia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Dysphagia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Enteritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastric ulcer	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastritis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastritis erosive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrooesophageal reflux disease	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haematochezia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haemorrhoids	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Irritable bowel syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Mouth ulceration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nausea	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Odynophagia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oesophagitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oral pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pancreatitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Rectal prolapse	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Stomatitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Toothache	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Vomiting	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
General disorders and administration site conditions	-Total	0	116	41.3	34	29.3	21.8	38.2
		1	77	27.4	24	31.2	21.9	42.2
		>= 2	88	31.3	29	33.0	24.0	43.3
	Asthenia	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	4	4.5	1.8	11.1
	Chest pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Disease progression	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Face oedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Facial pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fatigue	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	11	12.5	7.1	21.0
	Gait disturbance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	General physical health deterioration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Influenza like illness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Malaise	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Mucosal inflammation	0	116	41.3	3	2.6	0.9	7.3

		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	1	1.1	0.2	6.2
	Non-cardiac chest pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oedema peripheral	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Peripheral swelling	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pyrexia	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	6	6.8	3.2	14.1
Hepatobiliary disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperbilirubinaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Portal vein thrombosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Immune system disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Contrast media allergy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Seasonal allergy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Infections and infestations	-Total	0	116	41.3	25	21.6	15.0	29.9
		1	77	27.4	23	29.9	20.8	40.8
		>= 2	88	31.3	36	40.9	31.2	51.4
	Abdominal abscess	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Arthritis infective	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Atypical pneumonia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Bacteraemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bacterial vaginosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bronchitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Cellulitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Chronic sinusitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Conjunctivitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Corona virus infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cystitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cystitis escherichia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Epididymitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Escherichia infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Escherichia urinary tract infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Febrile infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Fungal infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastroenteritis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Genital herpes	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gingivitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Herpes virus infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Herpes zoster	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Influenza	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lung infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lyme disease	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lymph node tuberculosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nasopharyngitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oral candidiasis	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oral fungal infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oropharyngeal candidiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Otitis externa	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Paronychia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pharyngitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2

	Pneumonia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	7	8.0	3.9	15.5
	Pneumonia influenzal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonia pseudomonal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia streptococcal	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pyuria	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Respiratory tract infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiratory tract infection bacterial	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Sepsis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sinusitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Skin infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Staphylococcal infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Systemic infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tinea cruris	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tonsillitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Upper respiratory tract infection	0	116	41.3	2	1.7	0.5	6.1

		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Urethritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urinary tract infection	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	11	12.5	7.1	21.0
	Varicella	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Varicella zoster virus infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Viral hepatitis carrier	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Viral infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vulvovaginal candidiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Injury, poisoning and procedural complications	-Total	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	7	8.0	3.9	15.5
	Fall	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Joint dislocation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Muscle rupture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Procedural pneumothorax	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Thermal burn	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Wound	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Wound complication	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Wrist fracture	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Investigations	-Total	0	116	41.3	46	39.7	31.2	48.8
		1	77	27.4	27	35.1	25.3	46.2
		>= 2	88	31.3	40	45.5	35.5	55.8
	Alanine aminotransferase increased	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Amylase increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Aspartate aminotransferase increased	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	8	9.1	4.7	16.9
	Bilirubin conjugated increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Blood alkaline phosphatase increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	6	6.8	3.2	14.1
	Blood bilirubin increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Blood bilirubin unconjugated increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood cholesterol increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood creatine phosphokinase increased	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Blood creatinine increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Blood glucose increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood iron decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood potassium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Blood pressure increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	C-reactive protein increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Electrocardiogram QT prolonged	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gamma-glutamyltransferase increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Granulocyte count decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haemoglobin decreased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Liver function test increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lymphocyte count decreased	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Lymphocyte count increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neutrophil count decreased	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	11	12.5	7.1	21.0
	Neutrophil percentage increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Platelet count decreased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Platelet count increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Procalcitonin increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Serum amyloid A protein increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Total bile acids increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Weight decreased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Weight increased	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	White blood cell count decreased	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	15	17.0	10.6	26.2
Metabolism and nutrition disorders	-Total	0	116	41.3	19	16.4	10.7	24.2
		1	77	27.4	15	19.5	12.2	29.7
		>= 2	88	31.3	22	25.0	17.1	35.0
	Abnormal loss of weight	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Decreased appetite	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	5	5.7	2.5	12.6
	Dehydration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Electrolyte imbalance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypercalcaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperglycaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperkalaemia	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperlipidaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperphosphataemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hypertriglyceridaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypoalbuminaemia	0	116	41.3	5	4.3	1.9	9.7

		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	9	10.2	5.5	18.3
	Hypocalcaemia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hypochloraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypokalaemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Hypomagnesaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyponatraemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypophosphataemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hypoproteinaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
Musculoskeletal and connective tissue disorders	-Total	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	14	18.2	11.2	28.2
		>= 2	88	31.3	13	14.8	8.8	23.7
	Arthralgia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Back pain	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	6	6.8	3.2	14.1
	Bone pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bursitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Flank pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Joint range of motion decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Muscle spasms	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1	0.2	6.2
	Muscular weakness	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Musculoskeletal chest pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Musculoskeletal pain	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Myalgia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neck pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Pain in extremity	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Spinal column stenosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Spinal osteoarthritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tendon disorder	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Metastases to central nervous system	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Nervous system disorders	-Total	0	116	41.3	12	10.3	6.0	17.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	12	13.6	8.0	22.3
	Balance disorder	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Dizziness	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Dysgeusia	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Headache	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hemiplegia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypoaesthesia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lumbar radiculopathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Memory impairment	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Migraine with aura	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Neuropathy peripheral	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Paraesthesia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Polyneuropathy chronic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Presyncope	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Restless legs syndrome	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Seizure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Somnolence	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Syncope	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
Psychiatric disorders	-Total	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	6	6.8	3.2	14.1

	Abnormal behaviour	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Adjustment disorder with mixed anxiety and depressed mood	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Anxiety	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Delirium	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Depressed mood	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Insomnia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Mental status changes	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Renal and urinary disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	9	10.2	5.5	18.3
	Acute kidney injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Azotaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dysuria	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Haematuria	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemorrhage urinary tract	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Nephritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Proteinuria	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Strangury	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Urinary retention	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Reproductive system and breast disorders	-Total	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Benign prostatic hyperplasia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Erectile dysfunction	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Prostatitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Respiratory, thoracic and mediastinal disorders	-Total	0	116	41.3	26	22.4	15.8	30.8
		1	77	27.4	23	29.9	20.8	40.8
		>= 2	88	31.3	20	22.7	15.2	32.5
	Bronchospasm	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cough	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	11	14.3	8.2	23.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Dyspnoea	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	7	8.0	3.9	15.5
	Dyspnoea exertional	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Epistaxis	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haemoptysis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypoxia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Interstitial lung disease	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oropharyngeal pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	4	5.2	2.0	12.6

		>= 2	88	31.3	0	0.0	0.0	4.2
	Pleural effusion	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pneumonitis	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	7	8.0	3.9	15.5
	Productive cough	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pulmonary embolism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinalgia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhinorrhoea	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sputum discoloured	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vocal cord leukoplakia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Skin and subcutaneous tissue disorders	-Total	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	4	4.5	1.8	11.1
	Decubitus ulcer	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dermatitis allergic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dermatitis bullous	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Eczema	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Erythema	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hirsutism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Hyperhidrosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pruritus	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Rash	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rash macular	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Scab	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Swelling face	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Surgical and medical procedures	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Astringent therapy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Therapy cessation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Vascular disorders	-Total	0	116	41.3	15	12.9	8.0	20.2
		1	77	27.4	15	19.5	12.2	29.7
		>= 2	88	31.3	22	25.0	17.1	35.0
	Aortic dissection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Deep vein thrombosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Embolism	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haematoma	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypertension	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	12	15.6	9.1	25.3
		>= 2	88	31.3	16	18.2	11.5	27.5

	Lymphoedema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Orthostatic hypotension	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pallor	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Superior vena cava syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Thrombophlebitis superficial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Thrombosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR2_SG.xls
26MAR2021 13:39

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Asian	128	45.6	38	29.7	22.5	38.1
		Non-Asian	135	48.0	41	30.4	23.2	38.6
		Unknown	18	6.4	5	27.8	12.5	50.9
	Anaemia	Asian	128	45.6	25	19.5	13.6	27.2
		Non-Asian	135	48.0	28	20.7	14.8	28.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Aplastic anaemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bone marrow oedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Leukopenia	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutropenia	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	16	11.9	7.4	18.4
		Unknown	18	6.4	3	16.7	5.8	39.2
	Pancytopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytopenia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Cardiac disorders	-Total	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Acute coronary syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Angina pectoris	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Atrial fibrillation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cardiac failure	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nodal arrhythmia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pericardial effusion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tachycardia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Congenital, familial and genetic disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gilbert's syndrome	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Ear and labyrinth disorders	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ear pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinnitus	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vertigo	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Eye disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chalazion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Conjunctival cyst	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Keratitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Ocular discomfort	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Periorbital oedema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Photopsia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ulcerative keratitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vision blurred	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Gastrointestinal disorders	-Total	Asian	128	45.6	35	27.3	20.4	35.6
		Non-Asian	135	48.0	37	27.4	20.6	35.5
		Unknown	18	6.4	4	22.2	9.0	45.2
	Abdominal discomfort	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal distension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal pain	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal pain upper	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Ascites	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Constipation	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Diarrhoea	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dry mouth	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dyspepsia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Dysphagia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Enteritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastric ulcer	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastritis erosive	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrooesophageal reflux disease	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematochezia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhoids	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Irritable bowel syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mouth ulceration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nausea	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Odynophagia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oesophagitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancreatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Rectal prolapse	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Stomatitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Toothache	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vomiting	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	1	5.6	1.0	25.8
General disorders and administration site conditions	-Total	Asian	128	45.6	30	23.4	16.9	31.5
		Non-Asian	135	48.0	51	37.8	30.0	46.2
		Unknown	18	6.4	6	33.3	16.3	56.3
	Asthenia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	12	8.9	5.2	14.9
		Unknown	18	6.4	3	16.7	5.8	39.2
	Chest pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Disease progression	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Face oedema	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Facial pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fatigue	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	20	14.8	9.8	21.8
		Unknown	18	6.4	2	11.1	3.1	32.8
	Gait disturbance	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	General physical health deterioration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Influenza like illness	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Malaise	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Mucosal inflammation	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Non-cardiac chest pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oedema peripheral	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Peripheral swelling	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyrexia	Asian	128	45.6	14	10.9	6.6	17.5
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
Hepatobiliary disorders	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperbilirubinaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Portal vein thrombosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Immune system disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Contrast media allergy	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Seasonal allergy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Infections and infestations	-Total	Asian	128	45.6	30	23.4	16.9	31.5
		Non-Asian	135	48.0	50	37.0	29.4	45.4
		Unknown	18	6.4	4	22.2	9.0	45.2
	Abdominal abscess	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Arthritis infective	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Atypical pneumonia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Bacterial vaginosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bronchitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cellulitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chronic sinusitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Conjunctivitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Corona virus infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis escherichia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epididymitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Escherichia infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Escherichia urinary tract infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Febrile infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fungal infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastroenteritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Genital herpes	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gingivitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Herpes virus infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Herpes zoster	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Influenza	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lung infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Lyme disease	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymph node tuberculosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nasopharyngitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral candidiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oral fungal infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oropharyngeal candidiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Otitis externa	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Paronychia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pharyngitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

	Pneumonia	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia influenzal	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia pseudomonal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumonia streptococcal	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyuria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory tract infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory tract infection bacterial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sepsis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinusitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Skin infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Staphylococcal infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Systemic infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tinea cruris	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tonsillitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Upper respiratory tract infection	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urethritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary tract infection	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Varicella	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Varicella zoster virus infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Viral hepatitis carrier	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Viral infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vulvovaginal candidiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Injury, poisoning and procedural complications	-Total	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fall	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint dislocation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle rupture	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Procedural pneumothorax	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thermal burn	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wound	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wound complication	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Wrist fracture	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Investigations	-Total	Asian	128	45.6	67	52.3	43.7	60.8
		Non-Asian	135	48.0	40	29.6	22.6	37.8
		Unknown	18	6.4	6	33.3	16.3	56.3
	Alanine aminotransferase increased	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Amylase increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aspartate aminotransferase increased	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Bilirubin conjugated increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood alkaline phosphatase increased	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood bilirubin increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood bilirubin unconjugated increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood cholesterol increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine phosphokinase increased	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Blood creatinine increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Blood glucose increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood iron decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood potassium decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Blood pressure increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	C-reactive protein increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrocardiogram QT prolonged	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gamma-glutamyltransferase increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Granulocyte count decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemoglobin decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Liver function test increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphocyte count decreased	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphocyte count increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutrophil count decreased	Asian	128	45.6	23	18.0	12.3	25.5
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Neutrophil percentage increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Platelet count decreased	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Platelet count increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Procalcitonin increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Serum amyloid A protein increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Total bile acids increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Weight decreased	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Weight increased	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	White blood cell count decreased	Asian	128	45.6	22	17.2	11.6	24.7
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	1	5.6	1.0	25.8
Metabolism and nutrition disorders	-Total	Asian	128	45.6	37	28.9	21.8	37.3
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	Abnormal loss of weight	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Decreased appetite	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dehydration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Electrolyte imbalance	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercalcaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperglycaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperkalaemia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperlipidaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperphosphataemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypertriglyceridaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoalbuminaemia	Asian	128	45.6	17	13.3	8.5	20.2

		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypocalcaemia	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypochloraemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypokalaemia	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypomagnesaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyponatraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypophosphataemia	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoproteinaemia	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Musculoskeletal and connective tissue disorders	-Total	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	22	16.3	11.0	23.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Arthralgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Back pain	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bone pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bursitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Flank pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Joint range of motion decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle spasms	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2

		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscular weakness	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Musculoskeletal chest pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Musculoskeletal pain	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Myalgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neck pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pain in extremity	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Spinal column stenosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Spinal osteoarthritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tendon disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Metastases to central nervous system	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Nervous system disorders	-Total	Asian	128	45.6	15	11.7	7.2	18.4
		Non-Asian	135	48.0	19	14.1	9.2	20.9
		Unknown	18	6.4	3	16.7	5.8	39.2
	Balance disorder	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dizziness	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysgeusia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6

	Headache	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Hemiplegia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoaesthesia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lumbar radiculopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Memory impairment	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Migraine with aura	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Neuropathy peripheral	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Paraesthesia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Polyneuropathy chronic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Presyncope	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Restless legs syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Seizure	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Somnolence	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Syncope	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
Psychiatric disorders	-Total	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8

	Abnormal behaviour	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Adjustment disorder with mixed anxiety and depressed mood	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anxiety	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Delirium	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Depressed mood	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Insomnia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Mental status changes	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Renal and urinary disorders	-Total	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Acute kidney injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Azotaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dysuria	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematuria	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhage urinary tract	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nephritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Proteinuria	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Strangury	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary retention	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Reproductive system and breast disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Benign prostatic hyperplasia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Erectile dysfunction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Prostatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Respiratory, thoracic and mediastinal disorders	-Total	Asian	128	45.6	33	25.8	19.0	34.0
		Non-Asian	135	48.0	32	23.7	17.3	31.5
		Unknown	18	6.4	4	22.2	9.0	45.2
	Bronchospasm	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cough	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dyspnoea	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dyspnoea exertional	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epistaxis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Haemoptysis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoxia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Interstitial lung disease	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oropharyngeal pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4

		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleural effusion	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumonitis	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Productive cough	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary embolism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinalgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhinorrhoea	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sputum discoloured	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vocal cord leukoplakia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Skin and subcutaneous tissue disorders	-Total	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Decubitus ulcer	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermatitis allergic	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dermatitis bullous	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eczema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Erythema	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hirsutism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Hyperhidrosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pruritus	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rash	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rash macular	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Scab	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Swelling face	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Surgical and medical procedures	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Astringent therapy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Therapy cessation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Vascular disorders	-Total	Asian	128	45.6	27	21.1	14.9	29.0
		Non-Asian	135	48.0	23	17.0	11.6	24.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Aortic dissection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Deep vein thrombosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Embolism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypertension	Asian	128	45.6	25	19.5	13.6	27.2
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	2	11.1	3.1	32.8

	Lymphoedema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Orthostatic hypotension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pallor	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Superior vena cava syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombophlebitis superficial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR2_SG.xls
26MAR2021 13:39

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Female	152	54.1	52	34.2	27.1	42.1
		Male	129	45.9	32	24.8	18.2	32.9
	Anaemia	Female	152	54.1	34	22.4	16.5	29.6
		Male	129	45.9	21	16.3	10.9	23.6
	Aplastic anaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bone marrow oedema	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Leukopenia	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	5	3.9	1.7	8.8
	Lymphopenia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Neutropenia	Female	152	54.1	17	11.2	7.1	17.2
		Male	129	45.9	7	5.4	2.7	10.8
	Pancytopenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Thrombocytopenia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Thrombocytosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Cardiac disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	7	5.4	2.7	10.8
	Acute coronary syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Angina pectoris	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Atrial fibrillation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cardiac failure	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Nodal arrhythmia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pericardial effusion	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
	Tachycardia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
Congenital, familial and genetic disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gilbert's syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Ear and labyrinth disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ear pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tinnitus	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vertigo	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Eye disorders	-Total	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Chalazion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Conjunctival cyst	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Keratitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ocular discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Periorbital oedema	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Photopsia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ulcerative keratitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Vision blurred	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
Gastrointestinal disorders	-Total	Female	152	54.1	42	27.6	21.1	35.2
		Male	129	45.9	34	26.4	19.5	34.6
	Abdominal discomfort	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Abdominal distension	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Abdominal pain	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	2	1.6	0.4	5.5

	Abdominal pain upper	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Ascites	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Constipation	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	11	8.5	4.8	14.6
	Diarrhoea	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	7	5.4	2.7	10.8
	Dry mouth	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Dyspepsia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Dysphagia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Enteritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastric ulcer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastritis erosive	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gastrooesophageal reflux disease	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Haematochezia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Haemorrhoids	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Irritable bowel syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Mouth ulceration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nausea	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	6	4.7	2.1	9.8
	Odynophagia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Oesophagitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oral pain	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9

	Pancreatitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rectal prolapse	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Stomatitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Toothache	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Vomiting	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	4	3.1	1.2	7.7
General disorders and administration site conditions	-Total	Female	152	54.1	44	28.9	22.3	36.6
		Male	129	45.9	43	33.3	25.8	41.8
	Asthenia	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	8	6.2	3.2	11.8
	Chest pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Disease progression	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Face oedema	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Facial pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Fatigue	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	16	12.4	7.8	19.2
	Gait disturbance	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	General physical health deterioration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Influenza like illness	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Malaise	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Mucosal inflammation	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	1	0.8	0.1	4.3
	Non-cardiac chest pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Oedema peripheral	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	1	0.8	0.1	4.3
	Pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Peripheral swelling	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	2	1.6	0.4	5.5
	Pyrexia	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	14	10.9	6.6	17.4
Hepatobiliary disorders	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Hyperbilirubinaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Portal vein thrombosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Immune system disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Contrast media allergy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Seasonal allergy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Infections and infestations	-Total	Female	152	54.1	49	32.2	25.3	40.0
		Male	129	45.9	35	27.1	20.2	35.4
	Abdominal abscess	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Arthritis infective	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Atypical pneumonia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bacteraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Bacterial vaginosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bronchitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Cellulitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Chronic sinusitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Conjunctivitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Corona virus infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cystitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cystitis escherichia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Epididymitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Escherichia infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Escherichia urinary tract infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Febrile infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Fungal infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gastroenteritis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Genital herpes	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Gingivitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Herpes virus infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Herpes zoster	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	3	2.3	0.8	6.6
	Influenza	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lung infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lyme disease	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lymph node tuberculosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nasopharyngitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Oral candidiasis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	4	3.1	1.2	7.7
	Oral fungal infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Oropharyngeal candidiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Otitis externa	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Paronychia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Pharyngitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonia	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	7	5.4	2.7	10.8
	Pneumonia influenzal	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonia pseudomonal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pneumonia streptococcal	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pyuria	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Respiratory tract infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Respiratory tract infection bacterial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rhinitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Sepsis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sinusitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Skin infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Staphylococcal infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Systemic infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tinea cruris	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tonsillitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Upper respiratory tract infection	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	2	1.6	0.4	5.5
	Urethritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urinary tract infection	Female	152	54.1	18	11.8	7.6	17.9
		Male	129	45.9	5	3.9	1.7	8.8
	Varicella	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Varicella zoster virus infection	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
	Viral hepatitis carrier	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Viral infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Vulvovaginal candidiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Injury, poisoning and procedural complications	-Total	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	8	6.2	3.2	11.8
	Fall	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	5	3.9	1.7	8.8
	Joint dislocation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Muscle rupture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Procedural pneumothorax	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thermal burn	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Wound	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Wound complication	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Wrist fracture	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Investigations	-Total	Female	152	54.1	70	46.1	38.3	54.0
		Male	129	45.9	43	33.3	25.8	41.8
	Alanine aminotransferase increased	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	6	4.7	2.1	9.8
	Amylase increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Aspartate aminotransferase increased	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	4	3.1	1.2	7.7
	Bilirubin conjugated increased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Blood alkaline phosphatase increased	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Blood bilirubin increased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	3	2.3	0.8	6.6
	Blood bilirubin unconjugated increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5

	Blood cholesterol increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood creatine phosphokinase increased	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	5	3.9	1.7	8.8
	Blood creatinine increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	7	5.4	2.7	10.8
	Blood glucose increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood iron decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood potassium decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Blood pressure increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	C-reactive protein increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Electrocardiogram QT prolonged	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gamma-glutamyltransferase increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Granulocyte count decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haemoglobin decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Liver function test increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lymphocyte count decreased	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Lymphocyte count increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Neutrophil count decreased	Female	152	54.1	19	12.5	8.2	18.7
		Male	129	45.9	10	7.8	4.3	13.7
	Neutrophil percentage increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Platelet count decreased	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	2	1.6	0.4	5.5
	Platelet count increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Procalcitonin increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Serum amyloid A protein increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Total bile acids increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Weight decreased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Weight increased	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	4	3.1	1.2	7.7
	White blood cell count decreased	Female	152	54.1	21	13.8	9.2	20.2
		Male	129	45.9	13	10.1	6.0	16.5
Metabolism and nutrition disorders	-Total	Female	152	54.1	33	21.7	15.9	28.9
		Male	129	45.9	23	17.8	12.2	25.3
	Abnormal loss of weight	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Decreased appetite	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	6	4.7	2.1	9.8
	Dehydration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Electrolyte imbalance	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypercalcaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperglycaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperkalaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	4	3.1	1.2	7.7
	Hyperlipidaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperphosphataemia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypertriglyceridaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hypoalbuminaemia	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	9	7.0	3.7	12.7
	Hypocalcaemia	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	4	3.1	1.2	7.7
	Hypochloraemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypokalaemia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	4	3.1	1.2	7.7
	Hypomagnesaemia	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Hyponatraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypophosphataemia	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Hypoproteinaemia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
Musculoskeletal and connective tissue disorders	-Total	Female	152	54.1	20	13.2	8.7	19.5
		Male	129	45.9	20	15.5	10.3	22.7
	Arthralgia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Back pain	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	7	5.4	2.7	10.8
	Bone pain	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Bursitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Flank pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Joint range of motion decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Muscle spasms	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Muscular weakness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Musculoskeletal chest pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Musculoskeletal pain	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	6	4.7	2.1	9.8
	Myalgia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Neck pain	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Pain in extremity	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	4	3.1	1.2	7.7
	Spinal column stenosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Spinal osteoarthritis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tendon disorder	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Metastases to central nervous system	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Nervous system disorders	-Total	Female	152	54.1	22	14.5	9.8	20.9
		Male	129	45.9	15	11.6	7.2	18.3
	Balance disorder	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Dizziness	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	4	3.1	1.2	7.7
	Dysgeusia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Headache	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Hemiplegia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypoaesthesia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Lumbar radiculopathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Memory impairment	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Migraine with aura	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neuropathy peripheral	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Paraesthesia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Polyneuropathy chronic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Presyncope	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Restless legs syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Seizure	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Somnolence	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Syncope	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5

Psychiatric disorders	-Total	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	7	5.4	2.7	10.8
	Abnormal behaviour	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Adjustment disorder with mixed anxiety and depressed mood	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Anxiety	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Delirium	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Depressed mood	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Insomnia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Mental status changes	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Renal and urinary disorders	-Total	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	8	6.2	3.2	11.8
	Acute kidney injury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Azotaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dysuria	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	4	3.1	1.2	7.7
	Haematuria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Haemorrhage urinary tract	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Nephritis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Proteinuria	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Strangury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urinary retention	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Reproductive system and breast disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	6	4.7	2.1	9.8
	Benign prostatic hyperplasia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Erectile dysfunction	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	4	3.1	1.2	7.7
	Prostatitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Respiratory, thoracic and mediastinal disorders	-Total	Female	152	54.1	42	27.6	21.1	35.2
		Male	129	45.9	27	20.9	14.8	28.7
	Bronchospasm	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cough	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	7	5.4	2.7	10.8
	Dyspnoea	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	8	6.2	3.2	11.8
	Dyspnoea exertional	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	5	3.9	1.7	8.8
	Epistaxis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Haemoptysis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypoxia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Interstitial lung disease	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Oropharyngeal pain	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	0	0.0	0.0	2.9
	Pleural effusion	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Pneumonitis	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	5	3.9	1.7	8.8
	Productive cough	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Pulmonary embolism	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Rhinalgia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rhinorrhoea	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Sputum discoloured	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Vocal cord leukoplakia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Skin and subcutaneous tissue disorders	-Total	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	6	4.7	2.1	9.8

	Decubitus ulcer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dermatitis allergic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dermatitis bullous	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Eczema	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Erythema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hirsutism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hyperhidrosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pruritus	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Rash	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rash macular	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Scab	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Swelling face	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
Surgical and medical procedures	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Astringent therapy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Therapy cessation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Vascular disorders	-Total	Female	152	54.1	28	18.4	13.1	25.3
		Male	129	45.9	24	18.6	12.8	26.2
	Aortic dissection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Deep vein thrombosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Embolism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Haematoma	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Hypertension	Female	152	54.1	21	13.8	9.2	20.2
		Male	129	45.9	20	15.5	10.3	22.7
	Lymphoedema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Orthostatic hypotension	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pallor	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Superior vena cava syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombophlebitis superficial	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR2_SG.xls
26MAR2021 13:39

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	210	74.7	69.3	79.5
Sex	Female	152	54.1	116	76.3	69.0	82.4
	Male	129	45.9	94	72.9	64.6	79.8
Age	< 65	176	62.6	119	67.6	60.4	74.1
	>= 65	105	37.4	91	86.7	78.9	91.9
ECOG performance status	0	84	29.9	57	67.9	57.3	76.9
	1	190	67.6	147	77.4	70.9	82.7
	2	6	2.1	6	100.0	61.0	100.0
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	55	85.9	75.4	92.4
	Europe (EU)	95	33.8	60	63.2	53.1	72.2
	Asia (AS)	122	43.4	95	77.9	69.7	84.3
Race/ethnicity	Asian	128	45.6	101	78.9	71.0	85.1
	Non-Asian	135	48.0	97	71.9	63.7	78.8
	Unknown	18	6.4	12	66.7	43.7	83.7
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	81	69.8	60.9	77.4
	1	77	27.4	59	76.6	66.0	84.7
	>= 2	88	31.3	70	79.5	70.0	86.7

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AEGR345_SG.xls
26MAR2021 10:19

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	212	75.4	70.1	80.1
Sex	Female	152	54.1	117	77.0	69.7	83.0
	Male	129	45.9	95	73.6	65.4	80.5
Age	< 65	176	62.6	121	68.8	61.6	75.1
	>= 65	105	37.4	91	86.7	78.9	91.9
ECOG performance status	0	84	29.9	57	67.9	57.3	76.9
	1	190	67.6	149	78.4	72.0	83.7
	2	6	2.1	6	100.0	61.0	100.0
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	55	85.9	75.4	92.4
	Europe (EU)	95	33.8	60	63.2	53.1	72.2
	Asia (AS)	122	43.4	97	79.5	71.5	85.7
Race/ethnicity	Asian	128	45.6	103	80.5	72.8	86.4
	Non-Asian	135	48.0	97	71.9	63.7	78.8
	Unknown	18	6.4	12	66.7	43.7	83.7
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	82	70.7	61.8	78.2
	1	77	27.4	59	76.6	66.0	84.7
	>= 2	88	31.3	71	80.7	71.2	87.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw_B63_06NOV2020_SE_TO_AEGR345_SG.xls
26MAR2021 9:57

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	n/a	281	100.0	82	29.2	24.2	34.7
	Anaemia	n/a	281	100.0	46	16.4	12.5	21.1
	Anaemia macrocytic	n/a	281	100.0	1	0.4	0.1	2.0
	Disseminated intravascular coagulation	n/a	281	100.0	2	0.7	0.2	2.6
	Febrile neutropenia	n/a	281	100.0	4	1.4	0.6	3.6
	Haemorrhagic anaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Leukopenia	n/a	281	100.0	8	2.8	1.4	5.5
	Lymphopenia	n/a	281	100.0	17	6.0	3.8	9.5
	Neutropenia	n/a	281	100.0	30	10.7	7.6	14.8
	Pancytopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombocytopenia	n/a	281	100.0	8	2.8	1.4	5.5
Cardiac disorders	-Total	n/a	281	100.0	7	2.5	1.2	5.1
	Acute myocardial infarction	n/a	281	100.0	2	0.7	0.2	2.6
	Cardio-respiratory arrest	n/a	281	100.0	1	0.4	0.1	2.0
	Pericardial effusion	n/a	281	100.0	2	0.7	0.2	2.6
	Stress cardiomyopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Supraventricular tachycardia	n/a	281	100.0	1	0.4	0.1	2.0
Ear and labyrinth disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Vertigo	n/a	281	100.0	1	0.4	0.1	2.0
Endocrine disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Adrenal insufficiency	n/a	281	100.0	1	0.4	0.1	2.0
Eye disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1

	Cataract	n/a	281	100.0	2	0.7	0.2	2.6
	Keratitis	n/a	281	100.0	1	0.4	0.1	2.0
Gastrointestinal disorders	-Total	n/a	281	100.0	25	8.9	6.1	12.8
	Abdominal pain upper	n/a	281	100.0	1	0.4	0.1	2.0
	Aphthous ulcer	n/a	281	100.0	1	0.4	0.1	2.0
	Ascites	n/a	281	100.0	1	0.4	0.1	2.0
	Colitis	n/a	281	100.0	3	1.1	0.4	3.1
	Constipation	n/a	281	100.0	2	0.7	0.2	2.6
	Dental caries	n/a	281	100.0	1	0.4	0.1	2.0
	Diarrhoea	n/a	281	100.0	5	1.8	0.8	4.1
	Diverticular perforation	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal inflammation	n/a	281	100.0	1	0.4	0.1	2.0
	Intestinal obstruction	n/a	281	100.0	1	0.4	0.1	2.0
	Large intestine perforation	n/a	281	100.0	1	0.4	0.1	2.0
	Oesophagitis	n/a	281	100.0	1	0.4	0.1	2.0
	Pancreatitis acute	n/a	281	100.0	2	0.7	0.2	2.6
	Proctitis ulcerative	n/a	281	100.0	1	0.4	0.1	2.0
	Stomatitis	n/a	281	100.0	5	1.8	0.8	4.1
	Vomiting	n/a	281	100.0	3	1.1	0.4	3.1
General disorders and administration site conditions	-Total	n/a	281	100.0	22	7.8	5.2	11.6
	Asthenia	n/a	281	100.0	2	0.7	0.2	2.6
	Chest discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Chest pain	n/a	281	100.0	1	0.4	0.1	2.0
	Condition aggravated	n/a	281	100.0	1	0.4	0.1	2.0
	Death	n/a	281	100.0	2	0.7	0.2	2.6
	Fatigue	n/a	281	100.0	6	2.1	1.0	4.6
	General physical health deterioration	n/a	281	100.0	3	1.1	0.4	3.1

	Impaired healing	n/a	281	100.0	1	0.4	0.1	2.0
	Malaise	n/a	281	100.0	1	0.4	0.1	2.0
	Multiple organ dysfunction syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Non-cardiac chest pain	n/a	281	100.0	1	0.4	0.1	2.0
	Pain	n/a	281	100.0	1	0.4	0.1	2.0
	Pyrexia	n/a	281	100.0	1	0.4	0.1	2.0
Hepatobiliary disorders	-Total	n/a	281	100.0	8	2.8	1.4	5.5
	Cholecystitis	n/a	281	100.0	2	0.7	0.2	2.6
	Cholelithiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Gallbladder polyp	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperbilirubinaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Liver injury	n/a	281	100.0	1	0.4	0.1	2.0
	Portal vein thrombosis	n/a	281	100.0	2	0.7	0.2	2.6
Infections and infestations	-Total	n/a	281	100.0	66	23.5	18.9	28.8
	Appendicitis	n/a	281	100.0	2	0.7	0.2	2.6
	Bacteraemia	n/a	281	100.0	1	0.4	0.1	2.0
	Bacterial infection	n/a	281	100.0	1	0.4	0.1	2.0
	Cellulitis	n/a	281	100.0	1	0.4	0.1	2.0
	Clostridium difficile colitis	n/a	281	100.0	1	0.4	0.1	2.0
	Corona virus infection	n/a	281	100.0	1	0.4	0.1	2.0
	Cystitis	n/a	281	100.0	1	0.4	0.1	2.0
	Device related infection	n/a	281	100.0	1	0.4	0.1	2.0
	Diverticulitis	n/a	281	100.0	2	0.7	0.2	2.6
	Empyema	n/a	281	100.0	1	0.4	0.1	2.0
	Enterococcal bacteraemia	n/a	281	100.0	1	0.4	0.1	2.0
	Infectious colitis	n/a	281	100.0	1	0.4	0.1	2.0
	Lower respiratory tract infection	n/a	281	100.0	1	0.4	0.1	2.0
	Lung infection	n/a	281	100.0	3	1.1	0.4	3.1

	Meningitis	n/a	281	100.0	1	0.4	0.1	2.0
	Peritonitis	n/a	281	100.0	1	0.4	0.1	2.0
	Pleural infection	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumocystis jirovecii pneumonia	n/a	281	100.0	2	0.7	0.2	2.6
	Pneumonia	n/a	281	100.0	27	9.6	6.7	13.6
	Pneumonia bacterial	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia cytomegaloviral	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia haemophilus	n/a	281	100.0	1	0.4	0.1	2.0
	Pyelonephritis	n/a	281	100.0	1	0.4	0.1	2.0
	Pyelonephritis acute	n/a	281	100.0	1	0.4	0.1	2.0
	Rectal abscess	n/a	281	100.0	1	0.4	0.1	2.0
	Renal tuberculosis	n/a	281	100.0	1	0.4	0.1	2.0
	Sepsis	n/a	281	100.0	8	2.8	1.4	5.5
	Septic shock	n/a	281	100.0	1	0.4	0.1	2.0
	Sinusitis bacterial	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary tract infection	n/a	281	100.0	9	3.2	1.7	6.0
	Urosepsis	n/a	281	100.0	2	0.7	0.2	2.6
Injury, poisoning and procedural complications	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Fracture	n/a	281	100.0	1	0.4	0.1	2.0
	Heart injury	n/a	281	100.0	1	0.4	0.1	2.0
	Subdural haematoma	n/a	281	100.0	1	0.4	0.1	2.0
Investigations	-Total	n/a	281	100.0	89	31.7	26.5	37.3
	Alanine aminotransferase	n/a	281	100.0	1	0.4	0.1	2.0
	Alanine aminotransferase increased	n/a	281	100.0	9	3.2	1.7	6.0
	Alpha hydroxybutyrate dehydrogenase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Amylase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Aspartate aminotransferase increased	n/a	281	100.0	15	5.3	3.3	8.6
	Bilirubin conjugated increased	n/a	281	100.0	1	0.4	0.1	2.0

	Blood alkaline phosphatase increased	n/a	281	100.0	4	1.4	0.6	3.6
	Blood bilirubin increased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood bilirubin unconjugated increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood creatine phosphokinase increased	n/a	281	100.0	19	6.8	4.4	10.3
	Blood creatinine increased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood lactate dehydrogenase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood sodium decreased	n/a	281	100.0	1	0.4	0.1	2.0
	C-reactive protein increased	n/a	281	100.0	1	0.4	0.1	2.0
	Electrocardiogram QT prolonged	n/a	281	100.0	1	0.4	0.1	2.0
	Gamma-glutamyltransferase increased	n/a	281	100.0	3	1.1	0.4	3.1
	Haemoglobin decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Hepatic enzyme increased	n/a	281	100.0	1	0.4	0.1	2.0
	Lipase increased	n/a	281	100.0	3	1.1	0.4	3.1
	Lymphocyte count decreased	n/a	281	100.0	14	5.0	3.0	8.2
	Myoglobin blood increased	n/a	281	100.0	1	0.4	0.1	2.0
	Neutrophil count decreased	n/a	281	100.0	36	12.8	9.4	17.2
	Oxygen saturation decreased	n/a	281	100.0	1	0.4	0.1	2.0
	PO2 decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Platelet count decreased	n/a	281	100.0	8	2.8	1.4	5.5
	Transaminases increased	n/a	281	100.0	1	0.4	0.1	2.0
	Troponin T increased	n/a	281	100.0	1	0.4	0.1	2.0
	Troponin increased	n/a	281	100.0	1	0.4	0.1	2.0
	Weight increased	n/a	281	100.0	2	0.7	0.2	2.6
	White blood cell count decreased	n/a	281	100.0	15	5.3	3.3	8.6
Metabolism and nutrition disorders	-Total	n/a	281	100.0	46	16.4	12.5	21.1
	Acidosis	n/a	281	100.0	1	0.4	0.1	2.0
	Decreased appetite	n/a	281	100.0	2	0.7	0.2	2.6
	Dehydration	n/a	281	100.0	2	0.7	0.2	2.6

	Electrolyte imbalance	n/a	281	100.0	2	0.7	0.2	2.6
	Failure to thrive	n/a	281	100.0	1	0.4	0.1	2.0
	Hypercalcaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperkalaemia	n/a	281	100.0	4	1.4	0.6	3.6
	Hypernatraemia	n/a	281	100.0	2	0.7	0.2	2.6
	Hyperphosphataemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperuricaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypocalcaemia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypokalaemia	n/a	281	100.0	9	3.2	1.7	6.0
	Hyponatraemia	n/a	281	100.0	12	4.3	2.5	7.3
	Hypophosphataemia	n/a	281	100.0	20	7.1	4.7	10.7
Musculoskeletal and connective tissue disorders	-Total	n/a	281	100.0	13	4.6	2.7	7.8
	Arthralgia	n/a	281	100.0	1	0.4	0.1	2.0
	Back pain	n/a	281	100.0	3	1.1	0.4	3.1
	Intervertebral disc protrusion	n/a	281	100.0	4	1.4	0.6	3.6
	Muscle haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Muscular weakness	n/a	281	100.0	3	1.1	0.4	3.1
	Musculoskeletal chest pain	n/a	281	100.0	1	0.4	0.1	2.0
	Pain in extremity	n/a	281	100.0	1	0.4	0.1	2.0
	Rhabdomyolysis	n/a	281	100.0	1	0.4	0.1	2.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Cancer pain	n/a	281	100.0	1	0.4	0.1	2.0
	Gallbladder cancer	n/a	281	100.0	1	0.4	0.1	2.0
	Tumour pain	n/a	281	100.0	1	0.4	0.1	2.0
Nervous system disorders	-Total	n/a	281	100.0	14	5.0	3.0	8.2
	Ataxia	n/a	281	100.0	1	0.4	0.1	2.0
	Cerebral haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Cerebral microhaemorrhage	n/a	281	100.0	1	0.4	0.1	2.0

	Cerebrovascular accident	n/a	281	100.0	1	0.4	0.1	2.0
	Dizziness	n/a	281	100.0	1	0.4	0.1	2.0
	Epilepsy	n/a	281	100.0	1	0.4	0.1	2.0
	Facial paralysis	n/a	281	100.0	1	0.4	0.1	2.0
	Haemorrhage intracranial	n/a	281	100.0	1	0.4	0.1	2.0
	Headache	n/a	281	100.0	2	0.7	0.2	2.6
	Lumbosacral radiculopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Migraine	n/a	281	100.0	1	0.4	0.1	2.0
	Neuralgia	n/a	281	100.0	1	0.4	0.1	2.0
	Sciatica	n/a	281	100.0	2	0.7	0.2	2.6
	Seizure	n/a	281	100.0	1	0.4	0.1	2.0
	Spinal cord haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Syncope	n/a	281	100.0	3	1.1	0.4	3.1
Psychiatric disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Mental status changes	n/a	281	100.0	3	1.1	0.4	3.1
Renal and urinary disorders	-Total	n/a	281	100.0	6	2.1	1.0	4.6
	Acute kidney injury	n/a	281	100.0	2	0.7	0.2	2.6
	Haematuria	n/a	281	100.0	1	0.4	0.1	2.0
	Hydronephrosis	n/a	281	100.0	1	0.4	0.1	2.0
	Nephrolithiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Obstructive nephropathy	n/a	281	100.0	1	0.4	0.1	2.0
	Urethral stenosis	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary retention	n/a	281	100.0	1	0.4	0.1	2.0
Reproductive system and breast disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Metrorrhagia	n/a	281	100.0	1	0.4	0.1	2.0
	Ovarian cyst	n/a	281	100.0	1	0.4	0.1	2.0
	Prostatitis	n/a	281	100.0	1	0.4	0.1	2.0
Respiratory, thoracic and mediastinal disorders	-Total	n/a	281	100.0	33	11.7	8.5	16.0

	Acute respiratory failure	n/a	281	100.0	1	0.4	0.1	2.0
	Cough	n/a	281	100.0	1	0.4	0.1	2.0
	Dyspnoea	n/a	281	100.0	8	2.8	1.4	5.5
	Hypoxia	n/a	281	100.0	4	1.4	0.6	3.6
	Lung consolidation	n/a	281	100.0	1	0.4	0.1	2.0
	Pleural effusion	n/a	281	100.0	5	1.8	0.8	4.1
	Pleuritic pain	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonitis	n/a	281	100.0	6	2.1	1.0	4.6
	Pneumothorax	n/a	281	100.0	2	0.7	0.2	2.6
	Pulmonary embolism	n/a	281	100.0	9	3.2	1.7	6.0
	Pulmonary hypertension	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory distress	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory failure	n/a	281	100.0	1	0.4	0.1	2.0
Surgical and medical procedures	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Eye excision	n/a	281	100.0	1	0.4	0.1	2.0
	Hip arthroplasty	n/a	281	100.0	1	0.4	0.1	2.0
Vascular disorders	-Total	n/a	281	100.0	52	18.5	14.4	23.5
	Deep vein thrombosis	n/a	281	100.0	1	0.4	0.1	2.0
	Embolism	n/a	281	100.0	2	0.7	0.2	2.6
	Embolism venous	n/a	281	100.0	1	0.4	0.1	2.0
	Haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Hypertension	n/a	281	100.0	45	16.0	12.2	20.8
	Hypotension	n/a	281	100.0	3	1.1	0.4	3.1
	Orthostatic hypotension	n/a	281	100.0	1	0.4	0.1	2.0
	Shock haemorrhagic	n/a	281	100.0	1	0.4	0.1	2.0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR345_SG.xls
26MAR2021 14:25

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	< 65	176	62.6	51	29.0	22.8	36.1
		>= 65	105	37.4	31	29.5	21.6	38.8
	Anaemia	< 65	176	62.6	31	17.6	12.7	23.9
		>= 65	105	37.4	15	14.3	8.9	22.2
	Anaemia macrocytic	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Disseminated intravascular coagulation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Febrile neutropenia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Haemorrhagic anaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Leukopenia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Lymphopenia	< 65	176	62.6	11	6.3	3.5	10.8
		>= 65	105	37.4	6	5.7	2.6	11.9
	Neutropenia	< 65	176	62.6	20	11.4	7.5	16.9
		>= 65	105	37.4	10	9.5	5.3	16.6
	Pancytopenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Thrombocytopenia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	5	4.8	2.1	10.7
Cardiac disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Acute myocardial infarction	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Cardio-respiratory arrest	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pericardial effusion	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

	Stress cardiomyopathy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Supraventricular tachycardia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Ear and labyrinth disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vertigo	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Endocrine disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Adrenal insufficiency	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Eye disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Cataract	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Keratitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Gastrointestinal disorders	-Total	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	12	11.4	6.7	18.9
	Abdominal pain upper	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Aphthous ulcer	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ascites	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Colitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Constipation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Dental caries	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diarrhoea	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Diverticular perforation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastrointestinal haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrointestinal inflammation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Intestinal obstruction	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Large intestine perforation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oesophagitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pancreatitis acute	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Proctitis ulcerative	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Stomatitis	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Vomiting	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
General disorders and administration site conditions	-Total	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	10	9.5	5.3	16.6
	Asthenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Chest discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Chest pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Condition aggravated	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Death	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fatigue	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	General physical health deterioration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Impaired healing	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Malaise	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Multiple organ dysfunction syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Non-cardiac chest pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyrexia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Hepatobiliary disorders	-Total	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
	Cholecystitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cholelithiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gallbladder polyp	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperbilirubinaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Liver injury	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Portal vein thrombosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Infections and infestations	-Total	< 65	176	62.6	38	21.6	16.2	28.2
		>= 65	105	37.4	28	26.7	19.1	35.8
	Appendicitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bacteraemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bacterial infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cellulitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Clostridium difficile colitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Corona virus infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cystitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Device related infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diverticulitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Empyema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Enterococcal bacteraemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Infectious colitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lower respiratory tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lung infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Meningitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Peritonitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pleural infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumocystis jirovecii pneumonia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pneumonia	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	10	9.5	5.3	16.6
	Pneumonia bacterial	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia cytomegaloviral	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pneumonia haemophilus	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyelonephritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyelonephritis acute	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rectal abscess	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Renal tuberculosis	< 65	176	62.6	0	0.0	0.0	2.1

		>= 65	105	37.4	1	1.0	0.2	5.2
	Sepsis	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Septic shock	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sinusitis bacterial	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	8	7.6	3.9	14.3
	Urosepsis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Injury, poisoning and procedural complications	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Fracture	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Heart injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Subdural haematoma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Investigations	-Total	< 65	176	62.6	59	33.5	27.0	40.8
		>= 65	105	37.4	30	28.6	20.8	37.8
	Alanine aminotransferase	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Alanine aminotransferase increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	3	2.9	1.0	8.1
	Alpha hydroxybutyrate dehydrogenase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Amylase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Aspartate aminotransferase increased	< 65	176	62.6	11	6.3	3.5	10.8
		>= 65	105	37.4	4	3.8	1.5	9.4
	Bilirubin conjugated increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood alkaline phosphatase increased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood bilirubin increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

	Blood bilirubin unconjugated increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood creatine phosphokinase increased	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	7	6.7	3.3	13.1
	Blood creatinine increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood lactate dehydrogenase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood sodium decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	C-reactive protein increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Electrocardiogram QT prolonged	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gamma-glutamyltransferase increased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haemoglobin decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hepatic enzyme increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lipase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Lymphocyte count decreased	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	7	6.7	3.3	13.1
	Myoglobin blood increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neutrophil count decreased	< 65	176	62.6	26	14.8	10.3	20.8
		>= 65	105	37.4	10	9.5	5.3	16.6
	Oxygen saturation decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	PO2 decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Platelet count decreased	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Transaminases increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Troponin T increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Troponin increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Weight increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	White blood cell count decreased	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	5	4.8	2.1	10.7
Metabolism and nutrition disorders	-Total	< 65	176	62.6	23	13.1	8.9	18.8
		>= 65	105	37.4	23	21.9	15.1	30.7
	Acidosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Decreased appetite	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dehydration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Electrolyte imbalance	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Failure to thrive	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypercalcaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperkalaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hypernatraemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperphosphataemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperuricaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypocalcaemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypokalaemia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hyponatraemia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	6	5.7	2.6	11.9
	Hypophosphataemia	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	10	9.5	5.3	16.6
Musculoskeletal and connective tissue disorders	-Total	< 65	176	62.6	9	5.1	2.7	9.4

		>= 65	105	37.4	4	3.8	1.5	9.4
	Arthralgia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Back pain	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Intervertebral disc protrusion	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Muscle haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscular weakness	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Musculoskeletal chest pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pain in extremity	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rhabdomyolysis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cancer pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gallbladder cancer	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tumour pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Nervous system disorders	-Total	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	6	5.7	2.6	11.9
	Ataxia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cerebral haematoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cerebral microhaemorrhage	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cerebrovascular accident	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dizziness	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Epilepsy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Facial paralysis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haemorrhage intracranial	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Headache	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lumbosacral radiculopathy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Migraine	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neuralgia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sciatica	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Seizure	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Spinal cord haematoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Syncope	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
Psychiatric disorders	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mental status changes	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
Renal and urinary disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	4	3.8	1.5	9.4
	Acute kidney injury	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haematuria	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hydronephrosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nephrolithiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Obstructive nephropathy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Urethral stenosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Urinary retention	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Reproductive system and breast disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Metrorrhagia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ovarian cyst	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Prostatitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Respiratory, thoracic and mediastinal disorders	-Total	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	18	17.1	11.1	25.5
	Acute respiratory failure	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cough	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dyspnoea	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Hypoxia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Lung consolidation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pleural effusion	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pleuritic pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	4	3.8	1.5	9.4
	Pneumothorax	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pulmonary embolism	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	5	4.8	2.1	10.7
	Pulmonary hypertension	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Respiratory distress	< 65	176	62.6	0	0.0	0.0	2.1

		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory failure	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Surgical and medical procedures	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eye excision	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hip arthroplasty	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Vascular disorders	-Total	< 65	176	62.6	18	10.2	6.6	15.6
		>= 65	105	37.4	34	32.4	24.2	41.8
	Deep vein thrombosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Embolism	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Embolism venous	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haematoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypertension	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	29	27.6	20.0	36.8
	Hypotension	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Orthostatic hypotension	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Shock haemorrhagic	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR345_SG.xls
26MAR2021 14:25

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	84	29.9	21	25.0	17.0	35.2
		1	190	67.6	58	30.5	24.4	37.4
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	35	18.4	13.6	24.5
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia macrocytic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disseminated intravascular coagulation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Febrile neutropenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhagic anaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Leukopenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphopenia	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutropenia	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	18	9.5	6.1	14.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Pancytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytopenia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
Cardiac disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute myocardial infarction	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Cardio-respiratory arrest	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pericardial effusion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Stress cardiomyopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Supraventricular tachycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Ear and labyrinth disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vertigo	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Endocrine disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Adrenal insufficiency	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Eye disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cataract	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Keratitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Gastrointestinal disorders	-Total	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain upper	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aphthous ulcer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ascites	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Colitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Constipation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dental caries	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diarrhoea	0	84	29.9	2	2.4	0.7	8.3

		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diverticular perforation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal inflammation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intestinal obstruction	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Large intestine perforation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oesophagitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancreatitis acute	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Proctitis ulcerative	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Stomatitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Vomiting	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
General disorders and administration site conditions	-Total	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	16	8.4	5.2	13.2

		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Asthenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest discomfort	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Condition aggravated	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Death	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fatigue	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	General physical health deterioration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Impaired healing	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Malaise	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Multiple organ dysfunction syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Non-cardiac chest pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyrexia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Hepatobiliary disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Cholecystitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Cholelithiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gallbladder polyp	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperbilirubinaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Liver injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Portal vein thrombosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Infections and infestations	-Total	0	84	29.9	16	19.0	12.1	28.7
		1	190	67.6	46	24.2	18.7	30.8
		2	6	2.1	4	66.7	30.0	90.3
		Missing	1	0.4	0	0.0	0.0	79.3
	Appendicitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacterial infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cellulitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Clostridium difficile colitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Corona virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Device related infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diverticulitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Empyema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Enterococcal bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Infectious colitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Lower respiratory tract infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lung infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Meningitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Peritonitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumocystis jirovecii pneumonia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia bacterial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia cytomegaloviral	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia haemophilus	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyelonephritis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyelonephritis acute	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rectal abscess	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal tuberculosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sepsis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Septic shock	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinusitis bacterial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary tract infection	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urosepsis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Injury, poisoning and procedural complications	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Fracture	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Heart injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Subdural haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
Investigations	-Total	0	84	29.9	24	28.6	20.0	39.0
		1	190	67.6	62	32.6	26.4	39.6
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Alanine aminotransferase	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alanine aminotransferase increased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alpha hydroxybutyrate dehydrogenase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Amylase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aspartate aminotransferase increased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bilirubin conjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin unconjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase increased	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatinine increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood lactate dehydrogenase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood sodium decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	C-reactive protein increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrocardiogram QT prolonged	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gamma-glutamyltransferase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemoglobin decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic enzyme increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lipase increased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphocyte count decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Myoglobin blood increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Neutrophil count decreased	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	28	14.7	10.4	20.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oxygen saturation decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	PO2 decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Transaminases increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Troponin T increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Troponin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Weight increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	White blood cell count decreased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Metabolism and nutrition disorders	-Total	0	84	29.9	14	16.7	10.2	26.1
		1	190	67.6	29	15.3	10.8	21.1
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Acidosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Decreased appetite	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dehydration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrolyte imbalance	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Failure to thrive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercalcaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperkalaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypernatraemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperphosphataemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperuricaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypocalcaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypokalaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyponatraemia	0	84	29.9	4	4.8	1.9	11.6

		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypophosphataemia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
Musculoskeletal and connective tissue disorders	-Total	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Arthralgia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Back pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intervertebral disc protrusion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle haemorrhage	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscular weakness	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal chest pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain in extremity	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhabdomyolysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cancer pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gallbladder cancer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tumour pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Nervous system disorders	-Total	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ataxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebral haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebral microhaemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebrovascular accident	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dizziness	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epilepsy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Facial paralysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhage intracranial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Headache	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lumbosacral radiculopathy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Migraine	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neuralgia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sciatica	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Seizure	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Spinal cord haematoma	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Syncope	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Psychiatric disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mental status changes	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

Renal and urinary disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute kidney injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hydronephrosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nephrolithiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Obstructive nephropathy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urethral stenosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary retention	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Reproductive system and breast disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Metrorrhagia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ovarian cyst	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Prostatitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Respiratory, thoracic and mediastinal disorders	-Total	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	21	11.1	7.3	16.3
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute respiratory failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cough	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Lung consolidation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural effusion	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleuritic pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumothorax	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary embolism	0	84	29.9	3	3.6	1.2	10.0

		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary hypertension	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory distress	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Surgical and medical procedures	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eye excision	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hip arthroplasty	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Vascular disorders	-Total	0	84	29.9	18	21.4	14.0	31.3
		1	190	67.6	33	17.4	12.6	23.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Deep vein thrombosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism venous	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertension	0	84	29.9	17	20.2	13.0	30.0
		1	190	67.6	27	14.2	10.0	19.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypotension	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Orthostatic hypotension	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Shock haemorrhagic	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR345_SG.xls
26MAR2021 14:25

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	USA	64	22.8	22	34.4	23.9	46.6
		Europe (EU)	95	33.8	25	26.3	18.5	36.0
		Asia (AS)	122	43.4	35	28.7	21.4	37.3
	Anaemia	USA	64	22.8	13	20.3	12.3	31.7
		Europe (EU)	95	33.8	12	12.6	7.4	20.8
		Asia (AS)	122	43.4	21	17.2	11.5	24.9
	Anaemia macrocytic	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Disseminated intravascular coagulation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Febrile neutropenia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haemorrhagic anaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Leukopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Lymphopenia	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neutropenia	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Pancytopenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thrombocytopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	5	4.1	1.8	9.2

Cardiac disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Acute myocardial infarction	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cardio-respiratory arrest	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pericardial effusion	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Stress cardiomyopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Supraventricular tachycardia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Ear and labyrinth disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vertigo	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Endocrine disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Adrenal insufficiency	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Eye disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cataract	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Keratitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Gastrointestinal disorders	-Total	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	8	6.6	3.4	12.4

	Abdominal pain upper	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aphthous ulcer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ascites	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Colitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Constipation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dental caries	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Diarrhoea	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Diverticular perforation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal haemorrhage	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal inflammation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Intestinal obstruction	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Large intestine perforation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oesophagitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pancreatitis acute	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Proctitis ulcerative	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Stomatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Vomiting	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
General disorders and administration site conditions	-Total	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Asthenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Chest discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Chest pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Condition aggravated	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Death	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Fatigue	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	General physical health deterioration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Impaired healing	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Malaise	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Multiple organ dysfunction syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Non-cardiac chest pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pyrexia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Hepatobiliary disorders	-Total	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Cholecystitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Cholelithiasis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gallbladder polyp	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyperbilirubinaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Liver injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Portal vein thrombosis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Infections and infestations	-Total	USA	64	22.8	20	31.3	21.2	43.4
		Europe (EU)	95	33.8	21	22.1	14.9	31.4
		Asia (AS)	122	43.4	25	20.5	14.3	28.5
	Appendicitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacteraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacterial infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Cellulitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Clostridium difficile colitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Corona virus infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cystitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Device related infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Diverticulitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Empyema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Enterococcal bacteraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Infectious colitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lower respiratory tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lung infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Meningitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Peritonitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pleural infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Pneumocystis jirovecii pneumonia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonia	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
	Pneumonia bacterial	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonia cytomegaloviral	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonia haemophilus	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pyelonephritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pyelonephritis acute	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rectal abscess	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sepsis	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Septic shock	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinusitis bacterial	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urinary tract infection	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Urosepsis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

Injury, poisoning and procedural complications	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Fracture	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Heart injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Subdural haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Investigations	-Total	USA	64	22.8	17	26.6	17.3	38.5
		Europe (EU)	95	33.8	20	21.1	14.1	30.3
		Asia (AS)	122	43.4	52	42.6	34.2	51.5
	Alanine aminotransferase	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Alanine aminotransferase increased	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Alpha hydroxybutyrate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Amylase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aspartate aminotransferase increased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Bilirubin conjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood alkaline phosphatase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Blood bilirubin increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Blood bilirubin unconjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Blood creatine phosphokinase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	12	9.8	5.7	16.4
	Blood creatinine increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood lactate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood sodium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	C-reactive protein increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Electrocardiogram QT prolonged	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gamma-glutamyltransferase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Haemoglobin decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hepatic enzyme increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lipase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymphocyte count decreased	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Myoglobin blood increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Neutrophil count decreased	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	28	23.0	16.4	31.2
	Oxygen saturation decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	PO2 decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Platelet count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Transaminases increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Troponin T increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Troponin increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Weight increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	White blood cell count decreased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
Metabolism and nutrition disorders	-Total	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	29	23.8	17.1	32.1
	Acidosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Decreased appetite	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dehydration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Electrolyte imbalance	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Failure to thrive	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypercalcaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Hyperkalaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Hypernatraemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hyperphosphataemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperuricaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypocalcaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hypokalaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Hyponatraemia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Hypophosphataemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
Musculoskeletal and connective tissue disorders	-Total	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Arthralgia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Back pain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Intervertebral disc protrusion	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscular weakness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Musculoskeletal chest pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pain in extremity	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhabdomyolysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cancer pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gallbladder cancer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tumour pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Nervous system disorders	-Total	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Ataxia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebral haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebral microhaemorrhage	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebrovascular accident	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dizziness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epilepsy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Facial paralysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haemorrhage intracranial	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Headache	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lumbosacral radiculopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Migraine	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neuralgia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sciatica	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Seizure	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Spinal cord haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Syncope	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Psychiatric disorders	-Total	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Mental status changes	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Renal and urinary disorders	-Total	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Acute kidney injury	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Haematuria	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hydronephrosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nephrolithiasis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Obstructive nephropathy	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urethral stenosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary retention	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Reproductive system and breast disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Metrorrhagia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ovarian cyst	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Prostatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Respiratory, thoracic and mediastinal disorders	-Total	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	15	15.8	9.8	24.4
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Acute respiratory failure	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cough	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dyspnoea	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0

	Hypoxia	USA	64	22.8	2	3.1		0.9	10.7
		Europe (EU)	95	33.8	1	1.1		0.2	5.7
		Asia (AS)	122	43.4	1	0.8		0.1	4.5
	Lung consolidation	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	1	1.1		0.2	5.7
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
	Pleural effusion	USA	64	22.8	1	1.6		0.3	8.3
		Europe (EU)	95	33.8	1	1.1		0.2	5.7
		Asia (AS)	122	43.4	3	2.5		0.8	7.0
	Pleuritic pain	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	1	1.1		0.2	5.7
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
	Pneumonitis	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	3	3.2		1.1	8.9
		Asia (AS)	122	43.4	3	2.5		0.8	7.0
	Pneumothorax	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	2	1.6		0.5	5.8
	Pulmonary embolism	USA	64	22.8	3	4.7		1.6	12.9
		Europe (EU)	95	33.8	6	6.3		2.9	13.1
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
	Pulmonary hypertension	USA	64	22.8	1	1.6		0.3	8.3
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
	Respiratory distress	USA	64	22.8	1	1.6		0.3	8.3
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
	Respiratory failure	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	1	1.1		0.2	5.7
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
Surgical and medical procedures	-Total	USA	64	22.8	1	1.6		0.3	8.3
		Europe (EU)	95	33.8	1	1.1		0.2	5.7
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
	Eye excision	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	1	1.1		0.2	5.7
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
	Hip arthroplasty	USA	64	22.8	1	1.6		0.3	8.3
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
Vascular disorders	-Total	USA	64	22.8	19	29.7		19.9	41.8
		Europe (EU)	95	33.8	12	12.6		7.4	20.8
		Asia (AS)	122	43.4	21	17.2		11.5	24.9

	Deep vein thrombosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Embolism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Embolism venous	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypertension	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	10	10.5	5.8	18.3
		Asia (AS)	122	43.4	20	16.4	10.9	24.0
	Hypotension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Orthostatic hypotension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Shock haemorrhagic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR345_SG.xls
26MAR2021 14:25

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	116	41.3	24	20.7	14.3	28.9
		1	77	27.4	23	29.9	20.8	40.8
		>= 2	88	31.3	35	39.8	30.2	50.2
	Anaemia	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	16	20.8	13.2	31.1
		>= 2	88	31.3	19	21.6	14.3	31.3
	Anaemia macrocytic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Disseminated intravascular coagulation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Febrile neutropenia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Haemorrhagic anaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Leukopenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Lymphopenia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	4	4.5	1.8	11.1
	Neutropenia	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	16	18.2	11.5	27.5
	Pancytopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Thrombocytopenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	4	4.5	1.8	11.1

Cardiac disorders	-Total	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Acute myocardial infarction	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cardio-respiratory arrest	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pericardial effusion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Stress cardiomyopathy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Supraventricular tachycardia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Ear and labyrinth disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vertigo	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Endocrine disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Adrenal insufficiency	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Eye disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cataract	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Keratitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Gastrointestinal disorders	-Total	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	11	12.5	7.1	21.0

	Abdominal pain upper	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Aphthous ulcer	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ascites	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Colitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Constipation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dental caries	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Diarrhoea	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Diverticular perforation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrointestinal haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastrointestinal inflammation	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intestinal obstruction	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Large intestine perforation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oesophagitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pancreatitis acute	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9

	Proctitis ulcerative	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Stomatitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Vomiting	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
General disorders and administration site conditions	-Total	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	7	8.0	3.9	15.5
	Asthenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Chest discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Chest pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Condition aggravated	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Death	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fatigue	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	General physical health deterioration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Impaired healing	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Malaise	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Multiple organ dysfunction syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Non-cardiac chest pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pyrexia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Hepatobiliary disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Cholecystitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cholelithiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gallbladder polyp	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperbilirubinaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Liver injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Portal vein thrombosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Infections and infestations	-Total	0	116	41.3	20	17.2	11.4	25.1
		1	77	27.4	19	24.7	16.4	35.4
		>= 2	88	31.3	27	30.7	22.0	41.0
	Appendicitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bacteraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bacterial infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Cellulitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Clostridium difficile colitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Corona virus infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cystitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Device related infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Diverticulitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Empyema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Enterococcal bacteraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Infectious colitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lower respiratory tract infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lung infection	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Meningitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Peritonitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pleural infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Pneumocystis jirovecii pneumonia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	10	11.4	6.3	19.7
	Pneumonia bacterial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia cytomegaloviral	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia haemophilus	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pyelonephritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pyelonephritis acute	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rectal abscess	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Renal tuberculosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sepsis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	4	4.5	1.8	11.1
	Septic shock	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sinusitis bacterial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Urinary tract infection	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Urosepsis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

Injury, poisoning and procedural complications	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Fracture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Heart injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Subdural haematoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Investigations	-Total	0	116	41.3	37	31.9	24.1	40.8
		1	77	27.4	21	27.3	18.6	38.1
		>= 2	88	31.3	31	35.2	26.1	45.6
	Alanine aminotransferase	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Alanine aminotransferase increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Alpha hydroxybutyrate dehydrogenase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Amylase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Aspartate aminotransferase increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	8	9.1	4.7	16.9
	Bilirubin conjugated increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood alkaline phosphatase increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood bilirubin increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood bilirubin unconjugated increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Blood creatine phosphokinase increased	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	7	8.0	3.9	15.5
	Blood creatinine increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood lactate dehydrogenase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood sodium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	C-reactive protein increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Electrocardiogram QT prolonged	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gamma-glutamyltransferase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Haemoglobin decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hepatic enzyme increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lipase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lymphocyte count decreased	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Myoglobin blood increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neutrophil count decreased	0	116	41.3	17	14.7	9.4	22.2
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	10	11.4	6.3	19.7
	Oxygen saturation decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	PO2 decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Platelet count decreased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Transaminases increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Troponin T increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Troponin increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Weight increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	White blood cell count decreased	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
Metabolism and nutrition disorders	-Total	0	116	41.3	16	13.8	8.7	21.2
		1	77	27.4	14	18.2	11.2	28.2
		>= 2	88	31.3	16	18.2	11.5	27.5
	Acidosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Decreased appetite	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Dehydration	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Electrolyte imbalance	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Failure to thrive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypercalcaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Hyperkalaemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypernatraemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperphosphataemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperuricaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypocalcaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypokalaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Hyponatraemia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Hypophosphataemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	9	10.2	5.5	18.3
Musculoskeletal and connective tissue disorders	-Total	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	6	6.8	3.2	14.1
	Arthralgia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Back pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intervertebral disc protrusion	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Muscle haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Muscular weakness	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Musculoskeletal chest pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pain in extremity	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rhabdomyolysis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cancer pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gallbladder cancer	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tumour pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Nervous system disorders	-Total	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	5	5.7	2.5	12.6
	Ataxia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cerebral haematoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cerebral microhaemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cerebrovascular accident	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dizziness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Epilepsy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Facial paralysis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haemorrhage intracranial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Headache	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lumbosacral radiculopathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Migraine	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neuralgia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sciatica	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Seizure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Spinal cord haematoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Syncope	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Psychiatric disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Mental status changes	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
Renal and urinary disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Acute kidney injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2

	Haematuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hydronephrosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Nephrolithiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Obstructive nephropathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urethral stenosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urinary retention	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Reproductive system and breast disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Metrorrhagia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ovarian cyst	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Prostatitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Respiratory, thoracic and mediastinal disorders	-Total	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	11	12.5	7.1	21.0
	Acute respiratory failure	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cough	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dyspnoea	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	1	1.1	0.2	6.2

	Hypoxia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Lung consolidation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pleural effusion	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Pleuritic pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonitis	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumothorax	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pulmonary embolism	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Pulmonary hypertension	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiratory distress	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Respiratory failure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Surgical and medical procedures	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eye excision	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hip arthroplasty	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Vascular disorders	-Total	0	116	41.3	18	15.5	10.0	23.2
		1	77	27.4	17	22.1	14.3	32.5
		>= 2	88	31.3	17	19.3	12.4	28.8

	Deep vein thrombosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Embolism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Embolism venous	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haematoma	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypertension	0	116	41.3	17	14.7	9.4	22.2
		1	77	27.4	14	18.2	11.2	28.2
		>= 2	88	31.3	14	15.9	9.7	25.0
	Hypotension	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Orthostatic hypotension	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Shock haemorrhagic	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR345_SG.xls
26MAR2021 14:25

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Asian	128	45.6	37	28.9	21.8	37.3
		Non-Asian	135	48.0	43	31.9	24.6	40.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Anaemia	Asian	128	45.6	21	16.4	11.0	23.8
		Non-Asian	135	48.0	23	17.0	11.6	24.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Anaemia macrocytic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Disseminated intravascular coagulation	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Febrile neutropenia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhagic anaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Leukopenia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutropenia	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancytopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytopenia	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

Cardiac disorders	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Acute myocardial infarction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cardio-respiratory arrest	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pericardial effusion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Stress cardiomyopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Supraventricular tachycardia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Ear and labyrinth disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vertigo	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Endocrine disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Adrenal insufficiency	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Eye disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cataract	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Keratitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Gastrointestinal disorders	-Total	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	0	0.0	0.0	17.6

	Abdominal pain upper	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aphthous ulcer	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ascites	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Constipation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dental caries	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diarrhoea	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diverticular perforation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal inflammation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intestinal obstruction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Large intestine perforation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oesophagitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancreatitis acute	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

	Proctitis ulcerative	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Stomatitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vomiting	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
General disorders and administration site conditions	-Total	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	2	11.1	3.1	32.8
	Asthenia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chest discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chest pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Condition aggravated	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Death	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fatigue	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	General physical health deterioration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Impaired healing	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Malaise	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Multiple organ dysfunction syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Non-cardiac chest pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyrexia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Hepatobiliary disorders	-Total	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cholecystitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cholelithiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gallbladder polyp	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperbilirubinaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Liver injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Portal vein thrombosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Infections and infestations	-Total	Asian	128	45.6	28	21.9	15.6	29.8
		Non-Asian	135	48.0	35	25.9	19.3	33.9
		Unknown	18	6.4	3	16.7	5.8	39.2
	Appendicitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bacterial infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8

	Cellulitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Clostridium difficile colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Corona virus infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Device related infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diverticulitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Empyema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Enterococcal bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Infectious colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lower respiratory tract infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lung infection	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Meningitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Peritonitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleural infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Pneumocystis jirovecii pneumonia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia	Asian	128	45.6	14	10.9	6.6	17.5
		Non-Asian	135	48.0	12	8.9	5.2	14.9
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumonia bacterial	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia cytomegaloviral	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia haemophilus	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyelonephritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyelonephritis acute	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rectal abscess	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal tuberculosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sepsis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Septic shock	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinusitis bacterial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary tract infection	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urosepsis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

Injury, poisoning and procedural complications	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fracture	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Heart injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Subdural haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Investigations	-Total	Asian	128	45.6	57	44.5	36.2	53.2
		Non-Asian	135	48.0	27	20.0	14.1	27.5
		Unknown	18	6.4	5	27.8	12.5	50.9
	Alanine aminotransferase	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alanine aminotransferase increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Alpha hydroxybutyrate dehydrogenase increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Amylase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aspartate aminotransferase increased	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bilirubin conjugated increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood alkaline phosphatase increased	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood bilirubin increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood bilirubin unconjugated increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Blood creatine phosphokinase increased	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Blood creatinine increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood lactate dehydrogenase increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood sodium decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	C-reactive protein increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrocardiogram QT prolonged	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gamma-glutamyltransferase increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemoglobin decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatic enzyme increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lipase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphocyte count decreased	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Myoglobin blood increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutrophil count decreased	Asian	128	45.6	30	23.4	16.9	31.5
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oxygen saturation decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	PO2 decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Platelet count decreased	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Transaminases increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Troponin T increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Troponin increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Weight increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	White blood cell count decreased	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
Metabolism and nutrition disorders	-Total	Asian	128	45.6	29	22.7	16.3	30.6
		Non-Asian	135	48.0	16	11.9	7.4	18.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Acidosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Decreased appetite	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dehydration	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrolyte imbalance	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Failure to thrive	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercalcaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Hyperkalaemia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypernatraemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperphosphataemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperuricaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypocalcaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypokalaemia	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyponatraemia	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypophosphataemia	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
Musculoskeletal and connective tissue disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	1	5.6	1.0	25.8
	Arthralgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Back pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intervertebral disc protrusion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscular weakness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6

	Musculoskeletal chest pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pain in extremity	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhabdomyolysis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Cancer pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gallbladder cancer	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tumour pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Nervous system disorders	-Total	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	Ataxia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebral haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebral microhaemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebrovascular accident	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dizziness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epilepsy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Facial paralysis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Haemorrhage intracranial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Headache	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lumbosacral radiculopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Migraine	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neuralgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Sciatica	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Seizure	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Spinal cord haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Syncope	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Psychiatric disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mental status changes	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Renal and urinary disorders	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Acute kidney injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Haematuria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hydronephrosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nephrolithiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Obstructive nephropathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urethral stenosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary retention	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Reproductive system and breast disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Metrorrhagia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Ovarian cyst	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Prostatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Respiratory, thoracic and mediastinal disorders	-Total	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	4	22.2	9.0	45.2
	Acute respiratory failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cough	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dyspnoea	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8

	Hypoxia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Lung consolidation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleural effusion	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleuritic pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonitis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumothorax	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary embolism	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Pulmonary hypertension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory distress	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Respiratory failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Surgical and medical procedures	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eye excision	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hip arthroplasty	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Vascular disorders	-Total	Asian	128	45.6	22	17.2	11.6	24.7
		Non-Asian	135	48.0	27	20.0	14.1	27.5
		Unknown	18	6.4	3	16.7	5.8	39.2

	Deep vein thrombosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Embolism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Embolism venous	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematoma	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypertension	Asian	128	45.6	21	16.4	11.0	23.8
		Non-Asian	135	48.0	24	17.8	12.2	25.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypotension	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Orthostatic hypotension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Shock haemorrhagic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR345_SG.xls
26MAR2021 14:25

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Female	152	54.1	51	33.6	26.5	41.4
		Male	129	45.9	31	24.0	17.5	32.1
	Anaemia	Female	152	54.1	30	19.7	14.2	26.8
		Male	129	45.9	16	12.4	7.8	19.2
	Anaemia macrocytic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Disseminated intravascular coagulation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Febrile neutropenia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Haemorrhagic anaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Leukopenia	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	1	0.8	0.1	4.3
	Lymphopenia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	5	3.9	1.7	8.8
	Neutropenia	Female	152	54.1	19	12.5	8.2	18.7
		Male	129	45.9	11	8.5	4.8	14.6
	Pancytopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombocytopenia	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
Cardiac disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	Acute myocardial infarction	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cardio-respiratory arrest	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pericardial effusion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3

	Stress cardiomyopathy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Supraventricular tachycardia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Ear and labyrinth disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Vertigo	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Endocrine disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Adrenal insufficiency	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Eye disorders	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Cataract	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Keratitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Gastrointestinal disorders	-Total	Female	152	54.1	17	11.2	7.1	17.2
		Male	129	45.9	8	6.2	3.2	11.8
	Abdominal pain upper	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Aphthous ulcer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ascites	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Constipation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Dental caries	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Diarrhoea	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Diverticular perforation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gastrointestinal haemorrhage	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
	Gastrointestinal inflammation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Intestinal obstruction	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Large intestine perforation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oesophagitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pancreatitis acute	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Proctitis ulcerative	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Stomatitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Vomiting	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
General disorders and administration site conditions	-Total	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	10	7.8	4.3	13.7
	Asthenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Chest discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Chest pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Condition aggravated	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Death	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Fatigue	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	1	0.8	0.1	4.3
	General physical health deterioration	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Impaired healing	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Malaise	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Multiple organ dysfunction syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Non-cardiac chest pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pyrexia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Hepatobiliary disorders	-Total	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Cholecystitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cholelithiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gallbladder polyp	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hyperbilirubinaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Liver injury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Portal vein thrombosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Infections and infestations	-Total	Female	152	54.1	35	23.0	17.0	30.3
		Male	129	45.9	31	24.0	17.5	32.1
	Appendicitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Bacteraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bacterial infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cellulitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Clostridium difficile colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Corona virus infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cystitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Device related infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Diverticulitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Empyema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Enterococcal bacteraemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Infectious colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lower respiratory tract infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lung infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Meningitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Peritonitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pleural infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumocystis jirovecii pneumonia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Pneumonia	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	13	10.1	6.0	16.5
	Pneumonia bacterial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonia cytomegaloviral	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pneumonia haemophilus	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pyelonephritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pyelonephritis acute	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rectal abscess	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Renal tuberculosis	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
	Sepsis	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Septic shock	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sinusitis bacterial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urinary tract infection	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	6	4.7	2.1	9.8
	Urosepsis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Injury, poisoning and procedural complications	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Fracture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Heart injury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Subdural haematoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Investigations	-Total	Female	152	54.1	54	35.5	28.4	43.4
		Male	129	45.9	35	27.1	20.2	35.4
	Alanine aminotransferase	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Alanine aminotransferase increased	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	2	1.6	0.4	5.5
	Alpha hydroxybutyrate dehydrogenase increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Amylase increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Aspartate aminotransferase increased	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	7	5.4	2.7	10.8
	Bilirubin conjugated increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood alkaline phosphatase increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Blood bilirubin increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5

	Blood bilirubin unconjugated increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood creatine phosphokinase increased	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	12	9.3	5.4	15.6
	Blood creatinine increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Blood lactate dehydrogenase increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood sodium decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	C-reactive protein increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Electrocardiogram QT prolonged	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gamma-glutamyltransferase increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Haemoglobin decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Hepatic enzyme increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lipase increased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lymphocyte count decreased	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	8	6.2	3.2	11.8
	Myoglobin blood increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neutrophil count decreased	Female	152	54.1	27	17.8	12.5	24.6
		Male	129	45.9	9	7.0	3.7	12.7
	Oxygen saturation decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	PO2 decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Platelet count decreased	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	2	1.6	0.4	5.5
	Transaminases increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Troponin T increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Troponin increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Weight increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	White blood cell count decreased	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	3	2.3	0.8	6.6
Metabolism and nutrition disorders	-Total	Female	152	54.1	25	16.4	11.4	23.2
		Male	129	45.9	21	16.3	10.9	23.6
	Acidosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Decreased appetite	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Dehydration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Electrolyte imbalance	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Failure to thrive	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypercalcaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperkalaemia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hypernatraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperphosphataemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperuricaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypocalcaemia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hypokalaemia	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	2	1.6	0.4	5.5
	Hyponatraemia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	8	6.2	3.2	11.8
	Hypophosphataemia	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	7	5.4	2.7	10.8
Musculoskeletal and connective tissue disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6

		Male	129	45.9	10	7.8	4.3	13.7
	Arthralgia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Back pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Intervertebral disc protrusion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	4	3.1	1.2	7.7
	Muscle haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Muscular weakness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Musculoskeletal chest pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pain in extremity	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rhabdomyolysis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Cancer pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gallbladder cancer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tumour pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Nervous system disorders	-Total	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	9	7.0	3.7	12.7
	Ataxia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cerebral haematoma	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cerebral microhaemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cerebrovascular accident	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dizziness	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Epilepsy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Facial paralysis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Haemorrhage intracranial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Headache	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Lumbosacral radiculopathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Migraine	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neuralgia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Sciatica	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Seizure	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Spinal cord haematoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Syncope	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
Psychiatric disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Mental status changes	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
Renal and urinary disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	5	3.9	1.7	8.8
	Acute kidney injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Haematuria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hydronephrosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nephrolithiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Obstructive nephropathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Urethral stenosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urinary retention	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Reproductive system and breast disorders	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Metrorrhagia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ovarian cyst	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Prostatitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Respiratory, thoracic and mediastinal disorders	-Total	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	19	14.7	9.6	21.9
	Acute respiratory failure	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cough	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dyspnoea	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Hypoxia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	4	3.1	1.2	7.7
	Lung consolidation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pleural effusion	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Pleuritic pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pneumonitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	4	3.1	1.2	7.7
	Pneumothorax	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pulmonary embolism	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	6	4.7	2.1	9.8
	Pulmonary hypertension	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Respiratory distress	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
	Respiratory failure	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Surgical and medical procedures	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Eye excision	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hip arthroplasty	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Vascular disorders	-Total	Female	152	54.1	29	19.1	13.6	26.1
		Male	129	45.9	23	17.8	12.2	25.3
	Deep vein thrombosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Embolism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Embolism venous	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haematoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypertension	Female	152	54.1	27	17.8	12.5	24.6
		Male	129	45.9	18	14.0	9.0	21.0
	Hypotension	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Orthostatic hypotension	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Shock haemorrhagic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR345_SG.xls
26MAR2021 14:25

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	n/a	281	100.0	82	29.2	24.2	34.7
	Anaemia	n/a	281	100.0	46	16.4	12.5	21.1
	Anaemia macrocytic	n/a	281	100.0	1	0.4	0.1	2.0
	Disseminated intravascular coagulation	n/a	281	100.0	2	0.7	0.2	2.6
	Febrile neutropenia	n/a	281	100.0	4	1.4	0.6	3.6
	Haemorrhagic anaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Leukopenia	n/a	281	100.0	8	2.8	1.4	5.5
	Lymphopenia	n/a	281	100.0	17	6.0	3.8	9.5
	Neutropenia	n/a	281	100.0	30	10.7	7.6	14.8
	Pancytopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombocytopenia	n/a	281	100.0	8	2.8	1.4	5.5
Cardiac disorders	-Total	n/a	281	100.0	7	2.5	1.2	5.1
	Acute myocardial infarction	n/a	281	100.0	2	0.7	0.2	2.6
	Cardio-respiratory arrest	n/a	281	100.0	1	0.4	0.1	2.0
	Pericardial effusion	n/a	281	100.0	2	0.7	0.2	2.6
	Stress cardiomyopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Supraventricular tachycardia	n/a	281	100.0	1	0.4	0.1	2.0
Ear and labyrinth disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Vertigo	n/a	281	100.0	1	0.4	0.1	2.0
Endocrine disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Adrenal insufficiency	n/a	281	100.0	1	0.4	0.1	2.0
Eye disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1

	Cataract	n/a	281	100.0	2	0.7	0.2	2.6
	Keratitis	n/a	281	100.0	1	0.4	0.1	2.0
Gastrointestinal disorders	-Total	n/a	281	100.0	25	8.9	6.1	12.8
	Abdominal pain upper	n/a	281	100.0	1	0.4	0.1	2.0
	Aphthous ulcer	n/a	281	100.0	1	0.4	0.1	2.0
	Ascites	n/a	281	100.0	1	0.4	0.1	2.0
	Colitis	n/a	281	100.0	3	1.1	0.4	3.1
	Constipation	n/a	281	100.0	2	0.7	0.2	2.6
	Dental caries	n/a	281	100.0	1	0.4	0.1	2.0
	Diarrhoea	n/a	281	100.0	5	1.8	0.8	4.1
	Diverticular perforation	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal inflammation	n/a	281	100.0	1	0.4	0.1	2.0
	Intestinal obstruction	n/a	281	100.0	1	0.4	0.1	2.0
	Large intestine perforation	n/a	281	100.0	1	0.4	0.1	2.0
	Oesophagitis	n/a	281	100.0	1	0.4	0.1	2.0
	Pancreatitis acute	n/a	281	100.0	2	0.7	0.2	2.6
	Proctitis ulcerative	n/a	281	100.0	1	0.4	0.1	2.0
	Stomatitis	n/a	281	100.0	5	1.8	0.8	4.1
	Vomiting	n/a	281	100.0	3	1.1	0.4	3.1
General disorders and administration site conditions	-Total	n/a	281	100.0	42	14.9	11.3	19.6
	Asthenia	n/a	281	100.0	2	0.7	0.2	2.6
	Chest discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Chest pain	n/a	281	100.0	1	0.4	0.1	2.0
	Condition aggravated	n/a	281	100.0	1	0.4	0.1	2.0
	Death	n/a	281	100.0	2	0.7	0.2	2.6
	Disease progression	n/a	281	100.0	21	7.5	4.9	11.2
	Fatigue	n/a	281	100.0	6	2.1	1.0	4.6

	General physical health deterioration	n/a	281	100.0	3	1.1	0.4	3.1
	Impaired healing	n/a	281	100.0	1	0.4	0.1	2.0
	Malaise	n/a	281	100.0	1	0.4	0.1	2.0
	Multiple organ dysfunction syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Non-cardiac chest pain	n/a	281	100.0	1	0.4	0.1	2.0
	Pain	n/a	281	100.0	1	0.4	0.1	2.0
	Pyrexia	n/a	281	100.0	1	0.4	0.1	2.0
Hepatobiliary disorders	-Total	n/a	281	100.0	8	2.8	1.4	5.5
	Cholecystitis	n/a	281	100.0	2	0.7	0.2	2.6
	Cholelithiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Gallbladder polyp	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperbilirubinaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Liver injury	n/a	281	100.0	1	0.4	0.1	2.0
	Portal vein thrombosis	n/a	281	100.0	2	0.7	0.2	2.6
Infections and infestations	-Total	n/a	281	100.0	66	23.5	18.9	28.8
	Appendicitis	n/a	281	100.0	2	0.7	0.2	2.6
	Bacteraemia	n/a	281	100.0	1	0.4	0.1	2.0
	Bacterial infection	n/a	281	100.0	1	0.4	0.1	2.0
	Cellulitis	n/a	281	100.0	1	0.4	0.1	2.0
	Clostridium difficile colitis	n/a	281	100.0	1	0.4	0.1	2.0
	Corona virus infection	n/a	281	100.0	1	0.4	0.1	2.0
	Cystitis	n/a	281	100.0	1	0.4	0.1	2.0
	Device related infection	n/a	281	100.0	1	0.4	0.1	2.0
	Diverticulitis	n/a	281	100.0	2	0.7	0.2	2.6
	Empyema	n/a	281	100.0	1	0.4	0.1	2.0
	Enterococcal bacteraemia	n/a	281	100.0	1	0.4	0.1	2.0
	Infectious colitis	n/a	281	100.0	1	0.4	0.1	2.0
	Lower respiratory tract infection	n/a	281	100.0	1	0.4	0.1	2.0

	Lung infection	n/a	281	100.0	3	1.1	0.4	3.1
	Meningitis	n/a	281	100.0	1	0.4	0.1	2.0
	Peritonitis	n/a	281	100.0	1	0.4	0.1	2.0
	Pleural infection	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumocystis jirovecii pneumonia	n/a	281	100.0	2	0.7	0.2	2.6
	Pneumonia	n/a	281	100.0	27	9.6	6.7	13.6
	Pneumonia bacterial	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia cytomegaloviral	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia haemophilus	n/a	281	100.0	1	0.4	0.1	2.0
	Pyelonephritis	n/a	281	100.0	1	0.4	0.1	2.0
	Pyelonephritis acute	n/a	281	100.0	1	0.4	0.1	2.0
	Rectal abscess	n/a	281	100.0	1	0.4	0.1	2.0
	Renal tuberculosis	n/a	281	100.0	1	0.4	0.1	2.0
	Sepsis	n/a	281	100.0	8	2.8	1.4	5.5
	Septic shock	n/a	281	100.0	1	0.4	0.1	2.0
	Sinusitis bacterial	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary tract infection	n/a	281	100.0	9	3.2	1.7	6.0
	Urosepsis	n/a	281	100.0	2	0.7	0.2	2.6
Injury, poisoning and procedural complications	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Fracture	n/a	281	100.0	1	0.4	0.1	2.0
	Heart injury	n/a	281	100.0	1	0.4	0.1	2.0
	Subdural haematoma	n/a	281	100.0	1	0.4	0.1	2.0
Investigations	-Total	n/a	281	100.0	89	31.7	26.5	37.3
	Alanine aminotransferase	n/a	281	100.0	1	0.4	0.1	2.0
	Alanine aminotransferase increased	n/a	281	100.0	9	3.2	1.7	6.0
	Alpha hydroxybutyrate dehydrogenase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Amylase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Aspartate aminotransferase increased	n/a	281	100.0	15	5.3	3.3	8.6

	Bilirubin conjugated increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood alkaline phosphatase increased	n/a	281	100.0	4	1.4	0.6	3.6
	Blood bilirubin increased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood bilirubin unconjugated increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood creatine phosphokinase increased	n/a	281	100.0	19	6.8	4.4	10.3
	Blood creatinine increased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood lactate dehydrogenase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood sodium decreased	n/a	281	100.0	1	0.4	0.1	2.0
	C-reactive protein increased	n/a	281	100.0	1	0.4	0.1	2.0
	Electrocardiogram QT prolonged	n/a	281	100.0	1	0.4	0.1	2.0
	Gamma-glutamyltransferase increased	n/a	281	100.0	3	1.1	0.4	3.1
	Haemoglobin decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Hepatic enzyme increased	n/a	281	100.0	1	0.4	0.1	2.0
	Lipase increased	n/a	281	100.0	3	1.1	0.4	3.1
	Lymphocyte count decreased	n/a	281	100.0	14	5.0	3.0	8.2
	Myoglobin blood increased	n/a	281	100.0	1	0.4	0.1	2.0
	Neutrophil count decreased	n/a	281	100.0	36	12.8	9.4	17.2
	Oxygen saturation decreased	n/a	281	100.0	1	0.4	0.1	2.0
	PO2 decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Platelet count decreased	n/a	281	100.0	8	2.8	1.4	5.5
	Transaminases increased	n/a	281	100.0	1	0.4	0.1	2.0
	Troponin T increased	n/a	281	100.0	1	0.4	0.1	2.0
	Troponin increased	n/a	281	100.0	1	0.4	0.1	2.0
	Weight increased	n/a	281	100.0	2	0.7	0.2	2.6
	White blood cell count decreased	n/a	281	100.0	15	5.3	3.3	8.6
Metabolism and nutrition disorders	-Total	n/a	281	100.0	46	16.4	12.5	21.1
	Acidosis	n/a	281	100.0	1	0.4	0.1	2.0
	Decreased appetite	n/a	281	100.0	2	0.7	0.2	2.6

	Dehydration	n/a	281	100.0	2	0.7	0.2	2.6
	Electrolyte imbalance	n/a	281	100.0	2	0.7	0.2	2.6
	Failure to thrive	n/a	281	100.0	1	0.4	0.1	2.0
	Hypercalcaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperkalaemia	n/a	281	100.0	4	1.4	0.6	3.6
	Hypernatraemia	n/a	281	100.0	2	0.7	0.2	2.6
	Hyperphosphataemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperuricaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypocalcaemia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypokalaemia	n/a	281	100.0	9	3.2	1.7	6.0
	Hyponatraemia	n/a	281	100.0	12	4.3	2.5	7.3
	Hypophosphataemia	n/a	281	100.0	20	7.1	4.7	10.7
Musculoskeletal and connective tissue disorders	-Total	n/a	281	100.0	13	4.6	2.7	7.8
	Arthralgia	n/a	281	100.0	1	0.4	0.1	2.0
	Back pain	n/a	281	100.0	3	1.1	0.4	3.1
	Intervertebral disc protrusion	n/a	281	100.0	4	1.4	0.6	3.6
	Muscle haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Muscular weakness	n/a	281	100.0	3	1.1	0.4	3.1
	Musculoskeletal chest pain	n/a	281	100.0	1	0.4	0.1	2.0
	Pain in extremity	n/a	281	100.0	1	0.4	0.1	2.0
	Rhabdomyolysis	n/a	281	100.0	1	0.4	0.1	2.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Cancer pain	n/a	281	100.0	1	0.4	0.1	2.0
	Gallbladder cancer	n/a	281	100.0	1	0.4	0.1	2.0
	Tumour pain	n/a	281	100.0	1	0.4	0.1	2.0
Nervous system disorders	-Total	n/a	281	100.0	14	5.0	3.0	8.2
	Ataxia	n/a	281	100.0	1	0.4	0.1	2.0
	Cerebral haematoma	n/a	281	100.0	1	0.4	0.1	2.0

	Cerebral microhaemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Cerebrovascular accident	n/a	281	100.0	1	0.4	0.1	2.0
	Dizziness	n/a	281	100.0	1	0.4	0.1	2.0
	Epilepsy	n/a	281	100.0	1	0.4	0.1	2.0
	Facial paralysis	n/a	281	100.0	1	0.4	0.1	2.0
	Haemorrhage intracranial	n/a	281	100.0	1	0.4	0.1	2.0
	Headache	n/a	281	100.0	2	0.7	0.2	2.6
	Lumbosacral radiculopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Migraine	n/a	281	100.0	1	0.4	0.1	2.0
	Neuralgia	n/a	281	100.0	1	0.4	0.1	2.0
	Sciatica	n/a	281	100.0	2	0.7	0.2	2.6
	Seizure	n/a	281	100.0	1	0.4	0.1	2.0
	Spinal cord haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Syncope	n/a	281	100.0	3	1.1	0.4	3.1
Psychiatric disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Mental status changes	n/a	281	100.0	3	1.1	0.4	3.1
Renal and urinary disorders	-Total	n/a	281	100.0	6	2.1	1.0	4.6
	Acute kidney injury	n/a	281	100.0	2	0.7	0.2	2.6
	Haematuria	n/a	281	100.0	1	0.4	0.1	2.0
	Hydronephrosis	n/a	281	100.0	1	0.4	0.1	2.0
	Nephrolithiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Obstructive nephropathy	n/a	281	100.0	1	0.4	0.1	2.0
	Urethral stenosis	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary retention	n/a	281	100.0	1	0.4	0.1	2.0
Reproductive system and breast disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Metrorrhagia	n/a	281	100.0	1	0.4	0.1	2.0
	Ovarian cyst	n/a	281	100.0	1	0.4	0.1	2.0
	Prostatitis	n/a	281	100.0	1	0.4	0.1	2.0

Respiratory, thoracic and mediastinal disorders	-Total	n/a	281	100.0	33	11.7	8.5	16.0
	Acute respiratory failure	n/a	281	100.0	1	0.4	0.1	2.0
	Cough	n/a	281	100.0	1	0.4	0.1	2.0
	Dyspnoea	n/a	281	100.0	8	2.8	1.4	5.5
	Hypoxia	n/a	281	100.0	4	1.4	0.6	3.6
	Lung consolidation	n/a	281	100.0	1	0.4	0.1	2.0
	Pleural effusion	n/a	281	100.0	5	1.8	0.8	4.1
	Pleuritic pain	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonitis	n/a	281	100.0	6	2.1	1.0	4.6
	Pneumothorax	n/a	281	100.0	2	0.7	0.2	2.6
	Pulmonary embolism	n/a	281	100.0	9	3.2	1.7	6.0
	Pulmonary hypertension	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory distress	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory failure	n/a	281	100.0	1	0.4	0.1	2.0
Surgical and medical procedures	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Eye excision	n/a	281	100.0	1	0.4	0.1	2.0
	Hip arthroplasty	n/a	281	100.0	1	0.4	0.1	2.0
Vascular disorders	-Total	n/a	281	100.0	52	18.5	14.4	23.5
	Deep vein thrombosis	n/a	281	100.0	1	0.4	0.1	2.0
	Embolism	n/a	281	100.0	2	0.7	0.2	2.6
	Embolism venous	n/a	281	100.0	1	0.4	0.1	2.0
	Haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Hypertension	n/a	281	100.0	45	16.0	12.2	20.8
	Hypotension	n/a	281	100.0	3	1.1	0.4	3.1
	Orthostatic hypotension	n/a	281	100.0	1	0.4	0.1	2.0
	Shock haemorrhagic	n/a	281	100.0	1	0.4	0.1	2.0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas

Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR345_SG.xls
26MAR2021 13:48

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	< 65	176	62.6	51	29.0	22.8	36.1
		>= 65	105	37.4	31	29.5	21.6	38.8
	Anaemia	< 65	176	62.6	31	17.6	12.7	23.9
		>= 65	105	37.4	15	14.3	8.9	22.2
	Anaemia macrocytic	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Disseminated intravascular coagulation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Febrile neutropenia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Haemorrhagic anaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Leukopenia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Lymphopenia	< 65	176	62.6	11	6.3	3.5	10.8
		>= 65	105	37.4	6	5.7	2.6	11.9
	Neutropenia	< 65	176	62.6	20	11.4	7.5	16.9
		>= 65	105	37.4	10	9.5	5.3	16.6
	Pancytopenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Thrombocytopenia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	5	4.8	2.1	10.7
Cardiac disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Acute myocardial infarction	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Cardio-respiratory arrest	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pericardial effusion	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

	Stress cardiomyopathy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Supraventricular tachycardia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Ear and labyrinth disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vertigo	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Endocrine disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Adrenal insufficiency	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Eye disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Cataract	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Keratitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Gastrointestinal disorders	-Total	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	12	11.4	6.7	18.9
	Abdominal pain upper	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Aphthous ulcer	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ascites	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Colitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Constipation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Dental caries	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diarrhoea	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Diverticular perforation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastrointestinal haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrointestinal inflammation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Intestinal obstruction	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Large intestine perforation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oesophagitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pancreatitis acute	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Proctitis ulcerative	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Stomatitis	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Vomiting	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
General disorders and administration site conditions	-Total	< 65	176	62.6	25	14.2	9.8	20.1
		>= 65	105	37.4	17	16.2	10.4	24.4
	Asthenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Chest discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Chest pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Condition aggravated	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Death	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Disease progression	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	8	7.6	3.9	14.3
	Fatigue	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	General physical health deterioration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Impaired healing	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Malaise	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Multiple organ dysfunction syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Non-cardiac chest pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyrexia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Hepatobiliary disorders	-Total	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
	Cholecystitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cholelithiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gallbladder polyp	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperbilirubinaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Liver injury	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Portal vein thrombosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Infections and infestations	-Total	< 65	176	62.6	38	21.6	16.2	28.2
		>= 65	105	37.4	28	26.7	19.1	35.8
	Appendicitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bacteraemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bacterial infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cellulitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Clostridium difficile colitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Corona virus infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Cystitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Device related infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diverticulitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Empyema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Enterococcal bacteraemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Infectious colitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lower respiratory tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lung infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Meningitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Peritonitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pleural infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumocystis jirovecii pneumonia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pneumonia	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	10	9.5	5.3	16.6
	Pneumonia bacterial	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia cytomegaloviral	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pneumonia haemophilus	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyelonephritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyelonephritis acute	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rectal abscess	< 65	176	62.6	0	0.0	0.0	2.1

		>= 65	105	37.4	1	1.0	0.2	5.2
	Renal tuberculosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sepsis	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Septic shock	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sinusitis bacterial	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	8	7.6	3.9	14.3
	Urosepsis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Injury, poisoning and procedural complications	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Fracture	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Heart injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Subdural haematoma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Investigations	-Total	< 65	176	62.6	59	33.5	27.0	40.8
		>= 65	105	37.4	30	28.6	20.8	37.8
	Alanine aminotransferase	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Alanine aminotransferase increased	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	3	2.9	1.0	8.1
	Alpha hydroxybutyrate dehydrogenase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Amylase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Aspartate aminotransferase increased	< 65	176	62.6	11	6.3	3.5	10.8
		>= 65	105	37.4	4	3.8	1.5	9.4
	Bilirubin conjugated increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood alkaline phosphatase increased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2

	Blood bilirubin increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood bilirubin unconjugated increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood creatine phosphokinase increased	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	7	6.7	3.3	13.1
	Blood creatinine increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood lactate dehydrogenase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood sodium decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	C-reactive protein increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Electrocardiogram QT prolonged	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gamma-glutamyltransferase increased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haemoglobin decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hepatic enzyme increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lipase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Lymphocyte count decreased	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	7	6.7	3.3	13.1
	Myoglobin blood increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neutrophil count decreased	< 65	176	62.6	26	14.8	10.3	20.8
		>= 65	105	37.4	10	9.5	5.3	16.6
	Oxygen saturation decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	PO2 decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Platelet count decreased	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Transaminases increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Troponin T increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Troponin increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Weight increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	White blood cell count decreased	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	5	4.8	2.1	10.7
Metabolism and nutrition disorders	-Total	< 65	176	62.6	23	13.1	8.9	18.8
		>= 65	105	37.4	23	21.9	15.1	30.7
	Acidosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Decreased appetite	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dehydration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Electrolyte imbalance	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Failure to thrive	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypercalcaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperkalaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hypernatraemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperphosphataemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperuricaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypocalcaemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypokalaemia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hyponatraemia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	6	5.7	2.6	11.9
	Hypophosphataemia	< 65	176	62.6	10	5.7	3.1	10.1

		>= 65	105	37.4	10	9.5	5.3	16.6
Musculoskeletal and connective tissue disorders	-Total	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	4	3.8	1.5	9.4
	Arthralgia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Back pain	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Intervertebral disc protrusion	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Muscle haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscular weakness	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Musculoskeletal chest pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pain in extremity	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rhabdomyolysis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cancer pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gallbladder cancer	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tumour pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Nervous system disorders	-Total	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	6	5.7	2.6	11.9
	Ataxia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cerebral haematoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cerebral microhaemorrhage	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cerebrovascular accident	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Dizziness	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Epilepsy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Facial paralysis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haemorrhage intracranial	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Headache	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lumbosacral radiculopathy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Migraine	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neuralgia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sciatica	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Seizure	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Spinal cord haematoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Syncope	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
Psychiatric disorders	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mental status changes	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
Renal and urinary disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	4	3.8	1.5	9.4
	Acute kidney injury	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haematuria	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hydronephrosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nephrolithiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Obstructive nephropathy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urethral stenosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Urinary retention	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Reproductive system and breast disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Metrorrhagia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ovarian cyst	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Prostatitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Respiratory, thoracic and mediastinal disorders	-Total	< 65	176	62.6	15	8.5	5.2	13.6
		>= 65	105	37.4	18	17.1	11.1	25.5
	Acute respiratory failure	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cough	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dyspnoea	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Hypoxia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Lung consolidation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pleural effusion	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pleuritic pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	4	3.8	1.5	9.4
	Pneumothorax	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pulmonary embolism	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	5	4.8	2.1	10.7
	Pulmonary hypertension	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Respiratory distress	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory failure	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Surgical and medical procedures	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eye excision	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hip arthroplasty	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Vascular disorders	-Total	< 65	176	62.6	18	10.2	6.6	15.6
		>= 65	105	37.4	34	32.4	24.2	41.8
	Deep vein thrombosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Embolism	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Embolism venous	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haematoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypertension	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	29	27.6	20.0	36.8
	Hypotension	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Orthostatic hypotension	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Shock haemorrhagic	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR345_SG.xls
26MAR2021 13:48

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	84	29.9	21	25.0	17.0	35.2
		1	190	67.6	58	30.5	24.4	37.4
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	35	18.4	13.6	24.5
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia macrocytic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disseminated intravascular coagulation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Febrile neutropenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhagic anaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Leukopenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphopenia	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutropenia	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	18	9.5	6.1	14.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Pancytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytopenia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
Cardiac disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute myocardial infarction	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Cardio-respiratory arrest	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pericardial effusion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Stress cardiomyopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Supraventricular tachycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Ear and labyrinth disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vertigo	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Endocrine disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Adrenal insufficiency	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Eye disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cataract	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Keratitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Gastrointestinal disorders	-Total	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain upper	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aphthous ulcer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ascites	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Colitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Constipation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dental caries	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diarrhoea	0	84	29.9	2	2.4	0.7	8.3

		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diverticular perforation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal inflammation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intestinal obstruction	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Large intestine perforation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oesophagitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancreatitis acute	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Proctitis ulcerative	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Stomatitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Vomiting	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
General disorders and administration site conditions	-Total	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	33	17.4	12.6	23.4

		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Asthenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest discomfort	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Condition aggravated	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Death	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disease progression	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	18	9.5	6.1	14.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fatigue	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	General physical health deterioration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Impaired healing	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Malaise	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Multiple organ dysfunction syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Non-cardiac chest pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyrexia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Hepatobiliary disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Cholecystitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Cholelithiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gallbladder polyp	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperbilirubinaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Liver injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Portal vein thrombosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Infections and infestations	-Total	0	84	29.9	16	19.0	12.1	28.7
		1	190	67.6	46	24.2	18.7	30.8
		2	6	2.1	4	66.7	30.0	90.3
		Missing	1	0.4	0	0.0	0.0	79.3

	Appendicitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacterial infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cellulitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Clostridium difficile colitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Corona virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Device related infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diverticulitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Empyema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Enterococcal bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Infectious colitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lower respiratory tract infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lung infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Meningitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Peritonitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumocystis jirovecii pneumonia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	19	10.0	6.5	15.1
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia bacterial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia cytomegaloviral	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia haemophilus	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyelonephritis	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyelonephritis acute	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rectal abscess	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal tuberculosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sepsis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Septic shock	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinusitis bacterial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary tract infection	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urosepsis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Injury, poisoning and procedural complications	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Fracture	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Heart injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Subdural haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
Investigations	-Total	0	84	29.9	24	28.6	20.0	39.0
		1	190	67.6	62	32.6	26.4	39.6
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Alanine aminotransferase	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alanine aminotransferase increased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alpha hydroxybutyrate dehydrogenase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Amylase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aspartate aminotransferase increased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bilirubin conjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin unconjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase increased	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatinine increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood lactate dehydrogenase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood sodium decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	C-reactive protein increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrocardiogram QT prolonged	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gamma-glutamyltransferase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemoglobin decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic enzyme increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lipase increased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphocyte count decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Myoglobin blood increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil count decreased	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	28	14.7	10.4	20.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oxygen saturation decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	PO2 decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Transaminases increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Troponin T increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Troponin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Weight increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	White blood cell count decreased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	12	6.3	3.6	10.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Metabolism and nutrition disorders	-Total	0	84	29.9	14	16.7	10.2	26.1
		1	190	67.6	29	15.3	10.8	21.1
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3

	Acidosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Decreased appetite	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dehydration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrolyte imbalance	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Failure to thrive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercalcaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperkalaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypernatraemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperphosphataemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperuricaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypocalcaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypokalaemia	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyponatraemia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypophosphataemia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
Musculoskeletal and connective tissue disorders	-Total	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Arthralgia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Back pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intervertebral disc protrusion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle haemorrhage	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscular weakness	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal chest pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain in extremity	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhabdomyolysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cancer pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gallbladder cancer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tumour pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Nervous system disorders	-Total	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ataxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebral haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebral microhaemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebrovascular accident	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dizziness	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epilepsy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Facial paralysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhage intracranial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Headache	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lumbosacral radiculopathy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Migraine	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neuralgia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sciatica	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Seizure	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Spinal cord haematoma	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Syncope	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Psychiatric disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Mental status changes	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Renal and urinary disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute kidney injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hydronephrosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nephrolithiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Obstructive nephropathy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urethral stenosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary retention	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Reproductive system and breast disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Metrorrhagia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Ovarian cyst	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Prostatitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Respiratory, thoracic and mediastinal disorders	-Total	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	21	11.1	7.3	16.3
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute respiratory failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cough	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Lung consolidation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural effusion	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleuritic pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumothorax	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary embolism	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary hypertension	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory distress	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Surgical and medical procedures	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eye excision	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hip arthroplasty	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Vascular disorders	-Total	0	84	29.9	18	21.4	14.0	31.3
		1	190	67.6	33	17.4	12.6	23.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Deep vein thrombosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism venous	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertension	0	84	29.9	17	20.2	13.0	30.0
		1	190	67.6	27	14.2	10.0	19.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypotension	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Orthostatic hypotension	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Shock haemorrhagic	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR345_SG.xls
26MAR2021 13:48

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	USA	64	22.8	22	34.4	23.9	46.6
		Europe (EU)	95	33.8	25	26.3	18.5	36.0
		Asia (AS)	122	43.4	35	28.7	21.4	37.3
	Anaemia	USA	64	22.8	13	20.3	12.3	31.7
		Europe (EU)	95	33.8	12	12.6	7.4	20.8
		Asia (AS)	122	43.4	21	17.2	11.5	24.9
	Anaemia macrocytic	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Disseminated intravascular coagulation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Febrile neutropenia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haemorrhagic anaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Leukopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Lymphopenia	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neutropenia	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Pancytopenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thrombocytopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	5	4.1	1.8	9.2

Cardiac disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Acute myocardial infarction	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cardio-respiratory arrest	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pericardial effusion	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Stress cardiomyopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Supraventricular tachycardia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Ear and labyrinth disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vertigo	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Endocrine disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Adrenal insufficiency	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Eye disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cataract	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Keratitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Gastrointestinal disorders	-Total	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	8	6.6	3.4	12.4

	Abdominal pain upper	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aphthous ulcer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ascites	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Colitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Constipation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dental caries	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Diarrhoea	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Diverticular perforation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal haemorrhage	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal inflammation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Intestinal obstruction	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Large intestine perforation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oesophagitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pancreatitis acute	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Proctitis ulcerative	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Stomatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Vomiting	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
General disorders and administration site conditions	-Total	USA	64	22.8	11	17.2	9.9	28.2
		Europe (EU)	95	33.8	16	16.8	10.6	25.6
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Asthenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Chest discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Chest pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Condition aggravated	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Death	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Disease progression	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Fatigue	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	General physical health deterioration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Impaired healing	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Malaise	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Multiple organ dysfunction syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Non-cardiac chest pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pyrexia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Hepatobiliary disorders	-Total	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Cholecystitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Cholelithiasis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gallbladder polyp	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyperbilirubinaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Liver injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Portal vein thrombosis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Infections and infestations	-Total	USA	64	22.8	20	31.3	21.2	43.4
		Europe (EU)	95	33.8	21	22.1	14.9	31.4
		Asia (AS)	122	43.4	25	20.5	14.3	28.5
	Appendicitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacteraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Bacterial infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cellulitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Clostridium difficile colitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Corona virus infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cystitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Device related infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Diverticulitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Empyema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Enterococcal bacteraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Infectious colitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lower respiratory tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lung infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Meningitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Peritonitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Pleural infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumocystis jirovecii pneumonia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonia	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
	Pneumonia bacterial	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonia cytomegaloviral	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonia haemophilus	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pyelonephritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pyelonephritis acute	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rectal abscess	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sepsis	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Septic shock	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinusitis bacterial	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urinary tract infection	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0

	Urosepsis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Injury, poisoning and procedural complications	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Fracture	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Heart injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Subdural haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Investigations	-Total	USA	64	22.8	17	26.6	17.3	38.5
		Europe (EU)	95	33.8	20	21.1	14.1	30.3
		Asia (AS)	122	43.4	52	42.6	34.2	51.5
	Alanine aminotransferase	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Alanine aminotransferase increased	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Alpha hydroxybutyrate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Amylase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aspartate aminotransferase increased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Bilirubin conjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood alkaline phosphatase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Blood bilirubin increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

	Blood bilirubin unconjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood creatine phosphokinase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	12	9.8	5.7	16.4
	Blood creatinine increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood lactate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood sodium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	C-reactive protein increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Electrocardiogram QT prolonged	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gamma-glutamyltransferase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Haemoglobin decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hepatic enzyme increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lipase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymphocyte count decreased	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Myoglobin blood increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Neutrophil count decreased	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	28	23.0	16.4	31.2

	Oxygen saturation decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	PO2 decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Platelet count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Transaminases increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Troponin T increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Troponin increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Weight increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	White blood cell count decreased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
Metabolism and nutrition disorders	-Total	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	29	23.8	17.1	32.1
	Acidosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Decreased appetite	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dehydration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Electrolyte imbalance	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Failure to thrive	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Hypercalcaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyperkalaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Hypernatraemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hyperphosphataemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperuricaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypocalcaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hypokalaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Hyponatraemia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Hypophosphataemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	13	10.7	6.3	17.4
Musculoskeletal and connective tissue disorders	-Total	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Arthralgia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Back pain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Intervertebral disc protrusion	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Muscular weakness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Musculoskeletal chest pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pain in extremity	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhabdomyolysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cancer pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gallbladder cancer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tumour pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Nervous system disorders	-Total	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Ataxia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebral haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebral microhaemorrhage	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebrovascular accident	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dizziness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Epilepsy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Facial paralysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haemorrhage intracranial	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Headache	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lumbosacral radiculopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Migraine	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neuralgia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sciatica	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Seizure	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Spinal cord haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Syncope	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Psychiatric disorders	-Total	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Mental status changes	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Renal and urinary disorders	-Total	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

	Acute kidney injury	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haematuria	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hydronephrosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nephrolithiasis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Obstructive nephropathy	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urethral stenosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary retention	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Reproductive system and breast disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Metrorrhagia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ovarian cyst	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Prostatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Respiratory, thoracic and mediastinal disorders	-Total	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	15	15.8	9.8	24.4
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Acute respiratory failure	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cough	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Dyspnoea	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Hypoxia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lung consolidation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pleural effusion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Pleuritic pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Pneumothorax	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Pulmonary embolism	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pulmonary hypertension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory distress	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory failure	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Surgical and medical procedures	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eye excision	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hip arthroplasty	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

Vascular disorders	-Total	USA	64	22.8	19	29.7	19.9	41.8
		Europe (EU)	95	33.8	12	12.6	7.4	20.8
		Asia (AS)	122	43.4	21	17.2	11.5	24.9
	Deep vein thrombosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Embolism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Embolism venous	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypertension	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	10	10.5	5.8	18.3
		Asia (AS)	122	43.4	20	16.4	10.9	24.0
	Hypotension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Orthostatic hypotension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Shock haemorrhagic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR345_SG.xls
26MAR2021 13:48

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	116	41.3	24	20.7	14.3	28.9
		1	77	27.4	23	29.9	20.8	40.8
		>= 2	88	31.3	35	39.8	30.2	50.2
	Anaemia	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	16	20.8	13.2	31.1
		>= 2	88	31.3	19	21.6	14.3	31.3
	Anaemia macrocytic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Disseminated intravascular coagulation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Febrile neutropenia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Haemorrhagic anaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Leukopenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Lymphopenia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	4	4.5	1.8	11.1
	Neutropenia	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	16	18.2	11.5	27.5
	Pancytopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Thrombocytopenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	4	4.5	1.8	11.1

Cardiac disorders	-Total	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Acute myocardial infarction	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cardio-respiratory arrest	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pericardial effusion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Stress cardiomyopathy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Supraventricular tachycardia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Ear and labyrinth disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vertigo	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Endocrine disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Adrenal insufficiency	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Eye disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cataract	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Keratitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Gastrointestinal disorders	-Total	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	11	12.5	7.1	21.0

	Abdominal pain upper	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Aphthous ulcer	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ascites	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Colitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Constipation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dental caries	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Diarrhoea	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Diverticular perforation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrointestinal haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastrointestinal inflammation	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intestinal obstruction	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Large intestine perforation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oesophagitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pancreatitis acute	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9

	Proctitis ulcerative	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Stomatitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Vomiting	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
General disorders and administration site conditions	-Total	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	15	19.5	12.2	29.7
		>= 2	88	31.3	16	18.2	11.5	27.5
	Asthenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Chest discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Chest pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Condition aggravated	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Death	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Disease progression	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	9	10.2	5.5	18.3
	Fatigue	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	General physical health deterioration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Impaired healing	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Malaise	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Multiple organ dysfunction syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Non-cardiac chest pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pyrexia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Hepatobiliary disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Cholecystitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cholelithiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gallbladder polyp	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperbilirubinaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Liver injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Portal vein thrombosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Infections and infestations	-Total	0	116	41.3	20	17.2	11.4	25.1
		1	77	27.4	19	24.7	16.4	35.4
		>= 2	88	31.3	27	30.7	22.0	41.0
	Appendicitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bacteraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Bacterial infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cellulitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Clostridium difficile colitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Corona virus infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cystitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Device related infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Diverticulitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Empyema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Enterococcal bacteraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Infectious colitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lower respiratory tract infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lung infection	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Meningitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Peritonitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Pleural infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumocystis jirovecii pneumonia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	10	11.4	6.3	19.7
	Pneumonia bacterial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia cytomegaloviral	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia haemophilus	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pyelonephritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pyelonephritis acute	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rectal abscess	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Renal tuberculosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sepsis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	4	4.5	1.8	11.1
	Septic shock	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sinusitis bacterial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Urinary tract infection	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5

	Urosepsis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Injury, poisoning and procedural complications	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Fracture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Heart injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Subdural haematoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Investigations	-Total	0	116	41.3	37	31.9	24.1	40.8
		1	77	27.4	21	27.3	18.6	38.1
		>= 2	88	31.3	31	35.2	26.1	45.6
	Alanine aminotransferase	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Alanine aminotransferase increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Alpha hydroxybutyrate dehydrogenase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Amylase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Aspartate aminotransferase increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	8	9.1	4.7	16.9
	Bilirubin conjugated increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood alkaline phosphatase increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood bilirubin increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2

	Blood bilirubin unconjugated increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood creatine phosphokinase increased	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	7	8.0	3.9	15.5
	Blood creatinine increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood lactate dehydrogenase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood sodium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	C-reactive protein increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Electrocardiogram QT prolonged	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gamma-glutamyltransferase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Haemoglobin decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hepatic enzyme increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lipase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lymphocyte count decreased	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	4	4.5	1.8	11.1
	Myoglobin blood increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neutrophil count decreased	0	116	41.3	17	14.7	9.4	22.2
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	10	11.4	6.3	19.7

	Oxygen saturation decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	PO2 decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Platelet count decreased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Transaminases increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Troponin T increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Troponin increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Weight increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	White blood cell count decreased	0	116	41.3	8	6.9	3.5	13.0
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
Metabolism and nutrition disorders	-Total	0	116	41.3	16	13.8	8.7	21.2
		1	77	27.4	14	18.2	11.2	28.2
		>= 2	88	31.3	16	18.2	11.5	27.5
	Acidosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Decreased appetite	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Dehydration	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Electrolyte imbalance	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Failure to thrive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Hypercalcaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperkalaemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypernatraemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperphosphataemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperuricaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypocalcaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypokalaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Hyponatraemia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Hypophosphataemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	9	10.2	5.5	18.3
Musculoskeletal and connective tissue disorders	-Total	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	6	6.8	3.2	14.1
	Arthralgia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Back pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intervertebral disc protrusion	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Muscle haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Muscular weakness	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Musculoskeletal chest pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pain in extremity	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rhabdomyolysis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cancer pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gallbladder cancer	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tumour pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Nervous system disorders	-Total	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	5	5.7	2.5	12.6
	Ataxia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cerebral haematoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cerebral microhaemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cerebrovascular accident	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dizziness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Epilepsy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Facial paralysis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haemorrhage intracranial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Headache	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lumbosacral radiculopathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Migraine	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neuralgia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sciatica	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Seizure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Spinal cord haematoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Syncope	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Psychiatric disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Mental status changes	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
Renal and urinary disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9

	Acute kidney injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haematuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hydronephrosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Nephrolithiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Obstructive nephropathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urethral stenosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urinary retention	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Reproductive system and breast disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Metrorrhagia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ovarian cyst	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Prostatitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Respiratory, thoracic and mediastinal disorders	-Total	0	116	41.3	13	11.2	6.7	18.2
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	11	12.5	7.1	21.0
	Acute respiratory failure	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cough	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Dyspnoea	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypoxia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Lung consolidation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pleural effusion	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Pleuritic pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonitis	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumothorax	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pulmonary embolism	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Pulmonary hypertension	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiratory distress	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Respiratory failure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Surgical and medical procedures	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eye excision	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hip arthroplasty	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

Vascular disorders	-Total	0	116	41.3	18	15.5	10.0	23.2
		1	77	27.4	17	22.1	14.3	32.5
		>= 2	88	31.3	17	19.3	12.4	28.8
	Deep vein thrombosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Embolism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Embolism venous	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haematoma	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypertension	0	116	41.3	17	14.7	9.4	22.2
		1	77	27.4	14	18.2	11.2	28.2
		>= 2	88	31.3	14	15.9	9.7	25.0
	Hypotension	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Orthostatic hypotension	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Shock haemorrhagic	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR345_SG.xls
26MAR2021 13:48

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Asian	128	45.6	37	28.9	21.8	37.3
		Non-Asian	135	48.0	43	31.9	24.6	40.1
		Unknown	18	6.4	2	11.1	3.1	32.8
	Anaemia	Asian	128	45.6	21	16.4	11.0	23.8
		Non-Asian	135	48.0	23	17.0	11.6	24.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Anaemia macrocytic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Disseminated intravascular coagulation	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Febrile neutropenia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhagic anaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Leukopenia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutropenia	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancytopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytopenia	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

Cardiac disorders	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Acute myocardial infarction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cardio-respiratory arrest	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pericardial effusion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Stress cardiomyopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Supraventricular tachycardia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Ear and labyrinth disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vertigo	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Endocrine disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Adrenal insufficiency	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Eye disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cataract	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Keratitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Gastrointestinal disorders	-Total	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	0	0.0	0.0	17.6

	Abdominal pain upper	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aphthous ulcer	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ascites	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Constipation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dental caries	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diarrhoea	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diverticular perforation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal inflammation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intestinal obstruction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Large intestine perforation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oesophagitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancreatitis acute	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

	Proctitis ulcerative	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Stomatitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vomiting	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
General disorders and administration site conditions	-Total	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	23	17.0	11.6	24.3
		Unknown	18	6.4	3	16.7	5.8	39.2
	Asthenia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chest discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chest pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Condition aggravated	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Death	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Disease progression	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	10	7.4	4.1	13.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Fatigue	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	General physical health deterioration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Impaired healing	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Malaise	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Multiple organ dysfunction syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Non-cardiac chest pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyrexia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Hepatobiliary disorders	-Total	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cholecystitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cholelithiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gallbladder polyp	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperbilirubinaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Liver injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Portal vein thrombosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Infections and infestations	-Total	Asian	128	45.6	28	21.9	15.6	29.8
		Non-Asian	135	48.0	35	25.9	19.3	33.9
		Unknown	18	6.4	3	16.7	5.8	39.2
	Appendicitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Bacterial infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Cellulitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Clostridium difficile colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Corona virus infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Device related infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diverticulitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Empyema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Enterococcal bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Infectious colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lower respiratory tract infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lung infection	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Meningitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Peritonitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Pleural infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumocystis jirovecii pneumonia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia	Asian	128	45.6	14	10.9	6.6	17.5
		Non-Asian	135	48.0	12	8.9	5.2	14.9
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumonia bacterial	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia cytomegaloviral	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia haemophilus	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyelonephritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyelonephritis acute	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rectal abscess	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal tuberculosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sepsis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Septic shock	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinusitis bacterial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary tract infection	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6

	Urosepsis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Injury, poisoning and procedural complications	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fracture	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Heart injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Subdural haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Investigations	-Total	Asian	128	45.6	57	44.5	36.2	53.2
		Non-Asian	135	48.0	27	20.0	14.1	27.5
		Unknown	18	6.4	5	27.8	12.5	50.9
	Alanine aminotransferase	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alanine aminotransferase increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Alpha hydroxybutyrate dehydrogenase increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Amylase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aspartate aminotransferase increased	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bilirubin conjugated increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood alkaline phosphatase increased	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood bilirubin increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Blood bilirubin unconjugated increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine phosphokinase increased	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Blood creatinine increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood lactate dehydrogenase increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood sodium decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	C-reactive protein increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrocardiogram QT prolonged	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gamma-glutamyltransferase increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemoglobin decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatic enzyme increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lipase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphocyte count decreased	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Myoglobin blood increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutrophil count decreased	Asian	128	45.6	30	23.4	16.9	31.5
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6

	Oxygen saturation decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	PO2 decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Platelet count decreased	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Transaminases increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Troponin T increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Troponin increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Weight increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	White blood cell count decreased	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
Metabolism and nutrition disorders	-Total	Asian	128	45.6	29	22.7	16.3	30.6
		Non-Asian	135	48.0	16	11.9	7.4	18.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Acidosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Decreased appetite	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dehydration	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrolyte imbalance	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Failure to thrive	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Hypercalcaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperkalaemia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypernatraemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperphosphataemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperuricaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypocalcaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypokalaemia	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyponatraemia	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypophosphataemia	Asian	128	45.6	13	10.2	6.0	16.6
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
Musculoskeletal and connective tissue disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	1	5.6	1.0	25.8
	Arthralgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Back pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intervertebral disc protrusion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Muscular weakness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Musculoskeletal chest pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pain in extremity	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhabdomyolysis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Cancer pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gallbladder cancer	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tumour pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Nervous system disorders	-Total	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	Ataxia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebral haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebral microhaemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebrovascular accident	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dizziness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Epilepsy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Facial paralysis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Haemorrhage intracranial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Headache	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lumbosacral radiculopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Migraine	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neuralgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Sciatica	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Seizure	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Spinal cord haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Syncope	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Psychiatric disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mental status changes	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Renal and urinary disorders	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6

	Acute kidney injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematuria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hydronephrosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nephrolithiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Obstructive nephropathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urethral stenosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary retention	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Reproductive system and breast disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Metrorrhagia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Ovarian cyst	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Prostatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Respiratory, thoracic and mediastinal disorders	-Total	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	4	22.2	9.0	45.2
	Acute respiratory failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cough	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Dyspnoea	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypoxia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Lung consolidation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleural effusion	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleuritic pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonitis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumothorax	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary embolism	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Pulmonary hypertension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory distress	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Respiratory failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Surgical and medical procedures	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eye excision	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hip arthroplasty	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

Vascular disorders	-Total	Asian	128	45.6	22	17.2	11.6	24.7
		Non-Asian	135	48.0	27	20.0	14.1	27.5
		Unknown	18	6.4	3	16.7	5.8	39.2
	Deep vein thrombosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Embolism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Embolism venous	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematoma	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypertension	Asian	128	45.6	21	16.4	11.0	23.8
		Non-Asian	135	48.0	24	17.8	12.2	25.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypotension	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Orthostatic hypotension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Shock haemorrhagic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR345_SG.xls
26MAR2021 13:48

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Female	152	54.1	51	33.6	26.5	41.4
		Male	129	45.9	31	24.0	17.5	32.1
	Anaemia	Female	152	54.1	30	19.7	14.2	26.8
		Male	129	45.9	16	12.4	7.8	19.2
	Anaemia macrocytic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Disseminated intravascular coagulation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Febrile neutropenia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Haemorrhagic anaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Leukopenia	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	1	0.8	0.1	4.3
	Lymphopenia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	5	3.9	1.7	8.8
	Neutropenia	Female	152	54.1	19	12.5	8.2	18.7
		Male	129	45.9	11	8.5	4.8	14.6
	Pancytopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombocytopenia	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
Cardiac disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	Acute myocardial infarction	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cardio-respiratory arrest	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pericardial effusion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3

	Stress cardiomyopathy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Supraventricular tachycardia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Ear and labyrinth disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Vertigo	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Endocrine disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Adrenal insufficiency	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Eye disorders	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Cataract	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Keratitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Gastrointestinal disorders	-Total	Female	152	54.1	17	11.2	7.1	17.2
		Male	129	45.9	8	6.2	3.2	11.8
	Abdominal pain upper	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Aphthous ulcer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ascites	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Constipation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Dental caries	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Diarrhoea	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Diverticular perforation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gastrointestinal haemorrhage	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
	Gastrointestinal inflammation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Intestinal obstruction	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Large intestine perforation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oesophagitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pancreatitis acute	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Proctitis ulcerative	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Stomatitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Vomiting	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
General disorders and administration site conditions	-Total	Female	152	54.1	22	14.5	9.8	20.9
		Male	129	45.9	20	15.5	10.3	22.7
	Asthenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Chest discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Chest pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Condition aggravated	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Death	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Disease progression	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	11	8.5	4.8	14.6
	Fatigue	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	1	0.8	0.1	4.3
	General physical health deterioration	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Impaired healing	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Malaise	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Multiple organ dysfunction syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Non-cardiac chest pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pyrexia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Hepatobiliary disorders	-Total	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Cholecystitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cholelithiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gallbladder polyp	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hyperbilirubinaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Liver injury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Portal vein thrombosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Infections and infestations	-Total	Female	152	54.1	35	23.0	17.0	30.3
		Male	129	45.9	31	24.0	17.5	32.1
	Appendicitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Bacteraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bacterial infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cellulitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Clostridium difficile colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Corona virus infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Cystitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Device related infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Diverticulitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Empyema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Enterococcal bacteraemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Infectious colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lower respiratory tract infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lung infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Meningitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Peritonitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pleural infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumocystis jirovecii pneumonia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Pneumonia	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	13	10.1	6.0	16.5
	Pneumonia bacterial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonia cytomegaloviral	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pneumonia haemophilus	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pyelonephritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pyelonephritis acute	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rectal abscess	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Renal tuberculosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sepsis	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Septic shock	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sinusitis bacterial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urinary tract infection	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	6	4.7	2.1	9.8
	Urosepsis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Injury, poisoning and procedural complications	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Fracture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Heart injury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Subdural haematoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Investigations	-Total	Female	152	54.1	54	35.5	28.4	43.4
		Male	129	45.9	35	27.1	20.2	35.4
	Alanine aminotransferase	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Alanine aminotransferase increased	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	2	1.6	0.4	5.5
	Alpha hydroxybutyrate dehydrogenase increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Amylase increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Aspartate aminotransferase increased	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	7	5.4	2.7	10.8
	Bilirubin conjugated increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood alkaline phosphatase increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6

	Blood bilirubin increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Blood bilirubin unconjugated increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood creatine phosphokinase increased	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	12	9.3	5.4	15.6
	Blood creatinine increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Blood lactate dehydrogenase increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood sodium decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	C-reactive protein increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Electrocardiogram QT prolonged	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gamma-glutamyltransferase increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Haemoglobin decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Hepatic enzyme increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lipase increased	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lymphocyte count decreased	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	8	6.2	3.2	11.8
	Myoglobin blood increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neutrophil count decreased	Female	152	54.1	27	17.8	12.5	24.6
		Male	129	45.9	9	7.0	3.7	12.7
	Oxygen saturation decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	PO2 decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Platelet count decreased	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	2	1.6	0.4	5.5
	Transaminases increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Troponin T increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Troponin increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Weight increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	White blood cell count decreased	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	3	2.3	0.8	6.6
Metabolism and nutrition disorders	-Total	Female	152	54.1	25	16.4	11.4	23.2
		Male	129	45.9	21	16.3	10.9	23.6
	Acidosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Decreased appetite	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Dehydration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Electrolyte imbalance	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Failure to thrive	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypercalcaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperkalaemia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hypernatraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperphosphataemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperuricaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypocalcaemia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hypokalaemia	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	2	1.6	0.4	5.5
	Hyponatraemia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	8	6.2	3.2	11.8
	Hypophosphataemia	Female	152	54.1	13	8.6	5.1	14.1

		Male	129	45.9	7	5.4	2.7	10.8
Musculoskeletal and connective tissue disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	10	7.8	4.3	13.7
	Arthralgia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Back pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Intervertebral disc protrusion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	4	3.1	1.2	7.7
	Muscle haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Muscular weakness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Musculoskeletal chest pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pain in extremity	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rhabdomyolysis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Cancer pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gallbladder cancer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tumour pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Nervous system disorders	-Total	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	9	7.0	3.7	12.7
	Ataxia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cerebral haematoma	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cerebral microhaemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cerebrovascular accident	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Dizziness	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Epilepsy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Facial paralysis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Haemorrhage intracranial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Headache	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Lumbosacral radiculopathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Migraine	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neuralgia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Sciatica	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Seizure	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Spinal cord haematoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Syncope	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
Psychiatric disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Mental status changes	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
Renal and urinary disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	5	3.9	1.7	8.8
	Acute kidney injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Haematuria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hydronephrosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nephrolithiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Obstructive nephropathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urethral stenosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urinary retention	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Reproductive system and breast disorders	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Metrorrhagia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ovarian cyst	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Prostatitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Respiratory, thoracic and mediastinal disorders	-Total	Female	152	54.1	14	9.2	5.6	14.9
		Male	129	45.9	19	14.7	9.6	21.9
	Acute respiratory failure	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cough	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dyspnoea	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Hypoxia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	4	3.1	1.2	7.7
	Lung consolidation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pleural effusion	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Pleuritic pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pneumonitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	4	3.1	1.2	7.7
	Pneumothorax	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pulmonary embolism	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	6	4.7	2.1	9.8
	Pulmonary hypertension	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
	Respiratory distress	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Respiratory failure	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Surgical and medical procedures	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Eye excision	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hip arthroplasty	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Vascular disorders	-Total	Female	152	54.1	29	19.1	13.6	26.1
		Male	129	45.9	23	17.8	12.2	25.3
	Deep vein thrombosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Embolism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Embolism venous	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haematoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypertension	Female	152	54.1	27	17.8	12.5	24.6
		Male	129	45.9	18	14.0	9.0	21.0
	Hypotension	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Orthostatic hypotension	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Shock haemorrhagic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR345_SG.xls
26MAR2021 13:48

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	155	55.2	49.3	60.9
Sex	Female	152	54.1	90	59.2	51.3	66.7
	Male	129	45.9	65	50.4	41.9	58.9
Age	< 65	176	62.6	87	49.4	42.1	56.8
	>= 65	105	37.4	68	64.8	55.3	73.2
ECOG performance status	0	84	29.9	43	51.2	40.7	61.6
	1	190	67.6	111	58.4	51.3	65.2
	2	6	2.1	1	16.7	3.0	56.4
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	46	71.9	59.9	81.4
	Europe (EU)	95	33.8	42	44.2	34.6	54.2
	Asia (AS)	122	43.4	67	54.9	46.1	63.5
Race/ethnicity	Asian	128	45.6	73	57.0	48.4	65.3
	Non-Asian	135	48.0	74	54.8	46.4	63.0
	Unknown	18	6.4	8	44.4	24.6	66.3
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	66	56.9	47.8	65.5
	1	77	27.4	45	58.4	47.3	68.8
	>= 2	88	31.3	44	50.0	39.8	60.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AEGR3_SG.xls
26MAR2021 10:19

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	147	52.3	46.5	58.1
Sex	Female	152	54.1	85	55.9	48.0	63.6
	Male	129	45.9	62	48.1	39.6	56.6
Age	< 65	176	62.6	82	46.6	39.4	54.0
	>= 65	105	37.4	65	61.9	52.4	70.6
ECOG performance status	0	84	29.9	42	50.0	39.5	60.5
	1	190	67.6	104	54.7	47.6	61.7
	2	6	2.1	1	16.7	3.0	56.4
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	42	65.6	53.4	76.1
	Europe (EU)	95	33.8	38	40.0	30.7	50.1
	Asia (AS)	122	43.4	67	54.9	46.1	63.5
Race/ethnicity	Asian	128	45.6	72	56.3	47.6	64.5
	Non-Asian	135	48.0	67	49.6	41.3	58.0
	Unknown	18	6.4	8	44.4	24.6	66.3
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	67	57.8	48.7	66.4
	1	77	27.4	40	51.9	41.0	62.7
	>= 2	88	31.3	40	45.5	35.5	55.8

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw_B63_06NOV2020_SE_TO_AEGR3_SG.xls
26MAR2021 9:57

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	n/a	281	100.0	76	27.0	22.2	32.5
	Anaemia	n/a	281	100.0	45	16.0	12.2	20.8
	Anaemia macrocytic	n/a	281	100.0	1	0.4	0.1	2.0
	Disseminated intravascular coagulation	n/a	281	100.0	1	0.4	0.1	2.0
	Febrile neutropenia	n/a	281	100.0	3	1.1	0.4	3.1
	Haemorrhagic anaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Leukopenia	n/a	281	100.0	8	2.8	1.4	5.5
	Lymphopenia	n/a	281	100.0	14	5.0	3.0	8.2
	Neutropenia	n/a	281	100.0	22	7.8	5.2	11.6
	Pancytopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombocytopenia	n/a	281	100.0	5	1.8	0.8	4.1
Cardiac disorders	-Total	n/a	281	100.0	5	1.8	0.8	4.1
	Acute myocardial infarction	n/a	281	100.0	1	0.4	0.1	2.0
	Pericardial effusion	n/a	281	100.0	2	0.7	0.2	2.6
	Stress cardiomyopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Supraventricular tachycardia	n/a	281	100.0	1	0.4	0.1	2.0
Ear and labyrinth disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Vertigo	n/a	281	100.0	1	0.4	0.1	2.0
Endocrine disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Adrenal insufficiency	n/a	281	100.0	1	0.4	0.1	2.0
Eye disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Cataract	n/a	281	100.0	2	0.7	0.2	2.6

	Keratitis	n/a	281	100.0	1	0.4	0.1	2.0
Gastrointestinal disorders	-Total	n/a	281	100.0	24	8.5	5.8	12.4
	Abdominal pain upper	n/a	281	100.0	1	0.4	0.1	2.0
	Aphthous ulcer	n/a	281	100.0	1	0.4	0.1	2.0
	Ascites	n/a	281	100.0	1	0.4	0.1	2.0
	Colitis	n/a	281	100.0	3	1.1	0.4	3.1
	Constipation	n/a	281	100.0	2	0.7	0.2	2.6
	Dental caries	n/a	281	100.0	1	0.4	0.1	2.0
	Diarrhoea	n/a	281	100.0	5	1.8	0.8	4.1
	Diverticular perforation	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal inflammation	n/a	281	100.0	1	0.4	0.1	2.0
	Large intestine perforation	n/a	281	100.0	1	0.4	0.1	2.0
	Oesophagitis	n/a	281	100.0	1	0.4	0.1	2.0
	Pancreatitis acute	n/a	281	100.0	2	0.7	0.2	2.6
	Proctitis ulcerative	n/a	281	100.0	1	0.4	0.1	2.0
	Stomatitis	n/a	281	100.0	5	1.8	0.8	4.1
	Vomiting	n/a	281	100.0	3	1.1	0.4	3.1
General disorders and administration site conditions	-Total	n/a	281	100.0	16	5.7	3.5	9.0
	Asthenia	n/a	281	100.0	1	0.4	0.1	2.0
	Chest discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Chest pain	n/a	281	100.0	1	0.4	0.1	2.0
	Fatigue	n/a	281	100.0	6	2.1	1.0	4.6
	General physical health deterioration	n/a	281	100.0	2	0.7	0.2	2.6
	Impaired healing	n/a	281	100.0	1	0.4	0.1	2.0
	Malaise	n/a	281	100.0	1	0.4	0.1	2.0
	Non-cardiac chest pain	n/a	281	100.0	1	0.4	0.1	2.0
	Pain	n/a	281	100.0	1	0.4	0.1	2.0

	Pyrexia	n/a	281	100.0	1	0.4	0.1	2.0
Hepatobiliary disorders	-Total	n/a	281	100.0	8	2.8	1.4	5.5
	Cholecystitis	n/a	281	100.0	2	0.7	0.2	2.6
	Cholelithiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Gallbladder polyp	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperbilirubinaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Liver injury	n/a	281	100.0	1	0.4	0.1	2.0
	Portal vein thrombosis	n/a	281	100.0	2	0.7	0.2	2.6
Infections and infestations	-Total	n/a	281	100.0	56	19.9	15.7	25.0
	Appendicitis	n/a	281	100.0	2	0.7	0.2	2.6
	Bacteraemia	n/a	281	100.0	1	0.4	0.1	2.0
	Bacterial infection	n/a	281	100.0	1	0.4	0.1	2.0
	Cellulitis	n/a	281	100.0	1	0.4	0.1	2.0
	Clostridium difficile colitis	n/a	281	100.0	1	0.4	0.1	2.0
	Corona virus infection	n/a	281	100.0	1	0.4	0.1	2.0
	Cystitis	n/a	281	100.0	1	0.4	0.1	2.0
	Device related infection	n/a	281	100.0	1	0.4	0.1	2.0
	Diverticulitis	n/a	281	100.0	2	0.7	0.2	2.6
	Empyema	n/a	281	100.0	1	0.4	0.1	2.0
	Enterococcal bacteraemia	n/a	281	100.0	1	0.4	0.1	2.0
	Infectious colitis	n/a	281	100.0	1	0.4	0.1	2.0
	Lower respiratory tract infection	n/a	281	100.0	1	0.4	0.1	2.0
	Lung infection	n/a	281	100.0	3	1.1	0.4	3.1
	Meningitis	n/a	281	100.0	1	0.4	0.1	2.0
	Peritonitis	n/a	281	100.0	1	0.4	0.1	2.0
	Pleural infection	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumocystis jirovecii pneumonia	n/a	281	100.0	2	0.7	0.2	2.6
	Pneumonia	n/a	281	100.0	21	7.5	4.9	11.2

	Pneumonia bacterial	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia haemophilus	n/a	281	100.0	1	0.4	0.1	2.0
	Pyelonephritis	n/a	281	100.0	1	0.4	0.1	2.0
	Pyelonephritis acute	n/a	281	100.0	1	0.4	0.1	2.0
	Rectal abscess	n/a	281	100.0	1	0.4	0.1	2.0
	Renal tuberculosis	n/a	281	100.0	1	0.4	0.1	2.0
	Sepsis	n/a	281	100.0	4	1.4	0.6	3.6
	Sinusitis bacterial	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary tract infection	n/a	281	100.0	9	3.2	1.7	6.0
	Urosepsis	n/a	281	100.0	1	0.4	0.1	2.0
Injury, poisoning and procedural complications	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Fracture	n/a	281	100.0	1	0.4	0.1	2.0
	Heart injury	n/a	281	100.0	1	0.4	0.1	2.0
	Subdural haematoma	n/a	281	100.0	1	0.4	0.1	2.0
Investigations	-Total	n/a	281	100.0	84	29.9	24.8	35.5
	Alanine aminotransferase	n/a	281	100.0	1	0.4	0.1	2.0
	Alanine aminotransferase increased	n/a	281	100.0	7	2.5	1.2	5.1
	Alpha hydroxybutyrate dehydrogenase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Aspartate aminotransferase increased	n/a	281	100.0	11	3.9	2.2	6.9
	Blood alkaline phosphatase increased	n/a	281	100.0	4	1.4	0.6	3.6
	Blood bilirubin increased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood bilirubin unconjugated increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood creatine phosphokinase increased	n/a	281	100.0	15	5.3	3.3	8.6
	Blood creatinine increased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood lactate dehydrogenase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood sodium decreased	n/a	281	100.0	1	0.4	0.1	2.0
	C-reactive protein increased	n/a	281	100.0	1	0.4	0.1	2.0
	Electrocardiogram QT prolonged	n/a	281	100.0	1	0.4	0.1	2.0

	Gamma-glutamyltransferase increased	n/a	281	100.0	2	0.7	0.2	2.6
	Haemoglobin decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Hepatic enzyme increased	n/a	281	100.0	1	0.4	0.1	2.0
	Lipase increased	n/a	281	100.0	2	0.7	0.2	2.6
	Lymphocyte count decreased	n/a	281	100.0	12	4.3	2.5	7.3
	Neutrophil count decreased	n/a	281	100.0	31	11.0	7.9	15.2
	Platelet count decreased	n/a	281	100.0	7	2.5	1.2	5.1
	Transaminases increased	n/a	281	100.0	1	0.4	0.1	2.0
	Troponin T increased	n/a	281	100.0	1	0.4	0.1	2.0
	Troponin increased	n/a	281	100.0	1	0.4	0.1	2.0
	Weight increased	n/a	281	100.0	2	0.7	0.2	2.6
	White blood cell count decreased	n/a	281	100.0	14	5.0	3.0	8.2
Metabolism and nutrition disorders	-Total	n/a	281	100.0	43	15.3	11.6	20.0
	Acidosis	n/a	281	100.0	1	0.4	0.1	2.0
	Decreased appetite	n/a	281	100.0	2	0.7	0.2	2.6
	Dehydration	n/a	281	100.0	2	0.7	0.2	2.6
	Electrolyte imbalance	n/a	281	100.0	2	0.7	0.2	2.6
	Failure to thrive	n/a	281	100.0	1	0.4	0.1	2.0
	Hypercalcaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperkalaemia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypernatraemia	n/a	281	100.0	2	0.7	0.2	2.6
	Hyperphosphataemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypocalcaemia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypokalaemia	n/a	281	100.0	6	2.1	1.0	4.6
	Hyponatraemia	n/a	281	100.0	9	3.2	1.7	6.0
	Hypophosphataemia	n/a	281	100.0	19	6.8	4.4	10.3
Musculoskeletal and connective tissue disorders	-Total	n/a	281	100.0	12	4.3	2.5	7.3
	Arthralgia	n/a	281	100.0	1	0.4	0.1	2.0

	Back pain	n/a	281	100.0	3	1.1	0.4	3.1
	Intervertebral disc protrusion	n/a	281	100.0	4	1.4	0.6	3.6
	Muscle haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Muscular weakness	n/a	281	100.0	3	1.1	0.4	3.1
	Musculoskeletal chest pain	n/a	281	100.0	1	0.4	0.1	2.0
	Pain in extremity	n/a	281	100.0	1	0.4	0.1	2.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Cancer pain	n/a	281	100.0	1	0.4	0.1	2.0
	Gallbladder cancer	n/a	281	100.0	1	0.4	0.1	2.0
	Tumour pain	n/a	281	100.0	1	0.4	0.1	2.0
Nervous system disorders	-Total	n/a	281	100.0	14	5.0	3.0	8.2
	Ataxia	n/a	281	100.0	1	0.4	0.1	2.0
	Cerebral haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Cerebral microhaemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Dizziness	n/a	281	100.0	1	0.4	0.1	2.0
	Epilepsy	n/a	281	100.0	1	0.4	0.1	2.0
	Facial paralysis	n/a	281	100.0	1	0.4	0.1	2.0
	Headache	n/a	281	100.0	2	0.7	0.2	2.6
	Lumbosacral radiculopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Migraine	n/a	281	100.0	1	0.4	0.1	2.0
	Neuralgia	n/a	281	100.0	1	0.4	0.1	2.0
	Sciatica	n/a	281	100.0	2	0.7	0.2	2.6
	Seizure	n/a	281	100.0	1	0.4	0.1	2.0
	Spinal cord haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Syncope	n/a	281	100.0	3	1.1	0.4	3.1
Psychiatric disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Mental status changes	n/a	281	100.0	3	1.1	0.4	3.1
Renal and urinary disorders	-Total	n/a	281	100.0	6	2.1	1.0	4.6

	Acute kidney injury	n/a	281	100.0	2	0.7	0.2	2.6
	Haematuria	n/a	281	100.0	1	0.4	0.1	2.0
	Hydronephrosis	n/a	281	100.0	1	0.4	0.1	2.0
	Nephrolithiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Obstructive nephropathy	n/a	281	100.0	1	0.4	0.1	2.0
	Urethral stenosis	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary retention	n/a	281	100.0	1	0.4	0.1	2.0
Reproductive system and breast disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Metrorrhagia	n/a	281	100.0	1	0.4	0.1	2.0
	Ovarian cyst	n/a	281	100.0	1	0.4	0.1	2.0
	Prostatitis	n/a	281	100.0	1	0.4	0.1	2.0
Respiratory, thoracic and mediastinal disorders	-Total	n/a	281	100.0	28	10.0	7.0	14.0
	Acute respiratory failure	n/a	281	100.0	1	0.4	0.1	2.0
	Cough	n/a	281	100.0	1	0.4	0.1	2.0
	Dyspnoea	n/a	281	100.0	6	2.1	1.0	4.6
	Hypoxia	n/a	281	100.0	4	1.4	0.6	3.6
	Lung consolidation	n/a	281	100.0	1	0.4	0.1	2.0
	Pleural effusion	n/a	281	100.0	5	1.8	0.8	4.1
	Pleuritic pain	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonitis	n/a	281	100.0	4	1.4	0.6	3.6
	Pneumothorax	n/a	281	100.0	2	0.7	0.2	2.6
	Pulmonary embolism	n/a	281	100.0	8	2.8	1.4	5.5
	Pulmonary hypertension	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory distress	n/a	281	100.0	1	0.4	0.1	2.0
Surgical and medical procedures	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Eye excision	n/a	281	100.0	1	0.4	0.1	2.0
	Hip arthroplasty	n/a	281	100.0	1	0.4	0.1	2.0
Vascular disorders	-Total	n/a	281	100.0	50	17.8	13.8	22.7

	Deep vein thrombosis	n/a	281	100.0	1	0.4	0.1	2.0
	Embolism	n/a	281	100.0	1	0.4	0.1	2.0
	Embolism venous	n/a	281	100.0	1	0.4	0.1	2.0
	Haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Hypertension	n/a	281	100.0	45	16.0	12.2	20.8
	Hypotension	n/a	281	100.0	1	0.4	0.1	2.0
	Orthostatic hypotension	n/a	281	100.0	1	0.4	0.1	2.0
	Shock haemorrhagic	n/a	281	100.0	1	0.4	0.1	2.0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR3_SG.xls
26MAR2021 14:29

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	< 65	176	62.6	47	26.7	20.7	33.7
		>= 65	105	37.4	29	27.6	20.0	36.8
	Anaemia	< 65	176	62.6	30	17.0	12.2	23.3
		>= 65	105	37.4	15	14.3	8.9	22.2
	Anaemia macrocytic	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Disseminated intravascular coagulation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Febrile neutropenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Haemorrhagic anaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Leukopenia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Lymphopenia	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Neutropenia	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	6	5.7	2.6	11.9
	Pancytopenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Thrombocytopenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	4	3.8	1.5	9.4
Cardiac disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Acute myocardial infarction	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pericardial effusion	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Stress cardiomyopathy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Supraventricular tachycardia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Ear and labyrinth disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vertigo	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Endocrine disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Adrenal insufficiency	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Eye disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Cataract	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Keratitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Gastrointestinal disorders	-Total	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	11	10.5	6.0	17.8
	Abdominal pain upper	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Aphthous ulcer	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ascites	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Colitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Constipation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Dental caries	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diarrhoea	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Diverticular perforation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastrointestinal haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrointestinal inflammation	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Large intestine perforation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oesophagitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pancreatitis acute	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Proctitis ulcerative	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Stomatitis	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Vomiting	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
General disorders and administration site conditions	-Total	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	8	7.6	3.9	14.3
	Asthenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Chest discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Chest pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Fatigue	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	General physical health deterioration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Impaired healing	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Malaise	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Non-cardiac chest pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyrexia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Hepatobiliary disorders	-Total	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1

	Cholecystitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cholelithiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gallbladder polyp	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperbilirubinaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Liver injury	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Portal vein thrombosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Infections and infestations	-Total	< 65	176	62.6	31	17.6	12.7	23.9
		>= 65	105	37.4	25	23.8	16.7	32.8
	Appendicitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bacteraemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bacterial infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cellulitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Clostridium difficile colitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Corona virus infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cystitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Device related infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diverticulitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Empyema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Enterococcal bacteraemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Infectious colitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Lower respiratory tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lung infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Meningitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Peritonitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pleural infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumocystis jirovecii pneumonia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pneumonia	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	8	7.6	3.9	14.3
	Pneumonia bacterial	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia haemophilus	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyelonephritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyelonephritis acute	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rectal abscess	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Renal tuberculosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sepsis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Sinusitis bacterial	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	8	7.6	3.9	14.3
	Urosepsis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Injury, poisoning and procedural complications	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Fracture	< 65	176	62.6	0	0.0	0.0	2.1

		>= 65	105	37.4	1	1.0	0.2	5.2
	Heart injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Subdural haematoma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Investigations	-Total	< 65	176	62.6	55	31.3	24.9	38.4
		>= 65	105	37.4	29	27.6	20.0	36.8
	Alanine aminotransferase	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Alanine aminotransferase increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Alpha hydroxybutyrate dehydrogenase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Aspartate aminotransferase increased	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood alkaline phosphatase increased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood bilirubin increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood bilirubin unconjugated increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood creatine phosphokinase increased	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	7	6.7	3.3	13.1
	Blood creatinine increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood lactate dehydrogenase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood sodium decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	C-reactive protein increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Electrocardiogram QT prolonged	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gamma-glutamyltransferase increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haemoglobin decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Hepatic enzyme increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lipase increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Lymphocyte count decreased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	7	6.7	3.3	13.1
	Neutrophil count decreased	< 65	176	62.6	22	12.5	8.4	18.2
		>= 65	105	37.4	9	8.6	4.6	15.5
	Platelet count decreased	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Transaminases increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Troponin T increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Troponin increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Weight increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	White blood cell count decreased	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	5	4.8	2.1	10.7
Metabolism and nutrition disorders	-Total	< 65	176	62.6	21	11.9	7.9	17.6
		>= 65	105	37.4	22	21.0	14.3	29.7
	Acidosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Decreased appetite	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dehydration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Electrolyte imbalance	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Failure to thrive	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypercalcaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperkalaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hypernatraemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

	Hyperphosphataemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypocalcaemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypokalaemia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hyponatraemia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	6	5.7	2.6	11.9
	Hypophosphataemia	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	9	8.6	4.6	15.5
Musculoskeletal and connective tissue disorders	-Total	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Arthralgia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Back pain	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Intervertebral disc protrusion	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Muscle haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscular weakness	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Musculoskeletal chest pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pain in extremity	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cancer pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gallbladder cancer	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tumour pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Nervous system disorders	-Total	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	6	5.7	2.6	11.9
	Ataxia	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Cerebral haematoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cerebral microhaemorrhage	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dizziness	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Epilepsy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Facial paralysis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Headache	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lumbosacral radiculopathy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Migraine	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neuralgia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sciatica	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Seizure	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Spinal cord haematoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Syncope	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
Psychiatric disorders	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mental status changes	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
Renal and urinary disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	4	3.8	1.5	9.4
	Acute kidney injury	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haematuria	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Hydronephrosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nephrolithiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Obstructive nephropathy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urethral stenosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Urinary retention	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Reproductive system and breast disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Metrorrhagia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ovarian cyst	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Prostatitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Respiratory, thoracic and mediastinal disorders	-Total	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	15	14.3	8.9	22.2
	Acute respiratory failure	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cough	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dyspnoea	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hypoxia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Lung consolidation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pleural effusion	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pleuritic pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Pneumothorax	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Pulmonary embolism	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Pulmonary hypertension	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Respiratory distress	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Surgical and medical procedures	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eye excision	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hip arthroplasty	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Vascular disorders	-Total	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	33	31.4	23.3	40.8
	Deep vein thrombosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Embolism	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Embolism venous	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haematoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypertension	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	29	27.6	20.0	36.8
	Hypotension	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Orthostatic hypotension	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Shock haemorrhagic	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR3_SG.xls
26MAR2021 14:29

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	84	29.9	18	21.4	14.0	31.3
		1	190	67.6	55	28.9	23.0	35.8
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	34	17.9	13.1	24.0
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia macrocytic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disseminated intravascular coagulation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Febrile neutropenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhagic anaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Leukopenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphopenia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutropenia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Pancytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytopenia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Cardiac disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute myocardial infarction	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pericardial effusion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Stress cardiomyopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Supraventricular tachycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Ear and labyrinth disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vertigo	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Endocrine disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Adrenal insufficiency	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

Eye disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cataract	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Keratitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Gastrointestinal disorders	-Total	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain upper	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aphthous ulcer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ascites	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Colitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Constipation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dental caries	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diarrhoea	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diverticular perforation	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal inflammation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Large intestine perforation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oesophagitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancreatitis acute	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Proctitis ulcerative	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Stomatitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Vomiting	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
General disorders and administration site conditions	-Total	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Asthenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest discomfort	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fatigue	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	General physical health deterioration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Impaired healing	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Malaise	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Non-cardiac chest pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyrexia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Hepatobiliary disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Cholecystitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Cholelithiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Gallbladder polyp	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperbilirubinaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Liver injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Portal vein thrombosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Infections and infestations	-Total	0	84	29.9	15	17.9	11.1	27.4
		1	190	67.6	38	20.0	14.9	26.3
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Appendicitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacterial infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cellulitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Clostridium difficile colitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Corona virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Cystitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Device related infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diverticulitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Empyema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Enterococcal bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Infectious colitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lower respiratory tract infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lung infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Meningitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Peritonitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Pneumocystis jirovecii pneumonia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia bacterial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia haemophilus	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyelonephritis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyelonephritis acute	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rectal abscess	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal tuberculosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sepsis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinusitis bacterial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary tract infection	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urosepsis	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Injury, poisoning and procedural complications	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Fracture	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Heart injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Subdural haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
Investigations	-Total	0	84	29.9	23	27.4	19.0	37.7
		1	190	67.6	59	31.1	24.9	38.0
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alanine aminotransferase	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alanine aminotransferase increased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alpha hydroxybutyrate dehydrogenase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aspartate aminotransferase increased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin unconjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase increased	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatinine increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood lactate dehydrogenase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood sodium decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	C-reactive protein increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrocardiogram QT prolonged	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gamma-glutamyltransferase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemoglobin decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic enzyme increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lipase increased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphocyte count decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil count decreased	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	23	12.1	8.2	17.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Transaminases increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Troponin T increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Troponin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Weight increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	White blood cell count decreased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Metabolism and nutrition disorders	-Total	0	84	29.9	13	15.5	9.3	24.7
		1	190	67.6	27	14.2	10.0	19.9
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Acidosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Decreased appetite	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Dehydration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrolyte imbalance	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Failure to thrive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercalcaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperkalaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypernatraemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperphosphataemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypocalcaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypokalaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyponatraemia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypophosphataemia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

Musculoskeletal and connective tissue disorders	-Total	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Arthralgia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Back pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intervertebral disc protrusion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle haemorrhage	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscular weakness	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal chest pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain in extremity	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cancer pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gallbladder cancer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tumour pain	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Nervous system disorders	-Total	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ataxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebral haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebral microhaemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dizziness	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epilepsy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Facial paralysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Headache	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lumbosacral radiculopathy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Migraine	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neuralgia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sciatica	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Seizure	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Spinal cord haematoma	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Syncope	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Psychiatric disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mental status changes	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Renal and urinary disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute kidney injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hydronephrosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nephrolithiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Obstructive nephropathy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urethral stenosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary retention	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Reproductive system and breast disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Metrorrhagia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ovarian cyst	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Prostatitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Respiratory, thoracic and mediastinal disorders	-Total	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	17	8.9	5.7	13.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute respiratory failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cough	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Hypoxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Lung consolidation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural effusion	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleuritic pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumothorax	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary embolism	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary hypertension	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory distress	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Surgical and medical procedures	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eye excision	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Hip arthroplasty	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Vascular disorders	-Total	0	84	29.9	17	20.2	13.0	30.0
		1	190	67.6	32	16.8	12.2	22.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Deep vein thrombosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism venous	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertension	0	84	29.9	17	20.2	13.0	30.0
		1	190	67.6	27	14.2	10.0	19.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypotension	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Orthostatic hypotension	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Shock haemorrhagic	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR3_SG.xls
26MAR2021 14:29

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	USA	64	22.8	22	34.4	23.9	46.6
		Europe (EU)	95	33.8	24	25.3	17.6	34.8
		Asia (AS)	122	43.4	30	24.6	17.8	32.9
	Anaemia	USA	64	22.8	13	20.3	12.3	31.7
		Europe (EU)	95	33.8	12	12.6	7.4	20.8
		Asia (AS)	122	43.4	20	16.4	10.9	24.0
	Anaemia macrocytic	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Disseminated intravascular coagulation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Febrile neutropenia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haemorrhagic anaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Leukopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Lymphopenia	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neutropenia	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Pancytopenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thrombocytopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

Cardiac disorders	-Total	USA	64	22.8	1	1.6		0.3	8.3
		Europe (EU)	95	33.8	3	3.2		1.1	8.9
		Asia (AS)	122	43.4	1	0.8		0.1	4.5
	Acute myocardial infarction	USA	64	22.8	1	1.6		0.3	8.3
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
	Pericardial effusion	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	2	2.1		0.6	7.4
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
	Stress cardiomyopathy	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	1	1.1		0.2	5.7
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
	Supraventricular tachycardia	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	1	0.8		0.1	4.5
Ear and labyrinth disorders	-Total	USA	64	22.8	1	1.6		0.3	8.3
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
	Vertigo	USA	64	22.8	1	1.6		0.3	8.3
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
Endocrine disorders	-Total	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	1	1.1		0.2	5.7
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
	Adrenal insufficiency	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	1	1.1		0.2	5.7
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
Eye disorders	-Total	USA	64	22.8	1	1.6		0.3	8.3
		Europe (EU)	95	33.8	1	1.1		0.2	5.7
		Asia (AS)	122	43.4	1	0.8		0.1	4.5
	Cataract	USA	64	22.8	1	1.6		0.3	8.3
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	1	0.8		0.1	4.5
	Keratitis	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	1	1.1		0.2	5.7
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
Gastrointestinal disorders	-Total	USA	64	22.8	7	10.9		5.4	20.9
		Europe (EU)	95	33.8	9	9.5		5.1	17.0
		Asia (AS)	122	43.4	8	6.6		3.4	12.4
	Abdominal pain upper	USA	64	22.8	1	1.6		0.3	8.3
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	0	0.0		0.0	3.1

	Aphthous ulcer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ascites	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Colitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Constipation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dental caries	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Diarrhoea	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Diverticular perforation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal haemorrhage	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal inflammation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Large intestine perforation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oesophagitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pancreatitis acute	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Proctitis ulcerative	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Stomatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

	Vomiting	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
General disorders and administration site conditions	-Total	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Asthenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Chest discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Chest pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Fatigue	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	General physical health deterioration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Impaired healing	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Malaise	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Non-cardiac chest pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pyrexia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Hepatobiliary disorders	-Total	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Cholecystitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

	Cholelithiasis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gallbladder polyp	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyperbilirubinaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Liver injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Portal vein thrombosis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Infections and infestations	-Total	USA	64	22.8	19	29.7	19.9	41.8
		Europe (EU)	95	33.8	19	20.0	13.2	29.1
		Asia (AS)	122	43.4	18	14.8	9.5	22.1
	Appendicitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacteraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacterial infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cellulitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Clostridium difficile colitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Corona virus infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cystitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Device related infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Diverticulitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Empyema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Enterococcal bacteraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Infectious colitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lower respiratory tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lung infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Meningitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Peritonitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pleural infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumocystis jirovecii pneumonia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonia	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Pneumonia bacterial	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonia haemophilus	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pyelonephritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Pyelonephritis acute	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rectal abscess	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Renal tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sepsis	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sinusitis bacterial	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urinary tract infection	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Urosepsis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Injury, poisoning and procedural complications	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Fracture	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Heart injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Subdural haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Investigations	-Total	USA	64	22.8	16	25.0	16.0	36.8
		Europe (EU)	95	33.8	17	17.9	11.5	26.8
		Asia (AS)	122	43.4	51	41.8	33.4	50.7
	Alanine aminotransferase	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Alanine aminotransferase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0

	Alpha hydroxybutyrate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Aspartate aminotransferase increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Blood alkaline phosphatase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Blood bilirubin increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Blood bilirubin unconjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood creatine phosphokinase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Blood creatinine increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood lactate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood sodium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	C-reactive protein increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Electrocardiogram QT prolonged	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gamma-glutamyltransferase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Haemoglobin decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hepatic enzyme increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Lipase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymphocyte count decreased	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Neutrophil count decreased	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	25	20.5	14.3	28.5
	Platelet count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Transaminases increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Troponin T increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Troponin increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Weight increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	White blood cell count decreased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
Metabolism and nutrition disorders	-Total	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	26	21.3	15.0	29.4
	Acidosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Decreased appetite	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dehydration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Electrolyte imbalance	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

	Failure to thrive	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypercalcaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyperkalaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hypernatraemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hyperphosphataemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypocalcaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hypokalaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hyponatraemia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hypophosphataemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	12	9.8	5.7	16.4
Musculoskeletal and connective tissue disorders	-Total	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Arthralgia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Back pain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Intervertebral disc protrusion	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Muscular weakness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Musculoskeletal chest pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pain in extremity	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cancer pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gallbladder cancer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tumour pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Nervous system disorders	-Total	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Ataxia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebral haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebral microhaemorrhage	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dizziness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epilepsy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Facial paralysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Headache	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lumbosacral radiculopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Migraine	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neuralgia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sciatica	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Seizure	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Spinal cord haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Syncope	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Psychiatric disorders	-Total	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Mental status changes	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Renal and urinary disorders	-Total	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Acute kidney injury	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haematuria	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hydronephrosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Nephrolithiasis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Obstructive nephropathy	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urethral stenosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary retention	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Reproductive system and breast disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Metrorrhagia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ovarian cyst	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Prostatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Respiratory, thoracic and mediastinal disorders	-Total	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	12	12.6	7.4	20.8
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Acute respiratory failure	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cough	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dyspnoea	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hypoxia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lung consolidation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Pleural effusion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Pleuritic pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Pneumothorax	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Pulmonary embolism	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pulmonary hypertension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory distress	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Surgical and medical procedures	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eye excision	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hip arthroplasty	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Vascular disorders	-Total	USA	64	22.8	19	29.7	19.9	41.8
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	20	16.4	10.9	24.0
	Deep vein thrombosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Embolism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Embolism venous	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypertension	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	10	10.5	5.8	18.3
		Asia (AS)	122	43.4	20	16.4	10.9	24.0
	Hypotension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Orthostatic hypotension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Shock haemorrhagic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR3_SG.xls
26MAR2021 14:29

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	116	41.3	22	19.0	12.9	27.0
		1	77	27.4	22	28.6	19.7	39.5
		>= 2	88	31.3	32	36.4	27.1	46.8
	Anaemia	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	16	20.8	13.2	31.1
		>= 2	88	31.3	18	20.5	13.3	30.0
	Anaemia macrocytic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Disseminated intravascular coagulation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Febrile neutropenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Haemorrhagic anaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Leukopenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Lymphopenia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	4	4.5	1.8	11.1
	Neutropenia	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	10	11.4	6.3	19.7
	Pancytopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Thrombocytopenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9

Cardiac disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Acute myocardial infarction	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pericardial effusion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Stress cardiomyopathy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Supraventricular tachycardia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Ear and labyrinth disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vertigo	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Endocrine disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Adrenal insufficiency	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Eye disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cataract	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Keratitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Gastrointestinal disorders	-Total	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	11	12.5	7.1	21.0
	Abdominal pain upper	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Aphthous ulcer	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ascites	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Colitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Constipation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dental caries	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Diarrhoea	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Diverticular perforation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrointestinal haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastrointestinal inflammation	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Large intestine perforation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oesophagitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pancreatitis acute	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Proctitis ulcerative	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Stomatitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9

	Vomiting	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
General disorders and administration site conditions	-Total	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	4	4.5	1.8	11.1
	Asthenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Chest discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Chest pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fatigue	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	General physical health deterioration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Impaired healing	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Malaise	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Non-cardiac chest pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pyrexia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Hepatobiliary disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Cholecystitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2

	Cholelithiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gallbladder polyp	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperbilirubinaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Liver injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Portal vein thrombosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Infections and infestations	-Total	0	116	41.3	16	13.8	8.7	21.2
		1	77	27.4	18	23.4	15.3	34.0
		>= 2	88	31.3	22	25.0	17.1	35.0
	Appendicitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bacteraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bacterial infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cellulitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Clostridium difficile colitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Corona virus infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cystitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Device related infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Diverticulitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Empyema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Enterococcal bacteraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Infectious colitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lower respiratory tract infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lung infection	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Meningitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Peritonitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pleural infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumocystis jirovecii pneumonia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	8	9.1	4.7	16.9
	Pneumonia bacterial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia haemophilus	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pyelonephritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Pyelonephritis acute	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rectal abscess	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Renal tuberculosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sepsis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sinusitis bacterial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Urinary tract infection	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Urosepsis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Injury, poisoning and procedural complications	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Fracture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Heart injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Subdural haematoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Investigations	-Total	0	116	41.3	35	30.2	22.6	39.1
		1	77	27.4	21	27.3	18.6	38.1
		>= 2	88	31.3	28	31.8	23.0	42.1
	Alanine aminotransferase	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Alanine aminotransferase increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	1	1.1	0.2	6.2

	Alpha hydroxybutyrate dehydrogenase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Aspartate aminotransferase increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Blood alkaline phosphatase increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood bilirubin increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood bilirubin unconjugated increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood creatine phosphokinase increased	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	6	6.8	3.2	14.1
	Blood creatinine increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood lactate dehydrogenase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood sodium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	C-reactive protein increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Electrocardiogram QT prolonged	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gamma-glutamyltransferase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemoglobin decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hepatic enzyme increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Lipase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymphocyte count decreased	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Neutrophil count decreased	0	116	41.3	14	12.1	7.3	19.2
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	8	9.1	4.7	16.9
	Platelet count decreased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Transaminases increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Troponin T increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Troponin increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Weight increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	White blood cell count decreased	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
Metabolism and nutrition disorders	-Total	0	116	41.3	15	12.9	8.0	20.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	15	17.0	10.6	26.2
	Acidosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Decreased appetite	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Dehydration	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Electrolyte imbalance	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Failure to thrive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypercalcaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperkalaemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypernatraemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperphosphataemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypocalcaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypokalaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hyponatraemia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hypophosphataemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	8	9.1	4.7	16.9
Musculoskeletal and connective tissue disorders	-Total	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	6	6.8	3.2	14.1
	Arthralgia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Back pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intervertebral disc protrusion	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Muscle haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Muscular weakness	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Musculoskeletal chest pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pain in extremity	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cancer pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gallbladder cancer	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tumour pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Nervous system disorders	-Total	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	5	5.7	2.5	12.6
	Ataxia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cerebral haematoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cerebral microhaemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dizziness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Epilepsy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Facial paralysis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Headache	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lumbosacral radiculopathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Migraine	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neuralgia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sciatica	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Seizure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Spinal cord haematoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Syncope	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Psychiatric disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Mental status changes	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
Renal and urinary disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Acute kidney injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haematuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hydronephrosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Nephrolithiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Obstructive nephropathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urethral stenosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urinary retention	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Reproductive system and breast disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Metrorrhagia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ovarian cyst	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Prostatitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Respiratory, thoracic and mediastinal disorders	-Total	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	9	10.2	5.5	18.3
	Acute respiratory failure	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cough	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dyspnoea	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypoxia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Lung consolidation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Pleural effusion	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Pleuritic pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonitis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumothorax	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pulmonary embolism	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Pulmonary hypertension	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiratory distress	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Surgical and medical procedures	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eye excision	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hip arthroplasty	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Vascular disorders	-Total	0	116	41.3	17	14.7	9.4	22.2
		1	77	27.4	16	20.8	13.2	31.1
		>= 2	88	31.3	17	19.3	12.4	28.8
	Deep vein thrombosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Embolism	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Embolism venous	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Haematoma	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypertension	0	116	41.3	17	14.7	9.4	22.2
		1	77	27.4	14	18.2	11.2	28.2
		>= 2	88	31.3	14	15.9	9.7	25.0
	Hypotension	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Orthostatic hypotension	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Shock haemorrhagic	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR3_SG.xls
26MAR2021 14:29

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Asian	128	45.6	32	25.0	18.3	33.2
		Non-Asian	135	48.0	42	31.1	23.9	39.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Anaemia	Asian	128	45.6	20	15.6	10.3	22.9
		Non-Asian	135	48.0	23	17.0	11.6	24.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Anaemia macrocytic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Disseminated intravascular coagulation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Febrile neutropenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhagic anaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Leukopenia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutropenia	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancytopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytopenia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

Cardiac disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Acute myocardial infarction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pericardial effusion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Stress cardiomyopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Supraventricular tachycardia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Ear and labyrinth disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vertigo	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Endocrine disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Adrenal insufficiency	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Eye disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cataract	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Keratitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Gastrointestinal disorders	-Total	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	16	11.9	7.4	18.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal pain upper	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Aphthous ulcer	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ascites	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Constipation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dental caries	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diarrhoea	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diverticular perforation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal inflammation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Large intestine perforation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oesophagitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancreatitis acute	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Proctitis ulcerative	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Stomatitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6

	Vomiting	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
General disorders and administration site conditions	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	13	9.6	5.7	15.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Asthenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chest discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chest pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fatigue	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	General physical health deterioration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Impaired healing	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Malaise	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Non-cardiac chest pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyrexia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Hepatobiliary disorders	-Total	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cholecystitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Cholelithiasis	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Gallbladder polyp	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6
	Hyperbilirubinaemia	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6
	Liver injury	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6
	Portal vein thrombosis	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	2	1.5		0.4	5.2
		Unknown	18	6.4	0	0.0		0.0	17.6
Infections and infestations	-Total	Asian	128	45.6	21	16.4		11.0	23.8
		Non-Asian	135	48.0	33	24.4		18.0	32.3
		Unknown	18	6.4	2	11.1		3.1	32.8
	Appendicitis	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	1	5.6		1.0	25.8
	Bacteraemia	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Bacterial infection	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	1	5.6		1.0	25.8
	Cellulitis	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Clostridium difficile colitis	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Corona virus infection	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Cystitis	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6
	Device related infection	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6

	Diverticulitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Empyema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Enterococcal bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Infectious colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lower respiratory tract infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lung infection	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Meningitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Peritonitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleural infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumocystis jirovecii pneumonia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumonia bacterial	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia haemophilus	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyelonephritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Pyelonephritis acute	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rectal abscess	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal tuberculosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sepsis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinusitis bacterial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary tract infection	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urosepsis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Injury, poisoning and procedural complications	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fracture	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Heart injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Subdural haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Investigations	-Total	Asian	128	45.6	56	43.8	35.5	52.4
		Non-Asian	135	48.0	23	17.0	11.6	24.3
		Unknown	18	6.4	5	27.8	12.5	50.9
	Alanine aminotransferase	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alanine aminotransferase increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8

	Alpha hydroxybutyrate dehydrogenase increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aspartate aminotransferase increased	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood alkaline phosphatase increased	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood bilirubin increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood bilirubin unconjugated increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine phosphokinase increased	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Blood creatinine increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood lactate dehydrogenase increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood sodium decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	C-reactive protein increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrocardiogram QT prolonged	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gamma-glutamyltransferase increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemoglobin decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatic enzyme increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Lipase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphocyte count decreased	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Neutrophil count decreased	Asian	128	45.6	27	21.1	14.9	29.0
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Platelet count decreased	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Transaminases increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Troponin T increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Troponin increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Weight increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	White blood cell count decreased	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
Metabolism and nutrition disorders	-Total	Asian	128	45.6	26	20.3	14.3	28.1
		Non-Asian	135	48.0	16	11.9	7.4	18.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Acidosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Decreased appetite	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dehydration	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrolyte imbalance	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Failure to thrive	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercalcaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperkalaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypernatraemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperphosphataemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypocalcaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypokalaemia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyponatraemia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypophosphataemia	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
Musculoskeletal and connective tissue disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	1	5.6	1.0	25.8
	Arthralgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Back pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intervertebral disc protrusion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Muscular weakness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Musculoskeletal chest pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pain in extremity	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Cancer pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gallbladder cancer	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tumour pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Nervous system disorders	-Total	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	Ataxia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebral haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebral microhaemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dizziness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epilepsy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Facial paralysis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8

	Headache	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lumbosacral radiculopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Migraine	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neuralgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Sciatica	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Seizure	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Spinal cord haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Syncope	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Psychiatric disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mental status changes	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Renal and urinary disorders	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Acute kidney injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematuria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hydronephrosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Nephrolithiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Obstructive nephropathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urethral stenosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary retention	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Reproductive system and breast disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Metrorrhagia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Ovarian cyst	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Prostatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Respiratory, thoracic and mediastinal disorders	-Total	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	15	11.1	6.9	17.5
		Unknown	18	6.4	3	16.7	5.8	39.2
	Acute respiratory failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cough	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dyspnoea	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypoxia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Lung consolidation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Pleural effusion	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleuritic pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumothorax	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary embolism	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Pulmonary hypertension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory distress	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Surgical and medical procedures	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eye excision	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hip arthroplasty	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Vascular disorders	-Total	Asian	128	45.6	21	16.4	11.0	23.8
		Non-Asian	135	48.0	26	19.3	13.5	26.7
		Unknown	18	6.4	3	16.7	5.8	39.2
	Deep vein thrombosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Embolism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Embolism venous	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Haematoma	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypertension	Asian	128	45.6	21	16.4	11.0	23.8
		Non-Asian	135	48.0	24	17.8	12.2	25.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypotension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Orthostatic hypotension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Shock haemorrhagic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR3_SG.xls
26MAR2021 14:29

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Female	152	54.1	47	30.9	24.1	38.7
		Male	129	45.9	29	22.5	16.1	30.4
	Anaemia	Female	152	54.1	29	19.1	13.6	26.1
		Male	129	45.9	16	12.4	7.8	19.2
	Anaemia macrocytic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Disseminated intravascular coagulation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Febrile neutropenia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Haemorrhagic anaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Leukopenia	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	1	0.8	0.1	4.3
	Lymphopenia	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	4	3.1	1.2	7.7
	Neutropenia	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	9	7.0	3.7	12.7
	Pancytopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombocytopenia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
Cardiac disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Acute myocardial infarction	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pericardial effusion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Stress cardiomyopathy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Supraventricular tachycardia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Ear and labyrinth disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Vertigo	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Endocrine disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Adrenal insufficiency	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Eye disorders	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Cataract	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Keratitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Gastrointestinal disorders	-Total	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	8	6.2	3.2	11.8
	Abdominal pain upper	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Aphthous ulcer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ascites	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Constipation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Dental caries	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Diarrhoea	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Diverticular perforation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gastrointestinal haemorrhage	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gastrointestinal inflammation	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Large intestine perforation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oesophagitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pancreatitis acute	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Proctitis ulcerative	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Stomatitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Vomiting	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
General disorders and administration site conditions	-Total	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	4	3.1	1.2	7.7
	Asthenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Chest discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Chest pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Fatigue	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	1	0.8	0.1	4.3
	General physical health deterioration	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Impaired healing	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Malaise	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Non-cardiac chest pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pyrexia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Hepatobiliary disorders	-Total	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6

	Cholecystitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cholelithiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gallbladder polyp	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hyperbilirubinaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Liver injury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Portal vein thrombosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Infections and infestations	-Total	Female	152	54.1	32	21.1	15.3	28.2
		Male	129	45.9	24	18.6	12.8	26.2
	Appendicitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Bacteraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bacterial infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cellulitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Clostridium difficile colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Corona virus infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cystitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Device related infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Diverticulitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Empyema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Enterococcal bacteraemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Infectious colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Lower respiratory tract infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lung infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Meningitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Peritonitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pleural infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumocystis jirovecii pneumonia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Pneumonia	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	8	6.2	3.2	11.8
	Pneumonia bacterial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonia haemophilus	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pyelonephritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pyelonephritis acute	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rectal abscess	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Renal tuberculosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sepsis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	0	0.0	0.0	2.9
	Sinusitis bacterial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urinary tract infection	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	6	4.7	2.1	9.8
	Urosepsis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Injury, poisoning and procedural complications	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Fracture	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
	Heart injury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Subdural haematoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Investigations	-Total	Female	152	54.1	50	32.9	25.9	40.7
		Male	129	45.9	34	26.4	19.5	34.6
	Alanine aminotransferase	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Alanine aminotransferase increased	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	1	0.8	0.1	4.3
	Alpha hydroxybutyrate dehydrogenase increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Aspartate aminotransferase increased	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	5	3.9	1.7	8.8
	Blood alkaline phosphatase increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Blood bilirubin increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Blood bilirubin unconjugated increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood creatine phosphokinase increased	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	10	7.8	4.3	13.7
	Blood creatinine increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Blood lactate dehydrogenase increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood sodium decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	C-reactive protein increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Electrocardiogram QT prolonged	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gamma-glutamyltransferase increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Haemoglobin decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9

	Hepatic enzyme increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lipase increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Lymphocyte count decreased	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	6	4.7	2.1	9.8
	Neutrophil count decreased	Female	152	54.1	23	15.1	10.3	21.7
		Male	129	45.9	8	6.2	3.2	11.8
	Platelet count decreased	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Transaminases increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Troponin T increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Troponin increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Weight increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	White blood cell count decreased	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	2	1.6	0.4	5.5
Metabolism and nutrition disorders	-Total	Female	152	54.1	23	15.1	10.3	21.7
		Male	129	45.9	20	15.5	10.3	22.7
	Acidosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Decreased appetite	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Dehydration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Electrolyte imbalance	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Failure to thrive	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypercalcaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperkalaemia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypernatraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3

	Hyperphosphataemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypocalcaemia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hypokalaemia	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	0	0.0	0.0	2.9
	Hyponatraemia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	6	4.7	2.1	9.8
	Hypophosphataemia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	7	5.4	2.7	10.8
Musculoskeletal and connective tissue disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	9	7.0	3.7	12.7
	Arthralgia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Back pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Intervertebral disc protrusion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	4	3.1	1.2	7.7
	Muscle haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Muscular weakness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Musculoskeletal chest pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pain in extremity	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Cancer pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gallbladder cancer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tumour pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Nervous system disorders	-Total	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	9	7.0	3.7	12.7
	Ataxia	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Cerebral haematoma	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cerebral microhaemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dizziness	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Epilepsy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Facial paralysis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Headache	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Lumbosacral radiculopathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Migraine	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neuralgia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Sciatica	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Seizure	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Spinal cord haematoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Syncope	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
Psychiatric disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Mental status changes	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
Renal and urinary disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	5	3.9	1.7	8.8
	Acute kidney injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Haematuria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Hydronephrosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nephrolithiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Obstructive nephropathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urethral stenosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urinary retention	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Reproductive system and breast disorders	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Metrorrhagia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ovarian cyst	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Prostatitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Respiratory, thoracic and mediastinal disorders	-Total	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	16	12.4	7.8	19.2
	Acute respiratory failure	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cough	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dyspnoea	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypoxia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	4	3.1	1.2	7.7
	Lung consolidation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pleural effusion	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Pleuritic pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pneumonitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Pneumothorax	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3

	Pulmonary embolism	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	6	4.7	2.1	9.8
	Pulmonary hypertension	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Respiratory distress	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Surgical and medical procedures	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Eye excision	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hip arthroplasty	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Vascular disorders	-Total	Female	152	54.1	28	18.4	13.1	25.3
		Male	129	45.9	22	17.1	11.5	24.5
	Deep vein thrombosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Embolism	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Embolism venous	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haematoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypertension	Female	152	54.1	27	17.8	12.5	24.6
		Male	129	45.9	18	14.0	9.0	21.0
	Hypotension	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Orthostatic hypotension	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Shock haemorrhagic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR3_SG.xls
26MAR2021 14:29

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	n/a	281	100.0	76	27.0	22.2	32.5
	Anaemia	n/a	281	100.0	45	16.0	12.2	20.8
	Anaemia macrocytic	n/a	281	100.0	1	0.4	0.1	2.0
	Disseminated intravascular coagulation	n/a	281	100.0	1	0.4	0.1	2.0
	Febrile neutropenia	n/a	281	100.0	3	1.1	0.4	3.1
	Haemorrhagic anaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Leukopenia	n/a	281	100.0	8	2.8	1.4	5.5
	Lymphopenia	n/a	281	100.0	14	5.0	3.0	8.2
	Neutropenia	n/a	281	100.0	22	7.8	5.2	11.6
	Pancytopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombocytopenia	n/a	281	100.0	5	1.8	0.8	4.1
Cardiac disorders	-Total	n/a	281	100.0	5	1.8	0.8	4.1
	Acute myocardial infarction	n/a	281	100.0	1	0.4	0.1	2.0
	Pericardial effusion	n/a	281	100.0	2	0.7	0.2	2.6
	Stress cardiomyopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Supraventricular tachycardia	n/a	281	100.0	1	0.4	0.1	2.0
Ear and labyrinth disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Vertigo	n/a	281	100.0	1	0.4	0.1	2.0
Endocrine disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Adrenal insufficiency	n/a	281	100.0	1	0.4	0.1	2.0
Eye disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Cataract	n/a	281	100.0	2	0.7	0.2	2.6

	Keratitis	n/a	281	100.0	1	0.4	0.1	2.0
Gastrointestinal disorders	-Total	n/a	281	100.0	24	8.5	5.8	12.4
	Abdominal pain upper	n/a	281	100.0	1	0.4	0.1	2.0
	Aphthous ulcer	n/a	281	100.0	1	0.4	0.1	2.0
	Ascites	n/a	281	100.0	1	0.4	0.1	2.0
	Colitis	n/a	281	100.0	3	1.1	0.4	3.1
	Constipation	n/a	281	100.0	2	0.7	0.2	2.6
	Dental caries	n/a	281	100.0	1	0.4	0.1	2.0
	Diarrhoea	n/a	281	100.0	5	1.8	0.8	4.1
	Diverticular perforation	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal inflammation	n/a	281	100.0	1	0.4	0.1	2.0
	Large intestine perforation	n/a	281	100.0	1	0.4	0.1	2.0
	Oesophagitis	n/a	281	100.0	1	0.4	0.1	2.0
	Pancreatitis acute	n/a	281	100.0	2	0.7	0.2	2.6
	Proctitis ulcerative	n/a	281	100.0	1	0.4	0.1	2.0
	Stomatitis	n/a	281	100.0	5	1.8	0.8	4.1
	Vomiting	n/a	281	100.0	3	1.1	0.4	3.1
General disorders and administration site conditions	-Total	n/a	281	100.0	23	8.2	5.5	12.0
	Asthenia	n/a	281	100.0	1	0.4	0.1	2.0
	Chest discomfort	n/a	281	100.0	1	0.4	0.1	2.0
	Chest pain	n/a	281	100.0	1	0.4	0.1	2.0
	Disease progression	n/a	281	100.0	7	2.5	1.2	5.1
	Fatigue	n/a	281	100.0	6	2.1	1.0	4.6
	General physical health deterioration	n/a	281	100.0	2	0.7	0.2	2.6
	Impaired healing	n/a	281	100.0	1	0.4	0.1	2.0
	Malaise	n/a	281	100.0	1	0.4	0.1	2.0
	Non-cardiac chest pain	n/a	281	100.0	1	0.4	0.1	2.0

	Pain	n/a	281	100.0	1	0.4	0.1	2.0
	Pyrexia	n/a	281	100.0	1	0.4	0.1	2.0
Hepatobiliary disorders	-Total	n/a	281	100.0	8	2.8	1.4	5.5
	Cholecystitis	n/a	281	100.0	2	0.7	0.2	2.6
	Cholelithiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Gallbladder polyp	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperbilirubinaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Liver injury	n/a	281	100.0	1	0.4	0.1	2.0
	Portal vein thrombosis	n/a	281	100.0	2	0.7	0.2	2.6
Infections and infestations	-Total	n/a	281	100.0	56	19.9	15.7	25.0
	Appendicitis	n/a	281	100.0	2	0.7	0.2	2.6
	Bacteraemia	n/a	281	100.0	1	0.4	0.1	2.0
	Bacterial infection	n/a	281	100.0	1	0.4	0.1	2.0
	Cellulitis	n/a	281	100.0	1	0.4	0.1	2.0
	Clostridium difficile colitis	n/a	281	100.0	1	0.4	0.1	2.0
	Corona virus infection	n/a	281	100.0	1	0.4	0.1	2.0
	Cystitis	n/a	281	100.0	1	0.4	0.1	2.0
	Device related infection	n/a	281	100.0	1	0.4	0.1	2.0
	Diverticulitis	n/a	281	100.0	2	0.7	0.2	2.6
	Empyema	n/a	281	100.0	1	0.4	0.1	2.0
	Enterococcal bacteraemia	n/a	281	100.0	1	0.4	0.1	2.0
	Infectious colitis	n/a	281	100.0	1	0.4	0.1	2.0
	Lower respiratory tract infection	n/a	281	100.0	1	0.4	0.1	2.0
	Lung infection	n/a	281	100.0	3	1.1	0.4	3.1
	Meningitis	n/a	281	100.0	1	0.4	0.1	2.0
	Peritonitis	n/a	281	100.0	1	0.4	0.1	2.0
	Pleural infection	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumocystis jirovecii pneumonia	n/a	281	100.0	2	0.7	0.2	2.6

	Pneumonia	n/a	281	100.0	21	7.5	4.9	11.2
	Pneumonia bacterial	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia haemophilus	n/a	281	100.0	1	0.4	0.1	2.0
	Pyelonephritis	n/a	281	100.0	1	0.4	0.1	2.0
	Pyelonephritis acute	n/a	281	100.0	1	0.4	0.1	2.0
	Rectal abscess	n/a	281	100.0	1	0.4	0.1	2.0
	Renal tuberculosis	n/a	281	100.0	1	0.4	0.1	2.0
	Sepsis	n/a	281	100.0	4	1.4	0.6	3.6
	Sinusitis bacterial	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary tract infection	n/a	281	100.0	9	3.2	1.7	6.0
	Urosepsis	n/a	281	100.0	1	0.4	0.1	2.0
Injury, poisoning and procedural complications	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Fracture	n/a	281	100.0	1	0.4	0.1	2.0
	Heart injury	n/a	281	100.0	1	0.4	0.1	2.0
	Subdural haematoma	n/a	281	100.0	1	0.4	0.1	2.0
Investigations	-Total	n/a	281	100.0	84	29.9	24.8	35.5
	Alanine aminotransferase	n/a	281	100.0	1	0.4	0.1	2.0
	Alanine aminotransferase increased	n/a	281	100.0	7	2.5	1.2	5.1
	Alpha hydroxybutyrate dehydrogenase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Aspartate aminotransferase increased	n/a	281	100.0	11	3.9	2.2	6.9
	Blood alkaline phosphatase increased	n/a	281	100.0	4	1.4	0.6	3.6
	Blood bilirubin increased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood bilirubin unconjugated increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood creatine phosphokinase increased	n/a	281	100.0	15	5.3	3.3	8.6
	Blood creatinine increased	n/a	281	100.0	2	0.7	0.2	2.6
	Blood lactate dehydrogenase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood sodium decreased	n/a	281	100.0	1	0.4	0.1	2.0
	C-reactive protein increased	n/a	281	100.0	1	0.4	0.1	2.0

	Electrocardiogram QT prolonged	n/a	281	100.0	1	0.4	0.1	2.0
	Gamma-glutamyltransferase increased	n/a	281	100.0	2	0.7	0.2	2.6
	Haemoglobin decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Hepatic enzyme increased	n/a	281	100.0	1	0.4	0.1	2.0
	Lipase increased	n/a	281	100.0	2	0.7	0.2	2.6
	Lymphocyte count decreased	n/a	281	100.0	12	4.3	2.5	7.3
	Neutrophil count decreased	n/a	281	100.0	31	11.0	7.9	15.2
	Platelet count decreased	n/a	281	100.0	7	2.5	1.2	5.1
	Transaminases increased	n/a	281	100.0	1	0.4	0.1	2.0
	Troponin T increased	n/a	281	100.0	1	0.4	0.1	2.0
	Troponin increased	n/a	281	100.0	1	0.4	0.1	2.0
	Weight increased	n/a	281	100.0	2	0.7	0.2	2.6
	White blood cell count decreased	n/a	281	100.0	14	5.0	3.0	8.2
Metabolism and nutrition disorders	-Total	n/a	281	100.0	43	15.3	11.6	20.0
	Acidosis	n/a	281	100.0	1	0.4	0.1	2.0
	Decreased appetite	n/a	281	100.0	2	0.7	0.2	2.6
	Dehydration	n/a	281	100.0	2	0.7	0.2	2.6
	Electrolyte imbalance	n/a	281	100.0	2	0.7	0.2	2.6
	Failure to thrive	n/a	281	100.0	1	0.4	0.1	2.0
	Hypercalcaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperkalaemia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypernatraemia	n/a	281	100.0	2	0.7	0.2	2.6
	Hyperphosphataemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypocalcaemia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypokalaemia	n/a	281	100.0	6	2.1	1.0	4.6
	Hyponatraemia	n/a	281	100.0	9	3.2	1.7	6.0
	Hypophosphataemia	n/a	281	100.0	19	6.8	4.4	10.3
Musculoskeletal and connective tissue disorders	-Total	n/a	281	100.0	12	4.3	2.5	7.3

	Arthralgia	n/a	281	100.0	1	0.4	0.1	2.0
	Back pain	n/a	281	100.0	3	1.1	0.4	3.1
	Intervertebral disc protrusion	n/a	281	100.0	4	1.4	0.6	3.6
	Muscle haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Muscular weakness	n/a	281	100.0	3	1.1	0.4	3.1
	Musculoskeletal chest pain	n/a	281	100.0	1	0.4	0.1	2.0
	Pain in extremity	n/a	281	100.0	1	0.4	0.1	2.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Cancer pain	n/a	281	100.0	1	0.4	0.1	2.0
	Gallbladder cancer	n/a	281	100.0	1	0.4	0.1	2.0
	Tumour pain	n/a	281	100.0	1	0.4	0.1	2.0
Nervous system disorders	-Total	n/a	281	100.0	14	5.0	3.0	8.2
	Ataxia	n/a	281	100.0	1	0.4	0.1	2.0
	Cerebral haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Cerebral microhaemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Dizziness	n/a	281	100.0	1	0.4	0.1	2.0
	Epilepsy	n/a	281	100.0	1	0.4	0.1	2.0
	Facial paralysis	n/a	281	100.0	1	0.4	0.1	2.0
	Headache	n/a	281	100.0	2	0.7	0.2	2.6
	Lumbosacral radiculopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Migraine	n/a	281	100.0	1	0.4	0.1	2.0
	Neuralgia	n/a	281	100.0	1	0.4	0.1	2.0
	Sciatica	n/a	281	100.0	2	0.7	0.2	2.6
	Seizure	n/a	281	100.0	1	0.4	0.1	2.0
	Spinal cord haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Syncope	n/a	281	100.0	3	1.1	0.4	3.1
Psychiatric disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Mental status changes	n/a	281	100.0	3	1.1	0.4	3.1

Renal and urinary disorders	-Total	n/a	281	100.0	6	2.1	1.0	4.6
	Acute kidney injury	n/a	281	100.0	2	0.7	0.2	2.6
	Haematuria	n/a	281	100.0	1	0.4	0.1	2.0
	Hydronephrosis	n/a	281	100.0	1	0.4	0.1	2.0
	Nephrolithiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Obstructive nephropathy	n/a	281	100.0	1	0.4	0.1	2.0
	Urethral stenosis	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary retention	n/a	281	100.0	1	0.4	0.1	2.0
Reproductive system and breast disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Metrorrhagia	n/a	281	100.0	1	0.4	0.1	2.0
	Ovarian cyst	n/a	281	100.0	1	0.4	0.1	2.0
	Prostatitis	n/a	281	100.0	1	0.4	0.1	2.0
Respiratory, thoracic and mediastinal disorders	-Total	n/a	281	100.0	28	10.0	7.0	14.0
	Acute respiratory failure	n/a	281	100.0	1	0.4	0.1	2.0
	Cough	n/a	281	100.0	1	0.4	0.1	2.0
	Dyspnoea	n/a	281	100.0	6	2.1	1.0	4.6
	Hypoxia	n/a	281	100.0	4	1.4	0.6	3.6
	Lung consolidation	n/a	281	100.0	1	0.4	0.1	2.0
	Pleural effusion	n/a	281	100.0	5	1.8	0.8	4.1
	Pleuritic pain	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonitis	n/a	281	100.0	4	1.4	0.6	3.6
	Pneumothorax	n/a	281	100.0	2	0.7	0.2	2.6
	Pulmonary embolism	n/a	281	100.0	8	2.8	1.4	5.5
	Pulmonary hypertension	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory distress	n/a	281	100.0	1	0.4	0.1	2.0
Surgical and medical procedures	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Eye excision	n/a	281	100.0	1	0.4	0.1	2.0
	Hip arthroplasty	n/a	281	100.0	1	0.4	0.1	2.0

Vascular disorders	-Total	n/a	281	100.0	50	17.8	13.8	22.7
	Deep vein thrombosis	n/a	281	100.0	1	0.4	0.1	2.0
	Embolism	n/a	281	100.0	1	0.4	0.1	2.0
	Embolism venous	n/a	281	100.0	1	0.4	0.1	2.0
	Haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Hypertension	n/a	281	100.0	45	16.0	12.2	20.8
	Hypotension	n/a	281	100.0	1	0.4	0.1	2.0
	Orthostatic hypotension	n/a	281	100.0	1	0.4	0.1	2.0
	Shock haemorrhagic	n/a	281	100.0	1	0.4	0.1	2.0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR3_SG.xls
26MAR2021 13:51

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	< 65	176	62.6	47	26.7	20.7	33.7
		>= 65	105	37.4	29	27.6	20.0	36.8
	Anaemia	< 65	176	62.6	30	17.0	12.2	23.3
		>= 65	105	37.4	15	14.3	8.9	22.2
	Anaemia macrocytic	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Disseminated intravascular coagulation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Febrile neutropenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Haemorrhagic anaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Leukopenia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Lymphopenia	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Neutropenia	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	6	5.7	2.6	11.9
	Pancytopenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Thrombocytopenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	4	3.8	1.5	9.4
Cardiac disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Acute myocardial infarction	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pericardial effusion	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Stress cardiomyopathy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Supraventricular tachycardia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Ear and labyrinth disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vertigo	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Endocrine disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Adrenal insufficiency	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Eye disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Cataract	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Keratitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Gastrointestinal disorders	-Total	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	11	10.5	6.0	17.8
	Abdominal pain upper	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Aphthous ulcer	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ascites	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Colitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Constipation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Dental caries	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diarrhoea	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Diverticular perforation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastrointestinal haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrointestinal inflammation	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Large intestine perforation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oesophagitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pancreatitis acute	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Proctitis ulcerative	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Stomatitis	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Vomiting	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
General disorders and administration site conditions	-Total	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	11	10.5	6.0	17.8
	Asthenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Chest discomfort	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Chest pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Disease progression	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	3	2.9	1.0	8.1
	Fatigue	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	General physical health deterioration	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Impaired healing	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Malaise	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Non-cardiac chest pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyrexia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

Hepatobiliary disorders	-Total	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
	Cholecystitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cholelithiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gallbladder polyp	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperbilirubinaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Liver injury	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Portal vein thrombosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Infections and infestations	-Total	< 65	176	62.6	31	17.6	12.7	23.9
		>= 65	105	37.4	25	23.8	16.7	32.8
	Appendicitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bacteraemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Bacterial infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cellulitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Clostridium difficile colitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Corona virus infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cystitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Device related infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diverticulitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Empyema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Enterococcal bacteraemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Infectious colitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lower respiratory tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lung infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Meningitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Peritonitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pleural infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumocystis jirovecii pneumonia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pneumonia	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	8	7.6	3.9	14.3
	Pneumonia bacterial	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia haemophilus	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyelonephritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyelonephritis acute	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rectal abscess	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Renal tuberculosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sepsis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Sinusitis bacterial	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	8	7.6	3.9	14.3
	Urosepsis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Injury, poisoning and procedural complications	-Total	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	2	1.9	0.5	6.7
	Fracture	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Heart injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Subdural haematoma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Investigations	-Total	< 65	176	62.6	55	31.3	24.9	38.4
		>= 65	105	37.4	29	27.6	20.0	36.8
	Alanine aminotransferase	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Alanine aminotransferase increased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Alpha hydroxybutyrate dehydrogenase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Aspartate aminotransferase increased	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood alkaline phosphatase increased	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Blood bilirubin increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood bilirubin unconjugated increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood creatine phosphokinase increased	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	7	6.7	3.3	13.1
	Blood creatinine increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood lactate dehydrogenase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood sodium decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	C-reactive protein increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Electrocardiogram QT prolonged	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gamma-glutamyltransferase increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

	Haemoglobin decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hepatic enzyme increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lipase increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Lymphocyte count decreased	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	7	6.7	3.3	13.1
	Neutrophil count decreased	< 65	176	62.6	22	12.5	8.4	18.2
		>= 65	105	37.4	9	8.6	4.6	15.5
	Platelet count decreased	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Transaminases increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Troponin T increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Troponin increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Weight increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	White blood cell count decreased	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	5	4.8	2.1	10.7
Metabolism and nutrition disorders	-Total	< 65	176	62.6	21	11.9	7.9	17.6
		>= 65	105	37.4	22	21.0	14.3	29.7
	Acidosis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Decreased appetite	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dehydration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Electrolyte imbalance	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Failure to thrive	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypercalcaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperkalaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1

	Hypernatraemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperphosphataemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypocalcaemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypokalaemia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hyponatraemia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	6	5.7	2.6	11.9
	Hypophosphataemia	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	9	8.6	4.6	15.5
Musculoskeletal and connective tissue disorders	-Total	< 65	176	62.6	8	4.5	2.3	8.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Arthralgia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Back pain	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Intervertebral disc protrusion	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Muscle haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscular weakness	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Musculoskeletal chest pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pain in extremity	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cancer pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gallbladder cancer	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tumour pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Nervous system disorders	-Total	< 65	176	62.6	8	4.5	2.3	8.7

		>= 65	105	37.4	6	5.7	2.6	11.9
	Ataxia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cerebral haematoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cerebral microhaemorrhage	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dizziness	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Epilepsy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Facial paralysis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Headache	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lumbosacral radiculopathy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Migraine	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neuralgia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sciatica	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Seizure	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Spinal cord haematoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Syncope	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
Psychiatric disorders	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mental status changes	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
Renal and urinary disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	4	3.8	1.5	9.4
	Acute kidney injury	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Haematuria	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hydronephrosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nephrolithiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Obstructive nephropathy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urethral stenosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Urinary retention	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Reproductive system and breast disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Metrorrhagia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ovarian cyst	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Prostatitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Respiratory, thoracic and mediastinal disorders	-Total	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	15	14.3	8.9	22.2
	Acute respiratory failure	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cough	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dyspnoea	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	3	2.9	1.0	8.1
	Hypoxia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Lung consolidation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pleural effusion	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pleuritic pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1

	Pneumothorax	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pulmonary embolism	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Pulmonary hypertension	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Respiratory distress	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Surgical and medical procedures	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eye excision	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hip arthroplasty	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Vascular disorders	-Total	< 65	176	62.6	17	9.7	6.1	14.9
		>= 65	105	37.4	33	31.4	23.3	40.8
	Deep vein thrombosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Embolism	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Embolism venous	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haematoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypertension	< 65	176	62.6	16	9.1	5.7	14.3
		>= 65	105	37.4	29	27.6	20.0	36.8
	Hypotension	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Orthostatic hypotension	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Shock haemorrhagic	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR3_SG.xls
26MAR2021 13:51

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	84	29.9	18	21.4	14.0	31.3
		1	190	67.6	55	28.9	23.0	35.8
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	34	17.9	13.1	24.0
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia macrocytic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disseminated intravascular coagulation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Febrile neutropenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhagic anaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Leukopenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphopenia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutropenia	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	14	7.4	4.4	12.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Pancytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytopenia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Cardiac disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute myocardial infarction	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pericardial effusion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Stress cardiomyopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Supraventricular tachycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Ear and labyrinth disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vertigo	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Endocrine disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Adrenal insufficiency	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

Eye disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cataract	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Keratitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Gastrointestinal disorders	-Total	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain upper	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aphthous ulcer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ascites	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Colitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Constipation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dental caries	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diarrhoea	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diverticular perforation	0	84	29.9	1	1.2	0.2	6.4

		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal inflammation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Large intestine perforation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oesophagitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancreatitis acute	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Proctitis ulcerative	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Stomatitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Vomiting	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
General disorders and administration site conditions	-Total	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	16	8.4	5.2	13.2
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Asthenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest discomfort	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disease progression	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fatigue	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	General physical health deterioration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Impaired healing	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Malaise	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Non-cardiac chest pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyrexia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Hepatobiliary disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Cholecystitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4

		Missing	1	0.4	0	0.0	0.0	79.3
	Cholelithiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gallbladder polyp	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperbilirubinaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Liver injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Portal vein thrombosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Infections and infestations	-Total	0	84	29.9	15	17.9	11.1	27.4
		1	190	67.6	38	20.0	14.9	26.3
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Appendicitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacterial infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cellulitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Clostridium difficile colitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Corona virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Device related infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diverticulitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Empyema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Enterococcal bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Infectious colitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lower respiratory tract infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lung infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Meningitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Peritonitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Pleural infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumocystis jirovecii pneumonia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia bacterial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia haemophilus	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyelonephritis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyelonephritis acute	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rectal abscess	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal tuberculosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sepsis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinusitis bacterial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary tract infection	0	84	29.9	2	2.4	0.7	8.3

		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urosepsis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Injury, poisoning and procedural complications	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Fracture	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Heart injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Subdural haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
Investigations	-Total	0	84	29.9	23	27.4	19.0	37.7
		1	190	67.6	59	31.1	24.9	38.0
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alanine aminotransferase	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alanine aminotransferase increased	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Alpha hydroxybutyrate dehydrogenase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aspartate aminotransferase increased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood alkaline phosphatase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood bilirubin unconjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase increased	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatinine increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood lactate dehydrogenase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood sodium decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	C-reactive protein increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrocardiogram QT prolonged	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gamma-glutamyltransferase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemoglobin decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic enzyme increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Lipase increased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphocyte count decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil count decreased	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	23	12.1	8.2	17.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count decreased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Transaminases increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Troponin T increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Troponin increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Weight increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	White blood cell count decreased	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Metabolism and nutrition disorders	-Total	0	84	29.9	13	15.5	9.3	24.7
		1	190	67.6	27	14.2	10.0	19.9
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Acidosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Decreased appetite	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dehydration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrolyte imbalance	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Failure to thrive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypercalcaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperkalaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypernatraemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperphosphataemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypocalcaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypokalaemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyponatraemia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3

	Hypophosphataemia	0	84	29.9	8	9.5	4.9	17.7
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
Musculoskeletal and connective tissue disorders	-Total	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Arthralgia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Back pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intervertebral disc protrusion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle haemorrhage	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscular weakness	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal chest pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain in extremity	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cancer pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gallbladder cancer	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tumour pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Nervous system disorders	-Total	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ataxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebral haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebral microhaemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dizziness	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epilepsy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Facial paralysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Headache	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lumbosacral radiculopathy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Migraine	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neuralgia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sciatica	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Seizure	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Spinal cord haematoma	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Syncope	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Psychiatric disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mental status changes	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Renal and urinary disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute kidney injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hydronephrosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Nephrolithiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Obstructive nephropathy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urethral stenosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary retention	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Reproductive system and breast disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Metrorrhagia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ovarian cyst	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Prostatitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Respiratory, thoracic and mediastinal disorders	-Total	0	84	29.9	10	11.9	6.6	20.5
		1	190	67.6	17	8.9	5.7	13.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute respiratory failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cough	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Dyspnoea	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Lung consolidation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural effusion	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleuritic pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumothorax	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary embolism	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary hypertension	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory distress	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Surgical and medical procedures	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Eye excision	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hip arthroplasty	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Vascular disorders	-Total	0	84	29.9	17	20.2	13.0	30.0
		1	190	67.6	32	16.8	12.2	22.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Deep vein thrombosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism venous	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertension	0	84	29.9	17	20.2	13.0	30.0
		1	190	67.6	27	14.2	10.0	19.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypotension	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Orthostatic hypotension	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Shock haemorrhagic	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

95% CI based on Wilson Scores.

Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR3_SG.xls
26MAR2021 13:51

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	USA	64	22.8	22	34.4	23.9	46.6
		Europe (EU)	95	33.8	24	25.3	17.6	34.8
		Asia (AS)	122	43.4	30	24.6	17.8	32.9
	Anaemia	USA	64	22.8	13	20.3	12.3	31.7
		Europe (EU)	95	33.8	12	12.6	7.4	20.8
		Asia (AS)	122	43.4	20	16.4	10.9	24.0
	Anaemia macrocytic	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Disseminated intravascular coagulation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Febrile neutropenia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haemorrhagic anaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Leukopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Lymphopenia	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neutropenia	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	10	8.2	4.5	14.4
	Pancytopenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thrombocytopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

Cardiac disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Acute myocardial infarction	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pericardial effusion	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Stress cardiomyopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Supraventricular tachycardia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Ear and labyrinth disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vertigo	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Endocrine disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Adrenal insufficiency	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Eye disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cataract	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Keratitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Gastrointestinal disorders	-Total	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Abdominal pain upper	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Aphthous ulcer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ascites	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Colitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Constipation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dental caries	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Diarrhoea	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Diverticular perforation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal haemorrhage	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal inflammation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Large intestine perforation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oesophagitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pancreatitis acute	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Proctitis ulcerative	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Stomatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

	Vomiting	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
General disorders and administration site conditions	-Total	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Asthenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Chest discomfort	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Chest pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Disease progression	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Fatigue	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	General physical health deterioration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Impaired healing	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Malaise	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Non-cardiac chest pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pyrexia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Hepatobiliary disorders	-Total	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	5	4.1	1.8	9.2

	Cholecystitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Cholelithiasis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gallbladder polyp	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyperbilirubinaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Liver injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Portal vein thrombosis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Infections and infestations	-Total	USA	64	22.8	19	29.7	19.9	41.8
		Europe (EU)	95	33.8	19	20.0	13.2	29.1
		Asia (AS)	122	43.4	18	14.8	9.5	22.1
	Appendicitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacteraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacterial infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cellulitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Clostridium difficile colitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Corona virus infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cystitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Device related infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Diverticulitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Empyema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Enterococcal bacteraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Infectious colitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lower respiratory tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lung infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Meningitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Peritonitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pleural infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumocystis jirovecii pneumonia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonia	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Pneumonia bacterial	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonia haemophilus	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Pyelonephritis	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	1	1.1		0.2	5.7
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
	Pyelonephritis acute	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	1	0.8		0.1	4.5
	Rectal abscess	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	1	1.1		0.2	5.7
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
	Renal tuberculosis	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	1	1.1		0.2	5.7
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
	Sepsis	USA	64	22.8	3	4.7		1.6	12.9
		Europe (EU)	95	33.8	1	1.1		0.2	5.7
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
	Sinusitis bacterial	USA	64	22.8	1	1.6		0.3	8.3
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
	Urinary tract infection	USA	64	22.8	3	4.7		1.6	12.9
		Europe (EU)	95	33.8	3	3.2		1.1	8.9
		Asia (AS)	122	43.4	3	2.5		0.8	7.0
	Urosepsis	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	1	1.1		0.2	5.7
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
Injury, poisoning and procedural complications	-Total	USA	64	22.8	1	1.6		0.3	8.3
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	2	1.6		0.5	5.8
	Fracture	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	1	0.8		0.1	4.5
	Heart injury	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	1	0.8		0.1	4.5
	Subdural haematoma	USA	64	22.8	1	1.6		0.3	8.3
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	0	0.0		0.0	3.1
Investigations	-Total	USA	64	22.8	16	25.0		16.0	36.8
		Europe (EU)	95	33.8	17	17.9		11.5	26.8
		Asia (AS)	122	43.4	51	41.8		33.4	50.7
	Alanine aminotransferase	USA	64	22.8	0	0.0		0.0	5.7
		Europe (EU)	95	33.8	0	0.0		0.0	3.9
		Asia (AS)	122	43.4	1	0.8		0.1	4.5

	Alanine aminotransferase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Alpha hydroxybutyrate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Aspartate aminotransferase increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Blood alkaline phosphatase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Blood bilirubin increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Blood bilirubin unconjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood creatine phosphokinase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Blood creatinine increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood lactate dehydrogenase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood sodium decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	C-reactive protein increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Electrocardiogram QT prolonged	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gamma-glutamyltransferase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Haemoglobin decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

	Hepatic enzyme increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lipase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymphocyte count decreased	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Neutrophil count decreased	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	25	20.5	14.3	28.5
	Platelet count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Transaminases increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Troponin T increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Troponin increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Weight increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	White blood cell count decreased	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
Metabolism and nutrition disorders	-Total	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	26	21.3	15.0	29.4
	Acidosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Decreased appetite	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dehydration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

	Electrolyte imbalance	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Failure to thrive	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypercalcaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyperkalaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hypernatraemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hyperphosphataemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypocalcaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hypokalaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hyponatraemia	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Hypophosphataemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	12	9.8	5.7	16.4
Musculoskeletal and connective tissue disorders	-Total	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Arthralgia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Back pain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Intervertebral disc protrusion	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Muscle haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscular weakness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Musculoskeletal chest pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pain in extremity	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cancer pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gallbladder cancer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tumour pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Nervous system disorders	-Total	USA	64	22.8	9	14.1	7.6	24.6
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Ataxia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebral haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebral microhaemorrhage	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dizziness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epilepsy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Facial paralysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Headache	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lumbosacral radiculopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Migraine	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neuralgia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sciatica	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Seizure	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Spinal cord haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Syncope	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Psychiatric disorders	-Total	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Mental status changes	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Renal and urinary disorders	-Total	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Acute kidney injury	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haematuria	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Hydronephrosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nephrolithiasis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Obstructive nephropathy	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urethral stenosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary retention	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Reproductive system and breast disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Metrorrhagia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ovarian cyst	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Prostatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Respiratory, thoracic and mediastinal disorders	-Total	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	12	12.6	7.4	20.8
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Acute respiratory failure	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cough	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dyspnoea	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hypoxia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Lung consolidation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pleural effusion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Pleuritic pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Pneumothorax	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Pulmonary embolism	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pulmonary hypertension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory distress	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Surgical and medical procedures	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eye excision	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hip arthroplasty	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Vascular disorders	-Total	USA	64	22.8	19	29.7	19.9	41.8
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	20	16.4	10.9	24.0
	Deep vein thrombosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Embolism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Embolism venous	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypertension	USA	64	22.8	15	23.4	14.7	35.1
		Europe (EU)	95	33.8	10	10.5	5.8	18.3
		Asia (AS)	122	43.4	20	16.4	10.9	24.0
	Hypotension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Orthostatic hypotension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Shock haemorrhagic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR3_SG.xls
26MAR2021 13:51

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	116	41.3	22	19.0	12.9	27.0
		1	77	27.4	22	28.6	19.7	39.5
		>= 2	88	31.3	32	36.4	27.1	46.8
	Anaemia	0	116	41.3	11	9.5	5.4	16.2
		1	77	27.4	16	20.8	13.2	31.1
		>= 2	88	31.3	18	20.5	13.3	30.0
	Anaemia macrocytic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Disseminated intravascular coagulation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Febrile neutropenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Haemorrhagic anaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Leukopenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Lymphopenia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	4	4.5	1.8	11.1
	Neutropenia	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	10	11.4	6.3	19.7
	Pancytopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Thrombocytopenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9

Cardiac disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Acute myocardial infarction	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pericardial effusion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Stress cardiomyopathy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Supraventricular tachycardia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Ear and labyrinth disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vertigo	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Endocrine disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Adrenal insufficiency	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Eye disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cataract	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Keratitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Gastrointestinal disorders	-Total	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	11	12.5	7.1	21.0
	Abdominal pain upper	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Aphthous ulcer	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ascites	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Colitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Constipation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dental caries	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Diarrhoea	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Diverticular perforation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrointestinal haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastrointestinal inflammation	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Large intestine perforation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oesophagitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pancreatitis acute	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Proctitis ulcerative	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Stomatitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9

	Vomiting	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
General disorders and administration site conditions	-Total	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	7	8.0	3.9	15.5
	Asthenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Chest discomfort	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Chest pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Disease progression	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Fatigue	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	General physical health deterioration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Impaired healing	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Malaise	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Non-cardiac chest pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pyrexia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Hepatobiliary disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5

	Cholecystitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cholelithiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gallbladder polyp	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperbilirubinaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Liver injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Portal vein thrombosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Infections and infestations	-Total	0	116	41.3	16	13.8	8.7	21.2
		1	77	27.4	18	23.4	15.3	34.0
		>= 2	88	31.3	22	25.0	17.1	35.0
	Appendicitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bacteraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Bacterial infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cellulitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Clostridium difficile colitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Corona virus infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cystitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Device related infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Diverticulitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Empyema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Enterococcal bacteraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Infectious colitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lower respiratory tract infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lung infection	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Meningitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Peritonitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pleural infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumocystis jirovecii pneumonia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	8	9.1	4.7	16.9
	Pneumonia bacterial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia haemophilus	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Pyelonephritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pyelonephritis acute	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Rectal abscess	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Renal tuberculosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sepsis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sinusitis bacterial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Urinary tract infection	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Urosepsis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Injury, poisoning and procedural complications	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Fracture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Heart injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Subdural haematoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Investigations	-Total	0	116	41.3	35	30.2	22.6	39.1
		1	77	27.4	21	27.3	18.6	38.1
		>= 2	88	31.3	28	31.8	23.0	42.1
	Alanine aminotransferase	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Alanine aminotransferase increased	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	1	1.1	0.2	6.2
	Alpha hydroxybutyrate dehydrogenase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Aspartate aminotransferase increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Blood alkaline phosphatase increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood bilirubin increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood bilirubin unconjugated increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood creatine phosphokinase increased	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	6	6.8	3.2	14.1
	Blood creatinine increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood lactate dehydrogenase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood sodium decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	C-reactive protein increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Electrocardiogram QT prolonged	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gamma-glutamyltransferase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemoglobin decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9

	Hepatic enzyme increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lipase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymphocyte count decreased	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
	Neutrophil count decreased	0	116	41.3	14	12.1	7.3	19.2
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	8	9.1	4.7	16.9
	Platelet count decreased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Transaminases increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Troponin T increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Troponin increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Weight increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	White blood cell count decreased	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
Metabolism and nutrition disorders	-Total	0	116	41.3	15	12.9	8.0	20.2
		1	77	27.4	13	16.9	10.1	26.8
		>= 2	88	31.3	15	17.0	10.6	26.2
	Acidosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Decreased appetite	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Dehydration	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Electrolyte imbalance	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Failure to thrive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypercalcaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperkalaemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypernatraemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperphosphataemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypocalcaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypokalaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hyponatraemia	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hypophosphataemia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	8	9.1	4.7	16.9
Musculoskeletal and connective tissue disorders	-Total	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	6	6.8	3.2	14.1
	Arthralgia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Back pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intervertebral disc protrusion	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9

	Muscle haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Muscular weakness	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Musculoskeletal chest pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pain in extremity	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cancer pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gallbladder cancer	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tumour pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Nervous system disorders	-Total	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	5	5.7	2.5	12.6
	Ataxia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cerebral haematoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cerebral microhaemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dizziness	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Epilepsy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Facial paralysis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Headache	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lumbosacral radiculopathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Migraine	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neuralgia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sciatica	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Seizure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Spinal cord haematoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Syncope	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Psychiatric disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Mental status changes	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
Renal and urinary disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Acute kidney injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haematuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Hydronephrosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Nephrolithiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Obstructive nephropathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urethral stenosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urinary retention	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Reproductive system and breast disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Metrorrhagia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Ovarian cyst	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Prostatitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Respiratory, thoracic and mediastinal disorders	-Total	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	9	10.2	5.5	18.3
	Acute respiratory failure	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cough	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dyspnoea	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypoxia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	3	3.4	1.2	9.5

	Lung consolidation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pleural effusion	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Pleuritic pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonitis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumothorax	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pulmonary embolism	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Pulmonary hypertension	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiratory distress	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Surgical and medical procedures	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eye excision	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hip arthroplasty	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Vascular disorders	-Total	0	116	41.3	17	14.7	9.4	22.2
		1	77	27.4	16	20.8	13.2	31.1
		>= 2	88	31.3	17	19.3	12.4	28.8
	Deep vein thrombosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Embolism	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Embolism venous	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haematoma	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypertension	0	116	41.3	17	14.7	9.4	22.2
		1	77	27.4	14	18.2	11.2	28.2
		>= 2	88	31.3	14	15.9	9.7	25.0
	Hypotension	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Orthostatic hypotension	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Shock haemorrhagic	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR3_SG.xls
26MAR2021 13:51

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Asian	128	45.6	32	25.0	18.3	33.2
		Non-Asian	135	48.0	42	31.1	23.9	39.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Anaemia	Asian	128	45.6	20	15.6	10.3	22.9
		Non-Asian	135	48.0	23	17.0	11.6	24.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Anaemia macrocytic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Disseminated intravascular coagulation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Febrile neutropenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhagic anaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Leukopenia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	14	10.4	6.3	16.7
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutropenia	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancytopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytopenia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

Cardiac disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Acute myocardial infarction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pericardial effusion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Stress cardiomyopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Supraventricular tachycardia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Ear and labyrinth disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vertigo	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Endocrine disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Adrenal insufficiency	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Eye disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cataract	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Keratitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Gastrointestinal disorders	-Total	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	16	11.9	7.4	18.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal pain upper	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Aphthous ulcer	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Ascites	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Colitis	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	3	2.2		0.8	6.3
		Unknown	18	6.4	0	0.0		0.0	17.6
	Constipation	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Dental caries	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6
	Diarrhoea	Asian	128	45.6	2	1.6		0.4	5.5
		Non-Asian	135	48.0	3	2.2		0.8	6.3
		Unknown	18	6.4	0	0.0		0.0	17.6
	Diverticular perforation	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Gastrointestinal haemorrhage	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Gastrointestinal inflammation	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Large intestine perforation	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Oesophagitis	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Pancreatitis acute	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	2	1.5		0.4	5.2
		Unknown	18	6.4	0	0.0		0.0	17.6
	Proctitis ulcerative	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Stomatitis	Asian	128	45.6	2	1.6		0.4	5.5
		Non-Asian	135	48.0	3	2.2		0.8	6.3
		Unknown	18	6.4	0	0.0		0.0	17.6

	Vomiting	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
General disorders and administration site conditions	-Total	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	15	11.1	6.9	17.5
		Unknown	18	6.4	1	5.6	1.0	25.8
	Asthenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chest discomfort	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chest pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Disease progression	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fatigue	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	General physical health deterioration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Impaired healing	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Malaise	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Non-cardiac chest pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyrexia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Hepatobiliary disorders	-Total	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6

	Cholecystitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cholelithiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gallbladder polyp	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperbilirubinaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Liver injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Portal vein thrombosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Infections and infestations	-Total	Asian	128	45.6	21	16.4	11.0	23.8
		Non-Asian	135	48.0	33	24.4	18.0	32.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Appendicitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bacterial infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Cellulitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Clostridium difficile colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Corona virus infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Device related infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diverticulitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Empyema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Enterococcal bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Infectious colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lower respiratory tract infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lung infection	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Meningitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Peritonitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleural infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumocystis jirovecii pneumonia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumonia bacterial	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia haemophilus	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Pyelonephritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyelonephritis acute	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rectal abscess	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal tuberculosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sepsis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinusitis bacterial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary tract infection	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urosepsis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Injury, poisoning and procedural complications	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fracture	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Heart injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Subdural haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Investigations	-Total	Asian	128	45.6	56	43.8	35.5	52.4
		Non-Asian	135	48.0	23	17.0	11.6	24.3
		Unknown	18	6.4	5	27.8	12.5	50.9
	Alanine aminotransferase	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Alanine aminotransferase increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Alpha hydroxybutyrate dehydrogenase increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aspartate aminotransferase increased	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood alkaline phosphatase increased	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood bilirubin increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood bilirubin unconjugated increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine phosphokinase increased	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Blood creatinine increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood lactate dehydrogenase increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood sodium decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	C-reactive protein increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrocardiogram QT prolonged	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gamma-glutamyltransferase increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemoglobin decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Hepatic enzyme increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lipase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphocyte count decreased	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Neutrophil count decreased	Asian	128	45.6	27	21.1	14.9	29.0
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Platelet count decreased	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Transaminases increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Troponin T increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Troponin increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Weight increased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	White blood cell count decreased	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
Metabolism and nutrition disorders	-Total	Asian	128	45.6	26	20.3	14.3	28.1
		Non-Asian	135	48.0	16	11.9	7.4	18.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Acidosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Decreased appetite	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dehydration	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Electrolyte imbalance	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Failure to thrive	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypercalcaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperkalaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypernatraemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperphosphataemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypocalcaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypokalaemia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyponatraemia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypophosphataemia	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	1	5.6	1.0	25.8
Musculoskeletal and connective tissue disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	1	5.6	1.0	25.8
	Arthralgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Back pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intervertebral disc protrusion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6

	Muscle haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscular weakness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Musculoskeletal chest pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pain in extremity	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Cancer pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gallbladder cancer	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tumour pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Nervous system disorders	-Total	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	2	11.1	3.1	32.8
	Ataxia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebral haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebral microhaemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dizziness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epilepsy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Facial paralysis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Headache	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lumbosacral radiculopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Migraine	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neuralgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Sciatica	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Seizure	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Spinal cord haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Syncope	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Psychiatric disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mental status changes	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Renal and urinary disorders	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Acute kidney injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematuria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Hydronephrosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nephrolithiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Obstructive nephropathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urethral stenosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary retention	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Reproductive system and breast disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Metrorrhagia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Ovarian cyst	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Prostatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Respiratory, thoracic and mediastinal disorders	-Total	Asian	128	45.6	10	7.8	4.3	13.8
		Non-Asian	135	48.0	15	11.1	6.9	17.5
		Unknown	18	6.4	3	16.7	5.8	39.2
	Acute respiratory failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cough	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dyspnoea	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Hypoxia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8

	Lung consolidation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleural effusion	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleuritic pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumothorax	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary embolism	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Pulmonary hypertension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory distress	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Surgical and medical procedures	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eye excision	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hip arthroplasty	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Vascular disorders	-Total	Asian	128	45.6	21	16.4	11.0	23.8
		Non-Asian	135	48.0	26	19.3	13.5	26.7
		Unknown	18	6.4	3	16.7	5.8	39.2
	Deep vein thrombosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Embolism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8

	Embolism venous	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematoma	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypertension	Asian	128	45.6	21	16.4	11.0	23.8
		Non-Asian	135	48.0	24	17.8	12.2	25.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypotension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Orthostatic hypotension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Shock haemorrhagic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR3_SG.xls
26MAR2021 13:51

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Female	152	54.1	47	30.9	24.1	38.7
		Male	129	45.9	29	22.5	16.1	30.4
	Anaemia	Female	152	54.1	29	19.1	13.6	26.1
		Male	129	45.9	16	12.4	7.8	19.2
	Anaemia macrocytic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Disseminated intravascular coagulation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Febrile neutropenia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Haemorrhagic anaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Leukopenia	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	1	0.8	0.1	4.3
	Lymphopenia	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	4	3.1	1.2	7.7
	Neutropenia	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	9	7.0	3.7	12.7
	Pancytopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombocytopenia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
Cardiac disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Acute myocardial infarction	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pericardial effusion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Stress cardiomyopathy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Supraventricular tachycardia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Ear and labyrinth disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Vertigo	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Endocrine disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Adrenal insufficiency	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Eye disorders	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Cataract	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Keratitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Gastrointestinal disorders	-Total	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	8	6.2	3.2	11.8
	Abdominal pain upper	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Aphthous ulcer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ascites	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Constipation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Dental caries	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Diarrhoea	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Diverticular perforation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gastrointestinal haemorrhage	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gastrointestinal inflammation	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Large intestine perforation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oesophagitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pancreatitis acute	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Proctitis ulcerative	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Stomatitis	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Vomiting	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
General disorders and administration site conditions	-Total	Female	152	54.1	15	9.9	6.1	15.6
		Male	129	45.9	8	6.2	3.2	11.8
	Asthenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Chest discomfort	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Chest pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Disease progression	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	4	3.1	1.2	7.7
	Fatigue	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	1	0.8	0.1	4.3
	General physical health deterioration	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Impaired healing	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Malaise	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Non-cardiac chest pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pyrexia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

Hepatobiliary disorders	-Total	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	3	2.3	0.8	6.6
	Cholecystitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cholelithiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gallbladder polyp	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hyperbilirubinaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Liver injury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Portal vein thrombosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Infections and infestations	-Total	Female	152	54.1	32	21.1	15.3	28.2
		Male	129	45.9	24	18.6	12.8	26.2
	Appendicitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Bacteraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Bacterial infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cellulitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Clostridium difficile colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Corona virus infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cystitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Device related infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Diverticulitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Empyema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Enterococcal bacteraemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Infectious colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lower respiratory tract infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lung infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Meningitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Peritonitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pleural infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumocystis jirovecii pneumonia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Pneumonia	Female	152	54.1	13	8.6	5.1	14.1
		Male	129	45.9	8	6.2	3.2	11.8
	Pneumonia bacterial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonia haemophilus	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pyelonephritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pyelonephritis acute	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rectal abscess	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Renal tuberculosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sepsis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	0	0.0	0.0	2.9
	Sinusitis bacterial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urinary tract infection	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	6	4.7	2.1	9.8
	Urosepsis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Injury, poisoning and procedural complications	-Total	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	2	1.6	0.4	5.5
	Fracture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Heart injury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Subdural haematoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Investigations	-Total	Female	152	54.1	50	32.9	25.9	40.7
		Male	129	45.9	34	26.4	19.5	34.6
	Alanine aminotransferase	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Alanine aminotransferase increased	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	1	0.8	0.1	4.3
	Alpha hydroxybutyrate dehydrogenase increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Aspartate aminotransferase increased	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	5	3.9	1.7	8.8
	Blood alkaline phosphatase increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Blood bilirubin increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Blood bilirubin unconjugated increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood creatine phosphokinase increased	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	10	7.8	4.3	13.7
	Blood creatinine increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Blood lactate dehydrogenase increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood sodium decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	C-reactive protein increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Electrocardiogram QT prolonged	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gamma-glutamyltransferase increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5

	Haemoglobin decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Hepatic enzyme increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lipase increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Lymphocyte count decreased	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	6	4.7	2.1	9.8
	Neutrophil count decreased	Female	152	54.1	23	15.1	10.3	21.7
		Male	129	45.9	8	6.2	3.2	11.8
	Platelet count decreased	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	2	1.6	0.4	5.5
	Transaminases increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Troponin T increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Troponin increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Weight increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	White blood cell count decreased	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	2	1.6	0.4	5.5
Metabolism and nutrition disorders	-Total	Female	152	54.1	23	15.1	10.3	21.7
		Male	129	45.9	20	15.5	10.3	22.7
	Acidosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Decreased appetite	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Dehydration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Electrolyte imbalance	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Failure to thrive	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypercalcaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperkalaemia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9

	Hypernatraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperphosphataemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypocalcaemia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Hypokalaemia	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	0	0.0	0.0	2.9
	Hyponatraemia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	6	4.7	2.1	9.8
	Hypophosphataemia	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	7	5.4	2.7	10.8
Musculoskeletal and connective tissue disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	9	7.0	3.7	12.7
	Arthralgia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Back pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Intervertebral disc protrusion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	4	3.1	1.2	7.7
	Muscle haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Muscular weakness	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Musculoskeletal chest pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pain in extremity	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Cancer pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gallbladder cancer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tumour pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Nervous system disorders	-Total	Female	152	54.1	5	3.3	1.4	7.5

		Male	129	45.9	9	7.0	3.7	12.7
	Ataxia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cerebral haematoma	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cerebral microhaemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dizziness	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Epilepsy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Facial paralysis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Headache	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Lumbosacral radiculopathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Migraine	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neuralgia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Sciatica	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Seizure	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Spinal cord haematoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Syncope	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
Psychiatric disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Mental status changes	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
Renal and urinary disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	5	3.9	1.7	8.8
	Acute kidney injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5

	Haematuria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hydronephrosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nephrolithiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Obstructive nephropathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urethral stenosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urinary retention	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Reproductive system and breast disorders	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Metrorrhagia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Ovarian cyst	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Prostatitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Respiratory, thoracic and mediastinal disorders	-Total	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	16	12.4	7.8	19.2
	Acute respiratory failure	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cough	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dyspnoea	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypoxia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	4	3.1	1.2	7.7
	Lung consolidation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pleural effusion	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Pleuritic pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pneumonitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6

	Pneumothorax	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pulmonary embolism	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	6	4.7	2.1	9.8
	Pulmonary hypertension	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Respiratory distress	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Surgical and medical procedures	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Eye excision	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hip arthroplasty	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Vascular disorders	-Total	Female	152	54.1	28	18.4	13.1	25.3
		Male	129	45.9	22	17.1	11.5	24.5
	Deep vein thrombosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Embolism	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Embolism venous	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haematoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypertension	Female	152	54.1	27	17.8	12.5	24.6
		Male	129	45.9	18	14.0	9.0	21.0
	Hypotension	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Orthostatic hypotension	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Shock haemorrhagic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR3_SG.xls
26MAR2021 13:51

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	34	12.1	8.8	16.4
Sex	Female	152	54.1	20	13.2	8.7	19.5
	Male	129	45.9	14	10.9	6.6	17.4
Age	< 65	176	62.6	19	10.8	7.0	16.2
	>= 65	105	37.4	15	14.3	8.9	22.2
ECOG performance status	0	84	29.9	11	13.1	7.5	21.9
	1	190	67.6	21	11.1	7.3	16.3
	2	6	2.1	2	33.3	9.7	70.0
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	8	12.5	6.5	22.8
	Europe (EU)	95	33.8	12	12.6	7.4	20.8
	Asia (AS)	122	43.4	14	11.5	7.0	18.3
Race/ethnicity	Asian	128	45.6	14	10.9	6.6	17.5
	Non-Asian	135	48.0	17	12.6	8.0	19.2
	Unknown	18	6.4	3	16.7	5.8	39.2
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	7	6.0	3.0	11.9
	1	77	27.4	11	14.3	8.2	23.8
	>= 2	88	31.3	16	18.2	11.5	27.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AEGR4_SG.xls
26MAR2021 10:20

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	30	10.7	7.6	14.8
Sex	Female	152	54.1	19	12.5	8.2	18.7
	Male	129	45.9	11	8.5	4.8	14.6
Age	< 65	176	62.6	17	9.7	6.1	14.9
	>= 65	105	37.4	13	12.4	7.4	20.0
ECOG performance status	0	84	29.9	11	13.1	7.5	21.9
	1	190	67.6	17	8.9	5.7	13.9
	2	6	2.1	2	33.3	9.7	70.0
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	8	12.5	6.5	22.8
	Europe (EU)	95	33.8	10	10.5	5.8	18.3
	Asia (AS)	122	43.4	12	9.8	5.7	16.4
Race/ethnicity	Asian	128	45.6	12	9.4	5.4	15.7
	Non-Asian	135	48.0	16	11.9	7.4	18.4
	Unknown	18	6.4	2	11.1	3.1	32.8
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	7	6.0	3.0	11.9
	1	77	27.4	8	10.4	5.4	19.2
	>= 2	88	31.3	15	17.0	10.6	26.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw_B63_06NOV2020_SE_TO_AEGR4_SG.xls
26MAR2021 9:58

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	n/a	281	100.0	15	5.3	3.3	8.6
	Anaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Febrile neutropenia	n/a	281	100.0	1	0.4	0.1	2.0
	Lymphopenia	n/a	281	100.0	3	1.1	0.4	3.1
	Neutropenia	n/a	281	100.0	8	2.8	1.4	5.5
	Thrombocytopenia	n/a	281	100.0	3	1.1	0.4	3.1
Gastrointestinal disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Intestinal obstruction	n/a	281	100.0	1	0.4	0.1	2.0
General disorders and administration site conditions	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Condition aggravated	n/a	281	100.0	1	0.4	0.1	2.0
Infections and infestations	-Total	n/a	281	100.0	6	2.1	1.0	4.6
	Pneumonia	n/a	281	100.0	2	0.7	0.2	2.6
	Sepsis	n/a	281	100.0	3	1.1	0.4	3.1
	Septic shock	n/a	281	100.0	1	0.4	0.1	2.0
Investigations	-Total	n/a	281	100.0	15	5.3	3.3	8.6
	Alanine aminotransferase increased	n/a	281	100.0	2	0.7	0.2	2.6
	Amylase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Aspartate aminotransferase increased	n/a	281	100.0	4	1.4	0.6	3.6
	Bilirubin conjugated increased	n/a	281	100.0	1	0.4	0.1	2.0

	Blood creatine phosphokinase increased	n/a	281	100.0	4	1.4	0.6	3.6
	Gamma-glutamyltransferase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Lipase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Lymphocyte count decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Myoglobin blood increased	n/a	281	100.0	1	0.4	0.1	2.0
	Neutrophil count decreased	n/a	281	100.0	5	1.8	0.8	4.1
	Oxygen saturation decreased	n/a	281	100.0	1	0.4	0.1	2.0
	PO2 decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Platelet count decreased	n/a	281	100.0	1	0.4	0.1	2.0
	White blood cell count decreased	n/a	281	100.0	1	0.4	0.1	2.0
Metabolism and nutrition disorders	-Total	n/a	281	100.0	5	1.8	0.8	4.1
	Hyperkalaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperuricaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypokalaemia	n/a	281	100.0	3	1.1	0.4	3.1
	Hyponatraemia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypophosphataemia	n/a	281	100.0	1	0.4	0.1	2.0
Nervous system disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Cerebrovascular accident	n/a	281	100.0	1	0.4	0.1	2.0
Respiratory, thoracic and mediastinal disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Pneumonitis	n/a	281	100.0	2	0.7	0.2	2.6
	Pulmonary embolism	n/a	281	100.0	1	0.4	0.1	2.0
Vascular disorders	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Hypotension	n/a	281	100.0	2	0.7	0.2	2.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas

Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR4_SG.xls
26MAR2021 14:33

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	6	5.7	2.6	11.9
	Anaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Febrile neutropenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lymphopenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Neutropenia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Thrombocytopenia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
Gastrointestinal disorders	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Intestinal obstruction	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
General disorders and administration site conditions	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Condition aggravated	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Infections and infestations	-Total	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pneumonia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sepsis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2

	Septic shock	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Investigations	-Total	< 65	176	62.6	11	6.3	3.5	10.8
		>= 65	105	37.4	4	3.8	1.5	9.4
	Alanine aminotransferase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Amylase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Aspartate aminotransferase increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Bilirubin conjugated increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood creatine phosphokinase increased	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gamma-glutamyltransferase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lipase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lymphocyte count decreased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Myoglobin blood increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neutrophil count decreased	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oxygen saturation decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	PO2 decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Platelet count decreased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	White blood cell count decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Metabolism and nutrition disorders	-Total	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2

	Hyperkalaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperuricaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypokalaemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyponatraemia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypophosphataemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Nervous system disorders	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cerebrovascular accident	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Respiratory, thoracic and mediastinal disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pneumonitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pulmonary embolism	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Vascular disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypotension	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR4_SG.xls
26MAR2021 14:33

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Febrile neutropenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphopenia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutropenia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
Gastrointestinal disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intestinal obstruction	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
General disorders and administration site conditions	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Condition aggravated	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Infections and infestations	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Sepsis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Septic shock	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Investigations	-Total	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Alanine aminotransferase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Amylase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aspartate aminotransferase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Bilirubin conjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase increased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gamma-glutamyltransferase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lipase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphocyte count decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Myoglobin blood increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil count decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oxygen saturation decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	PO2 decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	White blood cell count decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Metabolism and nutrition disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperkalaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperuricaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypokalaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyponatraemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypophosphataemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Nervous system disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebrovascular accident	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Respiratory, thoracic and mediastinal disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonitis	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary embolism	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Vascular disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypotension	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR4_SG.xls
26MAR2021 14:33

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Anaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Febrile neutropenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lymphopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neutropenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Thrombocytopenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
Gastrointestinal disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Intestinal obstruction	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
General disorders and administration site conditions	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Condition aggravated	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Infections and infestations	-Total	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Pneumonia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sepsis	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Septic shock	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Investigations	-Total	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Alanine aminotransferase increased	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Amylase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aspartate aminotransferase increased	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Bilirubin conjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood creatine phosphokinase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Gamma-glutamyltransferase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lipase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymphocyte count decreased	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Myoglobin blood increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Neutrophil count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Oxygen saturation decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	PO2 decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Platelet count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	White blood cell count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Metabolism and nutrition disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Hyperkalaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyperuricaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypokalaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Hyponatraemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Hypophosphataemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

Nervous system disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebrovascular accident	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Respiratory, thoracic and mediastinal disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pulmonary embolism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Vascular disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hypotension	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR4_SG.xls
26MAR2021 14:33

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	8	9.1	4.7	16.9
	Anaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Febrile neutropenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymphopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neutropenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	6	6.8	3.2	14.1
	Thrombocytopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
Gastrointestinal disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intestinal obstruction	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
General disorders and administration site conditions	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Condition aggravated	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
Infections and infestations	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Pneumonia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sepsis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Septic shock	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Investigations	-Total	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	8	9.1	4.7	16.9
	Alanine aminotransferase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Amylase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Aspartate aminotransferase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Bilirubin conjugated increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood creatine phosphokinase increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gamma-glutamyltransferase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lipase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lymphocyte count decreased	0	116	41.3	1	0.9	0.2	4.7

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Myoglobin blood increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neutrophil count decreased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oxygen saturation decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	PO2 decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Platelet count decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	White blood cell count decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Metabolism and nutrition disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hyperkalaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperuricaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypokalaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyponatraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypophosphataemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

Nervous system disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cerebrovascular accident	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Respiratory, thoracic and mediastinal disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pulmonary embolism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Vascular disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypotension	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR4_SG.xls
26MAR2021 14:33

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Febrile neutropenia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutropenia	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytopenia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Gastrointestinal disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intestinal obstruction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
General disorders and administration site conditions	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Condition aggravated	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
Infections and infestations	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumonia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sepsis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Septic shock	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Investigations	-Total	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alanine aminotransferase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Amylase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aspartate aminotransferase increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bilirubin conjugated increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine phosphokinase increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gamma-glutamyltransferase increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lipase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphocyte count decreased	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Myoglobin blood increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutrophil count decreased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oxygen saturation decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	PO2 decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Platelet count decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	White blood cell count decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Metabolism and nutrition disorders	-Total	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperkalaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperuricaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypokalaemia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyponatraemia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypophosphataemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

Nervous system disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Cerebrovascular accident	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Respiratory, thoracic and mediastinal disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumonitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pulmonary embolism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Vascular disorders	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypotension	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR4_SG.xls
26MAR2021 14:33

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	5	3.9	1.7	8.8
	Anaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Febrile neutropenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lymphopenia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Neutropenia	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	2	1.6	0.4	5.5
	Thrombocytopenia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
Gastrointestinal disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Intestinal obstruction	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
General disorders and administration site conditions	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Condition aggravated	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Infections and infestations	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	6	4.7	2.1	9.8
	Pneumonia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Sepsis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6

	Septic shock	Female	152	54.1	0	0.0		0.0	2.5
		Male	129	45.9	1	0.8		0.1	4.3
Investigations	-Total	Female	152	54.1	10	6.6		3.6	11.7
		Male	129	45.9	5	3.9		1.7	8.8
	Alanine aminotransferase increased	Female	152	54.1	1	0.7		0.1	3.6
		Male	129	45.9	1	0.8		0.1	4.3
	Amylase increased	Female	152	54.1	1	0.7		0.1	3.6
		Male	129	45.9	0	0.0		0.0	2.9
	Aspartate aminotransferase increased	Female	152	54.1	2	1.3		0.4	4.7
		Male	129	45.9	2	1.6		0.4	5.5
	Bilirubin conjugated increased	Female	152	54.1	0	0.0		0.0	2.5
		Male	129	45.9	1	0.8		0.1	4.3
	Blood creatine phosphokinase increased	Female	152	54.1	2	1.3		0.4	4.7
		Male	129	45.9	2	1.6		0.4	5.5
	Gamma-glutamyltransferase increased	Female	152	54.1	0	0.0		0.0	2.5
		Male	129	45.9	1	0.8		0.1	4.3
	Lipase increased	Female	152	54.1	1	0.7		0.1	3.6
		Male	129	45.9	0	0.0		0.0	2.9
	Lymphocyte count decreased	Female	152	54.1	0	0.0		0.0	2.5
		Male	129	45.9	2	1.6		0.4	5.5
	Myoglobin blood increased	Female	152	54.1	0	0.0		0.0	2.5
		Male	129	45.9	1	0.8		0.1	4.3
	Neutrophil count decreased	Female	152	54.1	4	2.6		1.0	6.6
		Male	129	45.9	1	0.8		0.1	4.3
	Oxygen saturation decreased	Female	152	54.1	0	0.0		0.0	2.5
		Male	129	45.9	1	0.8		0.1	4.3
	PO2 decreased	Female	152	54.1	0	0.0		0.0	2.5
		Male	129	45.9	1	0.8		0.1	4.3
	Platelet count decreased	Female	152	54.1	1	0.7		0.1	3.6
		Male	129	45.9	0	0.0		0.0	2.9
	White blood cell count decreased	Female	152	54.1	0	0.0		0.0	2.5
		Male	129	45.9	1	0.8		0.1	4.3
Metabolism and nutrition disorders	-Total	Female	152	54.1	2	1.3		0.4	4.7
		Male	129	45.9	3	2.3		0.8	6.6

	Hyperkalaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperuricaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypokalaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Hyponatraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Hypophosphataemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Nervous system disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cerebrovascular accident	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Respiratory, thoracic and mediastinal disorders	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pulmonary embolism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Vascular disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hypotension	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR4_SG.xls
26MAR2021 14:33

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	n/a	281	100.0	15	5.3	3.3	8.6
	Anaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Febrile neutropenia	n/a	281	100.0	1	0.4	0.1	2.0
	Lymphopenia	n/a	281	100.0	3	1.1	0.4	3.1
	Neutropenia	n/a	281	100.0	8	2.8	1.4	5.5
	Thrombocytopenia	n/a	281	100.0	3	1.1	0.4	3.1
Gastrointestinal disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Intestinal obstruction	n/a	281	100.0	1	0.4	0.1	2.0
General disorders and administration site conditions	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Condition aggravated	n/a	281	100.0	1	0.4	0.1	2.0
Infections and infestations	-Total	n/a	281	100.0	6	2.1	1.0	4.6
	Pneumonia	n/a	281	100.0	2	0.7	0.2	2.6
	Sepsis	n/a	281	100.0	3	1.1	0.4	3.1
	Septic shock	n/a	281	100.0	1	0.4	0.1	2.0
Investigations	-Total	n/a	281	100.0	15	5.3	3.3	8.6
	Alanine aminotransferase increased	n/a	281	100.0	2	0.7	0.2	2.6
	Amylase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Aspartate aminotransferase increased	n/a	281	100.0	4	1.4	0.6	3.6
	Bilirubin conjugated increased	n/a	281	100.0	1	0.4	0.1	2.0

	Blood creatine phosphokinase increased	n/a	281	100.0	4	1.4	0.6	3.6
	Gamma-glutamyltransferase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Lipase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Lymphocyte count decreased	n/a	281	100.0	2	0.7	0.2	2.6
	Myoglobin blood increased	n/a	281	100.0	1	0.4	0.1	2.0
	Neutrophil count decreased	n/a	281	100.0	5	1.8	0.8	4.1
	Oxygen saturation decreased	n/a	281	100.0	1	0.4	0.1	2.0
	PO2 decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Platelet count decreased	n/a	281	100.0	1	0.4	0.1	2.0
	White blood cell count decreased	n/a	281	100.0	1	0.4	0.1	2.0
Metabolism and nutrition disorders	-Total	n/a	281	100.0	5	1.8	0.8	4.1
	Hyperkalaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperuricaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypokalaemia	n/a	281	100.0	3	1.1	0.4	3.1
	Hyponatraemia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypophosphataemia	n/a	281	100.0	1	0.4	0.1	2.0
Nervous system disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Cerebrovascular accident	n/a	281	100.0	1	0.4	0.1	2.0
Respiratory, thoracic and mediastinal disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Pneumonitis	n/a	281	100.0	2	0.7	0.2	2.6
	Pulmonary embolism	n/a	281	100.0	1	0.4	0.1	2.0
Vascular disorders	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Hypotension	n/a	281	100.0	2	0.7	0.2	2.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas

Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR4_SG.xls
26MAR2021 13:54

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	6	5.7	2.6	11.9
	Anaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Febrile neutropenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lymphopenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Neutropenia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Thrombocytopenia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
Gastrointestinal disorders	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Intestinal obstruction	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
General disorders and administration site conditions	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Condition aggravated	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Infections and infestations	-Total	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pneumonia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sepsis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2

	Septic shock	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Investigations	-Total	< 65	176	62.6	11	6.3	3.5	10.8
		>= 65	105	37.4	4	3.8	1.5	9.4
	Alanine aminotransferase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Amylase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Aspartate aminotransferase increased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Bilirubin conjugated increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood creatine phosphokinase increased	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gamma-glutamyltransferase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lipase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lymphocyte count decreased	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Myoglobin blood increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neutrophil count decreased	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oxygen saturation decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	PO2 decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Platelet count decreased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	White blood cell count decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Metabolism and nutrition disorders	-Total	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2

	Hyperkalaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperuricaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypokalaemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyponatraemia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypophosphataemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Nervous system disorders	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cerebrovascular accident	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Respiratory, thoracic and mediastinal disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pneumonitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pulmonary embolism	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Vascular disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypotension	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR4_SG.xls
26MAR2021 13:54

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Febrile neutropenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphopenia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutropenia	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
Gastrointestinal disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intestinal obstruction	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
General disorders and administration site conditions	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Condition aggravated	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Infections and infestations	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Sepsis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Septic shock	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Investigations	-Total	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Alanine aminotransferase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Amylase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aspartate aminotransferase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Bilirubin conjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase increased	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gamma-glutamyltransferase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lipase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphocyte count decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Myoglobin blood increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutrophil count decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oxygen saturation decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	PO2 decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	White blood cell count decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Metabolism and nutrition disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperkalaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperuricaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypokalaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyponatraemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypophosphataemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Nervous system disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebrovascular accident	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Respiratory, thoracic and mediastinal disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonitis	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary embolism	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Vascular disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypotension	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR4_SG.xls
26MAR2021 13:54

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Anaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Febrile neutropenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lymphopenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neutropenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Thrombocytopenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
Gastrointestinal disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Intestinal obstruction	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
General disorders and administration site conditions	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Condition aggravated	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Infections and infestations	-Total	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Pneumonia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sepsis	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Septic shock	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Investigations	-Total	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Alanine aminotransferase increased	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Amylase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aspartate aminotransferase increased	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Bilirubin conjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood creatine phosphokinase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Gamma-glutamyltransferase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Lipase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymphocyte count decreased	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Myoglobin blood increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Neutrophil count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Oxygen saturation decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	PO2 decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Platelet count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	White blood cell count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Metabolism and nutrition disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Hyperkalaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyperuricaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypokalaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Hyponatraemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Hypophosphataemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

Nervous system disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebrovascular accident	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Respiratory, thoracic and mediastinal disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pulmonary embolism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Vascular disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hypotension	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR4_SG.xls
26MAR2021 13:54

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	8	9.1	4.7	16.9
	Anaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Febrile neutropenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymphopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neutropenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	6	6.8	3.2	14.1
	Thrombocytopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
Gastrointestinal disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intestinal obstruction	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
General disorders and administration site conditions	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Condition aggravated	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
Infections and infestations	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Pneumonia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sepsis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Septic shock	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Investigations	-Total	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	8	9.1	4.7	16.9
	Alanine aminotransferase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Amylase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Aspartate aminotransferase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Bilirubin conjugated increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood creatine phosphokinase increased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gamma-glutamyltransferase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lipase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lymphocyte count decreased	0	116	41.3	1	0.9	0.2	4.7

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Myoglobin blood increased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neutrophil count decreased	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Oxygen saturation decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	PO2 decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Platelet count decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	White blood cell count decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Metabolism and nutrition disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hyperkalaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperuricaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypokalaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyponatraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypophosphataemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

Nervous system disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cerebrovascular accident	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Respiratory, thoracic and mediastinal disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pulmonary embolism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Vascular disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypotension	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR4_SG.xls
26MAR2021 13:54

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Febrile neutropenia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutropenia	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytopenia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Gastrointestinal disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intestinal obstruction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
General disorders and administration site conditions	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Condition aggravated	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
Infections and infestations	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumonia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sepsis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Septic shock	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Investigations	-Total	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alanine aminotransferase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Amylase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aspartate aminotransferase increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bilirubin conjugated increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine phosphokinase increased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gamma-glutamyltransferase increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lipase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphocyte count decreased	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Myoglobin blood increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutrophil count decreased	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oxygen saturation decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	PO2 decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Platelet count decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	White blood cell count decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Metabolism and nutrition disorders	-Total	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperkalaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperuricaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypokalaemia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyponatraemia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypophosphataemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

Nervous system disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Cerebrovascular accident	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Respiratory, thoracic and mediastinal disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumonitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pulmonary embolism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Vascular disorders	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypotension	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR4_SG.xls
26MAR2021 13:54

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	5	3.9	1.7	8.8
	Anaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Febrile neutropenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lymphopenia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Neutropenia	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	2	1.6	0.4	5.5
	Thrombocytopenia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
Gastrointestinal disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Intestinal obstruction	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
General disorders and administration site conditions	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Condition aggravated	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Infections and infestations	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	6	4.7	2.1	9.8
	Pneumonia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Sepsis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6

	Septic shock	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Investigations	-Total	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	5	3.9	1.7	8.8
	Alanine aminotransferase increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Amylase increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Aspartate aminotransferase increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Bilirubin conjugated increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood creatine phosphokinase increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Gamma-glutamyltransferase increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lipase increased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lymphocyte count decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Myoglobin blood increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neutrophil count decreased	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Oxygen saturation decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	PO2 decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Platelet count decreased	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	White blood cell count decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Metabolism and nutrition disorders	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6

	Hyperkalaemia	Female	152	54.1	0	0.0	0.0	2.5	
		Male	129	45.9	1	0.8	0.1	4.3	
	Hyperuricaemia	Female	152	54.1	0	0.0	0.0	2.5	
		Male	129	45.9	1	0.8	0.1	4.3	
	Hypokalaemia	Female	152	54.1	1	0.7	0.1	3.6	
		Male	129	45.9	2	1.6	0.4	5.5	
	Hyponatraemia	Female	152	54.1	1	0.7	0.1	3.6	
		Male	129	45.9	2	1.6	0.4	5.5	
	Hypophosphataemia	Female	152	54.1	1	0.7	0.1	3.6	
		Male	129	45.9	0	0.0	0.0	2.9	
Nervous system disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5	
		Male	129	45.9	1	0.8	0.1	4.3	
	Cerebrovascular accident	Female	152	54.1	0	0.0	0.0	2.5	
		Male	129	45.9	1	0.8	0.1	4.3	
Respiratory, thoracic and mediastinal disorders	-Total	Female	152	54.1	2	1.3	0.4	4.7	
		Male	129	45.9	1	0.8	0.1	4.3	
	Pneumonitis	Female	152	54.1	1	0.7	0.1	3.6	
		Male	129	45.9	1	0.8	0.1	4.3	
	Pulmonary embolism	Female	152	54.1	1	0.7	0.1	3.6	
		Male	129	45.9	0	0.0	0.0	2.9	
Vascular disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6	
		Male	129	45.9	1	0.8	0.1	4.3	
	Hypotension	Female	152	54.1	1	0.7	0.1	3.6	
		Male	129	45.9	1	0.8	0.1	4.3	

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR4_SG.xls
26MAR2021 13:54

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 5
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	21	7.5	4.9	11.2
Sex	Female	152	54.1	6	3.9	1.8	8.3
	Male	129	45.9	15	11.6	7.2	18.3
Age	< 65	176	62.6	13	7.4	4.4	12.2
	>= 65	105	37.4	8	7.6	3.9	14.3
ECOG performance status	0	84	29.9	3	3.6	1.2	10.0
	1	190	67.6	15	7.9	4.8	12.6
	2	6	2.1	3	50.0	18.8	81.2
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	1	1.6	0.3	8.3
	Europe (EU)	95	33.8	6	6.3	2.9	13.1
	Asia (AS)	122	43.4	14	11.5	7.0	18.3
Race/ethnicity	Asian	128	45.6	14	10.9	6.6	17.5
	Non-Asian	135	48.0	6	4.4	2.1	9.4
	Unknown	18	6.4	1	5.6	1.0	25.8
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	8	6.9	3.5	13.0
	1	77	27.4	3	3.9	1.3	10.8
	>= 2	88	31.3	10	11.4	6.3	19.7

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AEGR5_SG.xls
26MAR2021 10:20

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 5
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	35	12.5	9.1	16.8
Sex	Female	152	54.1	13	8.6	5.1	14.1
	Male	129	45.9	22	17.1	11.5	24.5
Age	< 65	176	62.6	22	12.5	8.4	18.2
	>= 65	105	37.4	13	12.4	7.4	20.0
ECOG performance status	0	84	29.9	4	4.8	1.9	11.6
	1	190	67.6	28	14.7	10.4	20.5
	2	6	2.1	3	50.0	18.8	81.2
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	5	7.8	3.4	17.0
	Europe (EU)	95	33.8	12	12.6	7.4	20.8
	Asia (AS)	122	43.4	18	14.8	9.5	22.1
Race/ethnicity	Asian	128	45.6	19	14.8	9.7	22.0
	Non-Asian	135	48.0	14	10.4	6.3	16.7
	Unknown	18	6.4	2	11.1	3.1	32.8
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	8	6.9	3.5	13.0
	1	77	27.4	11	14.3	8.2	23.8
	>= 2	88	31.3	16	18.2	11.5	27.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw_B63_06NOV2020_SE_TO_AEGR5_SG.xls
26MAR2021 9:58

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 5
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Disseminated intravascular coagulation	n/a	281	100.0	1	0.4	0.1	2.0
Cardiac disorders	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Acute myocardial infarction	n/a	281	100.0	1	0.4	0.1	2.0
	Cardio-respiratory arrest	n/a	281	100.0	1	0.4	0.1	2.0
General disorders and administration site conditions	-Total	n/a	281	100.0	5	1.8	0.8	4.1
	Asthenia	n/a	281	100.0	1	0.4	0.1	2.0
	Death	n/a	281	100.0	2	0.7	0.2	2.6
	General physical health deterioration	n/a	281	100.0	1	0.4	0.1	2.0
	Multiple organ dysfunction syndrome	n/a	281	100.0	1	0.4	0.1	2.0
Infections and infestations	-Total	n/a	281	100.0	7	2.5	1.2	5.1
	Pneumonia	n/a	281	100.0	4	1.4	0.6	3.6
	Pneumonia cytomegaloviral	n/a	281	100.0	1	0.4	0.1	2.0
	Sepsis	n/a	281	100.0	1	0.4	0.1	2.0
	Urosepsis	n/a	281	100.0	1	0.4	0.1	2.0
Musculoskeletal and connective tissue disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Rhabdomyolysis	n/a	281	100.0	1	0.4	0.1	2.0
Nervous system disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Haemorrhage intracranial	n/a	281	100.0	1	0.4	0.1	2.0

Respiratory, thoracic and mediastinal disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Dyspnoea	n/a	281	100.0	2	0.7	0.2	2.6
	Respiratory failure	n/a	281	100.0	1	0.4	0.1	2.0
Vascular disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Embolism	n/a	281	100.0	1	0.4	0.1	2.0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR5_SG.xls
26MAR2021 14:35

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 5
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Disseminated intravascular coagulation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Cardiac disorders	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Acute myocardial infarction	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cardio-respiratory arrest	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
General disorders and administration site conditions	-Total	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Asthenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Death	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	General physical health deterioration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Multiple organ dysfunction syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Infections and infestations	-Total	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pneumonia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pneumonia cytomegaloviral	< 65	176	62.6	0	0.0	0.0	2.1

		>= 65	105	37.4	1	1.0	0.2	5.2
	Sepsis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urosepsis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Musculoskeletal and connective tissue disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rhabdomyolysis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Nervous system disorders	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haemorrhage intracranial	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Respiratory, thoracic and mediastinal disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dyspnoea	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory failure	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Vascular disorders	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Embolism	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR5_SG.xls
26MAR2021 14:35

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 5
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disseminated intravascular coagulation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Cardiac disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute myocardial infarction	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Cardio-respiratory arrest	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
General disorders and administration site conditions	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Asthenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Death	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	General physical health deterioration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Multiple organ dysfunction syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Infections and infestations	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia cytomegaloviral	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sepsis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Urosepsis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Musculoskeletal and connective tissue disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhabdomyolysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Nervous system disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhage intracranial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Respiratory, thoracic and mediastinal disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Vascular disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR5_SG.xls
26MAR2021 14:35

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 5
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Disseminated intravascular coagulation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Cardiac disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Acute myocardial infarction	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cardio-respiratory arrest	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
General disorders and administration site conditions	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Asthenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Death	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	General physical health deterioration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Multiple organ dysfunction syndrome	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Infections and infestations	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Pneumonia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Pneumonia cytomegaloviral	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sepsis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urosepsis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Musculoskeletal and connective tissue disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rhabdomyolysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Nervous system disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haemorrhage intracranial	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Respiratory, thoracic and mediastinal disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dyspnoea	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Respiratory failure	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

Vascular disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Embolism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR5_SG.xls
26MAR2021 14:35

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 5
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Disseminated intravascular coagulation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Cardiac disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Acute myocardial infarction	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cardio-respiratory arrest	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
General disorders and administration site conditions	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Asthenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Death	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	General physical health deterioration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Multiple organ dysfunction syndrome	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Infections and infestations	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Pneumonia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pneumonia cytomegaloviral	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sepsis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Urosepsis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Musculoskeletal and connective tissue disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhabdomyolysis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Nervous system disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haemorrhage intracranial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Respiratory, thoracic and mediastinal disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dyspnoea	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Respiratory failure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

Vascular disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Embolism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR5_SG.xls
26MAR2021 14:35

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 5
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Disseminated intravascular coagulation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Cardiac disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Acute myocardial infarction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cardio-respiratory arrest	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
General disorders and administration site conditions	-Total	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Asthenia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Death	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	General physical health deterioration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Multiple organ dysfunction syndrome	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Infections and infestations	-Total	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia cytomegaloviral	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sepsis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urosepsis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Musculoskeletal and connective tissue disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhabdomyolysis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Nervous system disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhage intracranial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Respiratory, thoracic and mediastinal disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dyspnoea	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

Vascular disorders	-Total	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Embolism	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR5_SG.xls
26MAR2021 14:35

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 5
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Disseminated intravascular coagulation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Cardiac disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Acute myocardial infarction	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cardio-respiratory arrest	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
General disorders and administration site conditions	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	5	3.9	1.7	8.8
	Asthenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Death	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	General physical health deterioration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Multiple organ dysfunction syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Infections and infestations	-Total	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Pneumonia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Pneumonia cytomegaloviral	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Sepsis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urosepsis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Musculoskeletal and connective tissue disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rhabdomyolysis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Nervous system disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Haemorrhage intracranial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Respiratory, thoracic and mediastinal disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Dyspnoea	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Respiratory failure	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Vascular disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Embolism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEGR5_SG.xls
26MAR2021 14:35

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 5
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Disseminated intravascular coagulation	n/a	281	100.0	1	0.4	0.1	2.0
Cardiac disorders	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Acute myocardial infarction	n/a	281	100.0	1	0.4	0.1	2.0
	Cardio-respiratory arrest	n/a	281	100.0	1	0.4	0.1	2.0
General disorders and administration site conditions	-Total	n/a	281	100.0	19	6.8	4.4	10.3
	Asthenia	n/a	281	100.0	1	0.4	0.1	2.0
	Death	n/a	281	100.0	2	0.7	0.2	2.6
	Disease progression	n/a	281	100.0	14	5.0	3.0	8.2
	General physical health deterioration	n/a	281	100.0	1	0.4	0.1	2.0
	Multiple organ dysfunction syndrome	n/a	281	100.0	1	0.4	0.1	2.0
Infections and infestations	-Total	n/a	281	100.0	7	2.5	1.2	5.1
	Pneumonia	n/a	281	100.0	4	1.4	0.6	3.6
	Pneumonia cytomegaloviral	n/a	281	100.0	1	0.4	0.1	2.0
	Sepsis	n/a	281	100.0	1	0.4	0.1	2.0
	Urosepsis	n/a	281	100.0	1	0.4	0.1	2.0
Musculoskeletal and connective tissue disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Rhabdomyolysis	n/a	281	100.0	1	0.4	0.1	2.0
Nervous system disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0

	Haemorrhage intracranial	n/a	281	100.0	1	0.4	0.1	2.0
Respiratory, thoracic and mediastinal disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Dyspnoea	n/a	281	100.0	2	0.7	0.2	2.6
	Respiratory failure	n/a	281	100.0	1	0.4	0.1	2.0
Vascular disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Embolism	n/a	281	100.0	1	0.4	0.1	2.0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR5_SG.xls
26MAR2021 13:57

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 5
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Disseminated intravascular coagulation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Cardiac disorders	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Acute myocardial infarction	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cardio-respiratory arrest	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
General disorders and administration site conditions	-Total	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	6	5.7	2.6	11.9
	Asthenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Death	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Disease progression	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	5	4.8	2.1	10.7
	General physical health deterioration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Multiple organ dysfunction syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Infections and infestations	-Total	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pneumonia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2

	Pneumonia cytomegaloviral	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sepsis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urosepsis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Musculoskeletal and connective tissue disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rhabdomyolysis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Nervous system disorders	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haemorrhage intracranial	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Respiratory, thoracic and mediastinal disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dyspnoea	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory failure	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Vascular disorders	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Embolism	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR5_SG.xls
26MAR2021 13:57

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 5
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disseminated intravascular coagulation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Cardiac disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute myocardial infarction	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Cardio-respiratory arrest	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
General disorders and administration site conditions	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	17	8.9	5.7	13.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Asthenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Death	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Disease progression	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	General physical health deterioration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Multiple organ dysfunction syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Infections and infestations	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia cytomegaloviral	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sepsis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Urosepsis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Musculoskeletal and connective tissue disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhabdomyolysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

Nervous system disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhage intracranial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Respiratory, thoracic and mediastinal disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Vascular disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR5_SG.xls
26MAR2021 13:57

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 5
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Disseminated intravascular coagulation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Cardiac disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Acute myocardial infarction	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cardio-respiratory arrest	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
General disorders and administration site conditions	-Total	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Asthenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Death	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Disease progression	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	General physical health deterioration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Multiple organ dysfunction syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Infections and infestations	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
	Pneumonia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Pneumonia cytomegaloviral	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sepsis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urosepsis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Musculoskeletal and connective tissue disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rhabdomyolysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Nervous system disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haemorrhage intracranial	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Respiratory, thoracic and mediastinal disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dyspnoea	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Respiratory failure	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Vascular disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Embolism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR5_SG.xls
26MAR2021 13:57

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 5
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Disseminated intravascular coagulation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Cardiac disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Acute myocardial infarction	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cardio-respiratory arrest	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
General disorders and administration site conditions	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	9	11.7	6.3	20.7
		>= 2	88	31.3	9	10.2	5.5	18.3
	Asthenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Death	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Disease progression	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	6	6.8	3.2	14.1
	General physical health deterioration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1	0.2	6.2
	Multiple organ dysfunction syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Infections and infestations	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	4	4.5	1.8	11.1
	Pneumonia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pneumonia cytomegaloviral	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sepsis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Urosepsis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Musculoskeletal and connective tissue disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhabdomyolysis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Nervous system disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haemorrhage intracranial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Respiratory, thoracic and mediastinal disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dyspnoea	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Respiratory failure	0	116	41.3	1	0.9	0.2	4.7

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Vascular disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Embolism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR5_SG.xls
26MAR2021 13:57

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 5
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Disseminated intravascular coagulation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Cardiac disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Acute myocardial infarction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cardio-respiratory arrest	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
General disorders and administration site conditions	-Total	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	2	11.1	3.1	32.8
	Asthenia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Death	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Disease progression	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	General physical health deterioration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	1	5.6	1.0	25.8
	Multiple organ dysfunction syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Infections and infestations	-Total	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia cytomegaloviral	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sepsis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urosepsis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Musculoskeletal and connective tissue disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhabdomyolysis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Nervous system disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhage intracranial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Respiratory, thoracic and mediastinal disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dyspnoea	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory failure	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Vascular disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Embolism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR5_SG.xls
26MAR2021 13:57

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs Grade 5
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Disseminated intravascular coagulation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Cardiac disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Acute myocardial infarction	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cardio-respiratory arrest	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
General disorders and administration site conditions	-Total	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	12	9.3	5.4	15.6
	Asthenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Death	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Disease progression	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	7	5.4	2.7	10.8
	General physical health deterioration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Multiple organ dysfunction syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Infections and infestations	-Total	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Pneumonia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6

	Pneumonia cytomegaloviral	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Sepsis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urosepsis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Musculoskeletal and connective tissue disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rhabdomyolysis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Nervous system disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Haemorrhage intracranial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Respiratory, thoracic and mediastinal disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	3	2.3	0.8	6.6
	Dyspnoea	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Respiratory failure	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Vascular disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Embolism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEGR5_SG.xls
26MAR2021 13:57

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any SAE
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	159	56.6	50.7	62.3
Sex	Female	152	54.1	82	53.9	46.0	61.7
	Male	129	45.9	77	59.7	51.1	67.8
Age	< 65	176	62.6	92	52.3	44.9	59.5
	>= 65	105	37.4	67	63.8	54.3	72.4
ECOG performance status	0	84	29.9	47	56.0	45.3	66.1
	1	190	67.6	106	55.8	48.7	62.7
	2	6	2.1	6	100.0	61.0	100.0
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	39	60.9	48.7	71.9
	Europe (EU)	95	33.8	59	62.1	52.1	71.2
	Asia (AS)	122	43.4	61	50.0	41.3	58.7
Race/ethnicity	Asian	128	45.6	65	50.8	42.2	59.3
	Non-Asian	135	48.0	85	63.0	54.6	70.6
	Unknown	18	6.4	9	50.0	29.0	71.0
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	55	47.4	38.6	56.4
	1	77	27.4	47	61.0	49.9	71.2
	>= 2	88	31.3	57	64.8	54.4	73.9

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AESAE_SG.xls
26MAR2021 10:21

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any SAE
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	166	59.1	53.2	64.7
Sex	Female	152	54.1	85	55.9	48.0	63.6
	Male	129	45.9	81	62.8	54.2	70.6
Age	< 65	176	62.6	95	54.0	46.6	61.2
	>= 65	105	37.4	71	67.6	58.2	75.8
ECOG performance status	0	84	29.9	49	58.3	47.7	68.3
	1	190	67.6	111	58.4	51.3	65.2
	2	6	2.1	6	100.0	61.0	100.0
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	42	65.6	53.4	76.1
	Europe (EU)	95	33.8	59	62.1	52.1	71.2
	Asia (AS)	122	43.4	65	53.3	44.5	61.9
Race/ethnicity	Asian	128	45.6	69	53.9	45.3	62.3
	Non-Asian	135	48.0	88	65.2	56.8	72.7
	Unknown	18	6.4	9	50.0	29.0	71.0
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	57	49.1	40.2	58.1
	1	77	27.4	50	64.9	53.8	74.7
	>= 2	88	31.3	59	67.0	56.7	76.0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw_B63_06NOV2020_SE_TO_AESAE_SG.xls
26MAR2021 9:59

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any SAE
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	n/a	281	100.0	19	6.8	4.4	10.3
	Anaemia	n/a	281	100.0	9	3.2	1.7	6.0
	Anaemia macrocytic	n/a	281	100.0	1	0.4	0.1	2.0
	Disseminated intravascular coagulation	n/a	281	100.0	1	0.4	0.1	2.0
	Febrile neutropenia	n/a	281	100.0	2	0.7	0.2	2.6
	Haemorrhagic anaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Lymphadenopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Neutropenia	n/a	281	100.0	5	1.8	0.8	4.1
	Pancytopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombocytopenia	n/a	281	100.0	1	0.4	0.1	2.0
Cardiac disorders	-Total	n/a	281	100.0	8	2.8	1.4	5.5
	Acute myocardial infarction	n/a	281	100.0	2	0.7	0.2	2.6
	Angina pectoris	n/a	281	100.0	1	0.4	0.1	2.0
	Cardio-respiratory arrest	n/a	281	100.0	1	0.4	0.1	2.0
	Pericardial effusion	n/a	281	100.0	2	0.7	0.2	2.6
	Stress cardiomyopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Supraventricular tachycardia	n/a	281	100.0	1	0.4	0.1	2.0
Ear and labyrinth disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Vertigo	n/a	281	100.0	1	0.4	0.1	2.0
Eye disorders	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Keratitis	n/a	281	100.0	2	0.7	0.2	2.6
	Ulcerative keratitis	n/a	281	100.0	1	0.4	0.1	2.0

Gastrointestinal disorders	-Total	n/a	281	100.0	20	7.1	4.7	10.7
	Abdominal pain	n/a	281	100.0	1	0.4	0.1	2.0
	Abdominal pain upper	n/a	281	100.0	1	0.4	0.1	2.0
	Aphthous ulcer	n/a	281	100.0	1	0.4	0.1	2.0
	Colitis	n/a	281	100.0	2	0.7	0.2	2.6
	Constipation	n/a	281	100.0	1	0.4	0.1	2.0
	Diarrhoea	n/a	281	100.0	3	1.1	0.4	3.1
	Diverticular perforation	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal inflammation	n/a	281	100.0	2	0.7	0.2	2.6
	Intestinal obstruction	n/a	281	100.0	1	0.4	0.1	2.0
	Large intestine perforation	n/a	281	100.0	1	0.4	0.1	2.0
	Nausea	n/a	281	100.0	1	0.4	0.1	2.0
	Oesophagitis	n/a	281	100.0	1	0.4	0.1	2.0
	Pancreatitis acute	n/a	281	100.0	2	0.7	0.2	2.6
	Proctitis ulcerative	n/a	281	100.0	1	0.4	0.1	2.0
	Stomatitis	n/a	281	100.0	2	0.7	0.2	2.6
	Vomiting	n/a	281	100.0	1	0.4	0.1	2.0
General disorders and administration site conditions	-Total	n/a	281	100.0	21	7.5	4.9	11.2
	Asthenia	n/a	281	100.0	2	0.7	0.2	2.6
	Condition aggravated	n/a	281	100.0	1	0.4	0.1	2.0
	Death	n/a	281	100.0	2	0.7	0.2	2.6
	Fatigue	n/a	281	100.0	1	0.4	0.1	2.0
	General physical health deterioration	n/a	281	100.0	2	0.7	0.2	2.6
	Impaired healing	n/a	281	100.0	1	0.4	0.1	2.0
	Malaise	n/a	281	100.0	1	0.4	0.1	2.0
	Multiple organ dysfunction syndrome	n/a	281	100.0	1	0.4	0.1	2.0

	Non-cardiac chest pain	n/a	281	100.0	1	0.4	0.1	2.0
	Oedema peripheral	n/a	281	100.0	1	0.4	0.1	2.0
	Pyrexia	n/a	281	100.0	8	2.8	1.4	5.5
Hepatobiliary disorders	-Total	n/a	281	100.0	5	1.8	0.8	4.1
	Cholecystitis	n/a	281	100.0	2	0.7	0.2	2.6
	Cholelithiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Gallbladder polyp	n/a	281	100.0	1	0.4	0.1	2.0
	Liver injury	n/a	281	100.0	1	0.4	0.1	2.0
Infections and infestations	-Total	n/a	281	100.0	72	25.6	20.9	31.0
	Appendicitis	n/a	281	100.0	2	0.7	0.2	2.6
	Bacteraemia	n/a	281	100.0	3	1.1	0.4	3.1
	Cellulitis	n/a	281	100.0	1	0.4	0.1	2.0
	Clostridium difficile colitis	n/a	281	100.0	1	0.4	0.1	2.0
	Corona virus infection	n/a	281	100.0	2	0.7	0.2	2.6
	Cystitis	n/a	281	100.0	1	0.4	0.1	2.0
	Device related infection	n/a	281	100.0	1	0.4	0.1	2.0
	Diverticulitis	n/a	281	100.0	2	0.7	0.2	2.6
	Empyema	n/a	281	100.0	1	0.4	0.1	2.0
	Enterococcal bacteraemia	n/a	281	100.0	1	0.4	0.1	2.0
	Gastroenteritis	n/a	281	100.0	1	0.4	0.1	2.0
	Infectious colitis	n/a	281	100.0	1	0.4	0.1	2.0
	Lower respiratory tract infection	n/a	281	100.0	1	0.4	0.1	2.0
	Lung infection	n/a	281	100.0	2	0.7	0.2	2.6
	Lymph node tuberculosis	n/a	281	100.0	2	0.7	0.2	2.6
	Pleural infection	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumocystis jirovecii pneumonia	n/a	281	100.0	2	0.7	0.2	2.6
	Pneumonia	n/a	281	100.0	33	11.7	8.5	16.0
	Pneumonia cytomegaloviral	n/a	281	100.0	1	0.4	0.1	2.0

	Pneumonia haemophilus	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia influenzal	n/a	281	100.0	1	0.4	0.1	2.0
	Pyelonephritis	n/a	281	100.0	1	0.4	0.1	2.0
	Pyelonephritis acute	n/a	281	100.0	1	0.4	0.1	2.0
	Renal tuberculosis	n/a	281	100.0	1	0.4	0.1	2.0
	Sepsis	n/a	281	100.0	8	2.8	1.4	5.5
	Septic shock	n/a	281	100.0	1	0.4	0.1	2.0
	Sinusitis bacterial	n/a	281	100.0	1	0.4	0.1	2.0
	Tonsillitis	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary tract infection	n/a	281	100.0	6	2.1	1.0	4.6
	Urosepsis	n/a	281	100.0	2	0.7	0.2	2.6
	Viral infection	n/a	281	100.0	1	0.4	0.1	2.0
Injury, poisoning and procedural complications	-Total	n/a	281	100.0	5	1.8	0.8	4.1
	Fracture	n/a	281	100.0	1	0.4	0.1	2.0
	Heart injury	n/a	281	100.0	1	0.4	0.1	2.0
	Procedural pneumothorax	n/a	281	100.0	1	0.4	0.1	2.0
	Subdural haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Wrist fracture	n/a	281	100.0	1	0.4	0.1	2.0
Investigations	-Total	n/a	281	100.0	10	3.6	1.9	6.4
	Alanine aminotransferase increased	n/a	281	100.0	2	0.7	0.2	2.6
	Aspartate aminotransferase increased	n/a	281	100.0	3	1.1	0.4	3.1
	Bilirubin conjugated increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood creatine phosphokinase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Electrocardiogram QT prolonged	n/a	281	100.0	2	0.7	0.2	2.6
	Hepatic enzyme increased	n/a	281	100.0	1	0.4	0.1	2.0
	Lymphocyte count decreased	n/a	281	100.0	1	0.4	0.1	2.0
	Platelet count decreased	n/a	281	100.0	2	0.7	0.2	2.6

Metabolism and nutrition disorders	-Total	n/a	281	100.0	12	4.3	2.5	7.3
	Decreased appetite	n/a	281	100.0	1	0.4	0.1	2.0
	Dehydration	n/a	281	100.0	2	0.7	0.2	2.6
	Electrolyte imbalance	n/a	281	100.0	1	0.4	0.1	2.0
	Failure to thrive	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperkalaemia	n/a	281	100.0	2	0.7	0.2	2.6
	Hyperuricaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypokalaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyponatraemia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypophosphataemia	n/a	281	100.0	2	0.7	0.2	2.6
Musculoskeletal and connective tissue disorders	-Total	n/a	281	100.0	11	3.9	2.2	6.9
	Back pain	n/a	281	100.0	4	1.4	0.6	3.6
	Intervertebral disc protrusion	n/a	281	100.0	2	0.7	0.2	2.6
	Muscle haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Muscular weakness	n/a	281	100.0	1	0.4	0.1	2.0
	Musculoskeletal pain	n/a	281	100.0	1	0.4	0.1	2.0
	Pain in extremity	n/a	281	100.0	1	0.4	0.1	2.0
	Rhabdomyolysis	n/a	281	100.0	1	0.4	0.1	2.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Cancer pain	n/a	281	100.0	1	0.4	0.1	2.0
	Gallbladder cancer	n/a	281	100.0	1	0.4	0.1	2.0
	Tumour pain	n/a	281	100.0	1	0.4	0.1	2.0
Nervous system disorders	-Total	n/a	281	100.0	17	6.0	3.8	9.5
	Ataxia	n/a	281	100.0	1	0.4	0.1	2.0
	Cerebral haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Cerebrovascular accident	n/a	281	100.0	1	0.4	0.1	2.0
	Dizziness	n/a	281	100.0	3	1.1	0.4	3.1
	Epilepsy	n/a	281	100.0	1	0.4	0.1	2.0

	Haemorrhage intracranial	n/a	281	100.0	1	0.4	0.1	2.0
	Lumbosacral radiculopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Migraine	n/a	281	100.0	1	0.4	0.1	2.0
	Neuralgia	n/a	281	100.0	1	0.4	0.1	2.0
	Polyneuropathy chronic	n/a	281	100.0	1	0.4	0.1	2.0
	Presyncope	n/a	281	100.0	1	0.4	0.1	2.0
	Seizure	n/a	281	100.0	5	1.8	0.8	4.1
	Syncope	n/a	281	100.0	1	0.4	0.1	2.0
Psychiatric disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Confusional state	n/a	281	100.0	1	0.4	0.1	2.0
	Mental status changes	n/a	281	100.0	2	0.7	0.2	2.6
Renal and urinary disorders	-Total	n/a	281	100.0	5	1.8	0.8	4.1
	Acute kidney injury	n/a	281	100.0	1	0.4	0.1	2.0
	Haematuria	n/a	281	100.0	1	0.4	0.1	2.0
	Hydronephrosis	n/a	281	100.0	1	0.4	0.1	2.0
	Nephrolithiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Obstructive nephropathy	n/a	281	100.0	1	0.4	0.1	2.0
	Urethral stenosis	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary retention	n/a	281	100.0	1	0.4	0.1	2.0
Reproductive system and breast disorders	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Ovarian cyst	n/a	281	100.0	1	0.4	0.1	2.0
	Prostatitis	n/a	281	100.0	1	0.4	0.1	2.0
Respiratory, thoracic and mediastinal disorders	-Total	n/a	281	100.0	38	13.5	10.0	18.0
	Acute respiratory failure	n/a	281	100.0	1	0.4	0.1	2.0
	Dyspnoea	n/a	281	100.0	6	2.1	1.0	4.6
	Epistaxis	n/a	281	100.0	1	0.4	0.1	2.0
	Haemoptysis	n/a	281	100.0	1	0.4	0.1	2.0

	Hypoxia	n/a	281	100.0	1	0.4	0.1	2.0
	Interstitial lung disease	n/a	281	100.0	2	0.7	0.2	2.6
	Lung consolidation	n/a	281	100.0	1	0.4	0.1	2.0
	Pleural effusion	n/a	281	100.0	6	2.1	1.0	4.6
	Pneumonitis	n/a	281	100.0	13	4.6	2.7	7.8
	Pneumothorax	n/a	281	100.0	2	0.7	0.2	2.6
	Pulmonary embolism	n/a	281	100.0	4	1.4	0.6	3.6
	Pulmonary hypertension	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory distress	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory failure	n/a	281	100.0	1	0.4	0.1	2.0
Surgical and medical procedures	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Eye excision	n/a	281	100.0	1	0.4	0.1	2.0
	Hip arthroplasty	n/a	281	100.0	1	0.4	0.1	2.0
Vascular disorders	-Total	n/a	281	100.0	10	3.6	1.9	6.4
	Embolism	n/a	281	100.0	1	0.4	0.1	2.0
	Haematoma	n/a	281	100.0	2	0.7	0.2	2.6
	Hypertension	n/a	281	100.0	4	1.4	0.6	3.6
	Hypotension	n/a	281	100.0	1	0.4	0.1	2.0
	Orthostatic hypotension	n/a	281	100.0	1	0.4	0.1	2.0
	Superior vena cava syndrome	n/a	281	100.0	1	0.4	0.1	2.0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AESAE_SG.xls
26MAR2021 14:38

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any SAE
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	7	6.7	3.3	13.1
	Anaemia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	3	2.9	1.0	8.1
	Anaemia macrocytic	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Disseminated intravascular coagulation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Febrile neutropenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haemorrhagic anaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymphadenopathy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neutropenia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pancytopenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Thrombocytopenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Cardiac disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	6	5.7	2.6	11.9
	Acute myocardial infarction	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Angina pectoris	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cardio-respiratory arrest	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pericardial effusion	< 65	176	62.6	2	1.1	0.3	4.0

		>= 65	105	37.4	0	0.0	0.0	3.5
	Stress cardiomyopathy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Supraventricular tachycardia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Ear and labyrinth disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vertigo	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Eye disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Keratitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ulcerative keratitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Gastrointestinal disorders	-Total	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	10	9.5	5.3	16.6
	Abdominal pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Abdominal pain upper	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Aphthous ulcer	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Colitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Constipation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Diarrhoea	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Diverticular perforation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastrointestinal haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrointestinal inflammation	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Intestinal obstruction	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Large intestine perforation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nausea	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oesophagitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pancreatitis acute	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Proctitis ulcerative	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Stomatitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Vomiting	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
General disorders and administration site conditions	-Total	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	8	7.6	3.9	14.3
	Asthenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Condition aggravated	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Death	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fatigue	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	General physical health deterioration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Impaired healing	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Malaise	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Multiple organ dysfunction syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Non-cardiac chest pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Oedema peripheral	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Pyrexia	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
Hepatobiliary disorders	-Total	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cholecystitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cholelithiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gallbladder polyp	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Liver injury	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Infections and infestations	-Total	< 65	176	62.6	42	23.9	18.2	30.7
		>= 65	105	37.4	30	28.6	20.8	37.8
	Appendicitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bacteraemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cellulitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Clostridium difficile colitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Corona virus infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cystitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Device related infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diverticulitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Empyema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Enterococcal bacteraemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastroenteritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Infectious colitis	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Lower respiratory tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lung infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lymph node tuberculosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pleural infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumocystis jirovecii pneumonia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pneumonia	< 65	176	62.6	20	11.4	7.5	16.9
		>= 65	105	37.4	13	12.4	7.4	20.0
	Pneumonia cytomegaloviral	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pneumonia haemophilus	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia influenzal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyelonephritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyelonephritis acute	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Renal tuberculosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sepsis	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Septic shock	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sinusitis bacterial	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tonsillitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary tract infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	6	5.7	2.6	11.9
	Urosepsis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Viral infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Injury, poisoning and procedural complications	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Fracture	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Heart injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Procedural pneumothorax	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Subdural haematoma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Wrist fracture	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Investigations	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	7	6.7	3.3	13.1
	Alanine aminotransferase increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Aspartate aminotransferase increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Bilirubin conjugated increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood creatine phosphokinase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Electrocardiogram QT prolonged	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hepatic enzyme increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymphocyte count decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Platelet count decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Metabolism and nutrition disorders	-Total	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Decreased appetite	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Dehydration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Electrolyte imbalance	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Failure to thrive	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperkalaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperuricaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypokalaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyponatraemia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypophosphataemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
Musculoskeletal and connective tissue disorders	-Total	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	5	4.8	2.1	10.7
	Back pain	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Intervertebral disc protrusion	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Muscle haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscular weakness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Musculoskeletal pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pain in extremity	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rhabdomyolysis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cancer pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gallbladder cancer	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Tumour pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Nervous system disorders	-Total	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	8	7.6	3.9	14.3
	Ataxia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cerebral haematoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cerebrovascular accident	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dizziness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Epilepsy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haemorrhage intracranial	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lumbosacral radiculopathy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Migraine	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neuralgia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Polyneuropathy chronic	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Presyncope	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Seizure	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Syncope	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Psychiatric disorders	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Confusional state	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Mental status changes	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

Renal and urinary disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Acute kidney injury	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haematuria	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hydronephrosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nephrolithiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Obstructive nephropathy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urethral stenosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Urinary retention	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Reproductive system and breast disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ovarian cyst	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Prostatitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Respiratory, thoracic and mediastinal disorders	-Total	< 65	176	62.6	21	11.9	7.9	17.6
		>= 65	105	37.4	17	16.2	10.4	24.4
	Acute respiratory failure	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dyspnoea	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	4	3.8	1.5	9.4
	Epistaxis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haemoptysis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypoxia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Interstitial lung disease	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5

	Lung consolidation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pleural effusion	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pneumonitis	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	6	5.7	2.6	11.9
	Pneumothorax	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pulmonary embolism	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pulmonary hypertension	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Respiratory distress	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory failure	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Surgical and medical procedures	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eye excision	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hip arthroplasty	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Vascular disorders	-Total	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	6	5.7	2.6	11.9
	Embolism	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haematoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hypertension	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hypotension	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Orthostatic hypotension	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Superior vena cava syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AESAE_SG.xls
26MAR2021 14:38

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any SAE
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia macrocytic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disseminated intravascular coagulation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Febrile neutropenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhagic anaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphadenopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutropenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Cardiac disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute myocardial infarction	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Angina pectoris	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cardio-respiratory arrest	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pericardial effusion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Stress cardiomyopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Supraventricular tachycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Ear and labyrinth disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vertigo	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Eye disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Keratitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ulcerative keratitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Gastrointestinal disorders	-Total	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain upper	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aphthous ulcer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Colitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Constipation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Diarrhoea	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diverticular perforation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal inflammation	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intestinal obstruction	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Large intestine perforation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nausea	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oesophagitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancreatitis acute	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Proctitis ulcerative	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Stomatitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vomiting	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
General disorders and administration site conditions	-Total	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	17	8.9	5.7	13.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Asthenia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Condition aggravated	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Death	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fatigue	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	General physical health deterioration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Impaired healing	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Malaise	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Multiple organ dysfunction syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Non-cardiac chest pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oedema peripheral	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyrexia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Hepatobiliary disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4

		Missing	1	0.4	0	0.0	0.0	79.3
	Cholecystitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Cholelithiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gallbladder polyp	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Liver injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Infections and infestations	-Total	0	84	29.9	23	27.4	19.0	37.7
		1	190	67.6	45	23.7	18.2	30.2
		2	6	2.1	4	66.7	30.0	90.3
		Missing	1	0.4	0	0.0	0.0	79.3
	Appendicitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cellulitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Clostridium difficile colitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Corona virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Device related infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diverticulitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Empyema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Enterococcal bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastroenteritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Infectious colitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lower respiratory tract infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lung infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymph node tuberculosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumocystis jirovecii pneumonia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia	0	84	29.9	13	15.5	9.3	24.7
		1	190	67.6	18	9.5	6.1	14.5
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia cytomegaloviral	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia haemophilus	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia influenzal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyelonephritis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyelonephritis acute	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal tuberculosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sepsis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Septic shock	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinusitis bacterial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Tonsillitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary tract infection	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urosepsis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Viral infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Injury, poisoning and procedural complications	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Fracture	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Heart injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Procedural pneumothorax	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Subdural haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Wrist fracture	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Investigations	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Alanine aminotransferase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Aspartate aminotransferase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Bilirubin conjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrocardiogram QT prolonged	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic enzyme increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphocyte count decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Metabolism and nutrition disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Decreased appetite	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dehydration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrolyte imbalance	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Failure to thrive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperkalaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperuricaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypokalaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyponatraemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypophosphataemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Musculoskeletal and connective tissue disorders	-Total	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Back pain	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intervertebral disc protrusion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle haemorrhage	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscular weakness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain in extremity	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhabdomyolysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cancer pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gallbladder cancer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tumour pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Nervous system disorders	-Total	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Ataxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebral haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebrovascular accident	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Dizziness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epilepsy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhage intracranial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lumbosacral radiculopathy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Migraine	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neuralgia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Polyneuropathy chronic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Presyncope	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Seizure	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Syncope	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Psychiatric disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Confusional state	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mental status changes	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Renal and urinary disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute kidney injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hydronephrosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nephrolithiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Obstructive nephropathy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urethral stenosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary retention	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Reproductive system and breast disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Ovarian cyst	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Prostatitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Respiratory, thoracic and mediastinal disorders	-Total	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	26	13.7	9.5	19.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute respiratory failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Epistaxis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemoptysis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Interstitial lung disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lung consolidation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural effusion	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonitis	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumothorax	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary embolism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary hypertension	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory distress	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Surgical and medical procedures	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eye excision	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hip arthroplasty	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Vascular disorders	-Total	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertension	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypotension	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Orthostatic hypotension	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Superior vena cava syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AESAE_SG.xls
26MAR2021 14:38

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any SAE
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Anaemia	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Anaemia macrocytic	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Disseminated intravascular coagulation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Febrile neutropenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haemorrhagic anaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymphadenopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neutropenia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Pancytopenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thrombocytopenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Cardiac disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

	Acute myocardial infarction	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Angina pectoris	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cardio-respiratory arrest	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pericardial effusion	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Stress cardiomyopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Supraventricular tachycardia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Ear and labyrinth disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vertigo	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Eye disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Keratitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ulcerative keratitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Gastrointestinal disorders	-Total	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Abdominal pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Abdominal pain upper	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aphthous ulcer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Colitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Constipation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Diarrhoea	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Diverticular perforation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal haemorrhage	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal inflammation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Intestinal obstruction	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Large intestine perforation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nausea	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oesophagitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pancreatitis acute	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Proctitis ulcerative	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Stomatitis	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Vomiting	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
General disorders and administration site conditions	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	8	8.4	4.3	15.7
		Asia (AS)	122	43.4	12	9.8	5.7	16.4
	Asthenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Condition aggravated	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Death	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Fatigue	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	General physical health deterioration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Impaired healing	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Malaise	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Multiple organ dysfunction syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Non-cardiac chest pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oedema peripheral	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pyrexia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	6	4.9	2.3	10.3

Hepatobiliary disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Cholecystitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Cholelithiasis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gallbladder polyp	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Liver injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Infections and infestations	-Total	USA	64	22.8	21	32.8	22.6	45.0
		Europe (EU)	95	33.8	23	24.2	16.7	33.7
		Asia (AS)	122	43.4	28	23.0	16.4	31.2
	Appendicitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacteraemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cellulitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Clostridium difficile colitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Corona virus infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cystitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Device related infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Diverticulitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Empyema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Enterococcal bacteraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastroenteritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Infectious colitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lower respiratory tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lung infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Lymph node tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pleural infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumocystis jirovecii pneumonia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonia	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Pneumonia cytomegaloviral	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonia haemophilus	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonia influenzal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pyelonephritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pyelonephritis acute	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Renal tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sepsis	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Septic shock	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinusitis bacterial	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tonsillitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urinary tract infection	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urosepsis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Viral infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Injury, poisoning and procedural complications	-Total	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Fracture	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Heart injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Procedural pneumothorax	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Subdural haematoma	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Wrist fracture	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Investigations	-Total	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Alanine aminotransferase increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aspartate aminotransferase increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bilirubin conjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood creatine phosphokinase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Electrocardiogram QT prolonged	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hepatic enzyme increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymphocyte count decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Platelet count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
Metabolism and nutrition disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Decreased appetite	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Dehydration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

	Electrolyte imbalance	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Failure to thrive	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperkalaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hyperuricaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypokalaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyponatraemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Hypophosphataemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
Musculoskeletal and connective tissue disorders	-Total	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Back pain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Intervertebral disc protrusion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscular weakness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Musculoskeletal pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pain in extremity	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Rhabdomyolysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cancer pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gallbladder cancer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tumour pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Nervous system disorders	-Total	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Ataxia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebral haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebrovascular accident	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dizziness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epilepsy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haemorrhage intracranial	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lumbosacral radiculopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Migraine	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neuralgia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Polyneuropathy chronic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Presyncope	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Seizure	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Syncope	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Psychiatric disorders	-Total	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Confusional state	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Mental status changes	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Renal and urinary disorders	-Total	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Acute kidney injury	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haematuria	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hydronephrosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nephrolithiasis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Obstructive nephropathy	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urethral stenosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary retention	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Reproductive system and breast disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ovarian cyst	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Prostatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Respiratory, thoracic and mediastinal disorders	-Total	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	18	18.9	12.3	28.0
		Asia (AS)	122	43.4	17	13.9	8.9	21.2
	Acute respiratory failure	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dyspnoea	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Epistaxis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haemoptysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypoxia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Interstitial lung disease	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Lung consolidation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Pleural effusion	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Pneumonitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Pneumothorax	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Pulmonary embolism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pulmonary hypertension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory distress	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory failure	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Surgical and medical procedures	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eye excision	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hip arthroplasty	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Vascular disorders	-Total	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Embolism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypertension	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

	Hypotension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Orthostatic hypotension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Superior vena cava syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AESAE_SG.xls
26MAR2021 14:38

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any SAE
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	9	10.2	5.5	18.3
	Anaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Anaemia macrocytic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Disseminated intravascular coagulation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Febrile neutropenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemorrhagic anaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymphadenopathy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neutropenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Pancytopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Thrombocytopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Cardiac disorders	-Total	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5

	Acute myocardial infarction	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Angina pectoris	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cardio-respiratory arrest	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pericardial effusion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Stress cardiomyopathy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Supraventricular tachycardia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Ear and labyrinth disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vertigo	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Eye disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Keratitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ulcerative keratitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Gastrointestinal disorders	-Total	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	9	10.2	5.5	18.3
	Abdominal pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Abdominal pain upper	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	0	0.0	0.0	4.2
	Aphthous ulcer	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Colitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Constipation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Diarrhoea	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Diverticular perforation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrointestinal haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastrointestinal inflammation	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intestinal obstruction	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Large intestine perforation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nausea	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oesophagitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pancreatitis acute	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Proctitis ulcerative	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Stomatitis	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vomiting	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
General disorders and administration site conditions	-Total	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	8	9.1	4.7	16.9
	Asthenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Condition aggravated	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Death	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fatigue	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	General physical health deterioration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Impaired healing	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Malaise	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Multiple organ dysfunction syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Non-cardiac chest pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oedema peripheral	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pyrexia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5

Hepatobiliary disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Cholecystitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cholelithiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gallbladder polyp	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Liver injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Infections and infestations	-Total	0	116	41.3	23	19.8	13.6	28.0
		1	77	27.4	19	24.7	16.4	35.4
		>= 2	88	31.3	30	34.1	25.0	44.5
	Appendicitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bacteraemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Cellulitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Clostridium difficile colitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Corona virus infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cystitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Device related infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Diverticulitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2

	Empyema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Enterococcal bacteraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastroenteritis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Infectious colitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lower respiratory tract infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lung infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lymph node tuberculosis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pleural infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumocystis jirovecii pneumonia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	11	14.3	8.2	23.8
		>= 2	88	31.3	13	14.8	8.8	23.7
	Pneumonia cytomegaloviral	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia haemophilus	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonia influenzal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pyelonephritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1	0.2	6.2
	Pyelonephritis acute	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Renal tuberculosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sepsis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	4	4.5	1.8	11.1
	Septic shock	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sinusitis bacterial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tonsillitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Urinary tract infection	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Urosepsis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Viral infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Injury, poisoning and procedural complications	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Fracture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Heart injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Procedural pneumothorax	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Subdural haematoma	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Wrist fracture	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Investigations	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	4	4.5	1.8	11.1
	Alanine aminotransferase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Aspartate aminotransferase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Bilirubin conjugated increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood creatine phosphokinase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Electrocardiogram QT prolonged	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hepatic enzyme increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lymphocyte count decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Platelet count decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Metabolism and nutrition disorders	-Total	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	4	4.5	1.8	11.1
	Decreased appetite	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dehydration	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Electrolyte imbalance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Failure to thrive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperkalaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperuricaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypokalaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyponatraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypophosphataemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
Musculoskeletal and connective tissue disorders	-Total	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	3	3.4	1.2	9.5
	Back pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intervertebral disc protrusion	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Muscle haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Muscular weakness	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Musculoskeletal pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pain in extremity	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Rhabdomyolysis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cancer pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gallbladder cancer	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tumour pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Nervous system disorders	-Total	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	5	5.7	2.5	12.6
	Ataxia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cerebral haematoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cerebrovascular accident	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dizziness	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Epilepsy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemorrhage intracranial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lumbosacral radiculopathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Migraine	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0

		>= 2	88	31.3	0	0.0	0.0	4.2
	Neuralgia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Polyneuropathy chronic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Presyncope	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Seizure	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Syncope	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Psychiatric disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Confusional state	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Mental status changes	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Renal and urinary disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Acute kidney injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haematuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hydronephrosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Nephrolithiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Obstructive nephropathy	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urethral stenosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urinary retention	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Reproductive system and breast disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ovarian cyst	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Prostatitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Respiratory, thoracic and mediastinal disorders	-Total	0	116	41.3	18	15.5	10.0	23.2
		1	77	27.4	11	14.3	8.2	23.8
		>= 2	88	31.3	9	10.2	5.5	18.3
	Acute respiratory failure	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dyspnoea	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Epistaxis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haemoptysis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypoxia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Interstitial lung disease	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lung consolidation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Pleural effusion	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Pneumonitis	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pneumothorax	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pulmonary embolism	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pulmonary hypertension	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiratory distress	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Respiratory failure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Surgical and medical procedures	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eye excision	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hip arthroplasty	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Vascular disorders	-Total	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Embolism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haematoma	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypertension	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9

	Hypotension	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Orthostatic hypotension	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Superior vena cava syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AESAE_SG.xls
26MAR2021 14:38

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any SAE
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anaemia macrocytic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Disseminated intravascular coagulation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Febrile neutropenia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhagic anaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphadenopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutropenia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancytopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytopenia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Cardiac disorders	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6

	Acute myocardial infarction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Angina pectoris	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cardio-respiratory arrest	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pericardial effusion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Stress cardiomyopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Supraventricular tachycardia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Ear and labyrinth disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vertigo	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Eye disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Keratitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ulcerative keratitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Gastrointestinal disorders	-Total	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	15	11.1	6.9	17.5
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal pain upper	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Aphthous ulcer	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Constipation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diarrhoea	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diverticular perforation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal inflammation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intestinal obstruction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Large intestine perforation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nausea	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oesophagitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancreatitis acute	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Proctitis ulcerative	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Stomatitis	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vomiting	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
General disorders and administration site conditions	-Total	Asian	128	45.6	12	9.4	5.4	15.7
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Asthenia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Condition aggravated	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Death	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fatigue	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	General physical health deterioration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Impaired healing	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Malaise	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Multiple organ dysfunction syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Non-cardiac chest pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oedema peripheral	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyrexia	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

Hepatobiliary disorders	-Total	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cholecystitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cholelithiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gallbladder polyp	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Liver injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Infections and infestations	-Total	Asian	128	45.6	30	23.4	16.9	31.5
		Non-Asian	135	48.0	39	28.9	21.9	37.0
		Unknown	18	6.4	3	16.7	5.8	39.2
	Appendicitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Cellulitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Clostridium difficile colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Corona virus infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Device related infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diverticulitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

	Empyema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Enterococcal bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastroenteritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Infectious colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lower respiratory tract infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lung infection	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymph node tuberculosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleural infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumocystis jirovecii pneumonia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	16	11.9	7.4	18.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumonia cytomegaloviral	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia haemophilus	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia influenzal	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyelonephritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyelonephritis acute	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal tuberculosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sepsis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Septic shock	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinusitis bacterial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tonsillitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary tract infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urosepsis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Viral infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Injury, poisoning and procedural complications	-Total	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fracture	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Heart injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Procedural pneumothorax	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Subdural haematoma	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wrist fracture	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Investigations	-Total	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alanine aminotransferase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aspartate aminotransferase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bilirubin conjugated increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine phosphokinase increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrocardiogram QT prolonged	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatic enzyme increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphocyte count decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Platelet count decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Metabolism and nutrition disorders	-Total	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Decreased appetite	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dehydration	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Electrolyte imbalance	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Failure to thrive	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperkalaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperuricaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypokalaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyponatraemia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypophosphataemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Musculoskeletal and connective tissue disorders	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Back pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intervertebral disc protrusion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscular weakness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Musculoskeletal pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pain in extremity	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Rhabdomyolysis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Cancer pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gallbladder cancer	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tumour pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Nervous system disorders	-Total	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	2	11.1	3.1	32.8
	Ataxia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebral haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebrovascular accident	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dizziness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epilepsy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhage intracranial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lumbosacral radiculopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Migraine	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Neuralgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Polyneuropathy chronic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Presyncope	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Seizure	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Syncope	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Psychiatric disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Confusional state	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mental status changes	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Renal and urinary disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Acute kidney injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematuria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hydronephrosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nephrolithiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Obstructive nephropathy	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urethral stenosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary retention	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Reproductive system and breast disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ovarian cyst	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Prostatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Respiratory, thoracic and mediastinal disorders	-Total	Asian	128	45.6	18	14.1	9.1	21.1
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	3	16.7	5.8	39.2
	Acute respiratory failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dyspnoea	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epistaxis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Haemoptysis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoxia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Interstitial lung disease	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lung consolidation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Pleural effusion	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonitis	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumothorax	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary embolism	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pulmonary hypertension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory distress	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Respiratory failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Surgical and medical procedures	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eye excision	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hip arthroplasty	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Vascular disorders	-Total	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Embolism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematoma	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypertension	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6

	Hypotension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Orthostatic hypotension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Superior vena cava syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AESAE_SG.xls
26MAR2021 14:38

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any SAE
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	9	7.0	3.7	12.7
	Anaemia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	5	3.9	1.7	8.8
	Anaemia macrocytic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Disseminated intravascular coagulation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Febrile neutropenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Haemorrhagic anaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lymphadenopathy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Neutropenia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Pancytopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombocytopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Cardiac disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	5	3.9	1.7	8.8
	Acute myocardial infarction	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Angina pectoris	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cardio-respiratory arrest	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pericardial effusion	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	1	0.8	0.1	4.3
	Stress cardiomyopathy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Supraventricular tachycardia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Ear and labyrinth disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Vertigo	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Eye disorders	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Keratitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Ulcerative keratitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Gastrointestinal disorders	-Total	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	8	6.2	3.2	11.8
	Abdominal pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Abdominal pain upper	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Aphthous ulcer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Colitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Constipation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Diarrhoea	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Diverticular perforation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gastrointestinal haemorrhage	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gastrointestinal inflammation	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Intestinal obstruction	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Large intestine perforation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Nausea	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oesophagitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pancreatitis acute	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Proctitis ulcerative	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Stomatitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Vomiting	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
General disorders and administration site conditions	-Total	Female	152	54.1	11	7.2	4.1	12.5
		Male	129	45.9	10	7.8	4.3	13.7
	Asthenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Condition aggravated	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Death	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Fatigue	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	General physical health deterioration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Impaired healing	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Malaise	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Multiple organ dysfunction syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Non-cardiac chest pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Oedema peripheral	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Pyrexia	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	2	1.6	0.4	5.5
Hepatobiliary disorders	-Total	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cholecystitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cholelithiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gallbladder polyp	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Liver injury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Infections and infestations	-Total	Female	152	54.1	38	25.0	18.8	32.4
		Male	129	45.9	34	26.4	19.5	34.6
	Appendicitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Bacteraemia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Cellulitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Clostridium difficile colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Corona virus infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Cystitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Device related infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Diverticulitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Empyema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Enterococcal bacteraemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gastroenteritis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Infectious colitis	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Lower respiratory tract infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lung infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Lymph node tuberculosis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Pleural infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumocystis jirovecii pneumonia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Pneumonia	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	17	13.2	8.4	20.1
	Pneumonia cytomegaloviral	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pneumonia haemophilus	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonia influenzal	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pyelonephritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pyelonephritis acute	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Renal tuberculosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sepsis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	4	3.1	1.2	7.7
	Septic shock	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sinusitis bacterial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tonsillitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urinary tract infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	4	3.1	1.2	7.7
	Urosepsis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3

	Viral infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Injury, poisoning and procedural complications	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Fracture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Heart injury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Procedural pneumothorax	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Subdural haematoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Wrist fracture	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Investigations	-Total	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	4	3.1	1.2	7.7
	Alanine aminotransferase increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Aspartate aminotransferase increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Bilirubin conjugated increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood creatine phosphokinase increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Electrocardiogram QT prolonged	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Hepatic enzyme increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lymphocyte count decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Platelet count decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
Metabolism and nutrition disorders	-Total	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	7	5.4	2.7	10.8
	Decreased appetite	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Dehydration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Electrolyte imbalance	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Failure to thrive	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperkalaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperuricaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypokalaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hyponatraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Hypophosphataemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Musculoskeletal and connective tissue disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	8	6.2	3.2	11.8
	Back pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Intervertebral disc protrusion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Muscle haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Muscular weakness	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Musculoskeletal pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pain in extremity	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rhabdomyolysis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Cancer pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gallbladder cancer	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9
	Tumour pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Nervous system disorders	-Total	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	8	6.2	3.2	11.8
	Ataxia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cerebral haematoma	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cerebrovascular accident	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dizziness	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Epilepsy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Haemorrhage intracranial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lumbosacral radiculopathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Migraine	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neuralgia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Polyneuropathy chronic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Presyncope	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Seizure	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Syncope	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Psychiatric disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Confusional state	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Mental status changes	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3

Renal and urinary disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	4	3.1	1.2	7.7
	Acute kidney injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Haematuria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hydronephrosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nephrolithiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Obstructive nephropathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urethral stenosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urinary retention	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Reproductive system and breast disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Ovarian cyst	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Prostatitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Respiratory, thoracic and mediastinal disorders	-Total	Female	152	54.1	19	12.5	8.2	18.7
		Male	129	45.9	19	14.7	9.6	21.9
	Acute respiratory failure	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dyspnoea	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	5	3.9	1.7	8.8
	Epistaxis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haemoptysis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypoxia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Interstitial lung disease	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3

	Lung consolidation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pleural effusion	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Pneumonitis	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	5	3.9	1.7	8.8
	Pneumothorax	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pulmonary embolism	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Pulmonary hypertension	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Respiratory distress	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Respiratory failure	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Surgical and medical procedures	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Eye excision	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hip arthroplasty	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Vascular disorders	-Total	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	3	2.3	0.8	6.6
	Embolism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haematoma	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hypertension	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypotension	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Orthostatic hypotension	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Superior vena cava syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AESAE_SG.xls
26MAR2021 14:38

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any SAE
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	n/a	281	100.0	19	6.8	4.4	10.3
	Anaemia	n/a	281	100.0	9	3.2	1.7	6.0
	Anaemia macrocytic	n/a	281	100.0	1	0.4	0.1	2.0
	Disseminated intravascular coagulation	n/a	281	100.0	1	0.4	0.1	2.0
	Febrile neutropenia	n/a	281	100.0	2	0.7	0.2	2.6
	Haemorrhagic anaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Lymphadenopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Neutropenia	n/a	281	100.0	5	1.8	0.8	4.1
	Pancytopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombocytopenia	n/a	281	100.0	1	0.4	0.1	2.0
Cardiac disorders	-Total	n/a	281	100.0	8	2.8	1.4	5.5
	Acute myocardial infarction	n/a	281	100.0	2	0.7	0.2	2.6
	Angina pectoris	n/a	281	100.0	1	0.4	0.1	2.0
	Cardio-respiratory arrest	n/a	281	100.0	1	0.4	0.1	2.0
	Pericardial effusion	n/a	281	100.0	2	0.7	0.2	2.6
	Stress cardiomyopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Supraventricular tachycardia	n/a	281	100.0	1	0.4	0.1	2.0
Ear and labyrinth disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Vertigo	n/a	281	100.0	1	0.4	0.1	2.0
Eye disorders	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Keratitis	n/a	281	100.0	2	0.7	0.2	2.6
	Ulcerative keratitis	n/a	281	100.0	1	0.4	0.1	2.0

Gastrointestinal disorders	-Total	n/a	281	100.0	20	7.1	4.7	10.7
	Abdominal pain	n/a	281	100.0	1	0.4	0.1	2.0
	Abdominal pain upper	n/a	281	100.0	1	0.4	0.1	2.0
	Aphthous ulcer	n/a	281	100.0	1	0.4	0.1	2.0
	Colitis	n/a	281	100.0	2	0.7	0.2	2.6
	Constipation	n/a	281	100.0	1	0.4	0.1	2.0
	Diarrhoea	n/a	281	100.0	3	1.1	0.4	3.1
	Diverticular perforation	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Gastrointestinal inflammation	n/a	281	100.0	2	0.7	0.2	2.6
	Intestinal obstruction	n/a	281	100.0	1	0.4	0.1	2.0
	Large intestine perforation	n/a	281	100.0	1	0.4	0.1	2.0
	Nausea	n/a	281	100.0	1	0.4	0.1	2.0
	Oesophagitis	n/a	281	100.0	1	0.4	0.1	2.0
	Pancreatitis acute	n/a	281	100.0	2	0.7	0.2	2.6
	Proctitis ulcerative	n/a	281	100.0	1	0.4	0.1	2.0
	Stomatitis	n/a	281	100.0	2	0.7	0.2	2.6
	Vomiting	n/a	281	100.0	1	0.4	0.1	2.0
General disorders and administration site conditions	-Total	n/a	281	100.0	40	14.2	10.6	18.8
	Asthenia	n/a	281	100.0	2	0.7	0.2	2.6
	Condition aggravated	n/a	281	100.0	1	0.4	0.1	2.0
	Death	n/a	281	100.0	2	0.7	0.2	2.6
	Disease progression	n/a	281	100.0	21	7.5	4.9	11.2
	Fatigue	n/a	281	100.0	1	0.4	0.1	2.0
	General physical health deterioration	n/a	281	100.0	2	0.7	0.2	2.6
	Impaired healing	n/a	281	100.0	1	0.4	0.1	2.0
	Malaise	n/a	281	100.0	1	0.4	0.1	2.0

	Multiple organ dysfunction syndrome	n/a	281	100.0	1	0.4	0.1	2.0
	Non-cardiac chest pain	n/a	281	100.0	1	0.4	0.1	2.0
	Oedema peripheral	n/a	281	100.0	1	0.4	0.1	2.0
	Pyrexia	n/a	281	100.0	8	2.8	1.4	5.5
Hepatobiliary disorders	-Total	n/a	281	100.0	5	1.8	0.8	4.1
	Cholecystitis	n/a	281	100.0	2	0.7	0.2	2.6
	Cholelithiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Gallbladder polyp	n/a	281	100.0	1	0.4	0.1	2.0
	Liver injury	n/a	281	100.0	1	0.4	0.1	2.0
Infections and infestations	-Total	n/a	281	100.0	72	25.6	20.9	31.0
	Appendicitis	n/a	281	100.0	2	0.7	0.2	2.6
	Bacteraemia	n/a	281	100.0	3	1.1	0.4	3.1
	Cellulitis	n/a	281	100.0	1	0.4	0.1	2.0
	Clostridium difficile colitis	n/a	281	100.0	1	0.4	0.1	2.0
	Corona virus infection	n/a	281	100.0	2	0.7	0.2	2.6
	Cystitis	n/a	281	100.0	1	0.4	0.1	2.0
	Device related infection	n/a	281	100.0	1	0.4	0.1	2.0
	Diverticulitis	n/a	281	100.0	2	0.7	0.2	2.6
	Empyema	n/a	281	100.0	1	0.4	0.1	2.0
	Enterococcal bacteraemia	n/a	281	100.0	1	0.4	0.1	2.0
	Gastroenteritis	n/a	281	100.0	1	0.4	0.1	2.0
	Infectious colitis	n/a	281	100.0	1	0.4	0.1	2.0
	Lower respiratory tract infection	n/a	281	100.0	1	0.4	0.1	2.0
	Lung infection	n/a	281	100.0	2	0.7	0.2	2.6
	Lymph node tuberculosis	n/a	281	100.0	2	0.7	0.2	2.6
	Pleural infection	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumocystis jirovecii pneumonia	n/a	281	100.0	2	0.7	0.2	2.6
	Pneumonia	n/a	281	100.0	33	11.7	8.5	16.0

	Pneumonia cytomegaloviral	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia haemophilus	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia influenzal	n/a	281	100.0	1	0.4	0.1	2.0
	Pyelonephritis	n/a	281	100.0	1	0.4	0.1	2.0
	Pyelonephritis acute	n/a	281	100.0	1	0.4	0.1	2.0
	Renal tuberculosis	n/a	281	100.0	1	0.4	0.1	2.0
	Sepsis	n/a	281	100.0	8	2.8	1.4	5.5
	Septic shock	n/a	281	100.0	1	0.4	0.1	2.0
	Sinusitis bacterial	n/a	281	100.0	1	0.4	0.1	2.0
	Tonsillitis	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary tract infection	n/a	281	100.0	6	2.1	1.0	4.6
	Urosepsis	n/a	281	100.0	2	0.7	0.2	2.6
	Viral infection	n/a	281	100.0	1	0.4	0.1	2.0
Injury, poisoning and procedural complications	-Total	n/a	281	100.0	5	1.8	0.8	4.1
	Fracture	n/a	281	100.0	1	0.4	0.1	2.0
	Heart injury	n/a	281	100.0	1	0.4	0.1	2.0
	Procedural pneumothorax	n/a	281	100.0	1	0.4	0.1	2.0
	Subdural haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Wrist fracture	n/a	281	100.0	1	0.4	0.1	2.0
Investigations	-Total	n/a	281	100.0	10	3.6	1.9	6.4
	Alanine aminotransferase increased	n/a	281	100.0	2	0.7	0.2	2.6
	Aspartate aminotransferase increased	n/a	281	100.0	3	1.1	0.4	3.1
	Bilirubin conjugated increased	n/a	281	100.0	1	0.4	0.1	2.0
	Blood creatine phosphokinase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Electrocardiogram QT prolonged	n/a	281	100.0	2	0.7	0.2	2.6
	Hepatic enzyme increased	n/a	281	100.0	1	0.4	0.1	2.0
	Lymphocyte count decreased	n/a	281	100.0	1	0.4	0.1	2.0

	Platelet count decreased	n/a	281	100.0	2	0.7	0.2	2.6
Metabolism and nutrition disorders	-Total	n/a	281	100.0	12	4.3	2.5	7.3
	Decreased appetite	n/a	281	100.0	1	0.4	0.1	2.0
	Dehydration	n/a	281	100.0	2	0.7	0.2	2.6
	Electrolyte imbalance	n/a	281	100.0	1	0.4	0.1	2.0
	Failure to thrive	n/a	281	100.0	1	0.4	0.1	2.0
	Hyperkalaemia	n/a	281	100.0	2	0.7	0.2	2.6
	Hyperuricaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hypokalaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Hyponatraemia	n/a	281	100.0	3	1.1	0.4	3.1
	Hypophosphataemia	n/a	281	100.0	2	0.7	0.2	2.6
Musculoskeletal and connective tissue disorders	-Total	n/a	281	100.0	11	3.9	2.2	6.9
	Back pain	n/a	281	100.0	4	1.4	0.6	3.6
	Intervertebral disc protrusion	n/a	281	100.0	2	0.7	0.2	2.6
	Muscle haemorrhage	n/a	281	100.0	1	0.4	0.1	2.0
	Muscular weakness	n/a	281	100.0	1	0.4	0.1	2.0
	Musculoskeletal pain	n/a	281	100.0	1	0.4	0.1	2.0
	Pain in extremity	n/a	281	100.0	1	0.4	0.1	2.0
	Rhabdomyolysis	n/a	281	100.0	1	0.4	0.1	2.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Cancer pain	n/a	281	100.0	1	0.4	0.1	2.0
	Gallbladder cancer	n/a	281	100.0	1	0.4	0.1	2.0
	Tumour pain	n/a	281	100.0	1	0.4	0.1	2.0
Nervous system disorders	-Total	n/a	281	100.0	17	6.0	3.8	9.5
	Ataxia	n/a	281	100.0	1	0.4	0.1	2.0
	Cerebral haematoma	n/a	281	100.0	1	0.4	0.1	2.0
	Cerebrovascular accident	n/a	281	100.0	1	0.4	0.1	2.0
	Dizziness	n/a	281	100.0	3	1.1	0.4	3.1

	Epilepsy	n/a	281	100.0	1	0.4	0.1	2.0
	Haemorrhage intracranial	n/a	281	100.0	1	0.4	0.1	2.0
	Lumbosacral radiculopathy	n/a	281	100.0	1	0.4	0.1	2.0
	Migraine	n/a	281	100.0	1	0.4	0.1	2.0
	Neuralgia	n/a	281	100.0	1	0.4	0.1	2.0
	Polyneuropathy chronic	n/a	281	100.0	1	0.4	0.1	2.0
	Presyncope	n/a	281	100.0	1	0.4	0.1	2.0
	Seizure	n/a	281	100.0	5	1.8	0.8	4.1
	Syncope	n/a	281	100.0	1	0.4	0.1	2.0
Psychiatric disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Confusional state	n/a	281	100.0	1	0.4	0.1	2.0
	Mental status changes	n/a	281	100.0	2	0.7	0.2	2.6
Renal and urinary disorders	-Total	n/a	281	100.0	5	1.8	0.8	4.1
	Acute kidney injury	n/a	281	100.0	1	0.4	0.1	2.0
	Haematuria	n/a	281	100.0	1	0.4	0.1	2.0
	Hydronephrosis	n/a	281	100.0	1	0.4	0.1	2.0
	Nephrolithiasis	n/a	281	100.0	1	0.4	0.1	2.0
	Obstructive nephropathy	n/a	281	100.0	1	0.4	0.1	2.0
	Urethral stenosis	n/a	281	100.0	1	0.4	0.1	2.0
	Urinary retention	n/a	281	100.0	1	0.4	0.1	2.0
Reproductive system and breast disorders	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Ovarian cyst	n/a	281	100.0	1	0.4	0.1	2.0
	Prostatitis	n/a	281	100.0	1	0.4	0.1	2.0
Respiratory, thoracic and mediastinal disorders	-Total	n/a	281	100.0	38	13.5	10.0	18.0
	Acute respiratory failure	n/a	281	100.0	1	0.4	0.1	2.0
	Dyspnoea	n/a	281	100.0	6	2.1	1.0	4.6
	Epistaxis	n/a	281	100.0	1	0.4	0.1	2.0

	Haemoptysis	n/a	281	100.0	1	0.4	0.1	2.0
	Hypoxia	n/a	281	100.0	1	0.4	0.1	2.0
	Interstitial lung disease	n/a	281	100.0	2	0.7	0.2	2.6
	Lung consolidation	n/a	281	100.0	1	0.4	0.1	2.0
	Pleural effusion	n/a	281	100.0	6	2.1	1.0	4.6
	Pneumonitis	n/a	281	100.0	13	4.6	2.7	7.8
	Pneumothorax	n/a	281	100.0	2	0.7	0.2	2.6
	Pulmonary embolism	n/a	281	100.0	4	1.4	0.6	3.6
	Pulmonary hypertension	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory distress	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory failure	n/a	281	100.0	1	0.4	0.1	2.0
Surgical and medical procedures	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Eye excision	n/a	281	100.0	1	0.4	0.1	2.0
	Hip arthroplasty	n/a	281	100.0	1	0.4	0.1	2.0
Vascular disorders	-Total	n/a	281	100.0	10	3.6	1.9	6.4
	Embolism	n/a	281	100.0	1	0.4	0.1	2.0
	Haematoma	n/a	281	100.0	2	0.7	0.2	2.6
	Hypertension	n/a	281	100.0	4	1.4	0.6	3.6
	Hypotension	n/a	281	100.0	1	0.4	0.1	2.0
	Orthostatic hypotension	n/a	281	100.0	1	0.4	0.1	2.0
	Superior vena cava syndrome	n/a	281	100.0	1	0.4	0.1	2.0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AESAE_SG.xls
26MAR2021 13:59

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any SAE
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	< 65	176	62.6	12	6.8	3.9	11.5
		>= 65	105	37.4	7	6.7	3.3	13.1
	Anaemia	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	3	2.9	1.0	8.1
	Anaemia macrocytic	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Disseminated intravascular coagulation	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Febrile neutropenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haemorrhagic anaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymphadenopathy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neutropenia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pancytopenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Thrombocytopenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Cardiac disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	6	5.7	2.6	11.9
	Acute myocardial infarction	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Angina pectoris	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cardio-respiratory arrest	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pericardial effusion	< 65	176	62.6	2	1.1	0.3	4.0

		>= 65	105	37.4	0	0.0	0.0	3.5
	Stress cardiomyopathy	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Supraventricular tachycardia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Ear and labyrinth disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Vertigo	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Eye disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Keratitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Ulcerative keratitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Gastrointestinal disorders	-Total	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	10	9.5	5.3	16.6
	Abdominal pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Abdominal pain upper	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Aphthous ulcer	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Colitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Constipation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Diarrhoea	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Diverticular perforation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastrointestinal haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gastrointestinal inflammation	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Intestinal obstruction	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Large intestine perforation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nausea	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Oesophagitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pancreatitis acute	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Proctitis ulcerative	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Stomatitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Vomiting	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
General disorders and administration site conditions	-Total	< 65	176	62.6	25	14.2	9.8	20.1
		>= 65	105	37.4	15	14.3	8.9	22.2
	Asthenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Condition aggravated	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Death	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Disease progression	< 65	176	62.6	13	7.4	4.4	12.2
		>= 65	105	37.4	8	7.6	3.9	14.3
	Fatigue	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	General physical health deterioration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Impaired healing	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Malaise	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Multiple organ dysfunction syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Non-cardiac chest pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Oedema peripheral	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyrexia	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	3	2.9	1.0	8.1
Hepatobiliary disorders	-Total	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cholecystitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cholelithiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gallbladder polyp	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Liver injury	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Infections and infestations	-Total	< 65	176	62.6	42	23.9	18.2	30.7
		>= 65	105	37.4	30	28.6	20.8	37.8
	Appendicitis	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Bacteraemia	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cellulitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Clostridium difficile colitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Corona virus infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cystitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Device related infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Diverticulitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Empyema	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Enterococcal bacteraemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Gastroenteritis	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Infectious colitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lower respiratory tract infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lung infection	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lymph node tuberculosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pleural infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumocystis jirovecii pneumonia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pneumonia	< 65	176	62.6	20	11.4	7.5	16.9
		>= 65	105	37.4	13	12.4	7.4	20.0
	Pneumonia cytomegaloviral	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pneumonia haemophilus	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia influenzal	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyelonephritis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pyelonephritis acute	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Renal tuberculosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Sepsis	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	4	3.8	1.5	9.4
	Septic shock	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Sinusitis bacterial	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tonsillitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urinary tract infection	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	6	5.7	2.6	11.9

	Urosepsis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Viral infection	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Injury, poisoning and procedural complications	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	4	3.8	1.5	9.4
	Fracture	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Heart injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Procedural pneumothorax	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Subdural haematoma	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Wrist fracture	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Investigations	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	7	6.7	3.3	13.1
	Alanine aminotransferase increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Aspartate aminotransferase increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Bilirubin conjugated increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Blood creatine phosphokinase increased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Electrocardiogram QT prolonged	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hepatic enzyme increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymphocyte count decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Platelet count decreased	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Metabolism and nutrition disorders	-Total	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	5	4.8	2.1	10.7

	Decreased appetite	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Dehydration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Electrolyte imbalance	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Failure to thrive	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hyperkalaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyperuricaemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypokalaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyponatraemia	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypophosphataemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
Musculoskeletal and connective tissue disorders	-Total	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	5	4.8	2.1	10.7
	Back pain	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	1	1.0	0.2	5.2
	Intervertebral disc protrusion	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Muscle haemorrhage	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Muscular weakness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Musculoskeletal pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pain in extremity	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Rhabdomyolysis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cancer pain	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5
	Gallbladder cancer	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Tumour pain	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Nervous system disorders	-Total	< 65	176	62.6	9	5.1	2.7	9.4
		>= 65	105	37.4	8	7.6	3.9	14.3
	Ataxia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Cerebral haematoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cerebrovascular accident	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dizziness	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Epilepsy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haemorrhage intracranial	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lumbosacral radiculopathy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Migraine	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Neuralgia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Polyneuropathy chronic	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Presyncope	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Seizure	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	1	1.0	0.2	5.2
	Syncope	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Psychiatric disorders	-Total	< 65	176	62.6	3	1.7	0.6	4.9
		>= 65	105	37.4	0	0.0	0.0	3.5
	Confusional state	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

	Mental status changes	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
Renal and urinary disorders	-Total	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	3	2.9	1.0	8.1
	Acute kidney injury	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haematuria	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hydronephrosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Nephrolithiasis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Obstructive nephropathy	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Urethral stenosis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Urinary retention	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Reproductive system and breast disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Ovarian cyst	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Prostatitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Respiratory, thoracic and mediastinal disorders	-Total	< 65	176	62.6	21	11.9	7.9	17.6
		>= 65	105	37.4	17	16.2	10.4	24.4
	Acute respiratory failure	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Dyspnoea	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	4	3.8	1.5	9.4
	Epistaxis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Haemoptysis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hypoxia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Interstitial lung disease	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Lung consolidation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pleural effusion	< 65	176	62.6	5	2.8	1.2	6.5
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pneumonitis	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	6	5.7	2.6	11.9
	Pneumothorax	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pulmonary embolism	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Pulmonary hypertension	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Respiratory distress	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory failure	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Surgical and medical procedures	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Eye excision	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Hip arthroplasty	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Vascular disorders	-Total	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	6	5.7	2.6	11.9
	Embolism	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haematoma	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hypertension	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	2	1.9	0.5	6.7
	Hypotension	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Orthostatic hypotension	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Superior vena cava syndrome	< 65	176	62.6	1	0.6	0.1	3.1

		>= 65	105	37.4	0	0.0	0.0	3.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AESAE_SG.xls
26MAR2021 13:59

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any SAE
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	15	7.9	4.8	12.6
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia macrocytic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disseminated intravascular coagulation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Febrile neutropenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhagic anaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphadenopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutropenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Cardiac disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute myocardial infarction	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Angina pectoris	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cardio-respiratory arrest	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pericardial effusion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Stress cardiomyopathy	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Supraventricular tachycardia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Ear and labyrinth disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vertigo	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Eye disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Keratitis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ulcerative keratitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Gastrointestinal disorders	-Total	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Abdominal pain upper	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aphthous ulcer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Colitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Constipation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Diarrhoea	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diverticular perforation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal haemorrhage	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Gastrointestinal inflammation	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intestinal obstruction	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Large intestine perforation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nausea	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oesophagitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancreatitis acute	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Proctitis ulcerative	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Stomatitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Vomiting	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
General disorders and administration site conditions	-Total	0	84	29.9	7	8.3	4.1	16.2
		1	190	67.6	32	16.8	12.2	22.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Asthenia	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Condition aggravated	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Death	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disease progression	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	17	8.9	5.7	13.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fatigue	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	General physical health deterioration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Impaired healing	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Malaise	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Multiple organ dysfunction syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Non-cardiac chest pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Oedema peripheral	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyrexia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
Hepatobiliary disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Cholecystitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Cholelithiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gallbladder polyp	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Liver injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Infections and infestations	-Total	0	84	29.9	23	27.4	19.0	37.7
		1	190	67.6	45	23.7	18.2	30.2
		2	6	2.1	4	66.7	30.0	90.3
		Missing	1	0.4	0	0.0	0.0	79.3
	Appendicitis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cellulitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Clostridium difficile colitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Corona virus infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Cystitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Device related infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Diverticulitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Empyema	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Enterococcal bacteraemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gastroenteritis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Infectious colitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lower respiratory tract infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lung infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymph node tuberculosis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural infection	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumocystis jirovecii pneumonia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia	0	84	29.9	13	15.5	9.3	24.7
		1	190	67.6	18	9.5	6.1	14.5
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia cytomegaloviral	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia haemophilus	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia influenzal	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyelonephritis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pyelonephritis acute	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Renal tuberculosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sepsis	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Septic shock	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sinusitis bacterial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4

		Missing	1	0.4	0	0.0	0.0	79.3
	Tonsillitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary tract infection	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urosepsis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Viral infection	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Injury, poisoning and procedural complications	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Fracture	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Heart injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Procedural pneumothorax	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Subdural haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Wrist fracture	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Investigations	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	1	16.7	3.0	56.4

		Missing	1	0.4	0	0.0	0.0	79.3
	Alanine aminotransferase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Aspartate aminotransferase increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Bilirubin conjugated increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrocardiogram QT prolonged	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hepatic enzyme increased	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphocyte count decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Platelet count decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Metabolism and nutrition disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	10	5.3	2.9	9.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Decreased appetite	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dehydration	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Electrolyte imbalance	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Failure to thrive	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperkalaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyperuricaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypokalaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyponatraemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypophosphataemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Musculoskeletal and connective tissue disorders	-Total	0	84	29.9	6	7.1	3.3	14.7
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Back pain	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Intervertebral disc protrusion	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Muscle haemorrhage	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Muscular weakness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Musculoskeletal pain	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pain in extremity	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhabdomyolysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cancer pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gallbladder cancer	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Tumour pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Nervous system disorders	-Total	0	84	29.9	5	6.0	2.6	13.2
		1	190	67.6	11	5.8	3.3	10.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Ataxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebral haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Cerebrovascular accident	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dizziness	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Epilepsy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhage intracranial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lumbosacral radiculopathy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Migraine	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neuralgia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Polyneuropathy chronic	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Presyncope	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Seizure	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Syncope	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
Psychiatric disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Confusional state	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Mental status changes	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Renal and urinary disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	5	2.6	1.1	6.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute kidney injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematuria	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hydronephrosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Nephrolithiasis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Obstructive nephropathy	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urethral stenosis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Urinary retention	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
Reproductive system and breast disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Ovarian cyst	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Prostatitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Respiratory, thoracic and mediastinal disorders	-Total	0	84	29.9	11	13.1	7.5	21.9
		1	190	67.6	26	13.7	9.5	19.3
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Acute respiratory failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Epistaxis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemoptysis	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Interstitial lung disease	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lung consolidation	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Pleural effusion	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonitis	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	9	4.7	2.5	8.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumothorax	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary embolism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	3	1.6	0.5	4.5
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary hypertension	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory distress	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Surgical and medical procedures	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Eye excision	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hip arthroplasty	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Vascular disorders	-Total	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haematoma	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertension	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypotension	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Orthostatic hypotension	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Superior vena cava syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AESAE_SG.xls
26MAR2021 13:59

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any SAE
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	USA	64	22.8	8	12.5	6.5	22.8
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Anaemia	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Anaemia macrocytic	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Disseminated intravascular coagulation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Febrile neutropenia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Haemorrhagic anaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymphadenopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neutropenia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Pancytopenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thrombocytopenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Cardiac disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

	Acute myocardial infarction	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Angina pectoris	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cardio-respiratory arrest	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pericardial effusion	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Stress cardiomyopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Supraventricular tachycardia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Ear and labyrinth disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Vertigo	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Eye disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Keratitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ulcerative keratitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Gastrointestinal disorders	-Total	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	9	9.5	5.1	17.0
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Abdominal pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Abdominal pain upper	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aphthous ulcer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Colitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Constipation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Diarrhoea	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Diverticular perforation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal haemorrhage	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastrointestinal inflammation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Intestinal obstruction	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Large intestine perforation	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nausea	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oesophagitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pancreatitis acute	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Proctitis ulcerative	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Stomatitis	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Vomiting	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
General disorders and administration site conditions	-Total	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	13	13.7	8.2	22.0
		Asia (AS)	122	43.4	20	16.4	10.9	24.0
	Asthenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Condition aggravated	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Death	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Disease progression	USA	64	22.8	6	9.4	4.4	19.0
		Europe (EU)	95	33.8	6	6.3	2.9	13.1
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Fatigue	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	General physical health deterioration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Impaired healing	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Malaise	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Multiple organ dysfunction syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Non-cardiac chest pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Oedema peripheral	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Pyrexia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	6	4.9	2.3	10.3
Hepatobiliary disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Cholecystitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Cholelithiasis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gallbladder polyp	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Liver injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Infections and infestations	-Total	USA	64	22.8	21	32.8	22.6	45.0
		Europe (EU)	95	33.8	23	24.2	16.7	33.7
		Asia (AS)	122	43.4	28	23.0	16.4	31.2
	Appendicitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bacteraemia	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cellulitis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Clostridium difficile colitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Corona virus infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cystitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Device related infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Diverticulitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Empyema	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Enterococcal bacteraemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gastroenteritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Infectious colitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lower respiratory tract infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lung infection	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Lymph node tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pleural infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumocystis jirovecii pneumonia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonia	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	11	11.6	6.6	19.6
		Asia (AS)	122	43.4	15	12.3	7.6	19.3
	Pneumonia cytomegaloviral	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonia haemophilus	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pneumonia influenzal	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9

		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pyelonephritis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pyelonephritis acute	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Renal tuberculosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Sepsis	USA	64	22.8	5	7.8	3.4	17.0
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Septic shock	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Sinusitis bacterial	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Tonsillitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urinary tract infection	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urosepsis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Viral infection	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Injury, poisoning and procedural complications	-Total	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Fracture	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Heart injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Procedural pneumothorax	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Subdural haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Wrist fracture	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Investigations	-Total	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Alanine aminotransferase increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Aspartate aminotransferase increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Bilirubin conjugated increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Blood creatine phosphokinase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Electrocardiogram QT prolonged	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hepatic enzyme increased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymphocyte count decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Platelet count decreased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
Metabolism and nutrition disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	11	9.0	5.1	15.4
	Decreased appetite	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Dehydration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Electrolyte imbalance	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Failure to thrive	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hyperkalaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hyperuricaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypokalaemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyponatraemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Hypophosphataemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
Musculoskeletal and connective tissue disorders	-Total	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Back pain	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Intervertebral disc protrusion	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscle haemorrhage	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Muscular weakness	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Musculoskeletal pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

	Pain in extremity	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Rhabdomyolysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cancer pain	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gallbladder cancer	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Tumour pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Nervous system disorders	-Total	USA	64	22.8	7	10.9	5.4	20.9
		Europe (EU)	95	33.8	7	7.4	3.6	14.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Ataxia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebral haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Cerebrovascular accident	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dizziness	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Epilepsy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haemorrhage intracranial	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lumbosacral radiculopathy	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Migraine	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neuralgia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Polyneuropathy chronic	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Presyncope	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Seizure	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Syncope	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Psychiatric disorders	-Total	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Confusional state	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Mental status changes	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Renal and urinary disorders	-Total	USA	64	22.8	4	6.3	2.5	15.0
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Acute kidney injury	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haematuria	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hydronephrosis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Nephrolithiasis	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Obstructive nephropathy	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Urethral stenosis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Urinary retention	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Reproductive system and breast disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Ovarian cyst	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Prostatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Respiratory, thoracic and mediastinal disorders	-Total	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	18	18.9	12.3	28.0
		Asia (AS)	122	43.4	17	13.9	8.9	21.2
	Acute respiratory failure	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Dyspnoea	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Epistaxis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haemoptysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypoxia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Interstitial lung disease	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8

	Lung consolidation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pleural effusion	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Pneumonitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	8	6.6	3.4	12.4
	Pneumothorax	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Pulmonary embolism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pulmonary hypertension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory distress	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory failure	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Surgical and medical procedures	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Eye excision	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hip arthroplasty	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Vascular disorders	-Total	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Embolism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haematoma	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Hypertension	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Hypotension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Orthostatic hypotension	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Superior vena cava syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AESAE_SG.xls
26MAR2021 13:59

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any SAE
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	9	10.2	5.5	18.3
	Anaemia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	3	3.4	1.2	9.5
	Anaemia macrocytic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Disseminated intravascular coagulation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Febrile neutropenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemorrhagic anaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymphadenopathy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neutropenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	5	5.7	2.5	12.6
	Pancytopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Thrombocytopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Cardiac disorders	-Total	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5

	Acute myocardial infarction	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Angina pectoris	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cardio-respiratory arrest	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pericardial effusion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Stress cardiomyopathy	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Supraventricular tachycardia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Ear and labyrinth disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Vertigo	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Eye disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Keratitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ulcerative keratitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Gastrointestinal disorders	-Total	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	6	7.8	3.6	16.0
		>= 2	88	31.3	9	10.2	5.5	18.3
	Abdominal pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Abdominal pain upper	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	0	0.0	0.0	4.2
	Aphthous ulcer	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Colitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Constipation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Diarrhoea	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Diverticular perforation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gastrointestinal haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastrointestinal inflammation	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intestinal obstruction	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Large intestine perforation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Nausea	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oesophagitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pancreatitis acute	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Proctitis ulcerative	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Stomatitis	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Vomiting	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
General disorders and administration site conditions	-Total	0	116	41.3	10	8.6	4.7	15.1
		1	77	27.4	14	18.2	11.2	28.2
		>= 2	88	31.3	16	18.2	11.5	27.5
	Asthenia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Condition aggravated	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Death	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Disease progression	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	10	13.0	7.2	22.3
		>= 2	88	31.3	8	9.1	4.7	16.9
	Fatigue	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	General physical health deterioration	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Impaired healing	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Malaise	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Multiple organ dysfunction syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Non-cardiac chest pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Oedema peripheral	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Pyrexia	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	3	3.4	1.2	9.5
Hepatobiliary disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Cholecystitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cholelithiasis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gallbladder polyp	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Liver injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Infections and infestations	-Total	0	116	41.3	23	19.8	13.6	28.0
		1	77	27.4	19	24.7	16.4	35.4
		>= 2	88	31.3	30	34.1	25.0	44.5
	Appendicitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Bacteraemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Cellulitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Clostridium difficile colitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Corona virus infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cystitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Device related infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Diverticulitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Empyema	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Enterococcal bacteraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gastroenteritis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Infectious colitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lower respiratory tract infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lung infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lymph node tuberculosis	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pleural infection	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumocystis jirovecii pneumonia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia	0	116	41.3	9	7.8	4.1	14.1
		1	77	27.4	11	14.3	8.2	23.8
		>= 2	88	31.3	13	14.8	8.8	23.7
	Pneumonia cytomegaloviral	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pneumonia haemophilus	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonia influenzal	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1	0.2	6.2
	Pyelonephritis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pyelonephritis acute	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Renal tuberculosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Sepsis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	4	4.5	1.8	11.1
	Septic shock	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Sinusitis bacterial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Tonsillitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Urinary tract infection	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Urosepsis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Viral infection	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Injury, poisoning and procedural complications	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Fracture	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Heart injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Procedural pneumothorax	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Subdural haematoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Wrist fracture	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Investigations	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	4	4.5	1.8	11.1
	Alanine aminotransferase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Aspartate aminotransferase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Bilirubin conjugated increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Blood creatine phosphokinase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Electrocardiogram QT prolonged	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hepatic enzyme increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Lymphocyte count decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Platelet count decreased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Metabolism and nutrition disorders	-Total	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	4	4.5	1.8	11.1
	Decreased appetite	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Dehydration	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Electrolyte imbalance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Failure to thrive	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyperkalaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyperuricaemia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypokalaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hyponatraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypophosphataemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
Musculoskeletal and connective tissue disorders	-Total	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	3	3.4	1.2	9.5
	Back pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	4	5.2	2.0	12.6
		>= 2	88	31.3	0	0.0	0.0	4.2
	Intervertebral disc protrusion	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Muscle haemorrhage	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Muscular weakness	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Musculoskeletal pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Pain in extremity	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhabdomyolysis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cancer pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Gallbladder cancer	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Tumour pain	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Nervous system disorders	-Total	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	7	9.1	4.5	17.6
		>= 2	88	31.3	5	5.7	2.5	12.6
	Ataxia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Cerebral haematoma	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Cerebrovascular accident	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Dizziness	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Epilepsy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Haemorrhage intracranial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lumbosacral radiculopathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1	0.2	6.2
	Migraine	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Neuralgia	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Polyneuropathy chronic	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Presyncope	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Seizure	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Syncope	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Psychiatric disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Confusional state	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Mental status changes	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Renal and urinary disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Acute kidney injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haematuria	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hydronephrosis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Nephrolithiasis	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Obstructive nephropathy	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urethral stenosis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Urinary retention	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Reproductive system and breast disorders	-Total	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Ovarian cyst	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Prostatitis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Respiratory, thoracic and mediastinal disorders	-Total	0	116	41.3	18	15.5	10.0	23.2
		1	77	27.4	11	14.3	8.2	23.8
		>= 2	88	31.3	9	10.2	5.5	18.3
	Acute respiratory failure	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Dyspnoea	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Epistaxis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haemoptysis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypoxia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Interstitial lung disease	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

	Lung consolidation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pleural effusion	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Pneumonitis	0	116	41.3	6	5.2	2.4	10.8
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	2	2.3	0.6	7.9
	Pneumothorax	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pulmonary embolism	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pulmonary hypertension	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiratory distress	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Respiratory failure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Surgical and medical procedures	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Eye excision	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hip arthroplasty	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Vascular disorders	-Total	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	5	5.7	2.5	12.6
	Embolism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haematoma	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Hypertension	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Hypotension	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Orthostatic hypotension	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Superior vena cava syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AESAE_SG.xls
26MAR2021 13:59

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any SAE
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anaemia macrocytic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Disseminated intravascular coagulation	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Febrile neutropenia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhagic anaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphadenopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutropenia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancytopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytopenia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Cardiac disorders	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	0	0.0	0.0	17.6

	Acute myocardial infarction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Angina pectoris	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cardio-respiratory arrest	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pericardial effusion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Stress cardiomyopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Supraventricular tachycardia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Ear and labyrinth disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Vertigo	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Eye disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Keratitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ulcerative keratitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Gastrointestinal disorders	-Total	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	15	11.1	6.9	17.5
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Abdominal pain upper	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Aphthous ulcer	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Constipation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diarrhoea	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Diverticular perforation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastrointestinal inflammation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intestinal obstruction	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Large intestine perforation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nausea	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Oesophagitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancreatitis acute	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Proctitis ulcerative	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Stomatitis	Asian	128	45.6	1	0.8	0.1	4.3

		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Vomiting	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6
General disorders and administration site conditions	-Total	Asian	128	45.6	21	16.4		11.0	23.8
		Non-Asian	135	48.0	17	12.6		8.0	19.2
		Unknown	18	6.4	2	11.1		3.1	32.8
	Asthenia	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Condition aggravated	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Death	Asian	128	45.6	2	1.6		0.4	5.5
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6
	Disease progression	Asian	128	45.6	10	7.8		4.3	13.8
		Non-Asian	135	48.0	10	7.4		4.1	13.1
		Unknown	18	6.4	1	5.6		1.0	25.8
	Fatigue	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	General physical health deterioration	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	1	5.6		1.0	25.8
	Impaired healing	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Malaise	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6
	Multiple organ dysfunction syndrome	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6
	Non-cardiac chest pain	Asian	128	45.6	0	0.0		0.0	2.9
		Non-Asian	135	48.0	1	0.7		0.1	4.1
		Unknown	18	6.4	0	0.0		0.0	17.6
	Oedema peripheral	Asian	128	45.6	1	0.8		0.1	4.3
		Non-Asian	135	48.0	0	0.0		0.0	2.8
		Unknown	18	6.4	0	0.0		0.0	17.6

	Pyrexia	Asian	128	45.6	6	4.7	2.2	9.8
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
Hepatobiliary disorders	-Total	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cholecystitis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cholelithiasis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gallbladder polyp	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Liver injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Infections and infestations	-Total	Asian	128	45.6	30	23.4	16.9	31.5
		Non-Asian	135	48.0	39	28.9	21.9	37.0
		Unknown	18	6.4	3	16.7	5.8	39.2
	Appendicitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Cellulitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Clostridium difficile colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Corona virus infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cystitis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Device related infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Diverticulitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Empyema	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Enterococcal bacteraemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gastroenteritis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Infectious colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lower respiratory tract infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lung infection	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymph node tuberculosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleural infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumocystis jirovecii pneumonia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia	Asian	128	45.6	16	12.5	7.8	19.3
		Non-Asian	135	48.0	16	11.9	7.4	18.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumonia cytomegaloviral	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia haemophilus	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia influenzal	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8

		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyelonephritis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pyelonephritis acute	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Renal tuberculosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sepsis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Septic shock	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sinusitis bacterial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tonsillitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary tract infection	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urosepsis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Viral infection	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Injury, poisoning and procedural complications	-Total	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fracture	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Heart injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Procedural pneumothorax	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Subdural haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Wrist fracture	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Investigations	-Total	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	7	5.2	2.5	10.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Alanine aminotransferase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Aspartate aminotransferase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Bilirubin conjugated increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Blood creatine phosphokinase increased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrocardiogram QT prolonged	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hepatic enzyme increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lymphocyte count decreased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Platelet count decreased	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Metabolism and nutrition disorders	-Total	Asian	128	45.6	11	8.6	4.9	14.7
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Decreased appetite	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Dehydration	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrolyte imbalance	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Failure to thrive	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperkalaemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyperuricaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypokalaemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyponatraemia	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypophosphataemia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Musculoskeletal and connective tissue disorders	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	9	6.7	3.5	12.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Back pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Intervertebral disc protrusion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscle haemorrhage	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Muscular weakness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Musculoskeletal pain	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Pain in extremity	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhabdomyolysis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	1	5.6	1.0	25.8
	Cancer pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gallbladder cancer	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Tumour pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
Nervous system disorders	-Total	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	11	8.1	4.6	14.0
		Unknown	18	6.4	2	11.1	3.1	32.8
	Ataxia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebral haematoma	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cerebrovascular accident	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Dizziness	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epilepsy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhage intracranial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Lumbosacral radiculopathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Migraine	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neuralgia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Polyneuropathy chronic	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Presyncope	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Seizure	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Syncope	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Psychiatric disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Confusional state	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Mental status changes	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Renal and urinary disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Acute kidney injury	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematuria	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hydronephrosis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Nephrolithiasis	Asian	128	45.6	0	0.0	0.0	2.9

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Obstructive nephropathy	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urethral stenosis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urinary retention	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Reproductive system and breast disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Ovarian cyst	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Prostatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Respiratory, thoracic and mediastinal disorders	-Total	Asian	128	45.6	18	14.1	9.1	21.1
		Non-Asian	135	48.0	17	12.6	8.0	19.2
		Unknown	18	6.4	3	16.7	5.8	39.2
	Acute respiratory failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Dyspnoea	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Epistaxis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Haemoptysis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoxia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Interstitial lung disease	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

	Lung consolidation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pleural effusion	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonitis	Asian	128	45.6	8	6.3	3.2	11.8
		Non-Asian	135	48.0	4	3.0	1.2	7.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumothorax	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pulmonary embolism	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pulmonary hypertension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory distress	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Respiratory failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Surgical and medical procedures	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Eye excision	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hip arthroplasty	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Vascular disorders	-Total	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	1	5.6	1.0	25.8
	Embolism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haematoma	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Hypertension	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypotension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Orthostatic hypotension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Superior vena cava syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AESAE_SG.xls
26MAR2021 13:59

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: Any SAE
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	9	7.0	3.7	12.7
	Anaemia	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	5	3.9	1.7	8.8
	Anaemia macrocytic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Disseminated intravascular coagulation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Febrile neutropenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Haemorrhagic anaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lymphadenopathy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Neutropenia	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Pancytopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombocytopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Cardiac disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	5	3.9	1.7	8.8
	Acute myocardial infarction	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Angina pectoris	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Cardio-respiratory arrest	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pericardial effusion	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	1	0.8	0.1	4.3
	Stress cardiomyopathy	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Supraventricular tachycardia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Ear and labyrinth disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Vertigo	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Eye disorders	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Keratitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Ulcerative keratitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Gastrointestinal disorders	-Total	Female	152	54.1	12	7.9	4.6	13.3
		Male	129	45.9	8	6.2	3.2	11.8
	Abdominal pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Abdominal pain upper	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Aphthous ulcer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Colitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Constipation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Diarrhoea	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Diverticular perforation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gastrointestinal haemorrhage	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gastrointestinal inflammation	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Intestinal obstruction	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Large intestine perforation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Nausea	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Oesophagitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pancreatitis acute	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Proctitis ulcerative	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Stomatitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Vomiting	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
General disorders and administration site conditions	-Total	Female	152	54.1	21	13.8	9.2	20.2
		Male	129	45.9	19	14.7	9.6	21.9
	Asthenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Condition aggravated	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Death	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Disease progression	Female	152	54.1	10	6.6	3.6	11.7
		Male	129	45.9	11	8.5	4.8	14.6
	Fatigue	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	General physical health deterioration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Impaired healing	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Malaise	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Multiple organ dysfunction syndrome	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Non-cardiac chest pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Oedema peripheral	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pyrexia	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	2	1.6	0.4	5.5
Hepatobiliary disorders	-Total	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cholecystitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cholelithiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gallbladder polyp	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Liver injury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Infections and infestations	-Total	Female	152	54.1	38	25.0	18.8	32.4
		Male	129	45.9	34	26.4	19.5	34.6
	Appendicitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Bacteraemia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Cellulitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Clostridium difficile colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Corona virus infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Cystitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Device related infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Diverticulitis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Empyema	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Enterococcal bacteraemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Gastroenteritis	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
	Infectious colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lower respiratory tract infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Lung infection	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Lymph node tuberculosis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Pleural infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumocystis jirovecii pneumonia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Pneumonia	Female	152	54.1	16	10.5	6.6	16.4
		Male	129	45.9	17	13.2	8.4	20.1
	Pneumonia cytomegaloviral	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pneumonia haemophilus	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonia influenzal	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pyelonephritis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pyelonephritis acute	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Renal tuberculosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sepsis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	4	3.1	1.2	7.7
	Septic shock	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Sinusitis bacterial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Tonsillitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Urinary tract infection	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	4	3.1	1.2	7.7

	Urosepsis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Viral infection	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Injury, poisoning and procedural complications	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	2	1.6	0.4	5.5
	Fracture	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Heart injury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Procedural pneumothorax	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Subdural haematoma	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Wrist fracture	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Investigations	-Total	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	4	3.1	1.2	7.7
	Alanine aminotransferase increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Aspartate aminotransferase increased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Bilirubin conjugated increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Blood creatine phosphokinase increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Electrocardiogram QT prolonged	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Hepatic enzyme increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lymphocyte count decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Platelet count decreased	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
Metabolism and nutrition disorders	-Total	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	7	5.4	2.7	10.8

	Decreased appetite	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dehydration	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Electrolyte imbalance	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Failure to thrive	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperkalaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hyperuricaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hypokalaemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hyponatraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Hypophosphataemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Musculoskeletal and connective tissue disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	8	6.2	3.2	11.8
	Back pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	3	2.3	0.8	6.6
	Intervertebral disc protrusion	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Muscle haemorrhage	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Muscular weakness	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Musculoskeletal pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pain in extremity	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Rhabdomyolysis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Cancer pain	Female	152	54.1	0	0.0	0.0	2.5

		Male	129	45.9	1	0.8	0.1	4.3
	Gallbladder cancer	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Tumour pain	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Nervous system disorders	-Total	Female	152	54.1	9	5.9	3.1	10.9
		Male	129	45.9	8	6.2	3.2	11.8
	Ataxia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cerebral haematoma	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Cerebrovascular accident	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Dizziness	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Epilepsy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Haemorrhage intracranial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lumbosacral radiculopathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Migraine	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neuralgia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Polyneuropathy chronic	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Presyncope	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Seizure	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	3	2.3	0.8	6.6
	Syncope	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Psychiatric disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	2	1.6	0.4	5.5
	Confusional state	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Mental status changes	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
Renal and urinary disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	4	3.1	1.2	7.7
	Acute kidney injury	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Haematuria	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Hydronephrosis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Nephrolithiasis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Obstructive nephropathy	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urethral stenosis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Urinary retention	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Reproductive system and breast disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Ovarian cyst	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Prostatitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Respiratory, thoracic and mediastinal disorders	-Total	Female	152	54.1	19	12.5	8.2	18.7
		Male	129	45.9	19	14.7	9.6	21.9
	Acute respiratory failure	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Dyspnoea	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	5	3.9	1.7	8.8
	Epistaxis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haemoptysis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypoxia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

	Interstitial lung disease	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Lung consolidation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pleural effusion	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	2	1.6	0.4	5.5
	Pneumonitis	Female	152	54.1	8	5.3	2.7	10.0
		Male	129	45.9	5	3.9	1.7	8.8
	Pneumothorax	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Pulmonary embolism	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	2	1.6	0.4	5.5
	Pulmonary hypertension	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Respiratory distress	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Respiratory failure	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Surgical and medical procedures	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Eye excision	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hip arthroplasty	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Vascular disorders	-Total	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	3	2.3	0.8	6.6
	Embolism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Haematoma	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Hypertension	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypotension	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Orthostatic hypotension	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Superior vena cava syndrome	Female	152	54.1	1	0.7	0.1	3.6

		Male	129	45.9	0	0.0	0.0	2.9

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AESAE_SG.xls
26MAR2021 13:59

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	45	16.0	12.2	20.8
Sex	Female	152	54.1	20	13.2	8.7	19.5
	Male	129	45.9	25	19.4	13.5	27.0
Age	< 65	176	62.6	21	11.9	7.9	17.6
	>= 65	105	37.4	24	22.9	15.9	31.8
ECOG performance status	0	84	29.9	10	11.9	6.6	20.5
	1	190	67.6	30	15.8	11.3	21.6
	2	6	2.1	5	83.3	43.6	97.0
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	7	10.9	5.4	20.9
	Europe (EU)	95	33.8	18	18.9	12.3	28.0
	Asia (AS)	122	43.4	20	16.4	10.9	24.0
Race/ethnicity	Asian	128	45.6	21	16.4	11.0	23.8
	Non-Asian	135	48.0	21	15.6	10.4	22.6
	Unknown	18	6.4	3	16.7	5.8	39.2
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	15	12.9	8.0	20.2
	1	77	27.4	12	15.6	9.1	25.3
	>= 2	88	31.3	18	20.5	13.3	30.0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AEDISC_SG.xls
26MAR2021 10:21

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	55	19.6	15.4	24.6
Sex	Female	152	54.1	25	16.4	11.4	23.2
	Male	129	45.9	30	23.3	16.8	31.3
Age	< 65	176	62.6	27	15.3	10.8	21.4
	>= 65	105	37.4	28	26.7	19.1	35.8
ECOG performance status	0	84	29.9	13	15.5	9.3	24.7
	1	190	67.6	37	19.5	14.5	25.7
	2	6	2.1	5	83.3	43.6	97.0
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	10	15.6	8.7	26.4
	Europe (EU)	95	33.8	20	21.1	14.1	30.3
	Asia (AS)	122	43.4	25	20.5	14.3	28.5
Race/ethnicity	Asian	128	45.6	26	20.3	14.3	28.1
	Non-Asian	135	48.0	26	19.3	13.5	26.7
	Unknown	18	6.4	3	16.7	5.8	39.2
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	17	14.7	9.4	22.2
	1	77	27.4	17	22.1	14.3	32.5
	>= 2	88	31.3	21	23.9	16.2	33.7

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw_B63_06NOV2020_SE_TO_AEDISC_SG.xls
26MAR2021 9:59

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	n/a	281	100.0	4	1.4	0.6	3.6
	Anaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Neutropenia	n/a	281	100.0	1	0.4	0.1	2.0
	Pancytopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombocytopenia	n/a	281	100.0	2	0.7	0.2	2.6
Cardiac disorders	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Cardio-respiratory arrest	n/a	281	100.0	1	0.4	0.1	2.0
	Pericardial effusion	n/a	281	100.0	1	0.4	0.1	2.0
Gastrointestinal disorders	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Colitis	n/a	281	100.0	1	0.4	0.1	2.0
	Constipation	n/a	281	100.0	1	0.4	0.1	2.0
	Stomatitis	n/a	281	100.0	1	0.4	0.1	2.0
General disorders and administration site conditions	-Total	n/a	281	100.0	7	2.5	1.2	5.1
	Asthenia	n/a	281	100.0	1	0.4	0.1	2.0
	Chest pain	n/a	281	100.0	1	0.4	0.1	2.0
	Death	n/a	281	100.0	2	0.7	0.2	2.6
	Fatigue	n/a	281	100.0	1	0.4	0.1	2.0
	Gait disturbance	n/a	281	100.0	1	0.4	0.1	2.0
	General physical health deterioration	n/a	281	100.0	1	0.4	0.1	2.0

Infections and infestations	-Total	n/a	281	100.0	12	4.3	2.5	7.3
	Clostridium difficile colitis	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia	n/a	281	100.0	7	2.5	1.2	5.1
	Sepsis	n/a	281	100.0	3	1.1	0.4	3.1
	Urosepsis	n/a	281	100.0	1	0.4	0.1	2.0
Injury, poisoning and procedural complications	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Heart injury	n/a	281	100.0	1	0.4	0.1	2.0
Investigations	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Blood creatine phosphokinase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Lymphocyte count decreased	n/a	281	100.0	1	0.4	0.1	2.0
Metabolism and nutrition disorders	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Electrolyte imbalance	n/a	281	100.0	1	0.4	0.1	2.0
	Hyponatraemia	n/a	281	100.0	1	0.4	0.1	2.0
Musculoskeletal and connective tissue disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Rhabdomyolysis	n/a	281	100.0	1	0.4	0.1	2.0
Nervous system disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Haemorrhage intracranial	n/a	281	100.0	1	0.4	0.1	2.0
Respiratory, thoracic and mediastinal disorders	-Total	n/a	281	100.0	12	4.3	2.5	7.3
	Dyspnoea	n/a	281	100.0	2	0.7	0.2	2.6
	Hypoxia	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonitis	n/a	281	100.0	7	2.5	1.2	5.1
	Pulmonary embolism	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory distress	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory failure	n/a	281	100.0	1	0.4	0.1	2.0
Surgical and medical procedures	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Therapy cessation	n/a	281	100.0	1	0.4	0.1	2.0

Vascular disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Embolism	n/a	281	100.0	1	0.4	0.1	2.0
	Hypertension	n/a	281	100.0	1	0.4	0.1	2.0
	Superior vena cava syndrome	n/a	281	100.0	1	0.4	0.1	2.0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEDISC_SG.xls
26MAR2021 14:41

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Anaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neutropenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pancytopenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Thrombocytopenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
Cardiac disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cardio-respiratory arrest	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pericardial effusion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Gastrointestinal disorders	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Colitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Constipation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Stomatitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
General disorders and administration site conditions	-Total	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	3	2.9	1.0	8.1

	Asthenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Chest pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Death	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Fatigue	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gait disturbance	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	General physical health deterioration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Infections and infestations	-Total	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Clostridium difficile colitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	3	2.9	1.0	8.1
	Sepsis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Urosepsis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Injury, poisoning and procedural complications	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Heart injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Investigations	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood creatine phosphokinase increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymphocyte count decreased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Metabolism and nutrition disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Electrolyte imbalance	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyponatraemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Musculoskeletal and connective tissue disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rhabdomyolysis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Nervous system disorders	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haemorrhage intracranial	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Respiratory, thoracic and mediastinal disorders	-Total	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	6	5.7	2.6	11.9
	Dyspnoea	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypoxia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pneumonitis	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	3	2.9	1.0	8.1
	Pulmonary embolism	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory distress	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory failure	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Surgical and medical procedures	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Therapy cessation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Vascular disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Embolism	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

	Hypertension	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Superior vena cava syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEDISC_SG.xls
26MAR2021 14:41

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutropenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Cardiac disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cardio-respiratory arrest	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pericardial effusion	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
Gastrointestinal disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Colitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Constipation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Stomatitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
General disorders and administration site conditions	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Asthenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Death	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fatigue	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Gait disturbance	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	General physical health deterioration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Infections and infestations	-Total	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Clostridium difficile colitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sepsis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Urosepsis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Injury, poisoning and procedural complications	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Heart injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Investigations	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Blood creatine phosphokinase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Lymphocyte count decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Metabolism and nutrition disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrolyte imbalance	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyponatraemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Musculoskeletal and connective tissue disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhabdomyolysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Nervous system disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhage intracranial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Respiratory, thoracic and mediastinal disorders	-Total	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoxia	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonitis	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary embolism	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory distress	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Surgical and medical procedures	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Therapy cessation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Vascular disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertension	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Superior vena cava syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEDISC_SG.xls
26MAR2021 14:41

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Anaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neutropenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pancytopenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thrombocytopenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
Cardiac disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cardio-respiratory arrest	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pericardial effusion	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Gastrointestinal disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Colitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Constipation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Stomatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
General disorders and administration site conditions	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Asthenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Chest pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Death	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Fatigue	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gait disturbance	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	General physical health deterioration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Infections and infestations	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Clostridium difficile colitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Sepsis	USA	64	22.8	1	1.6	0.3	8.3

		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Urosepsis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Injury, poisoning and procedural complications	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Heart injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Investigations	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood creatine phosphokinase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymphocyte count decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Metabolism and nutrition disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Electrolyte imbalance	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyponatraemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Musculoskeletal and connective tissue disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rhabdomyolysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Nervous system disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Haemorrhage intracranial	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Respiratory, thoracic and mediastinal disorders	-Total	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Dyspnoea	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypoxia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Pulmonary embolism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory distress	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory failure	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Surgical and medical procedures	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Therapy cessation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Vascular disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Embolism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Hypertension	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Superior vena cava syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEDISC_SG.xls
26MAR2021 14:41

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Anaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Neutropenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pancytopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Thrombocytopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
Cardiac disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Cardio-respiratory arrest	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pericardial effusion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Gastrointestinal disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Colitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1	0.2	6.2
	Constipation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Stomatitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
General disorders and administration site conditions	-Total	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Asthenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Chest pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Death	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Fatigue	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gait disturbance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	General physical health deterioration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Infections and infestations	-Total	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	6	6.8	3.2	14.1
	Clostridium difficile colitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonia	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Sepsis	0	116	41.3	0	0.0	0.0	3.2

		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Urosepsis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Injury, poisoning and procedural complications	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Heart injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Investigations	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood creatine phosphokinase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymphocyte count decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Metabolism and nutrition disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Electrolyte imbalance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyponatraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Musculoskeletal and connective tissue disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhabdomyolysis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Nervous system disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Haemorrhage intracranial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Respiratory, thoracic and mediastinal disorders	-Total	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Dyspnoea	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypoxia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonitis	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pulmonary embolism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiratory distress	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Respiratory failure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Surgical and medical procedures	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Therapy cessation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Vascular disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Embolism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hypertension	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2

	Superior vena cava syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEDISC_SG.xls
26MAR2021 14:41

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anaemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutropenia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancytopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytopenia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Cardiac disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cardio-respiratory arrest	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pericardial effusion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Gastrointestinal disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Constipation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Stomatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
General disorders and administration site conditions	-Total	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Asthenia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chest pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Death	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fatigue	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gait disturbance	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	General physical health deterioration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Infections and infestations	-Total	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Clostridium difficile colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sepsis	Asian	128	45.6	2	1.6	0.4	5.5

		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urosepsis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Injury, poisoning and procedural complications	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Heart injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Investigations	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Blood creatine phosphokinase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Lymphocyte count decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Metabolism and nutrition disorders	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrolyte imbalance	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyponatraemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Musculoskeletal and connective tissue disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhabdomyolysis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Nervous system disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Haemorrhage intracranial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Respiratory, thoracic and mediastinal disorders	-Total	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Dyspnoea	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoxia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumonitis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pulmonary embolism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory distress	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Respiratory failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Surgical and medical procedures	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Therapy cessation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Vascular disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Embolism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypertension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Superior vena cava syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEDISC_SG.xls
26MAR2021 14:41

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Anaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neutropenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pancytopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombocytopenia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
Cardiac disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cardio-respiratory arrest	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pericardial effusion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Gastrointestinal disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Colitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Constipation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Stomatitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
General disorders and administration site conditions	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	5	3.9	1.7	8.8

	Asthenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Chest pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Death	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Fatigue	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gait disturbance	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	General physical health deterioration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Infections and infestations	-Total	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	6	4.7	2.1	9.8
	Clostridium difficile colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pneumonia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	5	3.9	1.7	8.8
	Sepsis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Urosepsis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Injury, poisoning and procedural complications	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Heart injury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Investigations	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Blood creatine phosphokinase increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lymphocyte count decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Metabolism and nutrition disorders	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9

	Electrolyte imbalance	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hyponatraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Musculoskeletal and connective tissue disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rhabdomyolysis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Nervous system disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Haemorrhage intracranial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Respiratory, thoracic and mediastinal disorders	-Total	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	7	5.4	2.7	10.8
	Dyspnoea	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Hypoxia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonitis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Pulmonary embolism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Respiratory distress	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Respiratory failure	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Surgical and medical procedures	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Therapy cessation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Vascular disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9
	Embolism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

	Hypertension	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Superior vena cava syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp2_B63_06NOV2020_SE_TO_AEDISC_SG.xls
26MAR2021 14:41

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	n/a	281	100.0	4	1.4	0.6	3.6
	Anaemia	n/a	281	100.0	1	0.4	0.1	2.0
	Neutropenia	n/a	281	100.0	1	0.4	0.1	2.0
	Pancytopenia	n/a	281	100.0	1	0.4	0.1	2.0
	Thrombocytopenia	n/a	281	100.0	2	0.7	0.2	2.6
Cardiac disorders	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Cardio-respiratory arrest	n/a	281	100.0	1	0.4	0.1	2.0
	Pericardial effusion	n/a	281	100.0	1	0.4	0.1	2.0
Gastrointestinal disorders	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Colitis	n/a	281	100.0	1	0.4	0.1	2.0
	Constipation	n/a	281	100.0	1	0.4	0.1	2.0
	Stomatitis	n/a	281	100.0	1	0.4	0.1	2.0
General disorders and administration site conditions	-Total	n/a	281	100.0	17	6.0	3.8	9.5
	Asthenia	n/a	281	100.0	1	0.4	0.1	2.0
	Chest pain	n/a	281	100.0	1	0.4	0.1	2.0
	Death	n/a	281	100.0	2	0.7	0.2	2.6
	Disease progression	n/a	281	100.0	10	3.6	1.9	6.4
	Fatigue	n/a	281	100.0	1	0.4	0.1	2.0
	Gait disturbance	n/a	281	100.0	1	0.4	0.1	2.0

	General physical health deterioration	n/a	281	100.0	1	0.4	0.1	2.0
Infections and infestations	-Total	n/a	281	100.0	12	4.3	2.5	7.3
	Clostridium difficile colitis	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonia	n/a	281	100.0	7	2.5	1.2	5.1
	Sepsis	n/a	281	100.0	3	1.1	0.4	3.1
	Urosepsis	n/a	281	100.0	1	0.4	0.1	2.0
Injury, poisoning and procedural complications	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Heart injury	n/a	281	100.0	1	0.4	0.1	2.0
Investigations	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Blood creatine phosphokinase increased	n/a	281	100.0	1	0.4	0.1	2.0
	Lymphocyte count decreased	n/a	281	100.0	1	0.4	0.1	2.0
Metabolism and nutrition disorders	-Total	n/a	281	100.0	2	0.7	0.2	2.6
	Electrolyte imbalance	n/a	281	100.0	1	0.4	0.1	2.0
	Hyponatraemia	n/a	281	100.0	1	0.4	0.1	2.0
Musculoskeletal and connective tissue disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Rhabdomyolysis	n/a	281	100.0	1	0.4	0.1	2.0
Nervous system disorders	-Total	n/a	281	100.0	1	0.4	0.1	2.0
	Haemorrhage intracranial	n/a	281	100.0	1	0.4	0.1	2.0
Respiratory, thoracic and mediastinal disorders	-Total	n/a	281	100.0	12	4.3	2.5	7.3
	Dyspnoea	n/a	281	100.0	2	0.7	0.2	2.6
	Hypoxia	n/a	281	100.0	1	0.4	0.1	2.0
	Pneumonitis	n/a	281	100.0	7	2.5	1.2	5.1
	Pulmonary embolism	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory distress	n/a	281	100.0	1	0.4	0.1	2.0
	Respiratory failure	n/a	281	100.0	1	0.4	0.1	2.0
Surgical and medical procedures	-Total	n/a	281	100.0	1	0.4	0.1	2.0

	Therapy cessation	n/a	281	100.0	1	0.4	0.1	2.0
Vascular disorders	-Total	n/a	281	100.0	3	1.1	0.4	3.1
	Embolism	n/a	281	100.0	1	0.4	0.1	2.0
	Hypertension	n/a	281	100.0	1	0.4	0.1	2.0
	Superior vena cava syndrome	n/a	281	100.0	1	0.4	0.1	2.0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEDISC_SG.xls
26MAR2021 14:02

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	3	2.9	1.0	8.1
	Anaemia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Neutropenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pancytopenia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Thrombocytopenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
Cardiac disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Cardio-respiratory arrest	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pericardial effusion	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Gastrointestinal disorders	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Colitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Constipation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Stomatitis	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
General disorders and administration site conditions	-Total	< 65	176	62.6	10	5.7	3.1	10.1
		>= 65	105	37.4	7	6.7	3.3	13.1

	Asthenia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Chest pain	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Death	< 65	176	62.6	2	1.1	0.3	4.0
		>= 65	105	37.4	0	0.0	0.0	3.5
	Disease progression	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	4	3.8	1.5	9.4
	Fatigue	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Gait disturbance	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	General physical health deterioration	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Infections and infestations	-Total	< 65	176	62.6	7	4.0	1.9	8.0
		>= 65	105	37.4	5	4.8	2.1	10.7
	Clostridium difficile colitis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Pneumonia	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	3	2.9	1.0	8.1
	Sepsis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Urosepsis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Injury, poisoning and procedural complications	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Heart injury	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Investigations	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	2	1.9	0.5	6.7
	Blood creatine phosphokinase increased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Lymphocyte count decreased	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2

Metabolism and nutrition disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Electrolyte imbalance	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hyponatraemia	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Musculoskeletal and connective tissue disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
	Rhabdomyolysis	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Nervous system disorders	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Haemorrhage intracranial	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Respiratory, thoracic and mediastinal disorders	-Total	< 65	176	62.6	6	3.4	1.6	7.2
		>= 65	105	37.4	6	5.7	2.6	11.9
	Dyspnoea	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypoxia	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Pneumonitis	< 65	176	62.6	4	2.3	0.9	5.7
		>= 65	105	37.4	3	2.9	1.0	8.1
	Pulmonary embolism	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory distress	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Respiratory failure	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5
Surgical and medical procedures	-Total	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Therapy cessation	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
Vascular disorders	-Total	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	2	1.9	0.5	6.7

	Embolism	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Hypertension	< 65	176	62.6	0	0.0	0.0	2.1
		>= 65	105	37.4	1	1.0	0.2	5.2
	Superior vena cava syndrome	< 65	176	62.6	1	0.6	0.1	3.1
		>= 65	105	37.4	0	0.0	0.0	3.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEDISC_SG.xls
26MAR2021 14:02

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Anaemia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Neutropenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pancytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Thrombocytopenia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Cardiac disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Cardio-respiratory arrest	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pericardial effusion	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0

		Missing	1	0.4	0	0.0	0.0	79.3
Gastrointestinal disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Colitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Constipation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Stomatitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
General disorders and administration site conditions	-Total	0	84	29.9	4	4.8	1.9	11.6
		1	190	67.6	13	6.8	4.0	11.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Asthenia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Chest pain	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Death	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Disease progression	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	7	3.7	1.8	7.4
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Fatigue	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Gait disturbance	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	General physical health deterioration	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Infections and infestations	-Total	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	6	3.2	1.5	6.7
		2	6	2.1	3	50.0	18.8	81.2
		Missing	1	0.4	0	0.0	0.0	79.3
	Clostridium difficile colitis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonia	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	2	33.3	9.7	70.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Sepsis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Urosepsis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Injury, poisoning and procedural complications	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Heart injury	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Investigations	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	2	1.1	0.3	3.8
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

	Blood creatine phosphokinase increased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Lymphocyte count decreased	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Metabolism and nutrition disorders	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Electrolyte imbalance	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hyponatraemia	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Musculoskeletal and connective tissue disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Rhabdomyolysis	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Nervous system disorders	-Total	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Haemorrhage intracranial	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Respiratory, thoracic and mediastinal disorders	-Total	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	8	4.2	2.1	8.1
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Dyspnoea	0	84	29.9	0	0.0	0.0	4.4

		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	1	16.7	3.0	56.4
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypoxia	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pneumonitis	0	84	29.9	3	3.6	1.2	10.0
		1	190	67.6	4	2.1	0.8	5.3
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Pulmonary embolism	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory distress	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Respiratory failure	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Surgical and medical procedures	-Total	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Therapy cessation	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
Vascular disorders	-Total	0	84	29.9	2	2.4	0.7	8.3
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Embolism	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Hypertension	0	84	29.9	1	1.2	0.2	6.4
		1	190	67.6	0	0.0	0.0	2.0

		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3
	Superior vena cava syndrome	0	84	29.9	0	0.0	0.0	4.4
		1	190	67.6	1	0.5	0.1	2.9
		2	6	2.1	0	0.0	0.0	39.0
		Missing	1	0.4	0	0.0	0.0	79.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEDISC_SG.xls
26MAR2021 14:02

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Anaemia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Neutropenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pancytopenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Thrombocytopenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
Cardiac disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Cardio-respiratory arrest	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Pericardial effusion	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Gastrointestinal disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Colitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7

		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Constipation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Stomatitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
General disorders and administration site conditions	-Total	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	9	7.4	3.9	13.4
	Asthenia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Chest pain	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Death	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Disease progression	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	5	4.1	1.8	9.2
	Fatigue	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Gait disturbance	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	General physical health deterioration	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Infections and infestations	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	4	4.2	1.6	10.3
		Asia (AS)	122	43.4	7	5.7	2.8	11.4
	Clostridium difficile colitis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonia	USA	64	22.8	0	0.0	0.0	5.7

		Europe (EU)	95	33.8	3	3.2	1.1	8.9
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Sepsis	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Urosepsis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Injury, poisoning and procedural complications	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Heart injury	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Investigations	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Blood creatine phosphokinase increased	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Lymphocyte count decreased	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Metabolism and nutrition disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	2	1.6	0.5	5.8
	Electrolyte imbalance	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hyponatraemia	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
Musculoskeletal and connective tissue disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Rhabdomyolysis	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

Nervous system disorders	-Total	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Haemorrhage intracranial	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Respiratory, thoracic and mediastinal disorders	-Total	USA	64	22.8	3	4.7	1.6	12.9
		Europe (EU)	95	33.8	5	5.3	2.3	11.7
		Asia (AS)	122	43.4	4	3.3	1.3	8.1
	Dyspnoea	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Hypoxia	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Pneumonitis	USA	64	22.8	2	3.1	0.9	10.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	3	2.5	0.8	7.0
	Pulmonary embolism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory distress	USA	64	22.8	1	1.6	0.3	8.3
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Respiratory failure	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Surgical and medical procedures	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Therapy cessation	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
Vascular disorders	-Total	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	2	2.1	0.6	7.4
		Asia (AS)	122	43.4	1	0.8	0.1	4.5
	Embolism	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1

	Hypertension	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	1	1.1	0.2	5.7
		Asia (AS)	122	43.4	0	0.0	0.0	3.1
	Superior vena cava syndrome	USA	64	22.8	0	0.0	0.0	5.7
		Europe (EU)	95	33.8	0	0.0	0.0	3.9
		Asia (AS)	122	43.4	1	0.8	0.1	4.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEDISC_SG.xls
26MAR2021 14:02

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Anaemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Neutropenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Pancytopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Thrombocytopenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
Cardiac disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Cardio-respiratory arrest	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pericardial effusion	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Gastrointestinal disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	2	2.3	0.6	7.9
	Colitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8

		>= 2	88	31.3	1	1.1	0.2	6.2
	Constipation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Stomatitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
General disorders and administration site conditions	-Total	0	116	41.3	5	4.3	1.9	9.7
		1	77	27.4	8	10.4	5.4	19.2
		>= 2	88	31.3	4	4.5	1.8	11.1
	Asthenia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Chest pain	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Death	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Disease progression	0	116	41.3	2	1.7	0.5	6.1
		1	77	27.4	5	6.5	2.8	14.3
		>= 2	88	31.3	3	3.4	1.2	9.5
	Fatigue	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Gait disturbance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	General physical health deterioration	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Infections and infestations	-Total	0	116	41.3	3	2.6	0.9	7.3
		1	77	27.4	3	3.9	1.3	10.8
		>= 2	88	31.3	6	6.8	3.2	14.1
	Clostridium difficile colitis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonia	0	116	41.3	3	2.6	0.9	7.3

		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Sepsis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	2	2.3	0.6	7.9
	Urosepsis	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
Injury, poisoning and procedural complications	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Heart injury	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Investigations	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Blood creatine phosphokinase increased	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Lymphocyte count decreased	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Metabolism and nutrition disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Electrolyte imbalance	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Hyponatraemia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Musculoskeletal and connective tissue disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Rhabdomyolysis	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

Nervous system disorders	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Haemorrhage intracranial	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Respiratory, thoracic and mediastinal disorders	-Total	0	116	41.3	7	6.0	3.0	11.9
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	3	3.4	1.2	9.5
	Dyspnoea	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Hypoxia	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pneumonitis	0	116	41.3	4	3.4	1.3	8.5
		1	77	27.4	2	2.6	0.7	9.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Pulmonary embolism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
	Respiratory distress	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2
	Respiratory failure	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2
Surgical and medical procedures	-Total	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Therapy cessation	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
Vascular disorders	-Total	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	1	1.1	0.2	6.2
	Embolism	0	116	41.3	1	0.9	0.2	4.7
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	0	0.0	0.0	4.2

	Hypertension	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	1	1.3	0.2	7.0
		>= 2	88	31.3	0	0.0	0.0	4.2
	Superior vena cava syndrome	0	116	41.3	0	0.0	0.0	3.2
		1	77	27.4	0	0.0	0.0	4.8
		>= 2	88	31.3	1	1.1	0.2	6.2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEDISC_SG.xls
26MAR2021 14:02

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Anaemia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Neutropenia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pancytopenia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Thrombocytopenia	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Cardiac disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Cardio-respiratory arrest	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pericardial effusion	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Gastrointestinal disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1

		Unknown	18	6.4	0	0.0	0.0	17.6
	Constipation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Stomatitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
General disorders and administration site conditions	-Total	Asian	128	45.6	9	7.0	3.7	12.8
		Non-Asian	135	48.0	8	5.9	3.0	11.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Asthenia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Chest pain	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Death	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Disease progression	Asian	128	45.6	5	3.9	1.7	8.8
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Fatigue	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Gait disturbance	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	General physical health deterioration	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Infections and infestations	-Total	Asian	128	45.6	7	5.5	2.7	10.9
		Non-Asian	135	48.0	5	3.7	1.6	8.4
		Unknown	18	6.4	0	0.0	0.0	17.6
	Clostridium difficile colitis	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Pneumonia	Asian	128	45.6	4	3.1	1.2	7.8

		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	0	0.0	0.0	17.6
	Sepsis	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Urosepsis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Injury, poisoning and procedural complications	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Heart injury	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Investigations	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Blood creatine phosphokinase increased	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Lymphocyte count decreased	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Metabolism and nutrition disorders	-Total	Asian	128	45.6	2	1.6	0.4	5.5
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Electrolyte imbalance	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hyponatraemia	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
Musculoskeletal and connective tissue disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6
	Rhabdomyolysis	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

Nervous system disorders	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Haemorrhage intracranial	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Respiratory, thoracic and mediastinal disorders	-Total	Asian	128	45.6	4	3.1	1.2	7.8
		Non-Asian	135	48.0	6	4.4	2.1	9.4
		Unknown	18	6.4	2	11.1	3.1	32.8
	Dyspnoea	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Hypoxia	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pneumonitis	Asian	128	45.6	3	2.3	0.8	6.7
		Non-Asian	135	48.0	3	2.2	0.8	6.3
		Unknown	18	6.4	1	5.6	1.0	25.8
	Pulmonary embolism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Respiratory distress	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	1	5.6	1.0	25.8
	Respiratory failure	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Surgical and medical procedures	-Total	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Therapy cessation	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
Vascular disorders	-Total	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	2	1.5	0.4	5.2
		Unknown	18	6.4	0	0.0	0.0	17.6
	Embolism	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6

	Hypertension	Asian	128	45.6	0	0.0	0.0	2.9
		Non-Asian	135	48.0	1	0.7	0.1	4.1
		Unknown	18	6.4	0	0.0	0.0	17.6
	Superior vena cava syndrome	Asian	128	45.6	1	0.8	0.1	4.3
		Non-Asian	135	48.0	0	0.0	0.0	2.8
		Unknown	18	6.4	0	0.0	0.0	17.6

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEDISC_SG.xls
26MAR2021 14:02

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

			400 mg QD (N=281)					
			Patients		Patients with Event			
SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
Blood and lymphatic system disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	1	0.8	0.1	4.3
	Anaemia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Neutropenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pancytopenia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Thrombocytopenia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
Cardiac disorders	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	1	0.8	0.1	4.3
	Cardio-respiratory arrest	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pericardial effusion	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Gastrointestinal disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Colitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Constipation	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Stomatitis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
General disorders and administration site conditions	-Total	Female	152	54.1	7	4.6	2.2	9.2
		Male	129	45.9	10	7.8	4.3	13.7

	Asthenia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Chest pain	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Death	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Disease progression	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	5	3.9	1.7	8.8
	Fatigue	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Gait disturbance	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	General physical health deterioration	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Infections and infestations	-Total	Female	152	54.1	6	3.9	1.8	8.3
		Male	129	45.9	6	4.7	2.1	9.8
	Clostridium difficile colitis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Pneumonia	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	5	3.9	1.7	8.8
	Sepsis	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	1	0.8	0.1	4.3
	Urosepsis	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Injury, poisoning and procedural complications	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Heart injury	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Investigations	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Blood creatine phosphokinase increased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Lymphocyte count decreased	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3

Metabolism and nutrition disorders	-Total	Female	152	54.1	2	1.3	0.4	4.7
		Male	129	45.9	0	0.0	0.0	2.9
	Electrolyte imbalance	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hyponatraemia	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Musculoskeletal and connective tissue disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Rhabdomyolysis	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Nervous system disorders	-Total	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Haemorrhage intracranial	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Respiratory, thoracic and mediastinal disorders	-Total	Female	152	54.1	5	3.3	1.4	7.5
		Male	129	45.9	7	5.4	2.7	10.8
	Dyspnoea	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	2	1.6	0.4	5.5
	Hypoxia	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Pneumonitis	Female	152	54.1	4	2.6	1.0	6.6
		Male	129	45.9	3	2.3	0.8	6.6
	Pulmonary embolism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Respiratory distress	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
	Respiratory failure	Female	152	54.1	0	0.0	0.0	2.5
		Male	129	45.9	1	0.8	0.1	4.3
Surgical and medical procedures	-Total	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Therapy cessation	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
Vascular disorders	-Total	Female	152	54.1	3	2.0	0.7	5.6
		Male	129	45.9	0	0.0	0.0	2.9

	Embolism	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Hypertension	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9
	Superior vena cava syndrome	Female	152	54.1	1	0.7	0.1	3.6
		Male	129	45.9	0	0.0	0.0	2.9

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_rsp_B63_06NOV2020_SE_TO_AEDISC_SG.xls
26MAR2021 14:02

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Pneumonitis - Grade 1 or Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	30	10,7	7,6	14,8
Sex	Female	152	54,1	20	13,2	8,7	19,5
	Male	129	45,9	10	7,8	4,3	13,7
Age	< 65	176	62,6	21	11,9	7,9	17,6
	>= 65	105	37,4	9	8,6	4,6	15,5
ECOG performance status	0	84	29,9	14	16,7	10,2	26,1
	1	190	67,6	15	7,9	4,8	12,6
	2	6	2,1	1	16,7	3,0	56,4
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	8	12,5	6,5	22,8
	Europe (EU)	95	33,8	7	7,4	3,6	14,4
	Asia (AS)	122	43,4	15	12,3	7,6	19,3
Race/ethnicity	Asian	128	45,6	15	11,7	7,2	18,4
	Non-Asian	135	48,0	14	10,4	6,3	16,7
	Unknown	18	6,4	1	5,6	1,0	25,8
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	8	6,9	3,5	13,0
	1	77	27,4	9	11,7	6,3	20,7
	>= 2	88	31,3	13	14,8	8,8	23,7

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw2_B63_06NOV2020_SE_TO_APNS12_SG.xls
07MAY2021 11:39

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Pneumonitis - Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	6	2,1	1,0	4,6
Sex	Female	152	54,1	2	1,3	0,4	4,7
	Male	129	45,9	4	3,1	1,2	7,7
Age	< 65	176	62,6	2	1,1	0,3	4,0
	>= 65	105	37,4	4	3,8	1,5	9,4
ECOG performance status	0	84	29,9	1	1,2	0,2	6,4
	1	190	67,6	5	2,6	1,1	6,0
	2	6	2,1	0	0,0	0,0	39,0
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	0	0,0	0,0	5,7
	Europe (EU)	95	33,8	3	3,2	1,1	8,9
	Asia (AS)	122	43,4	3	2,5	0,8	7,0
Race/ethnicity	Asian	128	45,6	3	2,3	0,8	6,7
	Non-Asian	135	48,0	2	1,5	0,4	5,2
	Unknown	18	6,4	1	5,6	1,0	25,8
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	3	2,6	0,9	7,3
	1	77	27,4	2	2,6	0,7	9,0
	>= 2	88	31,3	1	1,1	0,2	6,2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw2_B63_06NOV2020_SE_TO_APNS345_SG.xls
07MAY2021 11:40

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Pneumonitis - SAEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	15	5,3	3,3	8,6
Sex	Female	152	54,1	9	5,9	3,1	10,9
	Male	129	45,9	6	4,7	2,1	9,8
Age	< 65	176	62,6	9	5,1	2,7	9,4
	>= 65	105	37,4	6	5,7	2,6	11,9
ECOG performance status	0	84	29,9	4	4,8	1,9	11,6
	1	190	67,6	11	5,8	3,3	10,1
	2	6	2,1	0	0,0	0,0	39,0
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	0	0,0	0,0	5,7
	Europe (EU)	95	33,8	5	5,3	2,3	11,7
	Asia (AS)	122	43,4	10	8,2	4,5	14,4
Race/ethnicity	Asian	128	45,6	10	7,8	4,3	13,8
	Non-Asian	135	48,0	4	3,0	1,2	7,4
	Unknown	18	6,4	1	5,6	1,0	25,8
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	7	6,0	3,0	11,9
	1	77	27,4	5	6,5	2,8	14,3
	>= 2	88	31,3	3	3,4	1,2	9,5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw2_B63_06NOV2020_SE_TO_APNSSAE_SG.xls
07MAY2021 11:41

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Pneumonitis
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	36	12,8	9,4	17,2
Sex	Female	152	54,1	22	14,5	9,8	20,9
	Male	129	45,9	14	10,9	6,6	17,4
Age	< 65	176	62,6	23	13,1	8,9	18,8
	>= 65	105	37,4	13	12,4	7,4	20,0
ECOG performance status	0	84	29,9	15	17,9	11,1	27,4
	1	190	67,6	20	10,5	6,9	15,7
	2	6	2,1	1	16,7	3,0	56,4
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	8	12,5	6,5	22,8
	Europe (EU)	95	33,8	10	10,5	5,8	18,3
	Asia (AS)	122	43,4	18	14,8	9,5	22,1
Race/ethnicity	Asian	128	45,6	18	14,1	9,1	21,1
	Non-Asian	135	48,0	16	11,9	7,4	18,4
	Unknown	18	6,4	2	11,1	3,1	32,8
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	11	9,5	5,4	16,2
	1	77	27,4	11	14,3	8,2	23,8
	>= 2	88	31,3	14	15,9	9,7	25,0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas

Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw2_B63_06NOV2020_SE_TO_APNS_SG.xls
07MAY2021 11:39

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Pneumonitis - Grade 1 or Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	30	10,7	7,6	14,8
Sex	Female	152	54,1	20	13,2	8,7	19,5
	Male	129	45,9	10	7,8	4,3	13,7
Age	< 65	176	62,6	21	11,9	7,9	17,6
	>= 65	105	37,4	9	8,6	4,6	15,5
ECOG performance status	0	84	29,9	14	16,7	10,2	26,1
	1	190	67,6	15	7,9	4,8	12,6
	2	6	2,1	1	16,7	3,0	56,4
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	8	12,5	6,5	22,8
	Europe (EU)	95	33,8	7	7,4	3,6	14,4
	Asia (AS)	122	43,4	15	12,3	7,6	19,3
Race/ethnicity	Asian	128	45,6	15	11,7	7,2	18,4
	Non-Asian	135	48,0	14	10,4	6,3	16,7
	Unknown	18	6,4	1	5,6	1,0	25,8
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	8	6,9	3,5	13,0
	1	77	27,4	9	11,7	6,3	20,7
	>= 2	88	31,3	13	14,8	8,8	23,7

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw_B63_06NOV2020_SE_TO_APNS12_SG.xls
07MAY2021 11:20

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Pneumonitis - Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	6	2,1	1,0	4,6
Sex	Female	152	54,1	2	1,3	0,4	4,7
	Male	129	45,9	4	3,1	1,2	7,7
Age	< 65	176	62,6	2	1,1	0,3	4,0
	>= 65	105	37,4	4	3,8	1,5	9,4
ECOG performance status	0	84	29,9	1	1,2	0,2	6,4
	1	190	67,6	5	2,6	1,1	6,0
	2	6	2,1	0	0,0	0,0	39,0
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	0	0,0	0,0	5,7
	Europe (EU)	95	33,8	3	3,2	1,1	8,9
	Asia (AS)	122	43,4	3	2,5	0,8	7,0
Race/ethnicity	Asian	128	45,6	3	2,3	0,8	6,7
	Non-Asian	135	48,0	2	1,5	0,4	5,2
	Unknown	18	6,4	1	5,6	1,0	25,8
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	3	2,6	0,9	7,3
	1	77	27,4	2	2,6	0,7	9,0
	>= 2	88	31,3	1	1,1	0,2	6,2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw_B63_06NOV2020_SE_TO_APNS345_SG.xls
07MAY2021 11:21

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Pneumonitis - SAEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	15	5,3	3,3	8,6
Sex	Female	152	54,1	9	5,9	3,1	10,9
	Male	129	45,9	6	4,7	2,1	9,8
Age	< 65	176	62,6	9	5,1	2,7	9,4
	>= 65	105	37,4	6	5,7	2,6	11,9
ECOG performance status	0	84	29,9	4	4,8	1,9	11,6
	1	190	67,6	11	5,8	3,3	10,1
	2	6	2,1	0	0,0	0,0	39,0
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	0	0,0	0,0	5,7
	Europe (EU)	95	33,8	5	5,3	2,3	11,7
	Asia (AS)	122	43,4	10	8,2	4,5	14,4
Race/ethnicity	Asian	128	45,6	10	7,8	4,3	13,8
	Non-Asian	135	48,0	4	3,0	1,2	7,4
	Unknown	18	6,4	1	5,6	1,0	25,8
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	7	6,0	3,0	11,9
	1	77	27,4	5	6,5	2,8	14,3
	>= 2	88	31,3	3	3,4	1,2	9,5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw_B63_06NOV2020_SE_TO_APNSSAE_SG.xls
07MAY2021 11:21

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Pneumonitis
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	36	12,8	9,4	17,2
Sex	Female	152	54,1	22	14,5	9,8	20,9
	Male	129	45,9	14	10,9	6,6	17,4
Age	< 65	176	62,6	23	13,1	8,9	18,8
	>= 65	105	37,4	13	12,4	7,4	20,0
ECOG performance status	0	84	29,9	15	17,9	11,1	27,4
	1	190	67,6	20	10,5	6,9	15,7
	2	6	2,1	1	16,7	3,0	56,4
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	8	12,5	6,5	22,8
	Europe (EU)	95	33,8	10	10,5	5,8	18,3
	Asia (AS)	122	43,4	18	14,8	9,5	22,1
Race/ethnicity	Asian	128	45,6	18	14,1	9,1	21,1
	Non-Asian	135	48,0	16	11,9	7,4	18,4
	Unknown	18	6,4	2	11,1	3,1	32,8
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	11	9,5	5,4	16,2
	1	77	27,4	11	14,3	8,2	23,8
	>= 2	88	31,3	14	15,9	9,7	25,0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw_B63_06NOV2020_SE_TO_APNS_SG.xls
07MAY2021 11:20

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Hypertension - Grade 1 or Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	52	18,5	14,4	23,5
Sex	Female	152	54,1	25	16,4	11,4	23,2
	Male	129	45,9	27	20,9	14,8	28,7
Age	< 65	176	62,6	31	17,6	12,7	23,9
	>= 65	105	37,4	21	20,0	13,5	28,6
ECOG performance status	0	84	29,9	12	14,3	8,4	23,3
	1	190	67,6	39	20,5	15,4	26,8
	2	6	2,1	1	16,7	3,0	56,4
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	10	15,6	8,7	26,4
	Europe (EU)	95	33,8	14	14,7	9,0	23,2
	Asia (AS)	122	43,4	28	23,0	16,4	31,2
Race/ethnicity	Asian	128	45,6	30	23,4	16,9	31,5
	Non-Asian	135	48,0	19	14,1	9,2	20,9
	Unknown	18	6,4	3	16,7	5,8	39,2
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	16	13,8	8,7	21,2
	1	77	27,4	14	18,2	11,2	28,2
	>= 2	88	31,3	22	25,0	17,1	35,0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AHYP12_SG.xls
07MAY2021 11:42

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Hypertension - Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	45	16,0	12,2	20,8
Sex	Female	152	54,1	27	17,8	12,5	24,6
	Male	129	45,9	18	14,0	9,0	21,0
Age	< 65	176	62,6	16	9,1	5,7	14,3
	>= 65	105	37,4	29	27,6	20,0	36,8
ECOG performance status	0	84	29,9	17	20,2	13,0	30,0
	1	190	67,6	27	14,2	10,0	19,9
	2	6	2,1	1	16,7	3,0	56,4
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	15	23,4	14,7	35,1
	Europe (EU)	95	33,8	10	10,5	5,8	18,3
	Asia (AS)	122	43,4	20	16,4	10,9	24,0
Race/ethnicity	Asian	128	45,6	21	16,4	11,0	23,8
	Non-Asian	135	48,0	24	17,8	12,2	25,1
	Unknown	18	6,4	0	0,0	0,0	17,6
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	17	14,7	9,4	22,2
	1	77	27,4	14	18,2	11,2	28,2
	>= 2	88	31,3	14	15,9	9,7	25,0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AHYP345_SG.xls
07MAY2021 11:43

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Hypertension - SAEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	4	1,4	0,6	3,6
Sex	Female	152	54,1	4	2,6	1,0	6,6
	Male	129	45,9	0	0,0	0,0	2,9
Age	< 65	176	62,6	2	1,1	0,3	4,0
	>= 65	105	37,4	2	1,9	0,5	6,7
ECOG performance status	0	84	29,9	2	2,4	0,7	8,3
	1	190	67,6	2	1,1	0,3	3,8
	2	6	2,1	0	0,0	0,0	39,0
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	0	0,0	0,0	5,7
	Europe (EU)	95	33,8	2	2,1	0,6	7,4
	Asia (AS)	122	43,4	2	1,6	0,5	5,8
Race/ethnicity	Asian	128	45,6	2	1,6	0,4	5,5
	Non-Asian	135	48,0	2	1,5	0,4	5,2
	Unknown	18	6,4	0	0,0	0,0	17,6
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	0	0,0	0,0	3,2
	1	77	27,4	2	2,6	0,7	9,0
	>= 2	88	31,3	2	2,3	0,6	7,9

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AHYPSAE_SG.xls
07MAY2021 11:43

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Hypertension
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	97	34,5	29,2	40,3
Sex	Female	152	54,1	52	34,2	27,1	42,1
	Male	129	45,9	45	34,9	27,2	43,4
Age	< 65	176	62,6	47	26,7	20,7	33,7
	>= 65	105	37,4	50	47,6	38,3	57,1
ECOG performance status	0	84	29,9	29	34,5	25,2	45,2
	1	190	67,6	66	34,7	28,3	41,7
	2	6	2,1	2	33,3	9,7	70,0
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	25	39,1	28,1	51,3
	Europe (EU)	95	33,8	24	25,3	17,6	34,8
	Asia (AS)	122	43,4	48	39,3	31,1	48,2
Race/ethnicity	Asian	128	45,6	51	39,8	31,8	48,5
	Non-Asian	135	48,0	43	31,9	24,6	40,1
	Unknown	18	6,4	3	16,7	5,8	39,2
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	33	28,4	21,0	37,2
	1	77	27,4	28	36,4	26,5	47,5
	>= 2	88	31,3	36	40,9	31,2	51,4

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas

Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AHYP_SG.xls
07MAY2021 11:42

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Hypertension - Grade 1 or Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	52	18,5	14,4	23,5
Sex	Female	152	54,1	25	16,4	11,4	23,2
	Male	129	45,9	27	20,9	14,8	28,7
Age	< 65	176	62,6	31	17,6	12,7	23,9
	>= 65	105	37,4	21	20,0	13,5	28,6
ECOG performance status	0	84	29,9	12	14,3	8,4	23,3
	1	190	67,6	39	20,5	15,4	26,8
	2	6	2,1	1	16,7	3,0	56,4
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	10	15,6	8,7	26,4
	Europe (EU)	95	33,8	14	14,7	9,0	23,2
	Asia (AS)	122	43,4	28	23,0	16,4	31,2
Race/ethnicity	Asian	128	45,6	30	23,4	16,9	31,5
	Non-Asian	135	48,0	19	14,1	9,2	20,9
	Unknown	18	6,4	3	16,7	5,8	39,2
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	16	13,8	8,7	21,2
	1	77	27,4	14	18,2	11,2	28,2
	>= 2	88	31,3	22	25,0	17,1	35,0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw_B63_06NOV2020_SE_TO_AHYP12_SG.xls
07MAY2021 11:23

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Hypertension - Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	45	16,0	12,2	20,8
Sex	Female	152	54,1	27	17,8	12,5	24,6
	Male	129	45,9	18	14,0	9,0	21,0
Age	< 65	176	62,6	16	9,1	5,7	14,3
	>= 65	105	37,4	29	27,6	20,0	36,8
ECOG performance status	0	84	29,9	17	20,2	13,0	30,0
	1	190	67,6	27	14,2	10,0	19,9
	2	6	2,1	1	16,7	3,0	56,4
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	15	23,4	14,7	35,1
	Europe (EU)	95	33,8	10	10,5	5,8	18,3
	Asia (AS)	122	43,4	20	16,4	10,9	24,0
Race/ethnicity	Asian	128	45,6	21	16,4	11,0	23,8
	Non-Asian	135	48,0	24	17,8	12,2	25,1
	Unknown	18	6,4	0	0,0	0,0	17,6
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	17	14,7	9,4	22,2
	1	77	27,4	14	18,2	11,2	28,2
	>= 2	88	31,3	14	15,9	9,7	25,0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw_B63_06NOV2020_SE_TO_AHYP345_SG.xls
07MAY2021 11:23

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Hypertension - SAEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	4	1,4	0,6	3,6
Sex	Female	152	54,1	4	2,6	1,0	6,6
	Male	129	45,9	0	0,0	0,0	2,9
Age	< 65	176	62,6	2	1,1	0,3	4,0
	>= 65	105	37,4	2	1,9	0,5	6,7
ECOG performance status	0	84	29,9	2	2,4	0,7	8,3
	1	190	67,6	2	1,1	0,3	3,8
	2	6	2,1	0	0,0	0,0	39,0
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	0	0,0	0,0	5,7
	Europe (EU)	95	33,8	2	2,1	0,6	7,4
	Asia (AS)	122	43,4	2	1,6	0,5	5,8
Race/ethnicity	Asian	128	45,6	2	1,6	0,4	5,5
	Non-Asian	135	48,0	2	1,5	0,4	5,2
	Unknown	18	6,4	0	0,0	0,0	17,6
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	0	0,0	0,0	3,2
	1	77	27,4	2	2,6	0,7	9,0
	>= 2	88	31,3	2	2,3	0,6	7,9

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw_B63_06NOV2020_SE_TO_AHYPSAE_SG.xls
07MAY2021 11:24

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Hypertension
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	97	34,5	29,2	40,3
Sex	Female	152	54,1	52	34,2	27,1	42,1
	Male	129	45,9	45	34,9	27,2	43,4
Age	< 65	176	62,6	47	26,7	20,7	33,7
	>= 65	105	37,4	50	47,6	38,3	57,1
ECOG performance status	0	84	29,9	29	34,5	25,2	45,2
	1	190	67,6	66	34,7	28,3	41,7
	2	6	2,1	2	33,3	9,7	70,0
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	25	39,1	28,1	51,3
	Europe (EU)	95	33,8	24	25,3	17,6	34,8
	Asia (AS)	122	43,4	48	39,3	31,1	48,2
Race/ethnicity	Asian	128	45,6	51	39,8	31,8	48,5
	Non-Asian	135	48,0	43	31,9	24,6	40,1
	Unknown	18	6,4	3	16,7	5,8	39,2
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	33	28,4	21,0	37,2
	1	77	27,4	28	36,4	26,5	47,5
	>= 2	88	31,3	36	40,9	31,2	51,4

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw_B63_06NOV2020_SE_TO_AHYP_SG.xls
07MAY2021 11:22

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Haemorrhage - Grade 1 or Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	46	16.4	12.5	21.1
Sex	Female	152	54.1	27	17.8	12.5	24.6
	Male	129	45.9	19	14.7	9.6	21.9
Age	< 65	176	62.6	29	16.5	11.7	22.7
	>= 65	105	37.4	17	16.2	10.4	24.4
ECOG performance status	0	84	29.9	10	11.9	6.6	20.5
	1	190	67.6	35	18.4	13.6	24.5
	2	6	2.1	1	16.7	3.0	56.4
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	10	15.6	8.7	26.4
	Europe (EU)	95	33.8	18	18.9	12.3	28.0
	Asia (AS)	122	43.4	18	14.8	9.5	22.1
Race/ethnicity	Asian	128	45.6	18	14.1	9.1	21.1
	Non-Asian	135	48.0	26	19.3	13.5	26.7
	Unknown	18	6.4	2	11.1	3.1	32.8
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	18	15.5	10.0	23.2
	1	77	27.4	10	13.0	7.2	22.3
	>= 2	88	31.3	18	20.5	13.3	30.0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AHMR12_SG.xls
27OCT2021 20:03

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Haemorrhage - Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	9	3.2	1.7	6.0
Sex	Female	152	54.1	3	2.0	0.7	5.6
	Male	129	45.9	6	4.7	2.1	9.8
Age	< 65	176	62.6	4	2.3	0.9	5.7
	>= 65	105	37.4	5	4.8	2.1	10.7
ECOG performance status	0	84	29.9	2	2.4	0.7	8.3
	1	190	67.6	6	3.2	1.5	6.7
	2	6	2.1	1	16.7	3.0	56.4
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	7	10.9	5.4	20.9
	Europe (EU)	95	33.8	2	2.1	0.6	7.4
	Asia (AS)	122	43.4	0	0.0	0.0	3.1
Race/ethnicity	Asian	128	45.6	1	0.8	0.1	4.3
	Non-Asian	135	48.0	7	5.2	2.5	10.3
	Unknown	18	6.4	1	5.6	1.0	25.8
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	2	1.7	0.5	6.1
	1	77	27.4	1	1.3	0.2	7.0
	>= 2	88	31.3	6	6.8	3.2	14.1

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AHMR345_SG.xls
27OCT2021 20:04

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Haemorrhage - SAEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	10	3.6	1.9	6.4
Sex	Female	152	54.1	5	3.3	1.4	7.5
	Male	129	45.9	5	3.9	1.7	8.8
Age	< 65	176	62.6	5	2.8	1.2	6.5
	>= 65	105	37.4	5	4.8	2.1	10.7
ECOG performance status	0	84	29.9	3	3.6	1.2	10.0
	1	190	67.6	6	3.2	1.5	6.7
	2	6	2.1	1	16.7	3.0	56.4
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	6	9.4	4.4	19.0
	Europe (EU)	95	33.8	3	3.2	1.1	8.9
	Asia (AS)	122	43.4	1	0.8	0.1	4.5
Race/ethnicity	Asian	128	45.6	2	1.6	0.4	5.5
	Non-Asian	135	48.0	7	5.2	2.5	10.3
	Unknown	18	6.4	1	5.6	1.0	25.8
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	4	3.4	1.3	8.5
	1	77	27.4	2	2.6	0.7	9.0
	>= 2	88	31.3	4	4.5	1.8	11.1

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AHMRSAE_SG.xls
27OCT2021 20:06

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Haemorrhage
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	55	19.6	15.4	24.6
Sex	Female	152	54.1	30	19.7	14.2	26.8
	Male	129	45.9	25	19.4	13.5	27.0
Age	< 65	176	62.6	33	18.8	13.7	25.2
	>= 65	105	37.4	22	21.0	14.3	29.7
ECOG performance status	0	84	29.9	12	14.3	8.4	23.3
	1	190	67.6	41	21.6	16.3	28.0
	2	6	2.1	2	33.3	9.7	70.0
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	17	26.6	17.3	38.5
	Europe (EU)	95	33.8	20	21.1	14.1	30.3
	Asia (AS)	122	43.4	18	14.8	9.5	22.1
Race/ethnicity	Asian	128	45.6	19	14.8	9.7	22.0
	Non-Asian	135	48.0	33	24.4	18.0	32.3
	Unknown	18	6.4	3	16.7	5.8	39.2
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	20	17.2	11.4	25.1
	1	77	27.4	11	14.3	8.2	23.8
	>= 2	88	31.3	24	27.3	19.1	37.4

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas

Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AHMR_SG.xls
27OCT2021 20:00

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Haemorrhage - Grade 1 or Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	46	16.4	12.5	21.1
Sex	Female	152	54.1	27	17.8	12.5	24.6
	Male	129	45.9	19	14.7	9.6	21.9
Age	< 65	176	62.6	29	16.5	11.7	22.7
	>= 65	105	37.4	17	16.2	10.4	24.4
ECOG performance status	0	84	29.9	10	11.9	6.6	20.5
	1	190	67.6	35	18.4	13.6	24.5
	2	6	2.1	1	16.7	3.0	56.4
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	10	15.6	8.7	26.4
	Europe (EU)	95	33.8	18	18.9	12.3	28.0
	Asia (AS)	122	43.4	18	14.8	9.5	22.1
Race/ethnicity	Asian	128	45.6	18	14.1	9.1	21.1
	Non-Asian	135	48.0	26	19.3	13.5	26.7
	Unknown	18	6.4	2	11.1	3.1	32.8
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	18	15.5	10.0	23.2
	1	77	27.4	10	13.0	7.2	22.3
	>= 2	88	31.3	18	20.5	13.3	30.0

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw_B63_06NOV2020_SE_TO_AHMR12_SG.xls
27OCT2021 18:31

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Haemorrhage - Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	9	3.2	1.7	6.0
Sex	Female	152	54.1	3	2.0	0.7	5.6
	Male	129	45.9	6	4.7	2.1	9.8
Age	< 65	176	62.6	4	2.3	0.9	5.7
	>= 65	105	37.4	5	4.8	2.1	10.7
ECOG performance status	0	84	29.9	2	2.4	0.7	8.3
	1	190	67.6	6	3.2	1.5	6.7
	2	6	2.1	1	16.7	3.0	56.4
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	7	10.9	5.4	20.9
	Europe (EU)	95	33.8	2	2.1	0.6	7.4
	Asia (AS)	122	43.4	0	0.0	0.0	3.1
Race/ethnicity	Asian	128	45.6	1	0.8	0.1	4.3
	Non-Asian	135	48.0	7	5.2	2.5	10.3
	Unknown	18	6.4	1	5.6	1.0	25.8
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	2	1.7	0.5	6.1
	1	77	27.4	1	1.3	0.2	7.0
	>= 2	88	31.3	6	6.8	3.2	14.1

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw_B63_06NOV2020_SE_TO_AHMR345_SG.xls
27OCT2021 18:37

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Haemorrhage - SAEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	10	3.6	1.9	6.4
Sex	Female	152	54.1	5	3.3	1.4	7.5
	Male	129	45.9	5	3.9	1.7	8.8
Age	< 65	176	62.6	5	2.8	1.2	6.5
	>= 65	105	37.4	5	4.8	2.1	10.7
ECOG performance status	0	84	29.9	3	3.6	1.2	10.0
	1	190	67.6	6	3.2	1.5	6.7
	2	6	2.1	1	16.7	3.0	56.4
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	6	9.4	4.4	19.0
	Europe (EU)	95	33.8	3	3.2	1.1	8.9
	Asia (AS)	122	43.4	1	0.8	0.1	4.5
Race/ethnicity	Asian	128	45.6	2	1.6	0.4	5.5
	Non-Asian	135	48.0	7	5.2	2.5	10.3
	Unknown	18	6.4	1	5.6	1.0	25.8
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	4	3.4	1.3	8.5
	1	77	27.4	2	2.6	0.7	9.0
	>= 2	88	31.3	4	4.5	1.8	11.1

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw_B63_06NOV2020_SE_TO_AHMRSAE_SG.xls
27OCT2021 18:43

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Haemorrhage
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	55	19.6	15.4	24.6
Sex	Female	152	54.1	30	19.7	14.2	26.8
	Male	129	45.9	25	19.4	13.5	27.0
Age	< 65	176	62.6	33	18.8	13.7	25.2
	>= 65	105	37.4	22	21.0	14.3	29.7
ECOG performance status	0	84	29.9	12	14.3	8.4	23.3
	1	190	67.6	41	21.6	16.3	28.0
	2	6	2.1	2	33.3	9.7	70.0
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	17	26.6	17.3	38.5
	Europe (EU)	95	33.8	20	21.1	14.1	30.3
	Asia (AS)	122	43.4	18	14.8	9.5	22.1
Race/ethnicity	Asian	128	45.6	19	14.8	9.7	22.0
	Non-Asian	135	48.0	33	24.4	18.0	32.3
	Unknown	18	6.4	3	16.7	5.8	39.2
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	20	17.2	11.4	25.1
	1	77	27.4	11	14.3	8.2	23.8
	>= 2	88	31.3	24	27.3	19.1	37.4

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw_B63_06NOV2020_SE_TO_AHMR_SG.xls
27OCT2021 18:26

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Transaminase elevation - Grade 1 or Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	121	43.1	37.4	48.9
Sex	Female	152	54.1	70	46.1	38.3	54.0
	Male	129	45.9	51	39.5	31.5	48.2
Age	< 65	176	62.6	78	44.3	37.2	51.7
	>= 65	105	37.4	43	41.0	32.0	50.5
ECOG performance status	0	84	29.9	33	39.3	29.5	50.0
	1	190	67.6	86	45.3	38.3	52.4
	2	6	2.1	1	16.7	3.0	56.4
	Missing	1	0.4	1	100.0	20.7	100.0
Geographic region	USA	64	22.8	28	43.8	32.3	55.9
	Europe (EU)	95	33.8	26	27.4	19.4	37.1
	Asia (AS)	122	43.4	67	54.9	46.1	63.5
Race/ethnicity	Asian	128	45.6	69	53.9	45.3	62.3
	Non-Asian	135	48.0	49	36.3	28.7	44.7
	Unknown	18	6.4	3	16.7	5.8	39.2
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	51	44.0	35.3	53.0
	1	77	27.4	33	42.9	32.4	54.0
	>= 2	88	31.3	37	42.0	32.3	52.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas

Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AHEP12_SG.xls
27OCT2021 20:13

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Transaminase elevation - Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	17	6.0	3.8	9.5
Sex	Female	152	54.1	10	6.6	3.6	11.7
	Male	129	45.9	7	5.4	2.7	10.8
Age	< 65	176	62.6	13	7.4	4.4	12.2
	>= 65	105	37.4	4	3.8	1.5	9.4
ECOG performance status	0	84	29.9	5	6.0	2.6	13.2
	1	190	67.6	10	5.3	2.9	9.4
	2	6	2.1	2	33.3	9.7	70.0
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	3	4.7	1.6	12.9
	Europe (EU)	95	33.8	6	6.3	2.9	13.1
	Asia (AS)	122	43.4	8	6.6	3.4	12.4
Race/ethnicity	Asian	128	45.6	8	6.3	3.2	11.8
	Non-Asian	135	48.0	8	5.9	3.0	11.3
	Unknown	18	6.4	1	5.6	1.0	25.8
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	4	3.4	1.3	8.5
	1	77	27.4	5	6.5	2.8	14.3
	>= 2	88	31.3	8	9.1	4.7	16.9

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AHEP345_SG.xls
27OCT2021 20:16

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Transaminase elevation - SAEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	3	1.1	0.4	3.1
Sex	Female	152	54.1	2	1.3	0.4	4.7
	Male	129	45.9	1	0.8	0.1	4.3
Age	< 65	176	62.6	0	0.0	0.0	2.1
	>= 65	105	37.4	3	2.9	1.0	8.1
ECOG performance status	0	84	29.9	1	1.2	0.2	6.4
	1	190	67.6	1	0.5	0.1	2.9
	2	6	2.1	1	16.7	3.0	56.4
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	1	1.6	0.3	8.3
	Europe (EU)	95	33.8	2	2.1	0.6	7.4
	Asia (AS)	122	43.4	0	0.0	0.0	3.1
Race/ethnicity	Asian	128	45.6	0	0.0	0.0	2.9
	Non-Asian	135	48.0	3	2.2	0.8	6.3
	Unknown	18	6.4	0	0.0	0.0	17.6
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	0	0.0	0.0	3.2
	1	77	27.4	1	1.3	0.2	7.0
	>= 2	88	31.3	2	2.3	0.6	7.9

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AHEPSAE_SG.xls
27OCT2021 20:18

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Transaminase elevation
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	138	49.1	43.3	54.9
Sex	Female	152	54.1	80	52.6	44.7	60.4
	Male	129	45.9	58	45.0	36.6	53.6
Age	< 65	176	62.6	91	51.7	44.4	59.0
	>= 65	105	37.4	47	44.8	35.6	54.3
ECOG performance status	0	84	29.9	38	45.2	35.0	55.9
	1	190	67.6	96	50.5	43.5	57.6
	2	6	2.1	3	50.0	18.8	81.2
	Missing	1	0.4	1	100.0	20.7	100.0
Geographic region	USA	64	22.8	31	48.4	36.6	60.4
	Europe (EU)	95	33.8	32	33.7	25.0	43.7
	Asia (AS)	122	43.4	75	61.5	52.6	69.6
Race/ethnicity	Asian	128	45.6	77	60.2	51.5	68.2
	Non-Asian	135	48.0	57	42.2	34.2	50.7
	Unknown	18	6.4	4	22.2	9.0	45.2
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	55	47.4	38.6	56.4
	1	77	27.4	38	49.4	38.5	60.3
	>= 2	88	31.3	45	51.1	40.9	61.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas

Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AHEP_SG.xls
27OCT2021 20:09

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Transaminase elevation - Grade 1 or Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	121	43.1	37.4	48.9
Sex	Female	152	54.1	70	46.1	38.3	54.0
	Male	129	45.9	51	39.5	31.5	48.2
Age	< 65	176	62.6	78	44.3	37.2	51.7
	>= 65	105	37.4	43	41.0	32.0	50.5
ECOG performance status	0	84	29.9	33	39.3	29.5	50.0
	1	190	67.6	86	45.3	38.3	52.4
	2	6	2.1	1	16.7	3.0	56.4
	Missing	1	0.4	1	100.0	20.7	100.0
Geographic region	USA	64	22.8	28	43.8	32.3	55.9
	Europe (EU)	95	33.8	26	27.4	19.4	37.1
	Asia (AS)	122	43.4	67	54.9	46.1	63.5
Race/ethnicity	Asian	128	45.6	69	53.9	45.3	62.3
	Non-Asian	135	48.0	49	36.3	28.7	44.7
	Unknown	18	6.4	3	16.7	5.8	39.2
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	51	44.0	35.3	53.0
	1	77	27.4	33	42.9	32.4	54.0
	>= 2	88	31.3	37	42.0	32.3	52.5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw_B63_06NOV2020_SE_TO_AHEP12_SG.xls
27OCT2021 18:50

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Transaminase elevation - Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	17	6.0	3.8	9.5
Sex	Female	152	54.1	10	6.6	3.6	11.7
	Male	129	45.9	7	5.4	2.7	10.8
Age	< 65	176	62.6	13	7.4	4.4	12.2
	>= 65	105	37.4	4	3.8	1.5	9.4
ECOG performance status	0	84	29.9	5	6.0	2.6	13.2
	1	190	67.6	10	5.3	2.9	9.4
	2	6	2.1	2	33.3	9.7	70.0
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	3	4.7	1.6	12.9
	Europe (EU)	95	33.8	6	6.3	2.9	13.1
	Asia (AS)	122	43.4	8	6.6	3.4	12.4
Race/ethnicity	Asian	128	45.6	8	6.3	3.2	11.8
	Non-Asian	135	48.0	8	5.9	3.0	11.3
	Unknown	18	6.4	1	5.6	1.0	25.8
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	4	3.4	1.3	8.5
	1	77	27.4	5	6.5	2.8	14.3
	>= 2	88	31.3	8	9.1	4.7	16.9

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw_B63_06NOV2020_SE_TO_AHEP345_SG.xls
27OCT2021 18:54

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Transaminase elevation - SAEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	3	1.1	0.4	3.1
Sex	Female	152	54.1	2	1.3	0.4	4.7
	Male	129	45.9	1	0.8	0.1	4.3
Age	< 65	176	62.6	0	0.0	0.0	2.1
	>= 65	105	37.4	3	2.9	1.0	8.1
ECOG performance status	0	84	29.9	1	1.2	0.2	6.4
	1	190	67.6	1	0.5	0.1	2.9
	2	6	2.1	1	16.7	3.0	56.4
	Missing	1	0.4	0	0.0	0.0	79.3
Geographic region	USA	64	22.8	1	1.6	0.3	8.3
	Europe (EU)	95	33.8	2	2.1	0.6	7.4
	Asia (AS)	122	43.4	0	0.0	0.0	3.1
Race/ethnicity	Asian	128	45.6	0	0.0	0.0	2.9
	Non-Asian	135	48.0	3	2.2	0.8	6.3
	Unknown	18	6.4	0	0.0	0.0	17.6
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	0	0.0	0.0	3.2
	1	77	27.4	1	1.3	0.2	7.0
	>= 2	88	31.3	2	2.3	0.6	7.9

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw_B63_06NOV2020_SE_TO_AHEPSAE_SG.xls
27OCT2021 18:56

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: Transaminase elevation
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100.0	138	49.1	43.3	54.9
Sex	Female	152	54.1	80	52.6	44.7	60.4
	Male	129	45.9	58	45.0	36.6	53.6
Age	< 65	176	62.6	91	51.7	44.4	59.0
	>= 65	105	37.4	47	44.8	35.6	54.3
ECOG performance status	0	84	29.9	38	45.2	35.0	55.9
	1	190	67.6	96	50.5	43.5	57.6
	2	6	2.1	3	50.0	18.8	81.2
	Missing	1	0.4	1	100.0	20.7	100.0
Geographic region	USA	64	22.8	31	48.4	36.6	60.4
	Europe (EU)	95	33.8	32	33.7	25.0	43.7
	Asia (AS)	122	43.4	75	61.5	52.6	69.6
Race/ethnicity	Asian	128	45.6	77	60.2	51.5	68.2
	Non-Asian	135	48.0	57	42.2	34.2	50.7
	Unknown	18	6.4	4	22.2	9.0	45.2
Number of prior antineoplastic systemic therapy lines II	0	116	41.3	55	47.4	38.6	56.4
	1	77	27.4	38	49.4	38.5	60.3
	>= 2	88	31.3	45	51.1	40.9	61.3

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180/prod/output/saf_raw_B63_06NOV2020_SE_TO_AHEP_SG.xls
27OCT2021 18:48

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: QTc Prolongation - Grade 1 or Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	14	5,0	3,0	8,2
Sex	Female	152	54,1	12	7,9	4,6	13,3
	Male	129	45,9	2	1,6	0,4	5,5
Age	< 65	176	62,6	9	5,1	2,7	9,4
	>= 65	105	37,4	5	4,8	2,1	10,7
ECOG performance status	0	84	29,9	1	1,2	0,2	6,4
	1	190	67,6	13	6,8	4,0	11,4
	2	6	2,1	0	0,0	0,0	39,0
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	0	0,0	0,0	5,7
	Europe (EU)	95	33,8	3	3,2	1,1	8,9
	Asia (AS)	122	43,4	11	9,0	5,1	15,4
Race/ethnicity	Asian	128	45,6	11	8,6	4,9	14,7
	Non-Asian	135	48,0	3	2,2	0,8	6,3
	Unknown	18	6,4	0	0,0	0,0	17,6
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	2	1,7	0,5	6,1
	1	77	27,4	5	6,5	2,8	14,3
	>= 2	88	31,3	7	8,0	3,9	15,5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AQTP12_SG.xls
26MAR2021 10:37

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: QTc Prolongation - Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	1	0,4	0,1	2,0
Sex	Female	152	54,1	1	0,7	0,1	3,6
	Male	129	45,9	0	0,0	0,0	2,9
Age	< 65	176	62,6	0	0,0	0,0	2,1
	>= 65	105	37,4	1	1,0	0,2	5,2
ECOG performance status	0	84	29,9	0	0,0	0,0	4,4
	1	190	67,6	1	0,5	0,1	2,9
	2	6	2,1	0	0,0	0,0	39,0
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	1	1,6	0,3	8,3
	Europe (EU)	95	33,8	0	0,0	0,0	3,9
	Asia (AS)	122	43,4	0	0,0	0,0	3,1
Race/ethnicity	Asian	128	45,6	0	0,0	0,0	2,9
	Non-Asian	135	48,0	1	0,7	0,1	4,1
	Unknown	18	6,4	0	0,0	0,0	17,6
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	1	0,9	0,2	4,7
	1	77	27,4	0	0,0	0,0	4,8
	>= 2	88	31,3	0	0,0	0,0	4,2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AQTP345_SG.xls
26MAR2021 10:37

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: QTc Prolongation - SAEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	2	0,7	0,2	2,6
Sex	Female	152	54,1	2	1,3	0,4	4,7
	Male	129	45,9	0	0,0	0,0	2,9
Age	< 65	176	62,6	0	0,0	0,0	2,1
	>= 65	105	37,4	2	1,9	0,5	6,7
ECOG performance status	0	84	29,9	0	0,0	0,0	4,4
	1	190	67,6	2	1,1	0,3	3,8
	2	6	2,1	0	0,0	0,0	39,0
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	1	1,6	0,3	8,3
	Europe (EU)	95	33,8	1	1,1	0,2	5,7
	Asia (AS)	122	43,4	0	0,0	0,0	3,1
Race/ethnicity	Asian	128	45,6	0	0,0	0,0	2,9
	Non-Asian	135	48,0	2	1,5	0,4	5,2
	Unknown	18	6,4	0	0,0	0,0	17,6
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	2	1,7	0,5	6,1
	1	77	27,4	0	0,0	0,0	4,8
	>= 2	88	31,3	0	0,0	0,0	4,2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AQTPSAE_SG.xls
26MAR2021 10:38

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: QTc Prolongation
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis, disease-related events excluded (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	15	5,3	3,3	8,6
Sex	Female	152	54,1	13	8,6	5,1	14,1
	Male	129	45,9	2	1,6	0,4	5,5
Age	< 65	176	62,6	9	5,1	2,7	9,4
	>= 65	105	37,4	6	5,7	2,6	11,9
ECOG performance status	0	84	29,9	1	1,2	0,2	6,4
	1	190	67,6	14	7,4	4,4	12,0
	2	6	2,1	0	0,0	0,0	39,0
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	1	1,6	0,3	8,3
	Europe (EU)	95	33,8	3	3,2	1,1	8,9
	Asia (AS)	122	43,4	11	9,0	5,1	15,4
Race/ethnicity	Asian	128	45,6	11	8,6	4,9	14,7
	Non-Asian	135	48,0	4	3,0	1,2	7,4
	Unknown	18	6,4	0	0,0	0,0	17,6
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	3	2,6	0,9	7,3
	1	77	27,4	5	6,5	2,8	14,3
	>= 2	88	31,3	7	8,0	3,9	15,5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw2.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw2_B63_06NOV2020_SE_TO_AQTP_SG.xls
26MAR2021 10:36

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: QTc Prolongation - Grade 1 or Grade 2
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	14	5,0	3,0	8,2
Sex	Female	152	54,1	12	7,9	4,6	13,3
	Male	129	45,9	2	1,6	0,4	5,5
Age	< 65	176	62,6	9	5,1	2,7	9,4
	>= 65	105	37,4	5	4,8	2,1	10,7
ECOG performance status	0	84	29,9	1	1,2	0,2	6,4
	1	190	67,6	13	6,8	4,0	11,4
	2	6	2,1	0	0,0	0,0	39,0
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	0	0,0	0,0	5,7
	Europe (EU)	95	33,8	3	3,2	1,1	8,9
	Asia (AS)	122	43,4	11	9,0	5,1	15,4
Race/ethnicity	Asian	128	45,6	11	8,6	4,9	14,7
	Non-Asian	135	48,0	3	2,2	0,8	6,3
	Unknown	18	6,4	0	0,0	0,0	17,6
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	2	1,7	0,5	6,1
	1	77	27,4	5	6,5	2,8	14,3
	>= 2	88	31,3	7	8,0	3,9	15,5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw_B63_06NOV2020_SE_TO_AQTP12_SG.xls
26MAR2021 10:14

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: QTc Prolongation - Grade >= 3
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	1	0,4	0,1	2,0
Sex	Female	152	54,1	1	0,7	0,1	3,6
	Male	129	45,9	0	0,0	0,0	2,9
Age	< 65	176	62,6	0	0,0	0,0	2,1
	>= 65	105	37,4	1	1,0	0,2	5,2
ECOG performance status	0	84	29,9	0	0,0	0,0	4,4
	1	190	67,6	1	0,5	0,1	2,9
	2	6	2,1	0	0,0	0,0	39,0
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	1	1,6	0,3	8,3
	Europe (EU)	95	33,8	0	0,0	0,0	3,9
	Asia (AS)	122	43,4	0	0,0	0,0	3,1
Race/ethnicity	Asian	128	45,6	0	0,0	0,0	2,9
	Non-Asian	135	48,0	1	0,7	0,1	4,1
	Unknown	18	6,4	0	0,0	0,0	17,6
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	1	0,9	0,2	4,7
	1	77	27,4	0	0,0	0,0	4,8
	>= 2	88	31,3	0	0,0	0,0	4,2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw_B63_06NOV2020_SE_TO_AQTP345_SG.xls
26MAR2021 10:15

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: QTc Prolongation - SAEs
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	2	0,7	0,2	2,6
Sex	Female	152	54,1	2	1,3	0,4	4,7
	Male	129	45,9	0	0,0	0,0	2,9
Age	< 65	176	62,6	0	0,0	0,0	2,1
	>= 65	105	37,4	2	1,9	0,5	6,7
ECOG performance status	0	84	29,9	0	0,0	0,0	4,4
	1	190	67,6	2	1,1	0,3	3,8
	2	6	2,1	0	0,0	0,0	39,0
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	1	1,6	0,3	8,3
	Europe (EU)	95	33,8	1	1,1	0,2	5,7
	Asia (AS)	122	43,4	0	0,0	0,0	3,1
Race/ethnicity	Asian	128	45,6	0	0,0	0,0	2,9
	Non-Asian	135	48,0	2	1,5	0,4	5,2
	Unknown	18	6,4	0	0,0	0,0	17,6
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	2	1,7	0,5	6,1
	1	77	27,4	0	0,0	0,0	4,8
	>= 2	88	31,3	0	0,0	0,0	4,2

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw_B63_06NOV2020_SE_TO_AQTPSAE_SG.xls
26MAR2021 10:16

POPULATION: RET fusion NSCLC Patients Treated at 400 mg QD, Overall, Safety Population
ENDPOINT: AESI: QTc Prolongation
MODEL: Unstratified analysis
STUDY: BO42863
Dichotomous analysis (safety)

		400 mg QD (N=281)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	281	100,0	15	5,3	3,3	8,6
Sex	Female	152	54,1	13	8,6	5,1	14,1
	Male	129	45,9	2	1,6	0,4	5,5
Age	< 65	176	62,6	9	5,1	2,7	9,4
	>= 65	105	37,4	6	5,7	2,6	11,9
ECOG performance status	0	84	29,9	1	1,2	0,2	6,4
	1	190	67,6	14	7,4	4,4	12,0
	2	6	2,1	0	0,0	0,0	39,0
	Missing	1	0,4	0	0,0	0,0	79,3
Geographic region	USA	64	22,8	1	1,6	0,3	8,3
	Europe (EU)	95	33,8	3	3,2	1,1	8,9
	Asia (AS)	122	43,4	11	9,0	5,1	15,4
Race/ethnicity	Asian	128	45,6	11	8,6	4,9	14,7
	Non-Asian	135	48,0	4	3,0	1,2	7,4
	Unknown	18	6,4	0	0,0	0,0	17,6
Number of prior antineoplastic systemic therapy lines II	0	116	41,3	3	2,6	0,9	7,3
	1	77	27,4	5	6,5	2,8	14,3
	>= 2	88	31,3	7	8,0	3,9	15,5

95% CI based on Wilson Scores.
Clinical cut-off: 06NOV2020

Program: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7499790/CDT30370/BO42863/data_analysis/ACE_NSCLC_MAA_D180_import/prod/output/saf_raw_B63_06NOV2020_SE_TO_AQTP_SG.xls
26MAR2021 10:14

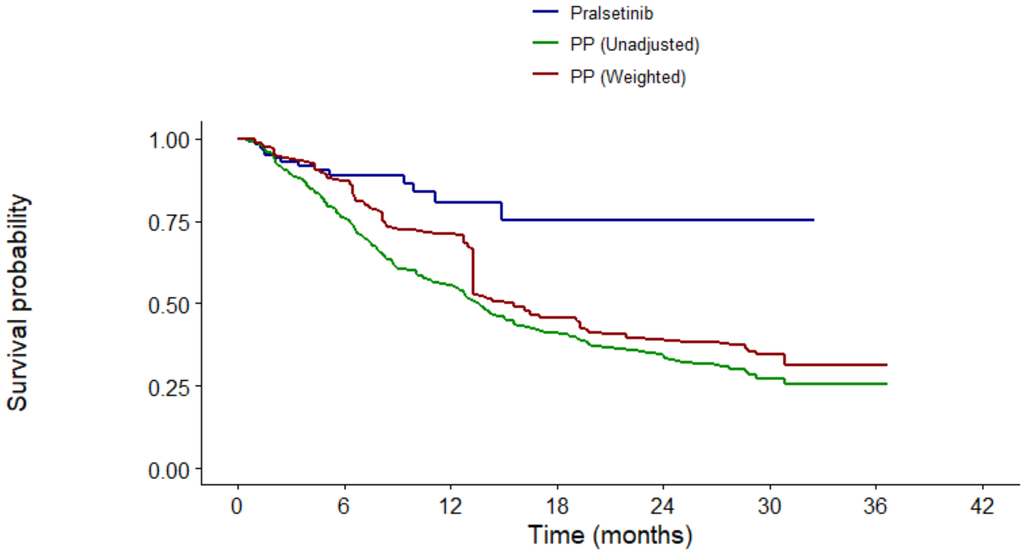
Overall survival

Table1: Comparison of baseline characteristics: Pralsetinib (ARROW) vs PP (IMpower132)

Baseline characteristic	IMpower132 (unadjusted)	IMpower132 (weighted)	ARROW
Arm	**PP**	**PP**	**Pralsetinib**
Population	**Chemotherapy-naïve population**	**Chemotherapy-naïve population**	**No prior systemic therapy – safety population**
N	**254**	**123**	**106**
Age (mean)	61.7	60.1	59.9
Gender (%): Male	68.1	29.4	45.3
ECOG PS (%): 1	59.4	77.3	70.8
CNS metastases (%): Yes	9.4	42.6	31.1
Smoking status (%): Never	10.6	65.8	59.4
Histology (%): Adenocarcinoma	96.5	99.1	99.1
Race (%): Asian	24.8	56.2	47.2

Abbreviations: CNS, central nervous system; ECOG, Eastern Cooperative Oncology Group; N, sample size; PP, carboplatin or cisplatin plus pemetrexed; PS, Performance Status.

Figure 1: Kaplan-Meier plot of OS – Pralsetinib (ARROW) vs PP (IMpower132)



Number at risk

	0	6	12	18	24	30	36	42
Pralsetinib	106	56	20	7	2	1	0	0
PP (Unadjusted)	254	191	136	100	82	21	1	0
PP (Weighted)	123	106	83	53	45	5	0	0

Notes: PP comprises carboplatin (AUC 6 mg/ml/min) or cisplatin (75 mg/m2) plus pemetrexed (500 mg/m2) every 21 days.

Table 2: Kaplan-Meier summary and hazard ratios for OS – Pralsetinib (ARROW) vs PP (IMpower132)

Comparison	Method	Median, months [95% CI] - Pralsetinib	Median, months [95% CI] - Comparator	Hazard Ratio [95% CI]
Pralsetinib vs PP	Unadjusted	NR [NR, NR]	13.6 [11.7, 15.7]	0.35 [0.20, 0.60]
	Weighted		15.5 [13.3, NR]	0.48 [0.23, 0.99]

Abbreviations: CI, confidence interval; OS, overall survival; PP, carboplatin or cisplatin plus pemetrexed.
Notes: Hazard Ratio estimate <1 favours pralsetinib over comparator.

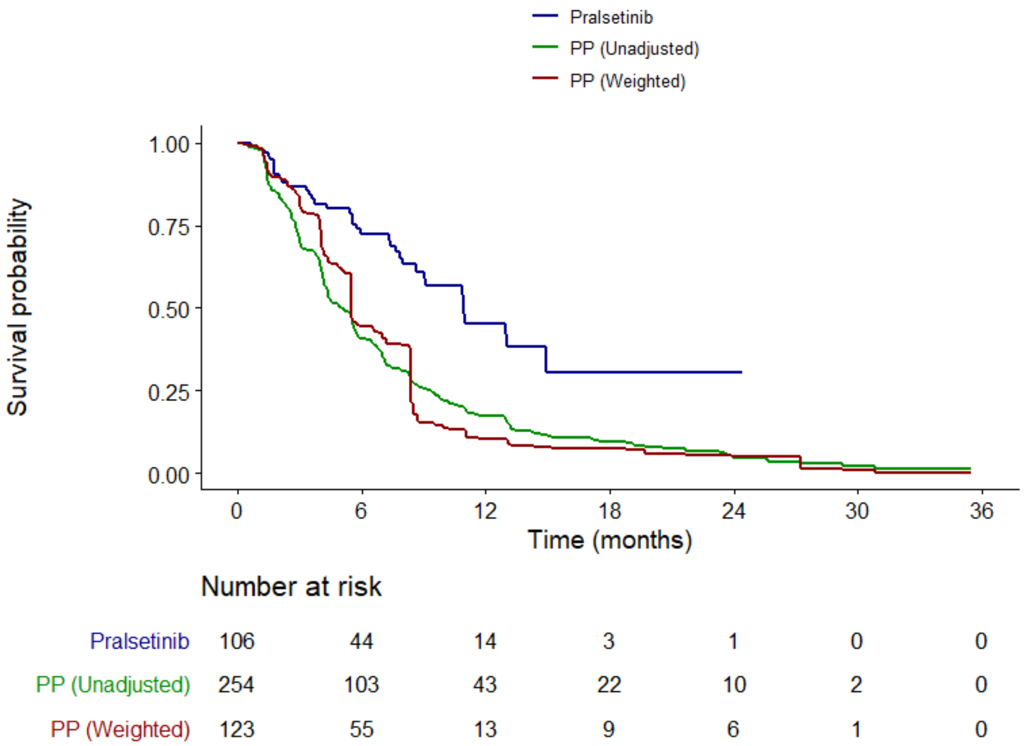
Progression-free survival

Table 3: Comparison of baseline characteristics: Pralsetinib (ARROW) vs PP (IMpower132)

Baseline characteristic	IMpower132 (unadjusted)	IMpower132 (weighted)	ARROW
Arm	**PP**	**PP**	**Pralsetinib**
Population	**Chemotherapy-naïve population**	**Chemotherapy-naïve population**	**No prior systemic therapy – safety population**
N	**254**	**123**	**106**
Age (mean)	61.7	60.1	59.9
Gender (%): Male	68.1	29.4	45.3
ECOG PS (%): 1	59.4	77.3	70.8
CNS metastases (%): Yes	9.4	42.6	31.1
Smoking status (%): Never	10.6	65.8	59.4
Histology (%): Adenocarcinoma	96.5	99.1	99.1
Race (%): Asian	24.8	56.2	47.2

Abbreviations: CNS, central nervous system; ECOG, Eastern Cooperative Oncology Group; N, sample size; PP, carboplatin or cisplatin plus pemetrexed; PS, Performance Status.

Figure 2: Kaplan-Meier plot of PFS – Pralsetinib (ARROW) vs PP (IMpower132)



Notes: PP comprises carboplatin (AUC 6 mg/ml/min) or cisplatin (75 mg/m2) plus pemetrexed (500 mg/m2) every 21 days.

Table 4: Kaplan-Meier summary and hazard ratios for PFS – Pralsetinib (ARROW) vs PP (IMpower132)

Comparison	Method	Median, months [95% CI] - Pralsetinib	Median, months [95% CI] - Comparator	Hazard Ratio [95% CI]
Pralsetinib vs PP	Unadjusted	10.9 [9.0, NR]	5.0 [4.3, 5.7]	0.42 [0.30, 0.59]
	Weighted		5.5 [4.4, 8.3]	0.40 [0.27, 0.61]

Abbreviations: CI, confidence interval; PFS, progression-free survival; PP, carboplatin or cisplatin plus pemetrexed.
Notes: Hazard Ratio estimate <1 favours pralsetinib over comparator.

Propensity Scoring Analysis Diagnostics

Figure 3: Covariate balance summary pre and post-weighting – Pralsetinib (ARROW) vs PP (IMpower132)

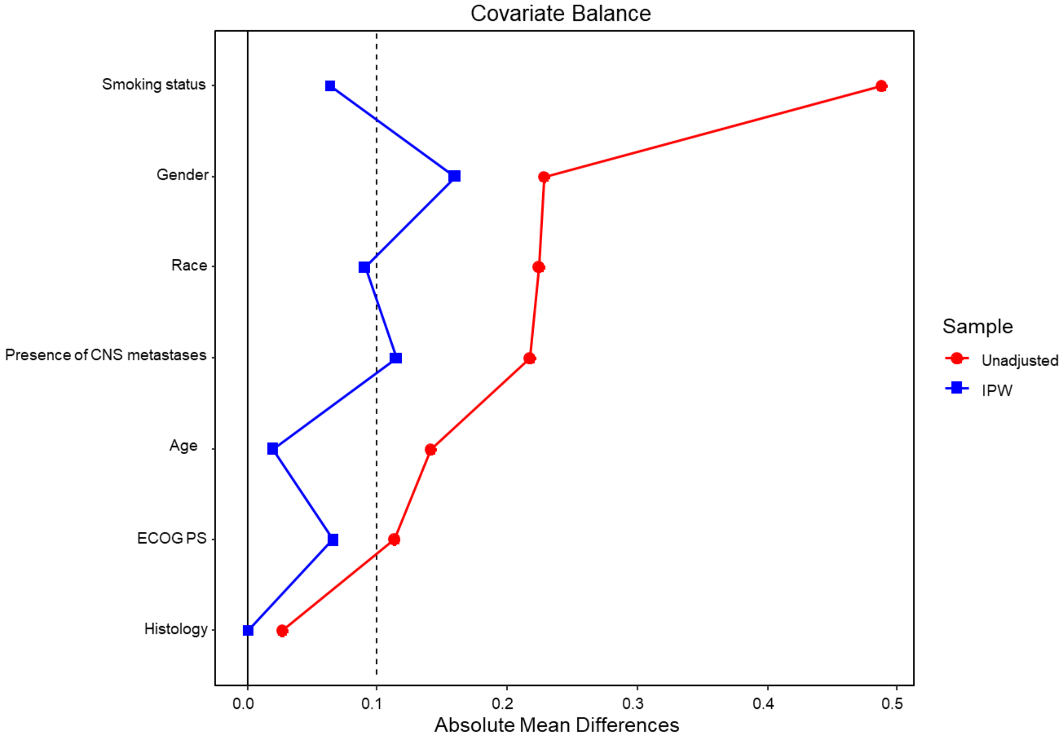


Figure 4: Histogram of propensity scoring weights – Pralsetinib (ARROW) vs PP (IMpower132)